IBM Clinical Development Unique Pages

Study Name:	DO IT MSU 8
Page Option	All

pAE

Page

(Visit ID = 618769, Page ID =)

Unique Identifier page-618769-618769-618769-

Instructions: Please complete the Adverse Event - Initial Report form for each new adverse event.

When an event that was ongoing at the time of initial data entry resolves or there is new information, record all updated information on the Adverse Event - Follow-up form.

	A1. AE - Initial Report (ID Number)	(auto calculated)	AE.AESPID	(format xxx)
SDV	* A2. Adverse Event term		AE.AETERM	
SDV	* A3. Onset date		AE.STDAT	
SDV	* A4. Onset time	:	AE.STTIM	(HH24:MI)
SDV	* A5. Study visit associated with AE onset date.		AE.AEVISIT	
SDV	* A6. Date site became aware of event		AE.AESAEDAT	
SDV	* A7. Severity	○ Grade 1 - Mild ○ Grade 2 – Moderate ○ Grade 3 – Severe ○ Grade 4 – Life-threatening Or disabling ○ Grade 5 – Death	AE.SEVERITY	
SDV	* A8. Was the subject on study medication at the time of the event?	○ Yes ○ No	AE.ONSTMED	
SDV	* A8a. Date of last dose of study medication prior to onset of the event		AE.LDOSDAT	
SDV	* A9. Was study drug temporarily stopped or permanently discontinued due to this event?	○ Yes ○ No	AE.STMACTN	
SDV	* A9a. Type of change to study drug	○ Temporarily stopped ○ Permanently discontinued	AE.STMEDACTYP	

If Temporarily Stopped, please complete the pTDIS (Temporary Discontinuation of Study Drug) form in the Study Drug Visit.

	If Permanently Discontinued, please complete the pPDIS (Permanent Discontinuation of Study Drug) form in the Study Drug Visit.		
SDV	* A10. Action taken or treatment for this event	○ Yes ○ No	AE.ACTN
SDV	* A10a. Labs, tests, or studies done to diagnose/evaluate event	○ Yes ○ No	AE.TESTACTN
	Please upload de-identified source documents.		
	Report all labs, tests, or studies in the narrative portion of this form.		
SDV	* A10b. Medication administered to treat event	○ Yes ○ No	AE.MEDACTN
	Report all medication on the CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit as well as in the narrative portion of this form.		
SDV	* A10c. Other	○ Yes ○ No	AE.ACTNOTH
SDV	* A10c1. Please specify the other action or treatment taken for the event		AE.ACTNOTHSP
SDV	* A11. Is this a Serious Adverse Event (SAE)?	○ Yes ○ No	AE.SAE
	If Yes, specify why this is considered serious by answering SAE criteria questions below.		
SDV	* A11a. Resulted in death	○ Yes ○ No	AE.DEATH
SDV	* A11b. Immediate life-threatening event (immediate danger of death from event)	○ Yes ○ No	AE.LIFE_THREAT
SDV	* A11c. Requires inpatient hospitalization or prolongation of existing hospitalization	○ Yes ○ No	AE.HOSP
SDV	* A11c1. Admission date		AE.ADMDAT
SDV	* A11c2. Is the subject still in the hospital?	○ Yes ○ No	AE.HOSPONG
SDV	* A11c3. Discharge date		AE.DISDAT
SDV	* A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	○ Yes ○ No	AE.LIFE_FUNC
SDV	* A11e. Results in a congenital anomaly in the offspring of a participant	○ Yes ○ No	AE.CONG_ANOM

SDV	* A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	○ Yes ○ No	AE.IMPORT_EVENT
SDV	* A12. Is this event an expected adverse event?	○ Yes ○ No	AE.EXPECTED
SDV	* A13. Causality related to study medication	○ Not related ○ Possibly Related ○ Probably Related ○ Definitely Related	AE.CAUSALITY
SDV	* A14. Outcome	○ Death ○ Resolved with sequelae ○ Resolved without sequelae ○ Ongoing	AE.OUTCOME
SDV	* A14a. Date of resolution, clinical stability or death		AE.ENDDAT
SDV	* A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)		AE.NARRATIVE

SUBMISSION INSTRUCTIONS

Instructions: Please follow reporting timeframes below based on seriousness of event.

Fatal or life threatening: Within 24 hours of first knowledge of event.

Serious, but not fatal or life threatening, and pregnancy: Within 24 hours of first knowledge of event.

All other AEs: Within 7 calendar days of first knowledge of event

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text

Page Information														
Page-1-618769	Help Text Line	0	Instructions: Please complete the <u>Adverse Event - Initial Report</u> form for each new adverse event. When an event that was ongoing at the time of initial data entry resolves or there is new information, record all updated information on the <u>Adverse Event - Follow-up</u> form.											
Page-2-618769	Auto Calc Field	0	A1. AE - Initial Report (ID Number)	AE.AESPID								3	0	
-- Auto Calc Rule (AE.AESPID): __NEW_EXPR__{"type":"PageSequenceIndex"														
Page-3-618769	Text Field	0	A2. Adverse Event term	AE.AETERM	Yes			Yes : MedDRA v20.1 - 5 Level		150	50			Please provide the Adverse Event term to best of knowledge. The term will then be coded.
Page-4-618769	Date	0	A3. Onset date	AE.STDAT	Yes									Please provide the date that the Adverse Event first started.
Page-5-618769	Time	0	A4. Onset time	AE.STTIM	Yes									Please provide the time that the Adverse Event started, to the best of the subject's knowledge. If unknown, leave blank and answer query as unknown.

Page Information														
Page-6-618769	Dropdown	0	A5. Study visit associated with AE onset date.	AE.AEVISIT	Yes				cVISITS					Indicate the visit interval associated with the onset (start date) of this AE. If the AE start date occurs between visits (i.e. between 3 and 6 Month Visits), associate it with the later of the 2 visits (i.e. 6 Month). A few examples: oIf AE start date was prior to the Baseline visit date, the interval should be “Screening”. oIf AE start date was between Baseline (after Baseline visit was completed) and Prior to 1 Month Visit, the interval should be "1 Month". oIf AE start date was between 1 Month (after 1 Month visit was completed) and Prior to 3 Month Visit, the interval should be "3 Month".
Page-7-618769	Date	0	A6. Date site became aware of event	AE.AESAEDAT	Yes									Please provide the date that the Adverse Event was first noted.
Page-8-618769	Radiolist	0	A7. Severity	AE.SEVERITY	Yes				cSEVERITY					
Page-9-618769	Radiolist Horizontal	0	A8. Was the subject on study medication at the time of the event?	AE.ONSTMED	Yes				cYN					

Page Information														
Page-10-618769	Date	1	A8a. Date of last dose of study medication prior to onset of the event	AE.LDOSDAT	Yes									Please answer to the best of your knowledge. If unknown, leave blank and answer query stating that this is unknown.
-- Page Dynamics (AE. LDOSDAT): Show When: AE.ONSTMED = 1														
Page-11-618769	Radiolist Horizontal	0	A9. Was study drug temporarily stopped or permanently discontinued due to this event?	AE.STMACTN	Yes				cYN					
Page-12-618769	Radiolist Horizontal	1	A9a. Type of change to study drug	AE.STMEDACTYP	Yes				cSTMEDACTION					
-- Page Dynamics (AE. STMEDACTYP): Show When: AE.STMACTN = 1														
Page-13-618769	Help Text Line	2	If Temporarily Stopped, please complete the pTDIS (Temporary Discontinuation of Study Drug) form in the Study Drug Visit.											
-- Page Dynamics (.): Show When: AE.STMEDACTYP = 1														
Page-14-618769	Help Text Line	2	If Permanently Discontinued, please complete the pPDIS (Permanent Discontinuation of Study Drug) form in the Study Drug Visit.											
-- Page Dynamics (.): Show When: AE.STMEDACTYP = 2														
Page-15-618769	Radiolist Horizontal	0	A10. Action taken or treatment for this event	AE.ACTN	Yes				cYN					
Page-16-618769	Radiolist Horizontal	1	A10a. Labs, tests, or studies done to diagnose/evaluate event	AE.TESTACTN	Yes				cYN					
-- Page Dynamics (AE. TESTACTN): Show When: AE.ACTN = 1														
Page-17-618769	Help Text Line	1	Please upload de-identified source documents.											
-- Page Dynamics (.): Show When: AE.TESTACTN = 1														
Page-18-618769	Help Text Line	1	Report all labs, tests, or studies in the narrative portion of this form.											
-- Page Dynamics (.): Show When: AE.TESTACTN = 1														
Page-19-618769	Radiolist Horizontal	1	A10b. Medication administered to treat event	AE.MEDACTN	Yes				cYN					
-- Page Dynamics (AE. MEDACTN): Show When: AE.ACTN = 1														

Page Information														
Page-20-618769	Help Text Line	1	Report all medication on the CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit <u>as well as</u> in the narrative portion of this form.											
-- Page Dynamics (.): Show When: AE.MEDACTN = 1														
Page-21-618769	Radiolist Horizontal	1	A10c. Other	AE. ACTNOTH	Yes				cYN					
-- Page Dynamics (AE. ACTNOTH): Show When: AE.ACTN = 1														
Page-22-618769	Text Field	2	A10c1. Please specify the other action or treatment taken for the event	AE. ACTNOTHSP	Yes					200	99			
-- Page Dynamics (AE. ACTNOTHSP): Show When: AE.ACTNOTH = 1														
Page-23-618769	Radiolist Horizontal	0	A11. Is this a Serious Adverse Event (SAE)?	AE. SAE	Yes				cYN					SAE consists of events that are fatal or life threatening, results in death, requires or prolongs existing hospitalization, results in disability, or causes a congenital anomaly/birth defect.
Page-24-618769	Help Text Line	1	If Yes, specify why this is considered serious by answering SAE criteria questions below.											
-- Page Dynamics (.): Show When: AE.SAE = 1														
Page-25-618769	Radiolist Horizontal	1	A11a. Resulted in death	AE. DEATH	Yes				cYN					
-- Page Dynamics (AE. DEATH): Show When: AE.SAE = 1														
Page-26-618769	Radiolist Horizontal	1	A11b. Immediate life-threatening event (immediate danger of death from event)	AE. LIFE_THREAT	Yes				cYN					
-- Page Dynamics (AE. LIFE_THREAT): Show When: AE.SAE = 1														
Page-27-618769	Radiolist Horizontal	1	A11c. Requires inpatient hospitalization or prolongation of existing hospitalization	AE. HOSP	Yes				cYN					
-- Page Dynamics (AE. HOSP): Show When: AE.SAE = 1														
Page-28-618769	Date	2	A11c1. Admission date	AE. ADMDAT	Yes									
-- Page Dynamics (AE. ADMDAT): Show When: AE.SAE = 1 AND AE.HOSP = 1														

Page Information														
Page-29-618769	Radiolist Horizontal	2	A11c2. Is the subject still in the hospital?	AE.HOSPONG	Yes				cYN					
-- Page Dynamics (AE. HOSPONG): Show When: AE.SAE = 1 AND AE.HOSP = 1														
Page-30-618769	Date	2	A11c3. Discharge date	AE.DISDAT	Yes									
-- Page Dynamics (AE. DISDAT): Show When: AE.HOSP = 1 AND AE.HOSPONG = 0														
Page-31-618769	Radiolist Horizontal	1	A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	AE.LIFE_FUNC	Yes				cYN					
-- Page Dynamics (AE. LIFE_FUNC): Show When: AE.SAE = 1														
Page-32-618769	Radiolist Horizontal	1	A11e. Results in a congenital anomaly in the offspring of a participant	AE.CONG_ANOM	Yes				cYN					
-- Page Dynamics (AE. CONG_ANOM): Show When: AE.SAE = 1														
Page-33-618769	Radiolist Horizontal	1	A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	AE.IMPORT_EVENT	Yes				cYN					
-- Page Dynamics (AE. IMPORT_EVENT): Show When: AE.SAE = 1														

Page Information														
Page-34-618769	Radiolist Horizontal	0	A12. Is this event an expected adverse event?	AE.EXPECTED	Yes				cYN					Expected: An event is considered expected if it is known to be associated with the study drug(s) and/or the disease state. For this protocol, expected events reported since market introduction regardless of evidence of causality and included in the product brochure are: o Myalgia, muscle spasms, pain in extremity, back pain, arthralgia, rhabdomyolysis o Asthenia, hypoesthesia, fatigue, malaise, dizziness, insomnia, depression, headache, weakness o Diarrhea, constipation, dyspepsia, nausea, abdominal pain o Hepatitis, jaundice, fatal and non-fatal liver failure o Diabetes o Pruritis, rash, urticaria o Interstitial lung disease o Erectile dysfunction o Rare post-marketing reports of cognitive impairment
Page-35-618769	Radiolist	0	A13. Causality related to study medication	AE.CAUSALITY	Yes				cRELATED					

Page Information														
Page-36-618769	Radiolist	0	A14. Outcome	AE.OUTCOME	Yes				cOUTCOME					If outcome is Ongoing at the time of initial entry, please complete an <u>Adverse Event - Follow-up</u> form, once there is new information or the event resolves.
Page-37-618769	Date	1	A14a. Date of resolution, clinical stability or death	AE.ENDDAT	Yes									
-- Page Dynamics (AE. ENDDAT): Show When: AE.OUTCOME = 1 OR AE.OUTCOME = 2 OR AE.OUTCOME = 3														
Page-38-618769	Comments	0	A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)	AE.NARRATIVE	Yes									
Page-39-618769	Section Header	0	SUBMISSION INSTRUCTIONS											
Page-40-618769	Help Text Line	0	Instructions: Please follow reporting timeframes below based on seriousness of event.											
Page-41-618769	Help Text Line	0	Fatal or life threatening: Within 24 hours of first knowledge of event.											
Page-42-618769	Help Text Line	0	Serious, but not fatal or life threatening, and pregnancy: Within 24 hours of first knowledge of event.											
Page-43-618769	Help Text Line	0	All other AEs: Within 7 calendar days of first knowledge of event											

System Queries													
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618870	SYSQ_0922	AE.OUTCOME	Other / Cross Page		AE.HOSPONG = 1 AND AE.OUTCOME <> 4	Outcome should be ongoing if subject is still in the hospital.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0

System Queries													
sysq-618871	SYSQ_1018	AE.SAE	Other / Cross Page		(AE.SAE = 0 AND AE.SEVERITY >= 3) OR (AE.SAE = 1 AND AE.SEVERITY < 3)	SAE has been defined as severity Grade 3-5. Please check for consistency.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618874	SYSQ_1483	AE.DISDAT	Other / Cross Page		AE.DISDAT < AE.ADMDAT	Discharge date should be on or after the hospitalization date.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-619001	SYSQ_4972	AE.STDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(AE.STDAT, 10-20-ICF.ICF_DT) > 0	This date is prior to the informed consent date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619004	SYSQ_4973	AE.STDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(AE.STDAT, 120-20-EOS.DATE) < 0	This date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619006	SYSQ_4974	AE.ENDDAT	Other / Cross Page		AE.ENDDAT < AE.STDAT	Date of resolution, clinical stability or death is prior to the event onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619008	SYSQ_4975	AE.ENDDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(AE.ENDDAT, 120-20-EOS.DATE) < 0	This date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619010	SYSQ_4976	AE.OUTCOME	Other / Cross Page		AE.OUTCOME = 1 AND AE.SAE <> 1	The Outcome of the event has been indicated as Death, however the event is reported as Not Serious. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619012	SYSQ_4977	AE.AESAEDAT	Other / Cross Page		AE.AESAEDAT < AE.STDAT	Date site became aware of the event must be on or after the onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0

System Queries														
sysq-619013	SYSQ_4978	AE.ACTN	Other / Cross Page		AE.ACTN = 1 AND AE.TESTACTN = 0 AND AE.MEDACTN = 0 AND AE.ACTNOTH = 0	Action taken or treatment for this event is Yes, however, the specific actions/treatments which include labs/tests, medications and other, all report No. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619015	SYSQ_4979	AE.LDOSDAT	Other / Cross Page		AE.LDOSDAT > AE.STDAT	Date of last dose of study medication prior to onset of the event must be on or prior to the onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-620108	SYSQ_5667	AE.AETERM	Field Null		AE.AETERM IS NULL	"A2. Adverse Event term" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620110	SYSQ_5668	AE.STDAT	Field Null		AE.STDAT IS NULL	"A3. Onset date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620112	SYSQ_5669	AE.STDAT	Future Date		AE.STDAT > Today	"A3. Onset date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620114	SYSQ_5670	AE.STTIM	Field Null		AE.STTIM IS NULL	"A4. Onset time" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620116	SYSQ_5671	AE.AEVISIT	Field Null		AE.AEVISIT IS NULL	"A5. Study visit associated with AE onset date." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620118	SYSQ_5672	AE.AESAEDAT	Field Null		AE.AESAEDAT IS NULL	"A6. Date site became aware of event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620120	SYSQ_5673	AE.AESAEDAT	Future Date		AE.AESAEDAT > Today	"A6. Date site became aware of event" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620122	SYSQ_5674	AE.SEVERITY	Field Null		AE.SEVERITY IS NULL	"A7. Severity" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0

System Queries														
sysq-620125	SYSQ_5675	AE.ONSTMED	Field Null		AE.ONSTMED IS NULL	"A8. Was the subject on study medication at the time of the event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620127	SYSQ_5676	AE.LDOSDAT	Field Null		AE.LDOSDAT IS NULL	"A8a. Date of last dose of study medication prior to onset of the event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620128	SYSQ_5677	AE.LDOSDAT	Future Date		AE.LDOSDAT > Today	"A8a. Date of last dose of study medication prior to onset of the event" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620131	SYSQ_5678	AE.STMACTN	Field Null		AE.STMACTN IS NULL	"A9. Was study drug temporarily stopped or permanently discontinued due to this event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620132	SYSQ_5679	AE.STMEDACTYP	Field Null		AE.STMEDACTYP IS NULL	"A9a. Type of change to study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620135	SYSQ_5680	AE.ACTN	Field Null		AE.ACTN IS NULL	"A10. Action taken or treatment for this event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620137	SYSQ_5681	AE.TESTACTN	Field Null		AE.TESTACTN IS NULL	"A10a. Labs, tests, or studies done to diagnose/evaluate event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620139	SYSQ_5682	AE.MEDACTN	Field Null		AE.MEDACTN IS NULL	"A10b. Medication administered to treat event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620140	SYSQ_5683	AE.ACTNOTH	Field Null		AE.ACTNOTH IS NULL	"A10c. Other" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620143	SYSQ_5684	AE.ACTNOTHSP	Field Null		AE.ACTNOTHSP IS NULL	"A10c1. Please specify the other action or treatment taken for the event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0

System Queries														
sysq-620144	SYSQ_5685	AE.SAE	Field Null		AE.SAE IS NULL	"A11. Is this a Serious Adverse Event (SAE)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620146	SYSQ_5686	AE.DEATH	Field Null		AE.DEATH IS NULL	"A11a. Resulted in death" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620149	SYSQ_5687	AE.LIFE_THREAT	Field Null		AE.LIFE_THREAT IS NULL	"A11b. Immediate life-threatening event (immediate danger of death from event)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620150	SYSQ_5688	AE.HOSP	Field Null		AE.HOSP IS NULL	"A11c. Requires inpatient hospitalization or prolongation of existing hospitalization" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620152	SYSQ_5689	AE.ADMDAT	Field Null		AE.ADMDAT IS NULL	"A11c1. Admission date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620154	SYSQ_5690	AE.ADMDAT	Future Date		AE.ADMDAT > Today	"A11c1. Admission date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620156	SYSQ_5691	AE.HOSPONG	Field Null		AE.HOSPONG IS NULL	"A11c2. Is the subject still in the hospital?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620159	SYSQ_5692	AE.DISDAT	Field Null		AE.DISDAT IS NULL	"A11c3. Discharge date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620160	SYSQ_5693	AE.DISDAT	Future Date		AE.DISDAT > Today	"A11c3. Discharge date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620163	SYSQ_5694	AE.LIFE_FUNC	Field Null		AE.LIFE_FUNC IS NULL	"A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0

System Queries														
sysq-620164	SYSQ_5695	AE.CONG_ANOM	Field Null		AE.CONG_ANOM IS NULL	"A11e. Results in a congenital anomaly in the offspring of a participant" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620166	SYSQ_5696	AE.IMPORT_EVENT	Field Null		AE.IMPORT_EVENT IS NULL	"A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620169	SYSQ_5697	AE.EXPECTED	Field Null		AE.EXPECTED IS NULL	"A12. Is this event an expected adverse event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620171	SYSQ_5698	AE.CAUSALITY	Field Null		AE.CAUSALITY IS NULL	"A13. Causality related to study medication" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620172	SYSQ_5699	AE.OUTCOME	Field Null		AE.OUTCOME IS NULL	"A14. Outcome" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620174	SYSQ_5700	AE.ENDDAT	Field Null		AE.ENDDAT IS NULL	"A14a. Date of resolution, clinical stability or death" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620177	SYSQ_5701	AE.ENDDAT	Future Date		AE.ENDDAT > Today	"A14a. Date of resolution, clinical stability or death" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620179	SYSQ_5702	AE.NARRATIVE	Field Null		AE.NARRATIVE IS NULL	"A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0

pAEFUP

Page

(Visit ID = 618770, Page ID =)

Unique Identifier page-618770-618770-618770-

Instructions: Please complete the Adverse Event - Initial Report form for each new adverse event.

When an event that was ongoing at the time of initial data entry resolves or there is new information, record all updated information on the Adverse Event - Follow-up form.

SDV	* A1. AE - Initial Report ID Number associated with this event follow-up		AEFUP.AENUM	(format xxx)
SDV	* A1a. Did anything change since the initial form was completed?	○ Yes ○ No	AEFUP.AECHANGE	
	If A1a. = "No", skip to A14. Outcome			
SDV	* A2. Adverse Event term		AEFUP.AETERM	
SDV	* A3. Onset date		AEFUP.STDAT	
SDV	* A4. Onset time	:	AEFUP.STTIM	(HH24:MI)
SDV	* A5. Study visit associated with AE onset date.		AEFUP.AEVISIT	
SDV	* A6. Date site became aware of event		AEFUP.AESAEDAT	
SDV	* A7. Severity	○ Grade 1 - Mild ○ Grade 2 – Moderate ○ Grade 3 – Severe ○ Grade 4 – Life-threatening Or disabling ○ Grade 5 – Death	AEFUP.SEVERITY	
SDV	* A8. Was the subject on study medication at the time of the event?	○ Yes ○ No	AEFUP.ONSTMED	
SDV	* A8a. Date of last dose of study medication prior to onset of the event		AEFUP.LDOSDAT	
SDV	* A9. Was study drug temporarily stopped or permanently discontinued due to this event?	○ Yes ○ No	AEFUP.STMACTN	

SDV	* A9a. Type of change to study drug	○ Temporarily stopped ○ Permanently discontinued	AEFUP.STMEDACTYP
	If Temporarily Stopped, please complete the pTDIS (Temporary Discontinuation of Study Drug) form in the Study Drug Visit. *If Permanently Discontinued, please complete the pPDIS (Permanent Discontinuation of Study Drug) form in the Study Drug Visit.*		
SDV	* A10. Action taken or treatment for this event	○ Yes ○ No	AEFUP.ACTN
SDV	* A10a. Labs, tests, or studies done to diagnose/evaluate event	○ Yes ○ No	AEFUP.TESTACTN
	Please upload de-identified source documents. *Report all labs, tests, or studies in the narrative portion of this form.*		
SDV	* A10b. Medication administered to treat event	○ Yes ○ No	AEFUP.MEDACTN
	Report all medication on the CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit as well as in the narrative portion of this form.		
SDV	* A10c. Other	○ Yes ○ No	AEFUP.ACTNOTH
SDV	* A10c1. Please specify the other action or treatment taken for the event		AEFUP.ACTNOTHSP
SDV	* A11. Is this a Serious Adverse Event (SAE)?	○ Yes ○ No	AEFUP.SAE
	If Yes, specify why this is considered serious by answering SAE criteria questions below.		
SDV	* A11a. Resulted in death	○ Yes ○ No	AEFUP.DEATH
SDV	* A11b. Immediate life-threatening event (immediate danger of death from event)	○ Yes ○ No	AEFUP.LIFE_THREAT
SDV	* A11c. Requires inpatient hospitalization or prolongation of existing hospitalization	○ Yes ○ No	AEFUP.HOSP
SDV	* A11c1. Admission date		AEFUP.ADMDAT
SDV	* A11c2. Is the subject still in the hospital?	○ Yes ○ No	AEFUP.HOSPONG
SDV	* A11c3. Discharge date		AEFUP.DISDAT

SDV	* A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	○ Yes ○ No	AEFUP.LIFE_FUNC
SDV	* A11e. Results in a congenital anomaly in the offspring of a participant	○ Yes ○ No	AEFUP.CONG_ANOM
SDV	* A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	○ Yes ○ No	AEFUP.IMPORT_EVENT
SDV	* A12. Is this event an expected adverse event?	○ Yes ○ No	AEFUP.EXPECTED
SDV	* A13. Causality related to study medication	○ Not related ○ Possibly Related ○ Probably Related ○ Definitely Related	AEFUP.CAUSALITY
SDV	* A14. Outcome	○ Death ○ Resolved with sequelae ○ Resolved without sequelae ○ Ongoing	AEFUP.OUTCOME
SDV	* A14a. Date of resolution, clinical stability or death		AEFUP.ENDDAT
SDV	* A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)		AEFUP.NARRATIVE

SUBMISSION INSTRUCTIONS

Instructions: Please follow reporting timeframes below based on seriousness of event.

Fatal or life threatening: Within 24 hours of first knowledge of event.

Serious, but not fatal or life threatening, and pregnancy: Within 24 hours of first knowledge of event.

All other AEs: Within 7 calendar days of first knowledge of event

Page Information														
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618770	Help Text Line	0	Instructions: Please complete the <u>Adverse Event - Initial Report</u> form for each new adverse event. When an event that was ongoing at the time of initial data entry resolves or there is new information, record all updated information on the <u>Adverse Event - Follow-up</u> form.											
Page-2-618770	Numeric	0	A1. AE - Initial Report ID Number associated with this event follow-up	AEFUP.AENUM	Yes							3	0	Enter the AE number of the event from the Adverse Event - Initial Report form that is associated with the Follow-up.
Page-3-618770	Radiolist Horizontal	1	A1a. Did anything change since the initial form was completed?	AEFUP.AECHANGE	Yes				cYN					
Page-4-618770	Help Text Line	1	If A1a. = "No", skip to A14. Outcome											
Page-5-618770	Text Field	0	A2. Adverse Event term	AEFUP.AETERM	Yes			Yes : MedDRA v20.1 - 5 Level		150	50			Please provide the Adverse Event term to best of knowledge. The term will then be coded.
-- Page Dynamics (AEFUP. AETERM): Show When: AEFUP.AECHANGE = 1														
Page-6-618770	Date	0	A3. Onset date	AEFUP.STDAT	Yes									Please provide the date that the Adverse Event first started.
-- Page Dynamics (AEFUP. STDAT): Show When: AEFUP.AECHANGE = 1														

Page Information													
Page-7-618770	Time	0	A4. Onset time	AEFUP.STTIM	Yes								Please provide the time that the Adverse Event started, to the best of the subject's knowledge. If unknown, leave blank and answer query as unknown.
-- Page Dynamics (AEFUP. STTIM): Show When: AEFUP.AECHANGE = 1													
Page-8-618770	Dropdown	0	A5. Study visit associated with AE onset date.	AEFUP.AEVISIT	Yes				cVISITS				Indicate the visit interval associated with the onset (start date) of this AE. If the AE start date occurs between visits (i.e. between 3 and 6 Month Visits), associate it with the later of the 2 visits (i.e. 6 Month). A few examples: olf AE start date was prior to the Baseline visit date, the interval should be “Screening”. olf AE start date was between Baseline (after Baseline visit was completed) and Prior to 1 Month Visit, the interval should be "1 Month". olf AE start date was between 1 Month (after 1 Month visit was completed) and Prior to 3 Month Visit, the interval should be "3 Month".
-- Page Dynamics (AEFUP. AEVISIT): Show When: AEFUP.AECHANGE = 1													

Page Information														
Page-9-618770	Date	0	A6. Date site became aware of event	AEFUP.AESAEDAT	Yes									Please provide the date that the Adverse Event was first noted.
-- Page Dynamics (AEFUP. AESAEDAT): Show When: AEFUP.AECHANGE = 1														
Page-10-618770	Radiolist	0	A7. Severity	AEFUP.SEVERITY	Yes				cSEVERITY					
-- Page Dynamics (AEFUP. SEVERITY): Show When: AEFUP.AECHANGE = 1														
Page-11-618770	Radiolist Horizontal	0	A8. Was the subject on study medication at the time of the event?	AEFUP.ONSTMED	Yes				cYN					
-- Page Dynamics (AEFUP. ONSTMED): Show When: AEFUP.AECHANGE = 1														
Page-12-618770	Date	1	A8a. Date of last dose of study medication prior to onset of the event	AEFUP.LDOSDAT	Yes									Please answer to the best of your knowledge. If unknown, leave blank and answer query stating that this is unknown.
-- Page Dynamics (AEFUP. LDOSDAT): Show When: AEFUP.ONSTMED = 1 AND AEFUP.AECHANGE = 1														
Page-13-618770	Radiolist Horizontal	0	A9. Was study drug temporarily stopped or permanently discontinued due to this event?	AEFUP.STMACTN	Yes				cYN					
-- Page Dynamics (AEFUP. STMACTN): Show When: AEFUP.AECHANGE = 1														
Page-14-618770	Radiolist Horizontal	1	A9a. Type of change to study drug	AEFUP.STMEDACTYP	Yes				cSTMEDACTION					
-- Page Dynamics (AEFUP. STMEDACTYP): Show When: AEFUP.STMACTN = 1 AND AEFUP.AECHANGE = 1														
Page-15-618770	Help Text Line	2	If Temporarily Stopped, please complete the pTDIS (Temporary Discontinuation of Study Drug) form in the Study Drug Visit.											
-- Page Dynamics (.): Show When: AEFUP.STMEDACTYP = 1 AND AEFUP.AECHANGE = 1														
Page-16-618770	Help Text Line	2	If Permanently Discontinued, please complete the pPDIS (Permanent Discontinuation of Study Drug) form in the Study Drug Visit.											
-- Page Dynamics (.): Show When: AEFUP.STMEDACTYP = 2 AND AEFUP.AECHANGE = 1														
Page-17-618770	Radiolist Horizontal	0	A10. Action taken or treatment for this event	AEFUP.ACTN	Yes				cYN					
-- Page Dynamics (AEFUP. ACTN): Show When: AEFUP.AECHANGE = 1														

Page Information														
Page-18-618770	Radiolist Horizontal	1	A10a. Labs, tests, or studies done to diagnose/evaluate event	AEFUP.TESTACTN	Yes				cYN					
-- Page Dynamics (AEFUP. TESTACTN): Show When: AEFUP.ACTN = 1 AND AEFUP.AECHANGE = 1														
Page-19-618770	Help Text Line	1	Please upload de-identified source documents.											
-- Page Dynamics (.): Show When: AEFUP.TESTACTN = 1 AND AEFUP.AECHANGE = 1														
Page-20-618770	Help Text Line	1	Report all labs, tests, or studies in the narrative portion of this form.											
-- Page Dynamics (.): Show When: AEFUP.TESTACTN = 1 AND AEFUP.AECHANGE = 1														
Page-21-618770	Radiolist Horizontal	1	A10b. Medication administered to treat event	AEFUP.MEDACTN	Yes				cYN					
-- Page Dynamics (AEFUP. MEDACTN): Show When: AEFUP.ACTN = 1 AND AEFUP.AECHANGE = 1														
Page-22-618770	Help Text Line	1	Report all medication on the CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit <u>as well as</u> in the narrative portion of this form.											
-- Page Dynamics (.): Show When: AEFUP.MEDACTN = 1 AND AEFUP.AECHANGE = 1														
Page-23-618770	Radiolist Horizontal	1	A10c. Other	AEFUP.ACTNOTH	Yes				cYN					
-- Page Dynamics (AEFUP. ACTNOTH): Show When: AEFUP.ACTN = 1 AND AEFUP.AECHANGE = 1														
Page-24-618770	Text Field	2	A10c1. Please specify the other action or treatment taken for the event	AEFUP.ACTNOTHSP	Yes					200	99			
-- Page Dynamics (AEFUP. ACTNOTHSP): Show When: AEFUP.ACTNOTH = 1 AND AEFUP.AECHANGE = 1														
Page-25-618770	Radiolist Horizontal	0	A11. Is this a Serious Adverse Event (SAE)?	AEFUP.SAE	Yes				cYN					SAE consists of events that are fatal or life threatening, results in death, requires or prolongs existing hospitalization, results in disability, or causes a congenital anomaly/birth defect.
-- Page Dynamics (AEFUP. SAE): Show When: AEFUP.AECHANGE = 1														
Page-26-618770	Help Text Line	1	If Yes, specify why this is considered serious by answering SAE criteria questions below.											
-- Page Dynamics (.): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														

Page Information														
Page-27-618770	Radiolist Horizontal	1	A11a. Resulted in death	AEFUP.DEATH	Yes				cYN					
-- Page Dynamics (AEFUP. DEATH): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-28-618770	Radiolist Horizontal	1	A11b. Immediate life-threatening event (immediate danger of death from event)	AEFUP.LIFE_THREAT	Yes				cYN					
-- Page Dynamics (AEFUP. LIFE_THREAT): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-29-618770	Radiolist Horizontal	1	A11c. Requires inpatient hospitalization or prolongation of existing hospitalization	AEFUP.HOSP	Yes				cYN					
-- Page Dynamics (AEFUP. HOSP): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-30-618770	Date	2	A11c1. Admission date	AEFUP.ADMDAT	Yes									
-- Page Dynamics (AEFUP. ADMDAT): Show When: AEFUP.SAE = 1 AND AEFUP.HOSP = 1 AND AEFUP.AECHANGE = 1														
Page-31-618770	Radiolist Horizontal	2	A11c2. Is the subject still in the hospital?	AEFUP.HOSPONG	Yes				cYN					
-- Page Dynamics (AEFUP. HOSPONG): Show When: AEFUP.SAE = 1 AND AEFUP.HOSP = 1 AND AEFUP.AECHANGE = 1														
Page-32-618770	Date	2	A11c3. Discharge date	AEFUP.DISDAT	Yes									
-- Page Dynamics (AEFUP. DISDAT): Show When: AEFUP.HOSP = 1 AND AEFUP.HOSPONG = 0 AND AEFUP.AECHANGE = 1														
Page-33-618770	Radiolist Horizontal	1	A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	AEFUP.LIFE_FUNC	Yes				cYN					
-- Page Dynamics (AEFUP. LIFE_FUNC): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-34-618770	Radiolist Horizontal	1	A11e. Results in a congenital anomaly in the offspring of a participant	AEFUP.CONG_ANOM	Yes				cYN					
-- Page Dynamics (AEFUP. CONG_ANOM): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-35-618770	Radiolist Horizontal	1	A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	AEFUP.IMPORT_EVENT	Yes				cYN					
-- Page Dynamics (AEFUP. IMPORT_EVENT): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														

Page Information														
Page-36-618770	Radiolist Horizontal	0	A12. Is this event an expected adverse event?	AEFUP.EXPECTED	Yes				cYN					Expected: An event is considered expected if it is known to be associated with the study drug(s) and/or the disease state. For this protocol, expected events reported since market introduction regardless of evidence of causality and included in the product brochure are: o Myalgia, muscle spasms, pain in extremity, back pain, arthralgia, rhabdomyolysis o Asthenia, hypoesthesia, fatigue, malaise, dizziness, insomnia, depression, headache, weakness o Diarrhea, constipation, dyspepsia, nausea, abdominal pain o Hepatitis, jaundice, fatal and non-fatal liver failure o Diabetes o Pruritis, rash, urticaria o Interstitial lung disease o Erectile dysfunction o Rare post-marketing reports of cognitive impairment
-- Page Dynamics (AEFUP. EXPECTED): Show When: AEFUP.AECHANGE = 1														
Page-37-618770	Radiolist	0	A13. Causality related to study medication	AEFUP.CAUSALITY	Yes				cRELATED					

Page Information														
-- Page Dynamics (AEFUP. CAUSALITY): Show When: AEFUP.AECHANGE = 1														
Page-38-618770	Radiolist	0	A14. Outcome	AEFUP.OUTCOME	Yes				cOUTCOME					If outcome is Ongoing at the time of initial entry, please complete an <u>Adverse Event - Follow-up</u> form, once there is new information or the event resolves.
Page-39-618770	Date	1	A14a. Date of resolution, clinical stability or death	AEFUP.ENDDAT	Yes									
-- Page Dynamics (AEFUP. ENDDAT): Show When: AEFUP.OUTCOME = 1 OR AEFUP.OUTCOME = 2 OR AEFUP.OUTCOME = 3														
Page-40-618770	Comments	0	A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)	AEFUP.NARRATIVE	Yes									
Page-41-618770	Section Header	0	SUBMISSION INSTRUCTIONS											
Page-42-618770	Help Text Line	0	Instructions: Please follow reporting timeframes below based on seriousness of event.											
Page-43-618770	Help Text Line	0	Fatal or life threatening: Within 24 hours of first knowledge of event.											
Page-44-618770	Help Text Line	0	Serious, but not fatal or life threatening, and pregnancy: Within 24 hours of first knowledge of event.											
Page-45-618770	Help Text Line	0	All other AEs: Within 7 calendar days of first knowledge of event											

System Queries													
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-620301	SYSQ_5768	AEFUP.OUTCOME	Other / Cross Page		AEFUP.HOSPONG = 1 AND AEFUP.OUTCOME <> 4	Outcome should be ongoing if subject is still in the hospital.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0

System Queries														
sysq-620303	SYSQ_5769	AEFUP.SAE	Other / Cross Page		(AEFUP.SAE = 0 AND AEFUP.SEVERITY >= 3) OR (AEFUP.SAE = 1 AND AEFUP.SEVERITY < 3)	SAE has been defined as severity Grade 3-5. Please check for consistency.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620304	SYSQ_5770	AEFUP.DISDAT	Other / Cross Page		AEFUP.DISDAT < AEFUP.ADMDAT	Discharge date should be on or after the hospitalization date.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620307	SYSQ_5771	AEFUP.STDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(AEFUP.STDAT, 10-20-ICF.ICF_DT) > 0	This date is prior to the informed consent date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620309	SYSQ_5772	AEFUP.STDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(AEFUP.STDAT, 120-20-EOS.DATE) < 0	This date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620311	SYSQ_5773	AEFUP.ENDDAT	Other / Cross Page		AEFUP.ENDDAT < AEFUP.STDAT	Date of resolution, clinical stability or death is prior to the event onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620313	SYSQ_5774	AEFUP.ENDDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(AEFUP.ENDDAT, 120-20-EOS.DATE) < 0	This date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620315	SYSQ_5775	AEFUP.OUTCOME	Other / Cross Page		AEFUP.OUTCOME = 1 AND AEFUP.SAE <> 1	The Outcome of the event has been indicated as Death, however the event is reported as Not Serious. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620316	SYSQ_5776	AEFUP.AESAEDAT	Other / Cross Page		AEFUP.AESAEDAT < AEFUP.STDAT	Date site became aware of the event must be on or after the onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0

System Queries														
sysq-620318	SYSQ_5777	AEFUP.ACTN	Other / Cross Page		AEFUP.ACTN = 1 AND AEFUP.TESTACTN = 0 AND AEFUP.MEDACTN = 0 AND AEFUP.ACTNOTH = 0	Action taken or treatment for this event is Yes, however, the specific actions/treatments which include labs/tests, medications and other, all report No. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620320	SYSQ_5778	AEFUP.LDOSDAT	Other / Cross Page		AEFUP.LDOSDAT > AEFUP.STDAT	Date of last dose of study medication prior to onset of the event must be on or prior to the onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620322	SYSQ_5779	AEFUP.AENUM	Field Null		AEFUP.AENUM IS NULL	"A1. AE - Initial Report ID Number associated with this event follow-up" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620324	SYSQ_5780	AEFUP.AECHANGE	Field Null		AEFUP.AECHANGE IS NULL	"A1a. Did anything change since the initial form was completed?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620327	SYSQ_5781	AEFUP.AETERM	Field Null		AEFUP.AETERM IS NULL	"A2. Adverse Event term" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620329	SYSQ_5782	AEFUP.STDAT	Field Null		AEFUP.STDAT IS NULL	"A3. Onset date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620331	SYSQ_5783	AEFUP.STDAT	Future Date		AEFUP.STDAT > Today	"A3. Onset date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620333	SYSQ_5784	AEFUP.STTIM	Field Null		AEFUP.STTIM IS NULL	"A4. Onset time" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620335	SYSQ_5785	AEFUP.AEVISIT	Field Null		AEFUP.AEVISIT IS NULL	"A5. Study visit associated with AE onset date." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0

System Queries														
sysq-620336	SYSQ_5786	AEFUP.AESAEDAT	Field Null		AEFUP.AESAEDAT IS NULL	"A6. Date site became aware of event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620339	SYSQ_5787	AEFUP.AESAEDAT	Future Date		AEFUP.AESAEDAT > Today	"A6. Date site became aware of event" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620341	SYSQ_5788	AEFUP.SEVERITY	Field Null		AEFUP.SEVERITY IS NULL	"A7. Severity" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620343	SYSQ_5789	AEFUP.ONSTMED	Field Null		AEFUP.ONSTMED IS NULL	"A8. Was the subject on study medication at the time of the event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620344	SYSQ_5790	AEFUP.LDOSDAT	Field Null		AEFUP.LDOSDAT IS NULL	"A8a. Date of last dose of study medication prior to onset of the event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620347	SYSQ_5791	AEFUP.LDOSDAT	Future Date		AEFUP.LDOSDAT > Today	"A8a. Date of last dose of study medication prior to onset of the event" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620349	SYSQ_5792	AEFUP.STMACTN	Field Null		AEFUP.STMACTN IS NULL	"A9. Was study drug temporarily stopped or permanently discontinued due to this event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620350	SYSQ_5793	AEFUP.STMEDACTYP	Field Null		AEFUP.STMEDACTYP IS NULL	"A9a. Type of change to study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620352	SYSQ_5794	AEFUP.ACTN	Field Null		AEFUP.ACTN IS NULL	"A10. Action taken or treatment for this event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620354	SYSQ_5795	AEFUP.TESTACTN	Field Null		AEFUP.TESTACTN IS NULL	"A10a. Labs, tests, or studies done to diagnose/evaluate event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0

System Queries														
sysq-620357	SYSQ_5796	AEFUP.MEDACTN	Field Null		AEFUP.MEDACTN IS NULL	"A10b. Medication administered to treat event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620358	SYSQ_5797	AEFUP.ACTNOTH	Field Null		AEFUP.ACTNOTH IS NULL	"A10c. Other" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620360	SYSQ_5798	AEFUP.ACTNOTHSP	Field Null		AEFUP.ACTNOTHSP IS NULL	"A10c1. Please specify the other action or treatment taken for the event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620362	SYSQ_5799	AEFUP.SAE	Field Null		AEFUP.SAE IS NULL	"A11. Is this a Serious Adverse Event (SAE)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620365	SYSQ_5800	AEFUP.DEATH	Field Null		AEFUP.DEATH IS NULL	"A11a. Resulted in death" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620367	SYSQ_5801	AEFUP.LIFE_THREAT	Field Null		AEFUP.LIFE_THREAT IS NULL	"A11b. Immediate life-threatening event (immediate danger of death from event)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620368	SYSQ_5802	AEFUP.HOSP	Field Null		AEFUP.HOSP IS NULL	"A11c. Requires inpatient hospitalization or prolongation of existing hospitalization" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620370	SYSQ_5803	AEFUP.ADMDAT	Field Null		AEFUP.ADMDAT IS NULL	"A11c1. Admission date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620372	SYSQ_5804	AEFUP.ADMDAT	Future Date		AEFUP.ADMDAT > Today	"A11c1. Admission date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620375	SYSQ_5805	AEFUP.HOSPONG	Field Null		AEFUP.HOSPONG IS NULL	"A11c2. Is the subject still in the hospital?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0

System Queries														
sysq-620376	SYSQ_5806	AEFUP.DISDAT	Field Null		AEFUP.DISDAT IS NULL	"A11c3. Discharge date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620378	SYSQ_5807	AEFUP.DISDAT	Future Date		AEFUP.DISDAT > Today	"A11c3. Discharge date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620381	SYSQ_5808	AEFUP.LIFE_FUNC	Field Null		AEFUP.LIFE_FUNC IS NULL	"A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620382	SYSQ_5809	AEFUP.CONG_ANOM	Field Null		AEFUP.CONG_ANOM IS NULL	"A11e. Results in a congenital anomaly in the offspring of a participant" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620384	SYSQ_5810	AEFUP.IMPORT_EVENT	Field Null		AEFUP.IMPORT_EVENT IS NULL	"A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620386	SYSQ_5811	AEFUP.EXPECTED	Field Null		AEFUP.EXPECTED IS NULL	"A12. Is this event an expected adverse event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620388	SYSQ_5812	AEFUP.CAUSALITY	Field Null		AEFUP.CAUSALITY IS NULL	"A13. Causality related to study medication" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620390	SYSQ_5813	AEFUP.OUTCOME	Field Null		AEFUP.OUTCOME IS NULL	"A14. Outcome" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620393	SYSQ_5814	AEFUP.ENDDAT	Field Null		AEFUP.ENDDAT IS NULL	"A14a. Date of resolution, clinical stability or death" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0

System Queries														
sysq-620394	SYSQ_5815	AEFUP.ENDDAT	Future Date		AEFUP.ENDDAT > Today	"A14a. Date of resolution, clinical stability or death" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620396	SYSQ_5816	AEFUP.NARRATIVE	Field Null		AEFUP.NARRATIVE IS NULL	"A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0

pAEFUP_3

Page

(Visit ID = 618771, Page ID =)

Unique Identifier page-618771-618771-618771-

Instructions: Please complete the Adverse Event - Initial Report form for each new adverse event.

When an event that was ongoing at the time of initial data entry resolves or there is new information, record all updated information on the Adverse Event - Follow-up form.

SDV	* A1. AE - Initial Report ID Number associated with this event follow-up		AEFUP.AENUM (format xxx)
SDV	* A1a. Did anything change since the initial form was completed?	○ Yes ○ No	AEFUP.AECHANGE

If A1a. = "No", skip to A14. Outcome

SDV	* A2. Adverse Event term		AEFUP.AETERM
SDV	A3. Onset date		AEFUP.STDAT
SDV	A3a. Check if a full Onset date was not reported aboveAND at least a partial onset date is known or can be estimated (Both Month and Year or only Year) (For example, the Year may be known if the AE occurred between visits that had been performed during the same year).	☐	AEFUP.AESTDCHX

A3a1. Onset Date - Month	A3a2. Onset Date - Year
SDV (xx)	SDV (xxxx)
AEFUP.STDATM	AEFUP.STDATY

SDV	* A4. Onset time	:	AEFUP.STTIM (HH24:MI)
SDV	* A5. Study visit associated with AE onset date.		AEFUP.AEVISIT
SDV	* A6. Date site became aware of event		AEFUP.AESAEDAT

SDV	* A7. Severity	○ Grade 1 - Mild ○ Grade 2 – Moderate ○ Grade 3 – Severe ○ Grade 4 – Life-threatening Or disabling ○ Grade 5 – Death	AEFUP.SEVERITY
SDV	* A8. Was the subject on study medication at the time of the event?	○ Yes ○ No	AEFUP.ONSTMED
SDV	A8a. Date of last dose of study medication prior to onset of the event		AEFUP.LDOSDAT
SDV	A8b. Check if a full date of last dose of study medication was not reported aboveAND at least a partial date is known or can be estimated (Both Month and Year or only Year)	☐	AEFUP.LDOSDCHX
		A8b1. Date of Last Dose - Month SDV (xx) AEFUP.LDOSDATM	**A8b2. Date of Last Dose - Year** SDV (xxxx) AEFUP.LDOSDATY
SDV	* A9. Was study drug temporarily stopped or permanently discontinued due to this event?	○ Yes ○ No	AEFUP.STMACTN
SDV	* A9a. Type of change to study drug	○ Temporarily stopped ○ Permanently discontinued	AEFUP.STMEDACTYP
	If Temporarily Stopped, please complete the pTDIS (Temporary Discontinuation of Study Drug) form in the Study Drug Visit. *If Permanently Discontinued, please complete the pPDIS (Permanent Discontinuation of Study Drug) form in the Study Drug Visit.*		
SDV	* A10. Action taken or treatment for this event	○ Yes ○ No	AEFUP.ACTN
SDV	* A10a. Labs, tests, or studies done to diagnose/evaluate event	○ Yes ○ No	AEFUP.TESTACTN
	Please upload de-identified source documents. *Report all labs, tests, or studies in the narrative portion of this form.*		

SDV	* A10b. Medication administered to treat event	○ Yes ○ No	AEFUP.MEDACTN
	Report all medication on the CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit as well as in the narrative portion of this form.		
SDV	* A10c. Other	○ Yes ○ No	AEFUP.ACTNOTH
SDV	* A10c1. Please specify the other action or treatment taken for the event		AEFUP.ACTNOTHSP
SDV	* A11. Is this a Serious Adverse Event (SAE)?	○ Yes ○ No	AEFUP.SAE
	If Yes, specify why this is considered serious by answering SAE criteria questions below.		
SDV	* A11a. Resulted in death	○ Yes ○ No	AEFUP.DEATH
SDV	* A11b. Immediate life-threatening event (immediate danger of death from event)	○ Yes ○ No	AEFUP.LIFE_THREAT
SDV	* A11c. Requires inpatient hospitalization or prolongation of existing hospitalization	○ Yes ○ No	AEFUP.HOSP
SDV	* A11c1. Admission date		AEFUP.ADMDAT
SDV	* A11c2. Is the subject still in the hospital?	○ Yes ○ No	AEFUP.HOSPONG
SDV	* A11c3. Discharge date		AEFUP.DISDAT
SDV	* A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	○ Yes ○ No	AEFUP.LIFE_FUNC
SDV	* A11e. Results in a congenital anomaly in the offspring of a participant	○ Yes ○ No	AEFUP.CONG_ANOM

SDV	* A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	○ Yes ○ No	AEFUP.IMPORT_EVENT
SDV	* A12. Is this event an expected adverse event?	○ Yes ○ No	AEFUP.EXPECTED
SDV	* A13. Causality related to study medication	○ Not related ○ Possibly Related ○ Probably Related ○ Definitely Related	AEFUP.CAUSALITY
SDV	* A14. Outcome	○ Death ○ Resolved with sequelae ○ Resolved without sequelae ○ Ongoing	AEFUP.OUTCOME
SDV	A14a. Date of resolution, clinical stability or death		AEFUP.ENDDAT
SDV	A14b. Check if a full Date of resolution, clinical stability or death was not reported aboveAND at least a partial date is known or can be estimated (Both Month and Year or only Year).	☐	AEFUP.ENDDCHX
		A14b1. Date of resolution, clinical stability or death - Month SDV (xx) AEFUP.ENDDATM	**A14b2. Date of resolution, clinical stability or death - Year** SDV (xxxx) AEFUP.ENDDATY
SDV	* A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)		AEFUP.NARRATIVE

SUBMISSION INSTRUCTIONS

Instructions: Please follow reporting timeframes below based on seriousness of event.

Fatal or life threatening: Within 24 hours of first knowledge of event.

Serious, but not fatal or life threatening, and pregnancy: Within 24 hours of first knowledge of event.

All other AEs: Within 7 calendar days of first knowledge of event

Page Information														
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618771	Help Text Line	0	Instructions: Please complete the <u>Adverse Event - Initial Report</u> form for each new adverse event. When an event that was ongoing at the time of initial data entry resolves or there is new information, record all updated information on the <u>Adverse Event - Follow-up</u> form.											
Page-2-618771	Numeric	0	A1. AE - Initial Report ID Number associated with this event follow-up	AEFUP.AENUM	Yes							3	0	Enter the AE number of the event from the Adverse Event - Initial Report form that is associated with the Follow-up.
Page-3-618771	Radiolist Horizontal	1	A1a. Did anything change since the initial form was completed?	AEFUP.AECHANGE	Yes				cYN					
Page-4-618771	Help Text Line	1	If A1a. = "No", skip to A14. Outcome											
Page-5-618771	Text Field	0	A2. Adverse Event term	AEFUP.AETERM	Yes			Yes: MedDRAv20.1-5Level		150	50			Please provide the Adverse Event term to best of knowledge. The term will then be coded.
-- Page Dynamics (AEFUP. AETERM): Show When: AEFUP.AECHANGE = 1														

Page Information														
Page-6-618771	Date	0	A3. Onset date	AEFUP.STDAT	Yes									Please provide the date that the Adverse Event first started.
-- Page Dynamics (AEFUP. STDAT): Show When: AEFUP.AECHANGE = 1														
Page-7-618771	Check Box	1	A3a. Check if a full Onset date was not reported above<u>AND at least a partial onset date is known or can be estimated</u> (Both Month and Year or only Year) (For example, the Year may be known if the AE occurred between visits that had been performed during the same year).	AEFUP.AESTDCHX	Yes									ALL efforts should be made to collect a complete event onset date. If however, it is not possible to provide a complete date, a known or estimated partial date (Month and Year) should be reported. To enter a partial date, select the checkbox and numeric fields will become visible to capture "Month" and/or "Year".
-- Page Dynamics (AEFUP. AESTDCHX): Show When: AEFUP.AECHANGE = 1 AND AEFUP.STDAT IS NULL														
Page-8-618771	Row Start/End	0												
Page-9-618771	Help Text Line	0												
-- Page Dynamics (.): Show When: AEFUP.STDAT IS NULL AND AEFUP.AESTDCHX IS NOT NULL														
Page-10-618771	Help Text Line	0	A3a1. Onset Date - Month											
-- Page Dynamics (.): Show When: AEFUP.STDAT IS NULL AND AEFUP.AESTDCHX IS NOT NULL														
Page-11-618771	Help Text Line	0	A3a2. Onset Date - Year											
-- Page Dynamics (.): Show When: AEFUP.STDAT IS NULL AND AEFUP.AESTDCHX IS NOT NULL														
Page-12-618771	Row Start/End	0												
Page-13-618771	Row Start/End	0												

Page Information														
Page-14-618771	Help Text Line	0												
-- Page Dynamics (.): Show When: AEFUP.STDAT IS NULL AND AEFUP.AESTDCHX IS NOT NULL														
Page-15-618771	Numeric	0	A3a1. Onset Date - Month	AEFUP.STDATM	Yes							2	0	Enter up to 2 digits for the Month (i.e. "10" for October)
-- Page Dynamics (AEFUP. STDATM): Show When: AEFUP.STDAT IS NULL AND AEFUP.AESTDCHX IS NOT NULL														
Page-16-618771	Numeric	0	A3a2. Onset Date - Year	AEFUP.STDATY	Yes							4	0	Enter 4 digits for the Year (i.e. "2018")
-- Page Dynamics (AEFUP. STDATY): Show When: AEFUP.STDAT IS NULL AND AEFUP.AESTDCHX IS NOT NULL														
Page-17-618771	Row Start/End	0												
Page-18-618771	Time	0	A4. Onset time	AEFUP.STTIM	Yes									Please provide the time that the Adverse Event started, to the best of the subject's knowledge. If unknown, leave blank and answer query as unknown.
-- Page Dynamics (AEFUP. STTIM): Show When: AEFUP.AECHANGE = 1														

Page Information														
Page-19-618771	Dropdown	0	A5. Study visit associated with AE onset date.	AEFUP.AEVISIT	Yes				cVISITS					Indicate the visit interval associated with the onset (start date) of this AE. If the AE start date occurs between visits (i.e. between 3 and 6 Month Visits), associate it with the later of the 2 visits (i.e. 6 Month). A few examples: oIf AE start date was prior to the Baseline visit date, the interval should be “Screening”. oIf AE start date was between Baseline (after Baseline visit was completed) and Prior to 1 Month Visit, the interval should be "1 Month". oIf AE start date was between 1 Month (after 1 Month visit was completed) and Prior to 3 Month Visit, the interval should be "3 Month".
-- Page Dynamics (AEFUP. AEVISIT): Show When: AEFUP.AECHANGE = 1														
Page-20-618771	Date	0	A6. Date site became aware of event	AEFUP.AESAEDAT	Yes									Please provide the date that the Adverse Event was first noted.
-- Page Dynamics (AEFUP. AESAEDAT): Show When: AEFUP.AECHANGE = 1														
Page-21-618771	Radiolist	0	A7. Severity	AEFUP.SEVERITY	Yes				cSEVERITY					
-- Page Dynamics (AEFUP. SEVERITY): Show When: AEFUP.AECHANGE = 1														
Page-22-618771	Radiolist Horizontal	0	A8. Was the subject on study medication at the time of the event?	AEFUP.ONSTMED	Yes				cYN					

Page Information														
-- Page Dynamics (AEFUP. ONSTMED): Show When: AEFUP.AECHANGE = 1														
Page-23-618771	Date	1	A8a. Date of last dose of study medication prior to onset of the event	AEFUP.LDOSDAT	Yes									Please answer to the best of your knowledge. If unknown, leave blank and answer query stating that this is unknown.
-- Page Dynamics (AEFUP. LDOSDAT): Show When: AEFUP.ONSTMED = 1 AND AEFUP.AECHANGE = 1														
Page-24-618771	Check Box	2	A8b. Check if a full date of last dose of study medication was not reported above<u>AND at least a partial date is known or can be estimated</u> (Both Month and Year or only Year)	AEFUP.LDOSDCHX	Yes									ALL efforts should be made to collect a complete date of last dose of study medication. If however, it is not possible to provide a complete date, a known or estimated partial date (Month and Year) should be reported. To enter a partial date, select the checkbox and numeric fields will become visible to capture "Month" and/or "Year".
-- Page Dynamics (AEFUP. LDOSDCHX): Show When: AEFUP.AECHANGE = 1 AND AEFUP.ONSTMED = 1 AND AEFUP.LDOSDAT IS NULL														
Page-25-618771	Row Start/End	0												
Page-26-618771	Help Text Line	0												
-- Page Dynamics (.): Show When: AEFUP.LDOSDAT IS NULL AND AEFUP.LDOSDCHX IS NOT NULL														
Page-27-618771	Help Text Line	0	A8b1. Date of Last Dose - Month											
-- Page Dynamics (.): Show When: AEFUP.LDOSDAT IS NULL AND AEFUP.LDOSDCHX IS NOT NULL														
Page-28-618771	Help Text Line	0	A8b2. Date of Last Dose - Year											
-- Page Dynamics (.): Show When: AEFUP.LDOSDAT IS NULL AND AEFUP.LDOSDCHX IS NOT NULL														

Page Information														
Page-29-618771	Row Start/End	0												
Page-30-618771	Row Start/End	0												
Page-31-618771	Help Text Line	0												
-- Page Dynamics (.): Show When: AEFUP.LDOSDAT IS NULL AND AEFUP.LDOSDCHX IS NOT NULL														
Page-32-618771	Numeric	0	A8b1. Date of Last Dose - Month	AEFUP.LDOSDATM	Yes							2	0	Enter up to 2 digits for the Month (i.e. "10" for October)
-- Page Dynamics (AEFUP. LDOSDATM): Show When: AEFUP.LDOSDAT IS NULL AND AEFUP.LDOSDCHX IS NOT NULL														
Page-33-618771	Numeric	0	A8b2. Date of Last Dose - Year	AEFUP.LDOSDATY	Yes							4	0	Enter 4 digits for the Year (i.e. "2018")
-- Page Dynamics (AEFUP. LDOSDATY): Show When: AEFUP.LDOSDAT IS NULL AND AEFUP.LDOSDCHX IS NOT NULL														
Page-34-618771	Row Start/End	0												
Page-35-618771	Radiolist Horizontal	0	A9. Was study drug temporarily stopped or permanently discontinued due to this event?	AEFUP.STMACTN	Yes				cYN					
-- Page Dynamics (AEFUP. STMACTN): Show When: AEFUP.AECHANGE = 1														
Page-36-618771	Radiolist Horizontal	1	A9a. Type of change to study drug	AEFUP.STMEDACTYP	Yes				cSTMEDACTION					
-- Page Dynamics (AEFUP. STMEDACTYP): Show When: AEFUP.STMACTN = 1 AND AEFUP.AECHANGE = 1														
Page-37-618771	Help Text Line	2	If Temporarily Stopped, please complete the pTDIS (Temporary Discontinuation of Study Drug) form in the Study Drug Visit.											
-- Page Dynamics (.): Show When: AEFUP.STMEDACTYP = 1 AND AEFUP.AECHANGE = 1														
Page-38-618771	Help Text Line	2	If Permanently Discontinued, please complete the pPDIS (Permanent Discontinuation of Study Drug) form in the Study Drug Visit.											
-- Page Dynamics (.): Show When: AEFUP.STMEDACTYP = 2 AND AEFUP.AECHANGE = 1														
Page-39-618771	Radiolist Horizontal	0	A10. Action taken or treatment for this event	AEFUP.ACTN	Yes				cYN					

Page Information															
-- Page Dynamics (AEFUP. ACTN): Show When: AEFUP.AECHANGE = 1															
Page-40-618771	Radiolist Horizontal	1	A10a. Labs, tests, or studies done to diagnose/evaluate event	AEFUP.TESTACTN	Yes				cYN						
-- Page Dynamics (AEFUP. TESTACTN): Show When: AEFUP.ACTN = 1 AND AEFUP.AECHANGE = 1															
Page-41-618771	Help Text Line	1	Please upload de-identified source documents.												
-- Page Dynamics (.): Show When: AEFUP.TESTACTN = 1 AND AEFUP.AECHANGE = 1															
Page-42-618771	Help Text Line	1	Report all labs, tests, or studies in the narrative portion of this form.												
-- Page Dynamics (.): Show When: AEFUP.TESTACTN = 1 AND AEFUP.AECHANGE = 1															
Page-43-618771	Radiolist Horizontal	1	A10b. Medication administered to treat event	AEFUP.MEDACTN	Yes				cYN						
-- Page Dynamics (AEFUP. MEDACTN): Show When: AEFUP.ACTN = 1 AND AEFUP.AECHANGE = 1															
Page-44-618771	Help Text Line	1	Report all medication on the CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit <u>as well as</u> in the narrative portion of this form.												
-- Page Dynamics (.): Show When: AEFUP.MEDACTN = 1 AND AEFUP.AECHANGE = 1															
Page-45-618771	Radiolist Horizontal	1	A10c. Other	AEFUP.ACTNOTH	Yes				cYN						
-- Page Dynamics (AEFUP. ACTNOTH): Show When: AEFUP.ACTN = 1 AND AEFUP.AECHANGE = 1															
Page-46-618771	Text Field	2	A10c1. Please specify the other action or treatment taken for the event	AEFUP.ACTNOTHSP	Yes					200	99				
-- Page Dynamics (AEFUP. ACTNOTHSP): Show When: AEFUP.ACTNOTH = 1 AND AEFUP.AECHANGE = 1															
Page-47-618771	Radiolist Horizontal	0	A11. Is this a Serious Adverse Event (SAE)?	AEFUP.SAE	Yes				cYN						SAE consists of events that are fatal or life threatening, results in death, requires or prolongs existing hospitalization, results in disability, or causes a congenital anomaly/birth defect.
-- Page Dynamics (AEFUP. SAE): Show When: AEFUP.AECHANGE = 1															
Page-48-618771	Help Text Line	1	If Yes, specify why this is considered serious by answering SAE criteria questions below.												

Page Information														
-- Page Dynamics (.): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-49-618771	Radiolist Horizontal	1	A11a. Resulted in death	AEFUP.DEATH	Yes				cYN					
-- Page Dynamics (AEFUP. DEATH): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-50-618771	Radiolist Horizontal	1	A11b. Immediate life-threatening event (immediate danger of death from event)	AEFUP.LIFE_THREAT	Yes				cYN					
-- Page Dynamics (AEFUP. LIFE_THREAT): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-51-618771	Radiolist Horizontal	1	A11c. Requires inpatient hospitalization or prolongation of existing hospitalization	AEFUP.HOSP	Yes				cYN					
-- Page Dynamics (AEFUP. HOSP): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-52-618771	Date	2	A11c1. Admission date	AEFUP.ADMDAT	Yes									
-- Page Dynamics (AEFUP. ADMDAT): Show When: AEFUP.SAE = 1 AND AEFUP.HOSP = 1 AND AEFUP.AECHANGE = 1														
Page-53-618771	Radiolist Horizontal	2	A11c2. Is the subject still in the hospital?	AEFUP.HOSPONG	Yes				cYN					
-- Page Dynamics (AEFUP. HOSPONG): Show When: AEFUP.SAE = 1 AND AEFUP.HOSP = 1 AND AEFUP.AECHANGE = 1														
Page-54-618771	Date	2	A11c3. Discharge date	AEFUP.DISDAT	Yes									
-- Page Dynamics (AEFUP. DISDAT): Show When: AEFUP.HOSP = 1 AND AEFUP.HOSPONG = 0 AND AEFUP.AECHANGE = 1														
Page-55-618771	Radiolist Horizontal	1	A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	AEFUP.LIFE_FUNC	Yes				cYN					
-- Page Dynamics (AEFUP. LIFE_FUNC): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-56-618771	Radiolist Horizontal	1	A11e. Results in a congenital anomaly in the offspring of a participant	AEFUP.CONG_ANOM	Yes				cYN					
-- Page Dynamics (AEFUP. CONG_ANOM): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														
Page-57-618771	Radiolist Horizontal	1	A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	AEFUP.IMPORT_EVENT	Yes				cYN					
-- Page Dynamics (AEFUP. IMPORT_EVENT): Show When: AEFUP.SAE = 1 AND AEFUP.AECHANGE = 1														

Page Information														
Page-58-618771	Radiolist Horizontal	0	A12. Is this event an expected adverse event?	AEFUP.EXPECTED	Yes				cYN					Expected: An event is considered expected if it is known to be associated with the study drug(s) and/or the disease state. For this protocol, expected events reported since market introduction regardless of evidence of causality and included in the product brochure are: o Myalgia, muscle spasms, pain in extremity, back pain, arthralgia, rhabdomyolysis o Asthenia, hypoesthesia, fatigue, malaise, dizziness, insomnia, depression, headache, weakness o Diarrhea, constipation, dyspepsia, nausea, abdominal pain o Hepatitis, jaundice, fatal and non-fatal liver failure o Diabetes o Pruritis, rash, urticaria o Interstitial lung disease o Erectile dysfunction o Rare post-marketing reports of cognitive impairment
-- Page Dynamics (AEFUP. EXPECTED): Show When: AEFUP.AECHANGE = 1														
Page-59-618771	Radiolist	0	A13. Causality related to study medication	AEFUP.CAUSALITY	Yes				cRELATED					

Page Information													
-- Page Dynamics (AEFUP. CAUSALITY): Show When: AEFUP.AECHANGE = 1													
Page-60-618771	Radiolist	0	A14. Outcome	AEFUP.OUTCOME	Yes				cOUTCOME					If outcome is Ongoing at the time of initial entry, please complete an <u>Adverse Event - Follow-up</u> form, once there is new information or the event resolves.
Page-61-618771	Date	1	A14a. Date of resolution, clinical stability or death	AEFUP.ENDDAT	Yes									
-- Page Dynamics (AEFUP. ENDDAT): Show When: AEFUP.OUTCOME = 1 OR AEFUP.OUTCOME = 2 OR AEFUP.OUTCOME = 3													
Page-62-618771	Check Box	2	A14b. Check if a full Date of resolution, clinical stability or death was not reported above<u>AND at least a partial date is known or can be estimated</u> (Both Month and Year or only Year).	AEFUP.ENDDCHX	Yes									ALL efforts should be made to collect a complete Date of resolution, clinical stability or death date. If however, it is not possible to provide a complete date, a known or estimated partial date (Month and Year) should be reported. To enter a partial date, select the checkbox and numeric fields will become visible to capture "Month" and/or "Year".
-- Page Dynamics (AEFUP. ENDDCHX): Show When: (AEFUP.OUTCOME = 1 OR AEFUP.OUTCOME = 2 OR AEFUP.OUTCOME = 3) AND AEFUP.ENDDAT IS NULL													
Page-63-618771	Row Start/End	0												
Page-64-618771	Help Text Line	0												
-- Page Dynamics (.): Show When: (AEFUP.OUTCOME = 1 OR AEFUP.OUTCOME = 2 OR AEFUP.OUTCOME = 3) AND AEFUP.ENDDAT IS NULL AND AEFUP.ENDDCHX IS NOT NULL													

Page Information														
Page-65-618771	Help Text Line	0	A14b1. Date of resolution, clinical stability or death - Month											
-- Page Dynamics (.): Show When: (AEFUP.OUTCOME = 1 OR AEFUP.OUTCOME = 2 OR AEFUP.OUTCOME = 3) AND AEFUP.ENDDAT IS NULL AND AEFUP.ENDDCHX IS NOT NULL														
Page-66-618771	Help Text Line	0	A14b2. Date of resolution, clinical stability or death - Year											
-- Page Dynamics (.): Show When: (AEFUP.OUTCOME = 1 OR AEFUP.OUTCOME = 2 OR AEFUP.OUTCOME = 3) AND AEFUP.ENDDAT IS NULL AND AEFUP.ENDDCHX IS NOT NULL														
Page-67-618771	Row Start/End	0												
Page-68-618771	Row Start/End	0												
Page-69-618771	Help Text Line	0												
-- Page Dynamics (.): Show When: (AEFUP.OUTCOME = 1 OR AEFUP.OUTCOME = 2 OR AEFUP.OUTCOME = 3) AND AEFUP.ENDDAT IS NULL AND AEFUP.ENDDCHX IS NOT NULL														
Page-70-618771	Numeric	0	A14b1. Date of resolution, clinical stability or death - Month	AEFUP.ENDDATM	Yes							2	0	Enter up to 2 digits for the Month (i.e. "10" for October)
-- Page Dynamics (AEFUP. ENDDATM): Show When: (AEFUP.OUTCOME = 1 OR AEFUP.OUTCOME = 2 OR AEFUP.OUTCOME = 3) AND AEFUP.ENDDAT IS NULL AND AEFUP.ENDDCHX IS NOT NULL														
Page-71-618771	Numeric	0	A14b2. Date of resolution, clinical stability or death - Year	AEFUP.ENDDATY	Yes							4	0	Enter 4 digits for the Year (i.e. "2018")
-- Page Dynamics (AEFUP. ENDDATY): Show When: (AEFUP.OUTCOME = 1 OR AEFUP.OUTCOME = 2 OR AEFUP.OUTCOME = 3) AND AEFUP.ENDDAT IS NULL AND AEFUP.ENDDCHX IS NOT NULL														
Page-72-618771	Row Start/End	0												
Page-73-618771	Comments	0	A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)	AEFUP.NARRATIVE	Yes									
Page-74-618771	Section Header	0	SUBMISSION INSTRUCTIONS											
Page-75-618771	Help Text Line	0	Instructions: Please follow reporting timeframes below based on seriousness of event.											
Page-76-618771	Help Text Line	0	Fatal or life threatening: Within 24 hours of first knowledge of event.											

Page Information														
Page-77-618771	Help Text Line	0	Serious, but not fatal or life threatening, and pregnancy: Within 24 hours of first knowledge of event.											
Page-78-618771	Help Text Line	0	All other AEs: Within 7 calendar days of first knowledge of event											

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-620300	SYSQ_5768	AEFUP.OUTCOME	Other / Cross Page		AEFUP.HOSPONG = 1 AND AEFUP.OUTCOME <> 4	Outcome should be ongoing if subject is still in the hospital.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620302	SYSQ_5769	AEFUP.SAE	Other / Cross Page		(AEFUP.SAE = 0 AND AEFUP.SEVERITY >= 3) OR (AEFUP.SAE = 1 AND AEFUP.SEVERITY < 3)	SAE has been defined as severity Grade 3-5. Please check for consistency.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620305	SYSQ_5770	AEFUP.DISDAT	Other / Cross Page		AEFUP.DISDAT < AEFUP.ADMDAT	Discharge date should be on or after the hospitalization date.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620306	SYSQ_5771	AEFUP.STDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(AEFUP.STDAT, 10-20-ICF.ICF_DT) > 0	This date is prior to the informed consent date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620308	SYSQ_5772	AEFUP.STDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(AEFUP.STDAT, 120-20-EOS.DATE) < 0	This date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620310	SYSQ_5773	AEFUP.ENDDAT	Other / Cross Page		AEFUP.ENDDAT < AEFUP.STDAT	Date of resolution, clinical stability or death is prior to the event onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0

System Queries														
sysq-620312	SYSQ_5774	AEFUP.ENDDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(AEFUP.ENDDAT, 120-20-EOS.DATE) < 0	This date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620314	SYSQ_5775	AEFUP.OUTCOME	Other / Cross Page		AEFUP.OUTCOME = 1 AND AEFUP.SAE <> 1	The Outcome of the event has been indicated as Death, however the event is reported as Not Serious. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620317	SYSQ_5776	AEFUP.AESAEDAT	Other / Cross Page		AEFUP.AESAEDAT < AEFUP.STDAT	Date site became aware of the event must be on or after the onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620319	SYSQ_5777	AEFUP.ACTN	Other / Cross Page		AEFUP.ACTN = 1 AND AEFUP.TESTACTN = 0 AND AEFUP.MEDACTN = 0 AND AEFUP.ACTNOTH = 0	Action taken or treatment for this event is Yes, however, the specific actions/treatments which include labs/tests, medications and other, all report No. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620321	SYSQ_5778	AEFUP.LDOSDAT	Other / Cross Page		AEFUP.LDOSDAT > AEFUP.STDAT	Date of last dose of study medication prior to onset of the event must be on or prior to the onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620323	SYSQ_5779	AEFUP.AENUM	Field Null		AEFUP.AENUM IS NULL	"A1. AE - Initial Report ID Number associated with this event follow-up" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620325	SYSQ_5780	AEFUP.AECHANGE	Field Null		AEFUP.AECHANGE IS NULL	"A1a. Did anything change since the initial form was completed?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620326	SYSQ_5781	AEFUP.AETERM	Field Null		AEFUP.AETERM IS NULL	"A2. Adverse Event term" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620328	SYSQ_5782	AEFUP.STDAT	Field Null		AEFUP.STDAT IS NULL	"A3. Onset date" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0

System Queries														
sysq-620330	SYSQ_5783	AEFUP.STDAT	Future Date		AEFUP.STDAT > Today	"A3. Onset date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620332	SYSQ_5784	AEFUP.STTIM	Field Null		AEFUP.STTIM IS NULL	"A4. Onset time" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620334	SYSQ_5785	AEFUP.AEVISIT	Field Null		AEFUP.AEVISIT IS NULL	"A5. Study visit associated with AE onset date." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620337	SYSQ_5786	AEFUP.AESAEDAT	Field Null		AEFUP.AESAEDAT IS NULL	"A6. Date site became aware of event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620338	SYSQ_5787	AEFUP.AESAEDAT	Future Date		AEFUP.AESAEDAT > Today	"A6. Date site became aware of event" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620340	SYSQ_5788	AEFUP.SEVERITY	Field Null		AEFUP.SEVERITY IS NULL	"A7. Severity" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620342	SYSQ_5789	AEFUP.ONSTMED	Field Null		AEFUP.ONSTMED IS NULL	"A8. Was the subject on study medication at the time of the event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620345	SYSQ_5790	AEFUP.LDOSDAT	Field Null		AEFUP.LDOSDAT IS NULL	"A8a. Date of last dose of study medication prior to onset of the event" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620346	SYSQ_5791	AEFUP.LDOSDAT	Future Date		AEFUP.LDOSDAT > Today	"A8a. Date of last dose of study medication prior to onset of the event" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0
sysq-620348	SYSQ_5792	AEFUP.STMACTN	Field Null		AEFUP.STMACTN IS NULL	"A9. Was study drug temporarily stopped or permanently discontinued due to this event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:58	0	0	0	0	0	0

System Queries														
sysq-620351	SYSQ_5793	AEFUP.STMEDACTYP	Field Null		AEFUP.STMEDACTYP IS NULL	"A9a. Type of change to study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620353	SYSQ_5794	AEFUP.ACTN	Field Null		AEFUP.ACTN IS NULL	"A10. Action taken or treatment for this event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620355	SYSQ_5795	AEFUP.TESTACTN	Field Null		AEFUP.TESTACTN IS NULL	"A10a. Labs, tests, or studies done to diagnose/evaluate event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620356	SYSQ_5796	AEFUP.MEDACTN	Field Null		AEFUP.MEDACTN IS NULL	"A10b. Medication administered to treat event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620359	SYSQ_5797	AEFUP.ACTNOTH	Field Null		AEFUP.ACTNOTH IS NULL	"A10c. Other" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620361	SYSQ_5798	AEFUP.ACTNOTHSP	Field Null		AEFUP.ACTNOTHSP IS NULL	"A10c1. Please specify the other action or treatment taken for the event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620363	SYSQ_5799	AEFUP.SAE	Field Null		AEFUP.SAE IS NULL	"A11. Is this a Serious Adverse Event (SAE)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620364	SYSQ_5800	AEFUP.DEATH	Field Null		AEFUP.DEATH IS NULL	"A11a. Resulted in death" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620366	SYSQ_5801	AEFUP.LIFE_THREAT	Field Null		AEFUP.LIFE_THREAT IS NULL	"A11b. Immediate life-threatening event (immediate danger of death from event)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620369	SYSQ_5802	AEFUP.HOSP	Field Null		AEFUP.HOSP IS NULL	"A11c. Requires inpatient hospitalization or prolongation of existing hospitalization" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0

System Queries														
sysq-620371	SYSQ_5803	AEFUP.ADMDAT	Field Null		AEFUP.ADMDAT IS NULL	"A11c1. Admission date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620373	SYSQ_5804	AEFUP.ADMDAT	Future Date		AEFUP.ADMDAT > Today	"A11c1. Admission date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620374	SYSQ_5805	AEFUP.HOSPONG	Field Null		AEFUP.HOSPONG IS NULL	"A11c2. Is the subject still in the hospital?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620377	SYSQ_5806	AEFUP.DISDAT	Field Null		AEFUP.DISDAT IS NULL	"A11c3. Discharge date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:59	0	0	0	0	0	0
sysq-620379	SYSQ_5807	AEFUP.DISDAT	Future Date		AEFUP.DISDAT > Today	"A11c3. Discharge date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620380	SYSQ_5808	AEFUP.LIFE_FUNC	Field Null		AEFUP.LIFE_FUNC IS NULL	"A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620383	SYSQ_5809	AEFUP.CONG_ANOM	Field Null		AEFUP.CONG_ANOM IS NULL	"A11e. Results in a congenital anomaly in the offspring of a participant" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620385	SYSQ_5810	AEFUP.IMPORT_EVENT	Field Null		AEFUP.IMPORT_EVENT IS NULL	"A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620387	SYSQ_5811	AEFUP.EXPECTED	Field Null		AEFUP.EXPECTED IS NULL	"A12. Is this event an expected adverse event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0

System Queries														
sysq-620389	SYSQ_5812	AEFUP.CAUSALITY	Field Null		AEFUP.CAUSALITY IS NULL	"A13. Causality related to study medication" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620391	SYSQ_5813	AEFUP.OUTCOME	Field Null		AEFUP.OUTCOME IS NULL	"A14. Outcome" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620392	SYSQ_5814	AEFUP.ENDDAT	Field Null		AEFUP.ENDDAT IS NULL	"A14a. Date of resolution, clinical stability or death" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620395	SYSQ_5815	AEFUP.ENDDAT	Future Date		AEFUP.ENDDAT > Today	"A14a. Date of resolution, clinical stability or death" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620397	SYSQ_5816	AEFUP.NARRATIVE	Field Null		AEFUP.NARRATIVE IS NULL	"A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620451	SYSQ_5864	AEFUP.STDATM	Field Null		AEFUP.STDATM IS NULL	"A3a1. Onset Date - Month" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620452	SYSQ_5865	AEFUP.STDATM	Range		AEFUP.STDATM < 1 OR AEFUP.STDATM > 12	"A3a1. Onset Date - Month" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620453	SYSQ_5866	AEFUP.STDATY	Field Null		AEFUP.STDATY IS NULL	"A3a2. Onset Date - Year" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620454	SYSQ_5867	AEFUP.STDATY	Range		AEFUP.STDATY < 2018 OR AEFUP.STDATY > 2025	"A3a2. Onset Date - Year" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620455	SYSQ_5868	AEFUP.LDOSDATM	Field Null		AEFUP.LDOSDATM IS NULL	"A8b1. Date of Last Dose - Month" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0

System Queries														
sysq-620456	SYSQ_5869	AEFUP.LDOSDATM	Range		AEFUP.LDOSDATM < 1 OR AEFUP.LDOSDATM > 12	"A8b1. Date of Last Dose - Month" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620457	SYSQ_5870	AEFUP.LDOSDATY	Field Null		AEFUP.LDOSDATY IS NULL	"A8b2. Date of Last Dose - Year" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620458	SYSQ_5871	AEFUP.LDOSDATY	Range		AEFUP.LDOSDATY < 2018 OR AEFUP.LDOSDATY > 2025	"A8b2. Date of Last Dose - Year" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620459	SYSQ_5872	AEFUP.ENDDATM	Field Null		AEFUP.ENDDATM IS NULL	"A14b1. Date of resolution, clinical stability or death - Month" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620460	SYSQ_5873	AEFUP.ENDDATM	Range		AEFUP.ENDDATM < 1 OR AEFUP.ENDDATM > 12	"A14b1. Date of resolution, clinical stability or death - Month" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620461	SYSQ_5874	AEFUP.ENDDATY	Field Null		AEFUP.ENDDATY IS NULL	"A14b2. Date of resolution, clinical stability or death - Year" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620462	SYSQ_5875	AEFUP.ENDDATY	Range		AEFUP.ENDDATY < 2018 OR AEFUP.ENDDATY > 2025	"A14b2. Date of resolution, clinical stability or death - Year" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620463	SYSQ_5876	AEFUP.STDAT	Other / Cross Page		AEFUP.STDAT IS NULL AND AEFUP.AESTDCHX IS NULL	Neither a complete nor partial Onset Date was reported. If a complete date is not known, a partial Month and Year (or worst case at least a Year) is expected by selecting the checkbox option on the question (A3a) below. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0

System Queries														
sysq-620464	SYSQ_5877	AEFUP.LDOSDAT	Other / Cross Page		AEFUP.LDOSDAT IS NULL AND AEFUP.LDOSDCHX IS NULL	Neither a complete nor partial "Date of last dose of study medication prior to onset of the event" was reported. If a complete date is not known, a partial Month and Year (or worst case at least a Year) is expected by selecting the checkbox option on the question (A8b) below. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620465	SYSQ_5878	AEFUP.ENDDAT	Other / Cross Page		AEFUP.ENDDAT IS NULL AND AEFUP.ENDDCHX IS NULL	Neither a complete nor partial "Date of resolution, clinical stability or death" was reported. If a complete date is not known, a partial Month and Year (or worst case at least a Year) is expected by selecting the checkbox option on the question (A14b) below. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0

pAE_3

Page

(Visit ID = 618772, Page ID =)

Unique Identifier page-618772-618772-618772-

Instructions: Please complete the Adverse Event - Initial Report form for each new adverse event.

When an event that was ongoing at the time of initial data entry resolves or there is new information, record all updated information on the Adverse Event - Follow-up form.

	A1. AE - Initial Report (ID Number)	(auto calculated)	AE.AESPID (format xxx)
SDV	* A2. Adverse Event term		AE.AETERM
SDV	A3. Onset date		AE.STDAT
SDV	A3a. Check if a full Onset date was not reported aboveAND at least a partial onset date is known or can be estimated (Both Month and Year or only Year) (For example, the Year may be known if the AE occurred between visits that had been performed during the same year).	☐	AE.AESTDCHX
		A3a1. Onset Date - Month SDV (xx)	A3a2. Onset Date - Year SDV (xxxx)
		AE.STDATM	AE.STDATY
SDV	* A4. Onset time	:	AE.STTIM (HH24:MI)
SDV	* A5. Study visit associated with AE onset date.		AE.AEVISIT
SDV	* A6. Date site became aware of event		AE.AESAEDAT
SDV	* A7. Severity	○ Grade 1 - Mild ○ Grade 2 – Moderate ○ Grade 3 – Severe ○ Grade 4 – Life-threatening Or disabling ○ Grade 5 – Death	AE.SEVERITY
SDV	* A8. Was the subject on study medication at the time of the event?	○ Yes ○ No	AE.ONSTMED

SDV	A8a. Date of last dose of study medication prior to onset of the event		AE.LDOSDAT
SDV	A8b. Check if a full date of last dose of study medication was not reported aboveAND at least a partial date is known or can be estimated (Both Month and Year or only Year)	☐	AE.LDOSDCHX
		A8b1. Date of Last Dose - Month SDV (xx) AE.LDOSDATM	**A8b2. Date of Last Dose - Year** SDV (xxxx) AE.LDOSDATY
SDV	* A9. Was study drug temporarily stopped or permanently discontinued due to this event?	○ Yes ○ No	AE.STMACTN
SDV	* A9a. Type of change to study drug	○ Temporarily stopped ○ Permanently discontinued	AE.STMEDACTYP
	If Temporarily Stopped, please complete the pTDIS (Temporary Discontinuation of Study Drug) form in the Study Drug Visit.		
	If Permanently Discontinued, please complete the pPDIS (Permanent Discontinuation of Study Drug) form in the Study Drug Visit.		
SDV	* A10. Action taken or treatment for this event	○ Yes ○ No	AE.ACTN
SDV	* A10a. Labs, tests, or studies done to diagnose/evaluate event	○ Yes ○ No	AE.TESTACTN
	Please upload de-identified source documents.		
	Report all labs, tests, or studies in the narrative portion of this form.		
SDV	* A10b. Medication administered to treat event	○ Yes ○ No	AE.MEDACTN
	Report all medication on the CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit as well as in the narrative portion of this form.		
SDV	* A10c. Other	○ Yes ○ No	AE.ACTNOTH
SDV	* A10c1. Please specify the other action or treatment taken for the event		AE.ACTNOTHSP
SDV	* A11. Is this a Serious Adverse Event (SAE)?	○ Yes ○ No	AE.SAE

	If Yes, specify why this is considered serious by answering SAE criteria questions below.		
SDV	* A11a. Resulted in death	○ Yes ○ No	AE.DEATH
SDV	* A11b. Immediate life-threatening event (immediate danger of death from event)	○ Yes ○ No	AE.LIFE_THREAT
SDV	* A11c. Requires inpatient hospitalization or prolongation of existing hospitalization	○ Yes ○ No	AE.HOSP
SDV	* A11c1. Admission date		AE.ADMDAT
SDV	* A11c2. Is the subject still in the hospital?	○ Yes ○ No	AE.HOSPONG
SDV	* A11c3. Discharge date		AE.DISDAT
SDV	* A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	○ Yes ○ No	AE.LIFE_FUNC
SDV	* A11e. Results in a congenital anomaly in the offspring of a participant	○ Yes ○ No	AE.CONG_ANOM
SDV	* A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	○ Yes ○ No	AE.IMPORT_EVENT
SDV	* A12. Is this event an expected adverse event?	○ Yes ○ No	AE.EXPECTED
SDV	* A13. Causality related to study medication	○ Not related ○ Possibly Related ○ Probably Related ○ Definitely Related	AE.CAUSALITY

SDV	* A14. Outcome	○ Death ○ Resolved with sequelae ○ Resolved without sequelae ○ Ongoing	AE.OUTCOME
SDV	A14a. Date of resolution, clinical stability or death		AE.ENDDAT
SDV	A14b. Check if a full Date of resolution, clinical stability or death was not reported aboveAND at least a partial date is known or can be estimated (Both Month and Year or only Year).	☐	AE.ENDDCHX
		A14b1. Date of resolution, clinical stability or death - Month SDV (xx) AE.ENDDATM	A14b2. Date of resolution, clinical stability or death - Year SDV (xxxx) AE.ENDDATY
SDV	* A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)		AE.NARRATIVE

SUBMISSION INSTRUCTIONS

Instructions: Please follow reporting timeframes below based on seriousness of event.

Fatal or life threatening: Within 24 hours of first knowledge of event.

Serious, but not fatal or life threatening, and pregnancy: Within 24 hours of first knowledge of event.

All other AEs: Within 7 calendar days of first knowledge of event

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text

Page Information														
Page-1-618772	Help Text Line	0	Instructions: Please complete the <u>Adverse Event - Initial Report</u> form for each new adverse event. When an event that was ongoing at the time of initial data entry resolves or there is new information, record all updated information on the <u>Adverse Event - Follow-up</u> form.											
Page-2-618772	Auto Calc Field	0	A1. AE - Initial Report (ID Number)	AE.AESPID								3	0	
-- Auto Calc Rule (AE.AESPID): __NEW_EXPR__{"type":"PageSequenceIndex"														
Page-3-618772	Text Field	0	A2. Adverse Event term	AE.AETERM	Yes			Yes : MedDRA v20.1 - 5 Level		150	50			Please provide the Adverse Event term to best of knowledge. The term will then be coded.
Page-4-618772	Date	0	A3. Onset date	AE.STDAT	Yes									Please provide the date that the Adverse Event first started.
Page-5-618772	Check Box	1	A3a. Check if a full Onset date was not reported above<u>AND at least a partial onset date is known or can be estimated</u> (Both Month and Year or only Year) (For example, the Year may be known if the AE occurred between visits that had been performed during the same year).	AE.AESTDCHX	Yes									ALL efforts should be made to collect a complete event onset date. If however, it is not possible to provide a complete date, a known or estimated partial date (Month and Year) should be reported. To enter a partial date, select the checkbox and numeric fields will become visible to capture "Month" and/or "Year".

Page Information														
-- Page Dynamics (AE. AESTDCHX): Show When: AE.STDAT IS NULL														
Page-6-618772	Row Start/End	0												
Page-7-618772	Help Text Line	0												
-- Page Dynamics (.): Show When: AE.STDAT IS NULL AND AE.AESTDCHX IS NOT NULL														
Page-8-618772	Help Text Line	0	A3a1. Onset Date - Month											
-- Page Dynamics (.): Show When: AE.STDAT IS NULL AND AE.AESTDCHX IS NOT NULL														
Page-9-618772	Help Text Line	0	A3a2. Onset Date - Year											
-- Page Dynamics (.): Show When: AE.STDAT IS NULL AND AE.AESTDCHX IS NOT NULL														
Page-10-618772	Row Start/End	0												
Page-11-618772	Row Start/End	0												
Page-12-618772	Help Text Line	0												
-- Page Dynamics (.): Show When: AE.STDAT IS NULL AND AE.AESTDCHX IS NOT NULL														
Page-13-618772	Numeric	0	A3a1. Onset Date - Month	AE. STDATM	Yes							2	0	Enter up to 2 digits for the Month (i.e. "10" for October)
-- Page Dynamics (AE. STDATM): Show When: AE.STDAT IS NULL AND AE.AESTDCHX IS NOT NULL														
Page-14-618772	Numeric	0	A3a2. Onset Date - Year	AE. STDATY	Yes							4	0	Enter 4 digits for the Year (i.e. "2018")
-- Page Dynamics (AE. STDATY): Show When: AE.STDAT IS NULL AND AE.AESTDCHX IS NOT NULL														
Page-15-618772	Row Start/End	0												
Page-16-618772	Time	0	A4. Onset time	AE. STTIM	Yes									Please provide the time that the Adverse Event started, to the best of the subject's knowledge. If unknown, leave blank and answer query as unknown.

Page Information														
Page-17-618772	Dropdown	0	A5. Study visit associated with AE onset date.	AE.AEVISIT	Yes				cVISITS					Indicate the visit interval associated with the onset (start date) of this AE. If the AE start date occurs between visits (i.e. between 3 and 6 Month Visits), associate it with the later of the 2 visits (i.e. 6 Month). A few examples: oIf AE start date was prior to the Baseline visit date, the interval should be “Screening”. oIf AE start date was between Baseline (after Baseline visit was completed) and Prior to 1 Month Visit, the interval should be "1 Month". oIf AE start date was between 1 Month (after 1 Month visit was completed) and Prior to 3 Month Visit, the interval should be "3 Month".
Page-18-618772	Date	0	A6. Date site became aware of event	AE.AESAEDAT	Yes									Please provide the date that the Adverse Event was first noted.
Page-19-618772	Radiolist	0	A7. Severity	AE.SEVERITY	Yes				cSEVERITY					
Page-20-618772	Radiolist Horizontal	0	A8. Was the subject on study medication at the time of the event?	AE.ONSTMED	Yes				cYN					

Page Information														
Page-21-618772	Date	1	A8a. Date of last dose of study medication prior to onset of the event	AE.LDOSDAT	Yes									Please answer to the best of your knowledge. If unknown, leave blank and answer query stating that this is unknown.
-- Page Dynamics (AE. LDOSDAT): Show When: AE.ONSTMED = 1														
Page-22-618772	Check Box	2	A8b. Check if a full date of last dose of study medication was not reported above<u>AND at least a partial date is known or can be estimated</u> (Both Month and Year or only Year)	AE.LDOSDCHX	Yes									ALL efforts should be made to collect a complete date of last dose of study medication. If however, it is not possible to provide a complete date, a known or estimated partial date (Month and Year) should be reported. To enter a partial date, select the checkbox and numeric fields will become visible to capture "Month" and/or "Year".
-- Page Dynamics (AE. LDOSDCHX): Show When: AE.ONSTMED = 1 AND AE.LDOSDAT IS NULL														
Page-23-618772	Row Start/End	0												
Page-24-618772	Help Text Line	0												
-- Page Dynamics (.): Show When: AE.LDOSDAT IS NULL AND AE.LDOSDCHX IS NOT NULL														
Page-25-618772	Help Text Line	0	A8b1. Date of Last Dose - Month											
-- Page Dynamics (.): Show When: AE.LDOSDAT IS NULL AND AE.LDOSDCHX IS NOT NULL														
Page-26-618772	Help Text Line	0	A8b2. Date of Last Dose - Year											
-- Page Dynamics (.): Show When: AE.LDOSDAT IS NULL AND AE.LDOSDCHX IS NOT NULL														
Page-27-618772	Row Start/End	0												

Page Information														
Page-28-618772	Row Start/End	0												
Page-29-618772	Help Text Line	0												
-- Page Dynamics (.): Show When: AE.LDOSDAT IS NULL AND AE.LDOSDCHX IS NOT NULL														
Page-30-618772	Numeric	0	A8b1. Date of Last Dose - Month	AE.LDOSDATM	Yes							2	0	Enter up to 2 digits for the Month (i.e. "10" for October)
-- Page Dynamics (AE. LDOSDATM): Show When: AE.LDOSDAT IS NULL AND AE.LDOSDCHX IS NOT NULL														
Page-31-618772	Numeric	0	A8b2. Date of Last Dose - Year	AE.LDOSDATY	Yes							4	0	Enter 4 digits for the Year (i.e. "2018")
-- Page Dynamics (AE. LDOSDATY): Show When: AE.LDOSDAT IS NULL AND AE.LDOSDCHX IS NOT NULL														
Page-32-618772	Row Start/End	0												
Page-33-618772	Radiolist Horizontal	0	A9. Was study drug temporarily stopped or permanently discontinued due to this event?	AE.STMACTN	Yes				cYN					
Page-34-618772	Radiolist Horizontal	1	A9a. Type of change to study drug	AE.STMEDACTYP	Yes				cSTMEDACTION					
-- Page Dynamics (AE. STMEDACTYP): Show When: AE.STMACTN = 1														
Page-35-618772	Help Text Line	2	If Temporarily Stopped, please complete the pTDIS (Temporary Discontinuation of Study Drug) form in the Study Drug Visit.											
-- Page Dynamics (.): Show When: AE.STMEDACTYP = 1														
Page-36-618772	Help Text Line	2	If Permanently Discontinued, please complete the pPDIS (Permanent Discontinuation of Study Drug) form in the Study Drug Visit.											
-- Page Dynamics (.): Show When: AE.STMEDACTYP = 2														
Page-37-618772	Radiolist Horizontal	0	A10. Action taken or treatment for this event	AE.ACTN	Yes				cYN					
Page-38-618772	Radiolist Horizontal	1	A10a. Labs, tests, or studies done to diagnose/evaluate event	AE.TESTACTN	Yes				cYN					
-- Page Dynamics (AE. TESTACTN): Show When: AE.ACTN = 1														

Page Information														
Page-39-618772	Help Text Line	1	Please upload de-identified source documents.											
-- Page Dynamics (.): Show When: AE.TESTACTN = 1														
Page-40-618772	Help Text Line	1	Report all labs, tests, or studies in the narrative portion of this form.											
-- Page Dynamics (.): Show When: AE.TESTACTN = 1														
Page-41-618772	Radiolist Horizontal	1	A10b. Medication administered to treat event	AE.MEDACTN	Yes				cYN					
-- Page Dynamics (AE. MEDACTN): Show When: AE.ACTN = 1														
Page-42-618772	Help Text Line	1	Report all medication on the CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit <u>as well as</u> in the narrative portion of this form.											
-- Page Dynamics (.): Show When: AE.MEDACTN = 1														
Page-43-618772	Radiolist Horizontal	1	A10c. Other	AE.ACTNOTH	Yes				cYN					
-- Page Dynamics (AE. ACTNOTH): Show When: AE.ACTN = 1														
Page-44-618772	Text Field	2	A10c1. Please specify the other action or treatment taken for the event	AE.ACTNOTHSP	Yes					200	99			
-- Page Dynamics (AE. ACTNOTHSP): Show When: AE.ACTNOTH = 1														
Page-45-618772	Radiolist Horizontal	0	A11. Is this a Serious Adverse Event (SAE)?	AE. SAE	Yes				cYN					SAE consists of events that are fatal or life threatening, results in death, requires or prolongs existing hospitalization, results in disability, or causes a congenital anomaly/birth defect.
Page-46-618772	Help Text Line	1	If Yes, specify why this is considered serious by answering SAE criteria questions below.											
-- Page Dynamics (.): Show When: AE.SAE = 1														
Page-47-618772	Radiolist Horizontal	1	A11a. Resulted in death	AE.DEATH	Yes				cYN					
-- Page Dynamics (AE. DEATH): Show When: AE.SAE = 1														

Page Information														
Page-48-618772	Radiolist Horizontal	1	A11b. Immediate life-threatening event (immediate danger of death from event)	AE.LIFE_THREAT	Yes				cYN					
-- Page Dynamics (AE. LIFE_THREAT): Show When: AE.SAE = 1														
Page-49-618772	Radiolist Horizontal	1	A11c. Requires inpatient hospitalization or prolongation of existing hospitalization	AE.HOSP	Yes				cYN					
-- Page Dynamics (AE. HOSP): Show When: AE.SAE = 1														
Page-50-618772	Date	2	A11c1. Admission date	AE.ADMDAT	Yes									
-- Page Dynamics (AE. ADMDAT): Show When: AE.SAE = 1 AND AE.HOSP = 1														
Page-51-618772	Radiolist Horizontal	2	A11c2. Is the subject still in the hospital?	AE.HOSPONG	Yes				cYN					
-- Page Dynamics (AE. HOSPONG): Show When: AE.SAE = 1 AND AE.HOSP = 1														
Page-52-618772	Date	2	A11c3. Discharge date	AE.DISDAT	Yes									
-- Page Dynamics (AE. DISDAT): Show When: AE.HOSP = 1 AND AE.HOSPONG = 0														
Page-53-618772	Radiolist Horizontal	1	A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	AE.LIFE_FUNC	Yes				cYN					
-- Page Dynamics (AE. LIFE_FUNC): Show When: AE.SAE = 1														
Page-54-618772	Radiolist Horizontal	1	A11e. Results in a congenital anomaly in the offspring of a participant	AE.CONG_ANOM	Yes				cYN					
-- Page Dynamics (AE. CONG_ANOM): Show When: AE.SAE = 1														
Page-55-618772	Radiolist Horizontal	1	A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	AE.IMPORT_EVENT	Yes				cYN					
-- Page Dynamics (AE. IMPORT_EVENT): Show When: AE.SAE = 1														

Page Information														
Page-56-618772	Radiolist Horizontal	0	A12. Is this event an expected adverse event?	AE.EXPECTED	Yes				cYN					Expected: An event is considered expected if it is known to be associated with the study drug(s) and/or the disease state. For this protocol, expected events reported since market introduction regardless of evidence of causality and included in the product brochure are: o Myalgia, muscle spasms, pain in extremity, back pain, arthralgia, rhabdomyolysis o Asthenia, hypoesthesia, fatigue, malaise, dizziness, insomnia, depression, headache, weakness o Diarrhea, constipation, dyspepsia, nausea, abdominal pain o Hepatitis, jaundice, fatal and non-fatal liver failure o Diabetes o Pruritis, rash, urticaria o Interstitial lung disease o Erectile dysfunction o Rare post-marketing reports of cognitive impairment
Page-57-618772	Radiolist	0	A13. Causality related to study medication	AE.CAUSALITY	Yes				cRELATED					

Page Information														
Page-58-618772	Radiolist	0	A14. Outcome	AE.OUTCOME	Yes				cOUTCOME					If outcome is Ongoing at the time of initial entry, please complete an <u>Adverse Event - Follow-up</u> form, once there is new information or the event resolves.
Page-59-618772	Date	1	A14a. Date of resolution, clinical stability or death	AE.ENDDAT	Yes									
-- Page Dynamics (AE. ENDDAT): Show When: AE.OUTCOME = 1 OR AE.OUTCOME = 2 OR AE.OUTCOME = 3														
Page-60-618772	Check Box	2	A14b. Check if a full Date of resolution, clinical stability or death was not reported above<u>AND at least a partial date is known or can be estimated</u> (Both Month and Year or only Year).	AE.ENDDCHX	Yes									ALL efforts should be made to collect a complete Date of resolution, clinical stability or death date. If however, it is not possible to provide a complete date, a known or estimated partial date (Month and Year) should be reported. To enter a partial date, select the checkbox and numeric fields will become visible to capture "Month" and/or "Year".
-- Page Dynamics (AE. ENDDCHX): Show When: (AE.OUTCOME = 1 OR AE.OUTCOME = 2 OR AE.OUTCOME = 3) AND AE.ENDDAT IS NULL														
Page-61-618772	Row Start/End	0												
Page-62-618772	Help Text Line	0												
-- Page Dynamics (.): Show When: (AE.OUTCOME = 1 OR AE.OUTCOME = 2 OR AE.OUTCOME = 3) AND AE.ENDDAT IS NULL AND AE.ENDDCHX IS NOT NULL														
Page-63-618772	Help Text Line	0	A14b1. Date of resolution, clinical stability or death - Month											

Page Information														
-- Page Dynamics (.): Show When: (AE.OUTCOME = 1 OR AE.OUTCOME = 2 OR AE.OUTCOME = 3) AND AE.ENDDAT IS NULL AND AE.ENDDCHX IS NOT NULL														
Page-64-618772	Help Text Line	0	A14b2. Date of resolution, clinical stability or death - Year											
-- Page Dynamics (.): Show When: (AE.OUTCOME = 1 OR AE.OUTCOME = 2 OR AE.OUTCOME = 3) AND AE.ENDDAT IS NULL AND AE.ENDDCHX IS NOT NULL														
Page-65-618772	Row Start/End	0												
Page-66-618772	Row Start/End	0												
Page-67-618772	Help Text Line	0												
-- Page Dynamics (.): Show When: (AE.OUTCOME = 1 OR AE.OUTCOME = 2 OR AE.OUTCOME = 3) AND AE.ENDDAT IS NULL AND AE.ENDDCHX IS NOT NULL														
Page-68-618772	Numeric	0	A14b1. Date of resolution, clinical stability or death - Month	AE.ENDDATM	Yes							2	0	Enter up to 2 digits for the Month (i.e. "10" for October)
-- Page Dynamics (AE. ENDDATM): Show When: (AE.OUTCOME = 1 OR AE.OUTCOME = 2 OR AE.OUTCOME = 3) AND AE.ENDDAT IS NULL AND AE.ENDDCHX IS NOT NULL														
Page-69-618772	Numeric	0	A14b2. Date of resolution, clinical stability or death - Year	AE.ENDDATY	Yes							4	0	Enter 4 digits for the Year (i.e. "2018")
-- Page Dynamics (AE. ENDDATY): Show When: (AE.OUTCOME = 1 OR AE.OUTCOME = 2 OR AE.OUTCOME = 3) AND AE.ENDDAT IS NULL AND AE.ENDDCHX IS NOT NULL														
Page-70-618772	Row Start/End	0												
Page-71-618772	Comments	0	A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)	AE.NARRATIVE	Yes									
Page-72-618772	Section Header	0	SUBMISSION INSTRUCTIONS											
Page-73-618772	Help Text Line	0	Instructions: Please follow reporting timeframes below based on seriousness of event.											
Page-74-618772	Help Text Line	0	Fatal or life threatening: Within 24 hours of first knowledge of event.											
Page-75-618772	Help Text Line	0	Serious, but not fatal or life threatening, and pregnancy: Within 24 hours of first knowledge of event.											

Page Information														
Page-76-618772	Help Text Line	0	All other AEs: Within 7 calendar days of first knowledge of event											

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618869	SYSQ_0922	AE.OUTCOME	Other / Cross Page		AE.HOSPONG = 1 AND AE.OUTCOME <> 4	Outcome should be ongoing if subject is still in the hospital.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618872	SYSQ_1018	AE.SAE	Other / Cross Page		(AE.SAE = 0 AND AE.SEVERITY >= 3) OR (AE.SAE = 1 AND AE.SEVERITY < 3)	SAE has been defined as severity Grade 3-5. Please check for consistency.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618873	SYSQ_1483	AE.DISDAT	Other / Cross Page		AE.DISDAT < AE.ADMDAT	Discharge date should be on or after the hospitalization date.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-619002	SYSQ_4972	AE.STDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(AE.STDAT, 10-20-ICF.ICF_DT) > 0	This date is prior to the informed consent date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619003	SYSQ_4973	AE.STDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(AE.STDAT, 120-20-EOS.DATE) < 0	This date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619005	SYSQ_4974	AE.ENDDAT	Other / Cross Page		AE.ENDDAT < AE.STDAT	Date of resolution, clinical stability or death is prior to the event onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619007	SYSQ_4975	AE.ENDDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(AE.ENDDAT, 120-20-EOS.DATE) < 0	This date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0

System Queries														
sysq-619009	SYSQ_4976	AE.OUTCOME	Other / Cross Page		AE.OUTCOME = 1 AND AE.SAE <> 1	The Outcome of the event has been indicated as Death, however the event is reported as Not Serious. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619011	SYSQ_4977	AE.AESAEDAT	Other / Cross Page		AE.AESAEDAT < AE.STDAT	Date site became aware of the event must be on or after the onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619014	SYSQ_4978	AE.ACTN	Other / Cross Page		AE.ACTN = 1 AND AE.TESTACTN = 0 AND AE.MEDACTN = 0 AND AE.ACTNOTH = 0	Action taken or treatment for this event is Yes, however, the specific actions/treatments which include labs/tests, medications and other, all report No. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619016	SYSQ_4979	AE.LDOSDAT	Other / Cross Page		AE.LDOSDAT > AE.STDAT	Date of last dose of study medication prior to onset of the event must be on or prior to the onset date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-620109	SYSQ_5667	AE.AETERM	Field Null		AE.AETERM IS NULL	"A2. Adverse Event term" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620111	SYSQ_5668	AE.STDAT	Field Null		AE.STDAT IS NULL	"A3. Onset date" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620113	SYSQ_5669	AE.STDAT	Future Date		AE.STDAT > Today	"A3. Onset date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620115	SYSQ_5670	AE.STTIM	Field Null		AE.STTIM IS NULL	"A4. Onset time" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620117	SYSQ_5671	AE.AEVISIT	Field Null		AE.AEVISIT IS NULL	"A5. Study visit associated with AE onset date." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0

System Queries														
sysq-620119	SYSQ_5672	AE.AESAEDAT	Field Null		AE.AESAEDAT IS NULL	"A6. Date site became aware of event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620121	SYSQ_5673	AE.AESAEDAT	Future Date		AE.AESAEDAT > Today	"A6. Date site became aware of event" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620123	SYSQ_5674	AE.SEVERITY	Field Null		AE.SEVERITY IS NULL	"A7. Severity" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620124	SYSQ_5675	AE.ONSTMED	Field Null		AE.ONSTMED IS NULL	"A8. Was the subject on study medication at the time of the event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620126	SYSQ_5676	AE.LDOSDAT	Field Null		AE.LDOSDAT IS NULL	"A8a. Date of last dose of study medication prior to onset of the event" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620129	SYSQ_5677	AE.LDOSDAT	Future Date		AE.LDOSDAT > Today	"A8a. Date of last dose of study medication prior to onset of the event" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620130	SYSQ_5678	AE.STMACTN	Field Null		AE.STMACTN IS NULL	"A9. Was study drug temporarily stopped or permanently discontinued due to this event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620133	SYSQ_5679	AE.STMEDACTYP	Field Null		AE.STMEDACTYP IS NULL	"A9a. Type of change to study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620134	SYSQ_5680	AE.ACTN	Field Null		AE.ACTN IS NULL	"A10. Action taken or treatment for this event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620136	SYSQ_5681	AE.TESTACTN	Field Null		AE.TESTACTN IS NULL	"A10a. Labs, tests, or studies done to diagnose/evaluate event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0

System Queries														
sysq-620138	SYSQ_5682	AE.MEDACTN	Field Null		AE.MEDACTN IS NULL	"A10b. Medication administered to treat event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620141	SYSQ_5683	AE.ACTNOTH	Field Null		AE.ACTNOTH IS NULL	"A10c. Other" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620142	SYSQ_5684	AE.ACTNOTHSP	Field Null		AE.ACTNOTHSP IS NULL	"A10c1. Please specify the other action or treatment taken for the event" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620145	SYSQ_5685	AE.SAE	Field Null		AE.SAE IS NULL	"A11. Is this a Serious Adverse Event (SAE)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620147	SYSQ_5686	AE.DEATH	Field Null		AE.DEATH IS NULL	"A11a. Resulted in death" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620148	SYSQ_5687	AE.LIFE_THREAT	Field Null		AE.LIFE_THREAT IS NULL	"A11b. Immediate life-threatening event (immediate danger of death from event)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:51	0	0	0	0	0	0
sysq-620151	SYSQ_5688	AE.HOSP	Field Null		AE.HOSP IS NULL	"A11c. Requires inpatient hospitalization or prolongation of existing hospitalization" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620153	SYSQ_5689	AE.ADMDAT	Field Null		AE.ADMDAT IS NULL	"A11c1. Admission date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620155	SYSQ_5690	AE.ADMDAT	Future Date		AE.ADMDAT > Today	"A11c1. Admission date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620157	SYSQ_5691	AE.HOSPONG	Field Null		AE.HOSPONG IS NULL	"A11c2. Is the subject still in the hospital?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0

System Queries														
sysq-620158	SYSQ_5692	AE.DISDAT	Field Null		AE.DISDAT IS NULL	"A11c3. Discharge date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620161	SYSQ_5693	AE.DISDAT	Future Date		AE.DISDAT > Today	"A11c3. Discharge date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620162	SYSQ_5694	AE.LIFE_FUNC	Field Null		AE.LIFE_FUNC IS NULL	"A11d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620165	SYSQ_5695	AE.CONG_ANOM	Field Null		AE.CONG_ANOM IS NULL	"A11e. Results in a congenital anomaly in the offspring of a participant" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620167	SYSQ_5696	AE.IMPORT_EVENT	Field Null		AE.IMPORT_EVENT IS NULL	"A11f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620168	SYSQ_5697	AE.EXPECTED	Field Null		AE.EXPECTED IS NULL	"A12. Is this event an expected adverse event?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620170	SYSQ_5698	AE.CAUSALITY	Field Null		AE.CAUSALITY IS NULL	"A13. Causality related to study medication" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620173	SYSQ_5699	AE.OUTCOME	Field Null		AE.OUTCOME IS NULL	"A14. Outcome" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0
sysq-620175	SYSQ_5700	AE.ENDDAT	Field Null		AE.ENDDAT IS NULL	"A14a. Date of resolution, clinical stability or death" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:52	0	0	0	0	0	0

System Queries														
sysq-620176	SYSQ_5701	AE.ENDDAT	Future Date		AE.ENDDAT > Today	"A14a. Date of resolution, clinical stability or death" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620178	SYSQ_5702	AE.NARRATIVE	Field Null		AE.NARRATIVE IS NULL	"A15. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620436	SYSQ_5849	AE.STDATM	Field Null		AE.STDATM IS NULL	"A3a1. Onset Date - Month" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620437	SYSQ_5850	AE.STDATY	Field Null		AE.STDATY IS NULL	"A3a2. Onset Date - Year" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620438	SYSQ_5851	AE.LDOSDATM	Field Null		AE.LDOSDATM IS NULL	"A8b1. Date of Last Dose - Month" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620439	SYSQ_5852	AE.LDOSDATY	Field Null		AE.LDOSDATY IS NULL	"A8b2. Date of Last Dose - Year" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620440	SYSQ_5853	AE.ENDDATM	Field Null		AE.ENDDATM IS NULL	"A14b1. Date of resolution, clinical stability or death - Month" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620441	SYSQ_5854	AE.ENDDATY	Field Null		AE.ENDDATY IS NULL	"A14b2. Date of resolution, clinical stability or death - Year" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620442	SYSQ_5855	AE.STDATM	Range		AE.STDATM < 1 OR AE.STDATM > 12	"A3a1. Onset Date - Month" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620443	SYSQ_5856	AE.STDATY	Range		AE.STDATY < 2018 OR AE.STDATY > 2025	"A3a2. Onset Date - Year" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0

System Queries														
sysq-620444	SYSQ_5857	AE.LDOSDATM	Range		AE.LDOSDATM < 1 OR AE.LDOSDATM > 12	"A8b1. Date of Last Dose - Month" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620445	SYSQ_5858	AE.LDOSDATY	Range		AE.LDOSDATY < 2018 OR AE.LDOSDATY > 2025	"A8b2. Date of Last Dose - Year" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620446	SYSQ_5859	AE.ENDDATM	Range		AE.ENDDATM < 1 OR AE.ENDDATM > 12	"A14b1. Date of resolution, clinical stability or death - Month" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620447	SYSQ_5860	AE.ENDDATY	Range		AE.ENDDATY < 2018 OR AE.ENDDATY > 2025	"A14b2. Date of resolution, clinical stability or death - Year" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620448	SYSQ_5861	AE.STDAT	Other / Cross Page		AE.STDAT IS NULL AND AE.AESTDCHX IS NULL	Neither a complete nor partial Onset Date was reported. If a complete date is not known, a partial Month and Year (or worst case at least a Year) is expected by selecting the checkbox option on the question (A3a) below. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620449	SYSQ_5862	AE.LDOSDAT	Other / Cross Page		AE.LDOSDAT IS NULL AND AE.LDOSDCHX IS NULL	Neither a complete nor partial "Date of last dose of study medication prior to onset of the event" was reported. If a complete date is not known, a partial Month and Year (or worst case at least a Year) is expected by selecting the checkbox option on the question (A8b) below. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620450	SYSQ_5863	AE.ENDDAT	Other / Cross Page		AE.ENDDAT IS NULL AND AE.ENDDCHX IS NULL	Neither a complete nor partial "Date of resolution, clinical stability or death" was reported. If a complete date is not known, a partial Month and Year (or worst case at least a Year) is expected by selecting the checkbox option on the question (A14b) below. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0

pBOTTLE_LOG

Page

(Visit ID = 618773, Page ID =)

Unique Identifier page-618773-618773-618773-

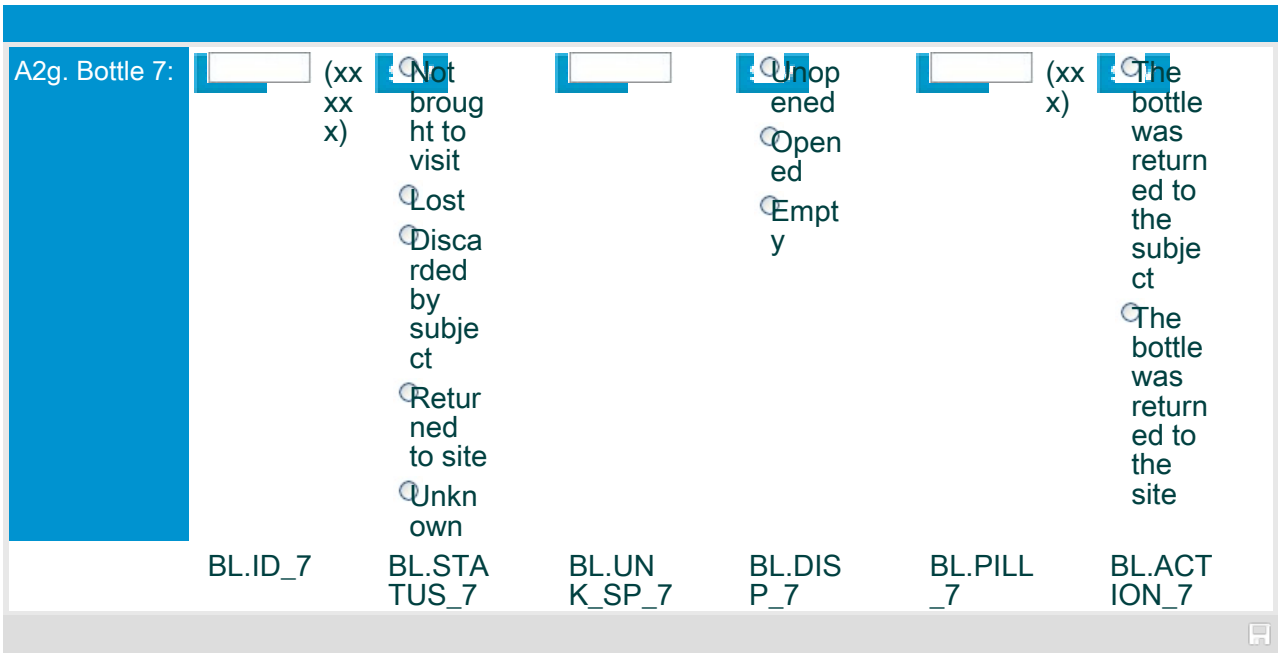
SECTION A: BOTTLE LOG			
SDV	* A1. Date:		BL.LOG_DT
SDV	* A2. How many bottles will be reported on this form?		BL.BOT_NUM (format x)

Please account for all bottles, including those lost or discarded since the last completed log, or otherwise not returned to the site at this visit. If more than 7 bottles are being reported, complete a second bottle log for the same date.

	Bottle ID	Bottle Status	Details if Unknown	Bottle Disposition	Pill Count	Bottle Action
A2a. Bottle 1:	(xxxx)	Not brought to visit Lost Discarded by subject Returned to site Unknown		Unopened Opened Empty	(xx)	The bottle was returned to the subject The bottle was returned to the site
	BL.ID_1	BL.STATUS_1	BL.UNK_SP_1	BL.DISP_1	BL.PILL_1	BL.ACTION_1
A2b. Bottle 2:	(xxxx)	Not brought to visit Lost Discarded by subject Returned to site Unknown		Unopened Opened Empty	(xx)	The bottle was returned to the subject The bottle was returned to the site
	BL.ID_2	BL.STATUS_2	BL.UNK_SP_2	BL.DISP_2	BL.PILL_2	BL.ACTION_2

A2c. Bottle 3:	(xxxx)	Not brought to visit Lost Discarded by subject Returned to site Unknown		Unopened Opened Empty	(xx)	The bottle was returned to the subject The bottle was returned to the site
	BL.ID_3	BL.STATUS_3	BL.UNK_SP_3	BL.DISP_3	BL.PILL_3	BL.ACTION_3
A2d. Bottle 4:	(xxxx)	Not brought to visit Lost Discarded by subject Returned to site Unknown		Unopened Opened Empty	(xx)	The bottle was returned to the subject The bottle was returned to the site
	BL.ID_4	BL.STATUS_4	BL.UNK_SP_4	BL.DISP_4	BL.PILL_4	BL.ACTION_4

A2e. Bottle 5:	(xxxx)	Not brought to visit Lost Discarded by subject Returned to site Unknown		Unopened Opened Empty	(xx)	The bottle was returned to the subject The bottle was returned to the site
	BL.ID_5	BL.STATUS_5	BL.UNK_SP_5	BL.DISP_5	BL.PILL_5	BL.ACTION_5
A2f. Bottle 6:	(xxxx)	Not brought to visit Lost Discarded by subject Returned to site Unknown		Unopened Opened Empty	(xx)	The bottle was returned to the subject The bottle was returned to the site
	BL.ID_6	BL.STATUS_6	BL.UNK_SP_6	BL.DISP_6	BL.PILL_6	BL.ACTION_6



Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618773	Section Header	0	SECTION A: BOTTLE LOG											
Page-2-618773	Date	0	A1. Date:	BL.LOG_DT	Yes									
Page-3-618773	Numeric	0	A2. How many bottles will be reported on this form?	BL.BOT_NUM	Yes							1	0	
Page-4-618773	Help Text Line	0	Please account for all bottles, including those lost or discarded since the last completed log, or otherwise not returned to the site at this visit. If more than 7 bottles are being reported, complete a second bottle log for the same date.											
Page-5-618773	Row Start/End	0												

Page Information														
Page-6-618773	Section Header	0												
-- Page Dynamics (.): Show When: BL.BOT_NUM IS NOT NULL														
Page-7-618773	Section Header	0	Bottle ID											
-- Page Dynamics (.): Show When: BL.BOT_NUM IS NOT NULL														
Page-8-618773	Section Header	0	Bottle Status											
-- Page Dynamics (.): Show When: BL.BOT_NUM IS NOT NULL														
Page-9-618773	Section Header	0	Details if Unknown											
-- Page Dynamics (.): Show When: BL.BOT_NUM IS NOT NULL														
Page-10-618773	Section Header	0	Bottle Disposition											
-- Page Dynamics (.): Show When: BL.BOT_NUM IS NOT NULL														
Page-11-618773	Section Header	0	Pill Count											
-- Page Dynamics (.): Show When: BL.BOT_NUM IS NOT NULL														
Page-12-618773	Section Header	0	Bottle Action											
-- Page Dynamics (.): Show When: BL.BOT_NUM IS NOT NULL														
Page-13-618773	Row Start/End	0												
Page-14-618773	Row Start/End	0	a. Bottle 1											
Page-15-618773	Section Header	0	A2a. Bottle 1:											
-- Page Dynamics (.): Show When: BL.BOT_NUM >= 1														
Page-16-618773	Numeric	0	Bottle Number 1	BL. ID_1	Yes							5	0	
-- Page Dynamics (BL. ID_1): Show When: BL.BOT_NUM >= 1														
Page-17-618773	Radiolist	2	Bottle Status 1	BL. STATUS_1	Yes				cBOT_STAT					
-- Page Dynamics (BL. STATUS_1): Show When: BL.BOT_NUM >= 1														

Page Information														
Page-18-618773	Text Field	0	Unknown Details 1	BL.UNK_SP_1	Yes					100	25			
-- Page Dynamics (BL. UNK_SP_1): Show When: BL.STATUS_1 = 5														
Page-19-618773	Radiolist	0	Bottle Disposition 1	BL.DISP_1	Yes				cBOT_DISP					
-- Page Dynamics (BL. DISP_1): Show When: BL.BOT_NUM >= 1														
Page-20-618773	Numeric	2	Pill Count 1	BL.PILL_1	Yes							3	0	
-- Page Dynamics (BL. PILL_1): Show When: BL.BOT_NUM >= 1 AND BL.STATUS_1 = 4 AND BL.DISP_1 = 2														
Page-21-618773	Radiolist	0	Action 1	BL.ACTION_1	Yes				cBOT_ACT					
-- Page Dynamics (BL. ACTION_1): Show When: BL.BOT_NUM >= 1 AND BL.STATUS_1 = 4														
Page-22-618773	Row Start/End	0	bottle 1 end											
Page-23-618773	Row Start/End	0												
Page-24-618773	Section Header	0	A2b. Bottle 2:											
-- Page Dynamics (.): Show When: BL.BOT_NUM >= 2														
Page-25-618773	Numeric	0	Bottle Number 2	BL. ID_2	Yes							5	0	
-- Page Dynamics (BL. ID_2): Show When: BL.BOT_NUM >= 2														
Page-26-618773	Radiolist	2	Bottle Status 2	BL.STATUS_2	Yes				cBOT_STAT					
-- Page Dynamics (BL. STATUS_2): Show When: BL.BOT_NUM >= 2														
Page-27-618773	Text Field	0	Uknown Details 2	BL.UNK_SP_2	Yes					100	25			
-- Page Dynamics (BL. UNK_SP_2): Show When: BL.STATUS_2 = 5														
Page-28-618773	Radiolist	0	Bottle Status 2	BL.DISP_2	Yes				cBOT_DISP					
-- Page Dynamics (BL. DISP_2): Show When: BL.BOT_NUM >= 2														
Page-29-618773	Numeric	2	Pill Count	BL.PILL_2	Yes							3	0	
-- Page Dynamics (BL. PILL_2): Show When: BL.BOT_NUM >= 2 AND BL.STATUS_2 = 4 AND BL.DISP_2 = 2														

Page Information														
Page-30-618773	Radiolist	0	Bottle 2	BL. ACTION_2	Yes				cBOT_ACT					
-- Page Dynamics (BL. ACTION_2): Show When: BL.BOT_NUM >= 2 AND BL.STATUS_2 = 4														
Page-31-618773	Row Start/End	0	bottle 2 end											
Page-32-618773	Row Start/End	0	bottle 3											
Page-33-618773	Section Header	0	A2c. Bottle 3:											
-- Page Dynamics (.): Show When: BL.BOT_NUM >= 3														
Page-34-618773	Numeric	0	Bottle Number 3	BL. ID_3	Yes							5	0	
-- Page Dynamics (BL. ID_3): Show When: BL.BOT_NUM >= 3														
Page-35-618773	Radiolist	2	Bottle Status 3	BL. STATUS_3	Yes				cBOT_STAT					
-- Page Dynamics (BL. STATUS_3): Show When: BL.BOT_NUM >= 3														
Page-36-618773	Text Field	0	Unknown Details 3	BL. UNK_SP_3	Yes					100	25			
-- Page Dynamics (BL. UNK_SP_3): Show When: BL.STATUS_3 = 5														
Page-37-618773	Radiolist	0	Bottle Status 3	BL. DISP_3	Yes				cBOT_DISP					
-- Page Dynamics (BL. DISP_3): Show When: BL.BOT_NUM >= 3														
Page-38-618773	Numeric	2	Pill Count	BL. PILL_3	Yes							3	0	
-- Page Dynamics (BL. PILL_3): Show When: BL.BOT_NUM >= 3 AND BL.STATUS_3 = 4 AND BL.DISP_3 = 2														
Page-39-618773	Radiolist	0	Bottle 3	BL. ACTION_3	Yes				cBOT_ACT					
-- Page Dynamics (BL. ACTION_3): Show When: BL.BOT_NUM >= 3 AND BL.STATUS_3 = 4														
Page-40-618773	Row Start/End	0	bottle 3 end											
Page-41-618773	Row Start/End	0	bottle 4											

Page Information														
Page-42-618773	Section Header	0	A2d. Bottle 4:											
-- Page Dynamics (.): Show When: BL.BOT_NUM >= 4														
Page-43-618773	Numeric	0	Bottle Number 4	BL. ID_4	Yes							5	0	
-- Page Dynamics (BL. ID_4): Show When: BL.BOT_NUM >= 4														
Page-44-618773	Radiolist	2	Bottle Status 4	BL. STATUS_4	Yes				cBOT_STAT					
-- Page Dynamics (BL. STATUS_4): Show When: BL.BOT_NUM >= 4														
Page-45-618773	Text Field	0	Unknown Details 4	BL. UNK_SP_4	Yes					100	25			
-- Page Dynamics (BL. UNK_SP_4): Show When: BL.STATUS_4 = 5														
Page-46-618773	Radiolist	0	Bottle Status 4	BL. DISP_4	Yes				cBOT_DISP					
-- Page Dynamics (BL. DISP_4): Show When: BL.BOT_NUM >= 4														
Page-47-618773	Numeric	2	Pill Count	BL. PILL_4	Yes							3	0	
-- Page Dynamics (BL. PILL_4): Show When: BL.BOT_NUM >= 4 AND BL.STATUS_4 = 4 AND BL.DISP_4 = 2														
Page-48-618773	Radiolist	0	Bottle 4	BL. ACTION_4	Yes				cBOT_ACT					
-- Page Dynamics (BL. ACTION_4): Show When: BL.BOT_NUM >= 4 AND BL.STATUS_4 = 4														
Page-49-618773	Row Start/End	0	bottle 5 end											
Page-50-618773	Row Start/End	0	bottle 5											
Page-51-618773	Section Header	0	A2e. Bottle 5:											
-- Page Dynamics (.): Show When: BL.BOT_NUM >= 5														
Page-52-618773	Numeric	0	Bottle Number 5	BL. ID_5	Yes							5	0	
-- Page Dynamics (BL. ID_5): Show When: BL.BOT_NUM >= 5														
Page-53-618773	Radiolist	2	Bottle Status 5	BL. STATUS_5	Yes				cBOT_STAT					
-- Page Dynamics (BL. STATUS_5): Show When: BL.BOT_NUM >= 5														

Page Information														
Page-54-618773	Text Field	0	Unknown Details 5	BL.UNK_SP_5	Yes					100	25			
-- Page Dynamics (BL. UNK_SP_5): Show When: BL.STATUS_5 = 5														
Page-55-618773	Radiolist	0	Bottle Status 5	BL.DISP_5	Yes				cBOT_DISP					
-- Page Dynamics (BL. DISP_5): Show When: BL.BOT_NUM >= 5														
Page-56-618773	Numeric	2	Pill Count	BL.PILL_5	Yes							3	0	
-- Page Dynamics (BL. PILL_5): Show When: BL.BOT_NUM >= 5 AND BL.STATUS_5 = 4 AND BL.DISP_5 = 2														
Page-57-618773	Radiolist	0	bottle 5	BL.ACTION_5	Yes				cBOT_ACT					
-- Page Dynamics (BL. ACTION_5): Show When: BL.BOT_NUM >= 5 AND BL.STATUS_5 = 4														
Page-58-618773	Row Start/End	0	bottle 5 end											
Page-59-618773	Row Start/End	0												
Page-60-618773	Section Header	0	A2f. Bottle 6:											
-- Page Dynamics (.): Show When: BL.BOT_NUM >= 6														
Page-61-618773	Numeric	0	Bottle Number 6	BL. ID_6	Yes							5	0	
-- Page Dynamics (BL. ID_6): Show When: BL.BOT_NUM >= 6														
Page-62-618773	Radiolist	0	Bottle Status 6	BL.STATUS_6	Yes				cBOT_STAT					
-- Page Dynamics (BL. STATUS_6): Show When: BL.BOT_NUM >= 6														
Page-63-618773	Text Field	0	Unknown Details 6	BL.UNK_SP_6	Yes					100	25			
-- Page Dynamics (BL. UNK_SP_6): Show When: BL.STATUS_6 = 5														
Page-64-618773	Radiolist	0	Bottle Status 6	BL.DISP_6	Yes				cBOT_DISP					
-- Page Dynamics (BL. DISP_6): Show When: BL.BOT_NUM >= 6														
Page-65-618773	Numeric	0	Pill Count	BL.PILL_6	Yes							3	0	
-- Page Dynamics (BL. PILL_6): Show When: BL.BOT_NUM >= 6 AND BL.STATUS_6 = 4 AND BL.DISP_6 = 2														

Page Information														
Page-66-618773	Radiolist	0	bottle 6	BL. ACTION_6	Yes				cBOT_ACT					
-- Page Dynamics (BL. ACTION_6): Show When: BL.BOT_NUM >= 6 AND BL.STATUS_6 = 4														
Page-67-618773	Row Start/End	0												
Page-68-618773	Row Start/End	0												
Page-69-618773	Section Header	0	A2g. Bottle 7:											
-- Page Dynamics (.): Show When: BL.BOT_NUM >= 7														
Page-70-618773	Numeric	0	Bottle Number 7	BL. ID_7	Yes							5	0	
-- Page Dynamics (BL. ID_7): Show When: BL.BOT_NUM >= 7														
Page-71-618773	Radiolist	0	Bottle Status 7	BL. STATUS_7	Yes				cBOT_STAT					
-- Page Dynamics (BL. STATUS_7): Show When: BL.BOT_NUM >= 7														
Page-72-618773	Text Field	0	Unknown Details 7	BL. UNK_SP_7	Yes					100	25			
-- Page Dynamics (BL. UNK_SP_7): Show When: BL.STATUS_7 = 5														
Page-73-618773	Radiolist	0	Bottle Status 7	BL. DISP_7	Yes				cBOT_DISP					
-- Page Dynamics (BL. DISP_7): Show When: BL.BOT_NUM >= 7														
Page-74-618773	Numeric	0	Pill Count	BL. PILL_7	Yes							3	0	
-- Page Dynamics (BL. PILL_7): Show When: BL.BOT_NUM >= 7 AND BL.STATUS_7 = 4 AND BL.DISP_7 = 2														
Page-75-618773	Radiolist	0	bottle 7	BL. ACTION_7	Yes				cBOT_ACT					
-- Page Dynamics (BL. ACTION_7): Show When: BL.BOT_NUM >= 7 AND BL.STATUS_7 = 4														
Page-76-618773	Row Start/End	0	bottle 6 end											

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph

System Queries														
sysq-620022	SYSQ_5585	BL.LOG_DT	Field Null		BL.LOG_DT IS NULL	"A1. Date:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620023	SYSQ_5586	BL.BOT_NUM	Field Null		BL.BOT_NUM IS NULL	"A2. How many bottles will be reported on this form?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620024	SYSQ_5587	BL.ID_1	Field Null		BL.ID_1 IS NULL	"Bottle Number 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620025	SYSQ_5588	BL.STATUS_1	Field Null		BL.STATUS_1 IS NULL	"Bottle Status 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620026	SYSQ_5589	BL.UNK_SP_1	Field Null		BL.UNK_SP_1 IS NULL	"Unknown Details 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620027	SYSQ_5590	BL.DISP_1	Field Null		BL.DISP_1 IS NULL	"Bottle Disposition 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620028	SYSQ_5591	BL.PILL_1	Field Null		BL.PILL_1 IS NULL	"Pill Count 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620029	SYSQ_5592	BL.ACTION_1	Field Null		BL.ACTION_1 IS NULL	"Action 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620030	SYSQ_5593	BL.ID_2	Field Null		BL.ID_2 IS NULL	"Bottle Number 2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620031	SYSQ_5594	BL.STATUS_2	Field Null		BL.STATUS_2 IS NULL	"Bottle Status 2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0

System Queries														
sysq-620032	SYSQ_5595	BL.UNK_SP_2	Field Null		BL.UNK_SP_2 IS NULL	"Uknown Details 2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620033	SYSQ_5596	BL.DISP_2	Field Null		BL.DISP_2 IS NULL	"Bottle Status 2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620034	SYSQ_5597	BL.PILL_2	Field Null		BL.PILL_2 IS NULL	"Pill Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620035	SYSQ_5598	BL.ACTION_2	Field Null		BL.ACTION_2 IS NULL	"Bottle 2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620036	SYSQ_5599	BL.STATUS_3	Field Null		BL.STATUS_3 IS NULL	"Bottle Status 3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620037	SYSQ_5600	BL.UNK_SP_3	Field Null		BL.UNK_SP_3 IS NULL	"Unknown Details 3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620038	SYSQ_5601	BL.DISP_3	Field Null		BL.DISP_3 IS NULL	"Bottle Status 3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620039	SYSQ_5602	BL.PILL_3	Field Null		BL.PILL_3 IS NULL	"Pill Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620040	SYSQ_5603	BL.ACTION_3	Field Null		BL.ACTION_3 IS NULL	"Bottle 3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620041	SYSQ_5604	BL.ID_4	Field Null		BL.ID_4 IS NULL	"Bottle Number 4" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0

System Queries														
sysq-620042	SYSQ_5605	BL.STATUS_4	Field Null		BL.STATUS_4 IS NULL	"Bottle Status 4" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620043	SYSQ_5606	BL.UNK_SP_4	Field Null		BL.UNK_SP_4 IS NULL	"Unknown Details 4" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620044	SYSQ_5607	BL.DISP_4	Field Null		BL.DISP_4 IS NULL	"Bottle Status 4" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620045	SYSQ_5608	BL.PILL_4	Field Null		BL.PILL_4 IS NULL	"Pill Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620046	SYSQ_5609	BL.ACTION_4	Field Null		BL.ACTION_4 IS NULL	"Bottle 4" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620047	SYSQ_5610	BL.ID_5	Field Null		BL.ID_5 IS NULL	"Bottle Number 5" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620048	SYSQ_5611	BL.STATUS_5	Field Null		BL.STATUS_5 IS NULL	"Bottle Status 5" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620049	SYSQ_5612	BL.UNK_SP_5	Field Null		BL.UNK_SP_5 IS NULL	"Unknown Details 5" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620050	SYSQ_5613	BL.DISP_5	Field Null		BL.DISP_5 IS NULL	"Bottle Status 5" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620051	SYSQ_5614	BL.PILL_5	Field Null		BL.PILL_5 IS NULL	"Pill Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0

System Queries														
sysq-620052	SYSQ_5615	BL.ACTION_5	Field Null		BL.ACTION_5 IS NULL	"bottle 5" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620053	SYSQ_5616	BL.ID_6	Field Null		BL.ID_6 IS NULL	"Bottle Number 6" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620054	SYSQ_5617	BL.STATUS_6	Field Null		BL.STATUS_6 IS NULL	"Bottle Status 6" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620055	SYSQ_5618	BL.UNK_SP_6	Field Null		BL.UNK_SP_6 IS NULL	"Unknown Details 6" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620056	SYSQ_5619	BL.DISP_6	Field Null		BL.DISP_6 IS NULL	"Bottle Status 6" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620057	SYSQ_5620	BL.PILL_6	Field Null		BL.PILL_6 IS NULL	"Pill Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620058	SYSQ_5621	BL.ACTION_6	Field Null		BL.ACTION_6 IS NULL	"bottle 6" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620059	SYSQ_5622	BL.ID_7	Field Null		BL.ID_7 IS NULL	"Bottle Number 7" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:48	0	0	0	0	0	0
sysq-620060	SYSQ_5623	BL.STATUS_7	Field Null		BL.STATUS_7 IS NULL	"Bottle Status 7" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620061	SYSQ_5624	BL.UNK_SP_7	Field Null		BL.UNK_SP_7 IS NULL	"Unknown Details 7" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0

System Queries														
sysq-620062	SYSQ_5625	BL.DISP_7	Field Null		BL.DISP_7 IS NULL	"Bottle Status 7" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620063	SYSQ_5626	BL.PILL_7	Field Null		BL.PILL_7 IS NULL	"Pill Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620064	SYSQ_5627	BL.ACTION_7	Field Null		BL.ACTION_7 IS NULL	"bottle 7" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620065	SYSQ_5628	BL.LOG_DT	Future Date		BL.LOG_DT > Today	"A1. Date:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620066	SYSQ_5629	BL.ID_3	Field Null		BL.ID_3 IS NULL	"Bottle Number 3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620067	SYSQ_5630	BL.PILL_1	Range		BL.PILL_1 > 90	Pill count in this bottle is reported to be greater than 90 pills, while the maximum expected number is 90 per bottle. Please confirm data entered.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620068	SYSQ_5631	BL.PILL_2	Range		BL.PILL_2 > 90	Pill count in this bottle is reported to be greater than 90 pills, while the maximum expected number is 90 per bottle. Please confirm data entered.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620069	SYSQ_5632	BL.PILL_3	Range		BL.PILL_3 > 90	Pill count in this bottle is reported to be greater than 90 pills, while the maximum expected number is 90 per bottle. Please confirm data entered.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620070	SYSQ_5633	BL.PILL_4	Range		BL.PILL_4 > 90	Pill count in this bottle is reported to be greater than 90 pills, while the maximum expected number is 90 per bottle. Please confirm data entered.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0

System Queries														
sysq-620071	SYSQ_5634	BL.PILL_5	Range		BL.PILL_5 > 90	Pill count in this bottle is reported to be greater than 90 pills, while the maximum expected number is 90 per bottle. Please confirm data entered.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620072	SYSQ_5635	BL.PILL_6	Range		BL.PILL_6 > 90	Pill count in this bottle is reported to be greater than 90 pills, while the maximum expected number is 90 per bottle. Please confirm data entered.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620073	SYSQ_5636	BL.PILL_7	Range		BL.PILL_7 > 90	Pill count in this bottle is reported to be greater than 90 pills, while the maximum expected number is 90 per bottle. Please confirm data entered.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620074	SYSQ_5637	BL.LOG_DT	Other / Cross Page		10-20-ICF.ICF_DT > BL.LOG_DT	Date of bottle log completion must be after date of consent.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620075	SYSQ_5638	BL.BOT_NUM	Range		BL.BOT_NUM < 1 OR BL.BOT_NUM > 7	"A2. How many bottles will be reported on this form?" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0

pCMED

Page

(Visit ID = 618774, Page ID =)

Unique Identifier page-618774-618774-618774-

SECTION A: Medications			
	Complete a CMD form for each medication taken by the subject, from the time of signed informed consent date through study exit. Only one medication should be reported per form.		
SDV	* A1. Medication		CM.CMED
SDV	* A2. Is this a non-prescription medication, vitamins or herbal supplements?	○ Yes ○ No	CM.CMEDTYP
SDV	* A3. Start Date		CM.CMSTDAT
SDV	* A4. Total Daily Dose		CM.CMDOSE (format xxxxxxx.xxx)
SDV	* A5. Dose Unit	○ mg ○ mcg ○ g ○ ml ○ unit ○ tablet ○ Other	CM.CMDOSU
SDV	* A5a. Specify other dose unit		CM.CMDOSUOT
SDV	* A6. Ongoing?	○ Yes ○ No	CM.CMONG
SDV	* A6a. Stop Date		CM.CMENDAT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618774	Section Header	0	SECTION A: Medications											

Page Information														
Page-2-618774	Help Text Line	0	Complete a CMD form for each medication taken by the subject, from the time of signed informed consent date through study exit. Only one medication should be reported per form.											
Page-3-618774	Text Field	0	A1. Medication	CM.CMED	Yes					100	50			Please enter all medications, both prescription and over-the-counter, as well as any vitamins or supplements that the subject is taking.
Page-4-618774	Radiolist Horizontal	0	A2. Is this a non-prescription medication, vitamins or herbal supplements?	CM.CMEDTYP	Yes				cYN					
Page-5-618774	Date Partial	0	A3. Start Date	CM.CMSTDAT	Yes									Enter the date the dose was started. Partial dates are accepted. If there was a change in dose, the stop date of the old dose and the start date of the new dose should not overlap.
Page-6-618774	Numeric	0	A4. Total Daily Dose	CM.CMDOSE	Yes							7	3	
Page-7-618774	Radiolist	0	A5. Dose Unit	CM.CMDOSU	Yes				cDOSEU					Enter the units of the dose reported above.
Page-8-618774	Text Field	1	A5a. Specify other dose unit	CM.CMDOSUOT	Yes					50	30			Only complete this field if the Other option was selected.
-- Page Dynamics (CM. CMDOSUOT): Show When: CM.CMDOSU = 99														
Page-9-618774	Radiolist	0	A6. Ongoing?	CM.CMONG	Yes				cYN					Indicate whether the medication/dose is currently continuing. If No, a field will appear to capture the stop date.

Page Information														
Page -10-61874	Date Partial	1	A6a. Stop Date	CM. CMENDAT	Yes									If Ongoing is No, enter the date the medication was stopped. Only dates before study exit should be entered. If there was a change in dose, the stop date of the old dose and the start date of the new dose should not overlap.
-- Page Dynamics (CM. CMENDAT): Show When: CM.CMONG = 0														

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619018	SYSQ_4980	CM.CMSTDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(CM.CMSTDAT, 120-20-EOS.DATE) < 0	Start date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619019	SYSQ_4981	CM.CMENDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(CM.CMSTDAT, CM.CMENDAT) < 0	The Stop date is before the reported Start date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619021	SYSQ_4982	CM.CMENDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(CM.CMENDAT, 120-20-EOS.DATE) < 0	Stop date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-620003	SYSQ_5575	CM.CMED	Field Null		CM.CMED IS NULL	"A1. Medication" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620004	SYSQ_5576	CM.CMEDTYP	Field Null		CM.CMEDTYP IS NULL	"A2. Is this a non-prescription medication, vitamins or herbal supplements?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0

System Queries														
sysq-620006	SYSQ_5577	CM.CMSTDAT	Field Null		CM.CMSTDAT IS NULL	"A3. Start Date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620009	SYSQ_5578	CM.CMSTDAT	Future Date		CM.CMSTDAT > Today	"A3. Start Date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620011	SYSQ_5579	CM.CMDOSE	Field Null		CM.CMDOSE IS NULL	"A4. Total Daily Dose" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620012	SYSQ_5580	CM.CMDOSU	Field Null		CM.CMDOSU IS NULL	"A5. Dose Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620015	SYSQ_5581	CM.CMDOSUOT	Field Null		CM.CMDOSUOT IS NULL	"A5a. Specify other dose unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620017	SYSQ_5582	CM.CMONG	Field Null		CM.CMONG IS NULL	"A6. Ongoing?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620019	SYSQ_5583	CM.CMENDAT	Field Null		CM.CMENDAT IS NULL	"A6a. Stop Date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620021	SYSQ_5584	CM.CMENDAT	Future Date		CM.CMENDAT > Today	"A6a. Stop Date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0

pCMED_2

Page

(Visit ID = 618775, Page ID =)

Unique Identifier page-618775-618775-618775-

SECTION A: Medications			
	Complete a CMD form for each medication taken by the subject, from the time of signed informed consent date through study exit. Only one medication should be reported per form.		
SDV	* A1. Medication		CM.CMED
SDV	* A2. Is this a non-prescription medication, vitamins or herbal supplements?	○ Yes ○ No	CM.CMEDTYP
SDV	* A3. Start Date		CM.CMSTDAT
SDV	* A4. Total Daily Dose		CM.CMDOSE (format xxxxxxx.xxx)
SDV	* A5. Dose Unit	○ mg ○ mcg ○ g ○ ml ○ unit ○ tablet ○ Other	CM.CMDOSU
SDV	* A5a. Specify other dose unit		CM.CMDOSUOT
SDV	A6. Check if this medication was Prescribed As Needed (PRN)	☐	CM.CMCHKPRN
SDV	* A7. Ongoing?	○ Yes ○ No	CM.CMONG
SDV	* A7a. Stop Date		CM.CMENDAT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text

Page Information														
Page-1-618775	Section Header	0	SECTION A: Medications											
Page-2-618775	Help Text Line	0	Complete a CMD form for each medication taken by the subject, from the time of signed informed consent date through study exit. Only one medication should be reported per form.											
Page-3-618775	Text Field	0	A1. Medication	CM.CMED	Yes					100	50			Please enter all medications, both prescription and over-the-counter, as well as any vitamins or supplements that the subject is taking.
Page-4-618775	Radiolist Horizontal	0	A2. Is this a non-prescription medication, vitamins or herbal supplements?	CM.CMEDTYP	Yes				cYN					This question refers to non-prescription medications (irregardless if they were prescribed or not). If a medication is available without prescription (i.e. Vitamins, Naproxen, Zyrtec etc.), the medication should be reported as a non-prescription medication or "Yes" to this question.
Page-5-618775	Date Partial	0	A3. Start Date	CM.CMSTDAT	Yes									Enter the date the dose was started. Partial dates are accepted. If there was a change in dose, the stop date of the old dose and the start date of the new dose should not overlap.
Page-6-618775	Numeric	0	A4. Total Daily Dose	CM.CMDOSE	Yes							7	3	

Page Information														
Page-7-618775	Radiolist	0	A5. Dose Unit	CM.CMDOSU	Yes				cDOSEU					Enter the units of the dose reported above.
Page-8-618775	Text Field	1	A5a. Specify other dose unit	CM.CMDOSUOT	Yes					50	30			Only complete this field if the Other option was selected.
-- Page Dynamics (CM. CMDOSUOT): Show When: CM.CMDOSU = 99														
Page-9-618775	Check Box	0	A6. Check if this medication was Prescribed As Needed (PRN)	CM.CMCHKPRN	Yes									Select the Checkbox if the medication is PRN. Enter the prescribed dose in the A4. Total Daily Dose response field above. For example, if a subject is prescribed 100 mg of a medication on an as needed basis, "100" should be reported for A4. Total Daily Dose, "mg" for A5. Dose Unit and A6. Should be checked to indicate the medication is PRN.
Page-10-618775	Radiolist	0	A7. Ongoing?	CM.CMONG	Yes				cYN					Indicate whether the medication/dose is currently continuing. If No, a field will appear to capture the stop date.
Page-11-618775	Date Partial	1	A7a. Stop Date	CM.CMENDAT	Yes									If Ongoing is No, enter the date the medication was stopped. Only dates before study exit should be entered. If there was a change in dose, the stop date of the old dose and the start date of the new dose should not overlap.
-- Page Dynamics (CM. CMENDAT): Show When: CM.CMONG = 0														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619017	SYSQ_4980	CM.CMSTDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(CM.CMSTDAT, 120-20-EOS.DATE) < 0	Start date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619020	SYSQ_4981	CM.CMENDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(CM.CMSTDAT, CM.CMENDAT) < 0	The Stop date is before the reported Start date. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619022	SYSQ_4982	CM.CMENDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(CM.CMENDAT, 120-20-EOS.DATE) < 0	Stop date is after the reported Date of study exit. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-620002	SYSQ_5575	CM.CMED	Field Null		CM.CMED IS NULL	"A1. Medication" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-620005	SYSQ_5576	CM.CMEDTYP	Field Null		CM.CMEDTYP IS NULL	"A2. Is this a non-prescription medication, vitamins or herbal supplements?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620007	SYSQ_5577	CM.CMSTDAT	Field Null		CM.CMSTDAT IS NULL	"A3. Start Date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620008	SYSQ_5578	CM.CMSTDAT	Future Date		CM.CMSTDAT > Today	"A3. Start Date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620010	SYSQ_5579	CM.CMDOSE	Field Null		CM.CMDOSE IS NULL	"A4. Total Daily Dose" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620013	SYSQ_5580	CM.CMDOSU	Field Null		CM.CMDOSU IS NULL	"A5. Dose Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0

System Queries														
sysq-620014	SYSQ_5581	CM.CMDOSUOT	Field Null		CM.CMDOSUOT IS NULL	"A5a. Specify other dose unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620016	SYSQ_5582	CM.CMONG	Field Null		CM.CMONG IS NULL	"A7. Ongoing?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620018	SYSQ_5583	CM.CMENDAT	Field Null		CM.CMENDAT IS NULL	"A7a. Stop Date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0
sysq-620020	SYSQ_5584	CM.CMENDAT	Future Date		CM.CMENDAT > Today	"A7a. Stop Date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:47	0	0	0	0	0	0

pCVDFHX

Page

(Visit ID = 618776, Page ID =)

Unique Identifier page-618776-618776-618776-

SECTION A: Family History of CVD

Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).

Please provide the details of the subject's relative with premature CVD below:

SDV	* A1. Relationship to Participant	○ Mother ○ Father ○ Sister ○ Brother ○ Maternal Aunt ○ Paternal Aunt ○ Maternal Uncle ○ Paternal Uncle ○ Maternal Grandmother ○ Paternal Grandmother ○ Maternal Grandfather ○ Paternal Grandfather ○ Other	CVDFHX.RELATION
SDV	* A1a. Specify other:		CVDFHX.RELATION_O
SDV	* A2. Approximate age at which this relative experienced their first occurrence of CVD		CVDFHX.AGE_CVD (format xxx)
SDV	* A3. Is this Relative alive today?	○ Yes ○ No ○ Unknown	CVDFHX.ALIVE
SDV	* A3a. Cause of Death	○ Cardiac ○ Non-Cardiac	CVDFHX.DEATH_CAUSE
SDV	* A3b. Age at Death		CVDFHX.DEATH_AGE (format xxx)

Does/Did the relative have a medical history of any of the following...

SDV	* A4. Myocardial Infarction	○ Yes ○ No ○ Unknown	CVDFHX.MI
SDV	* A5. Angina	○ Yes ○ No ○ Unknown	CVDFHX.ANGINA
SDV	* A6. Stroke	○ Yes ○ No ○ Unknown	CVDFHX.STROKE
SDV	* A7. Diabetes Mellitus	○ Yes ○ No ○ Unknown	CVDFHX.DIABETES
SDV	* A7a.Type	○ Type 1 ○ Type 2 ○ Unknown	CVDFHX.DIABTYPE
SDV	* A8. Fatty Liver Disease	○ Yes ○ No ○ Unknown	CVDFHX.FLD
SDV	* A8a. Is the Fatty Liver Disease related to alcohol?	○ Yes ○ No ○ Unknown	CVDFHX.FLDALC
SDV	* A9. CABG	○ Yes ○ No ○ Unknown	CVDFHX.CABG
SDV	* A10. Coronary Artery Angioplasty	○ Yes ○ No ○ Unknown	CVDFHX.ANGIO
SDV	* A11. Stent Placement	○ Yes ○ No ○ Unknown	CVDFHX.STENT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618776	Section Header	0	SECTION A: Family History of CVD											

Page Information														
Page-2-618776	Help Text Line	0	Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).											
Page-3-618776	Help Text Line	0	Please provide the details of the subject's relative with premature CVD below:											
Page-4-618776	Radiolist	0	A1. Relationship to Participant	CVDFHX.RELATION	Yes				cRelation					
Page-5-618776	Text Field	1	A1a. Specify other:	CVDFHX.RELATION_O	Yes					50	75			
-- Page Dynamics (CVDFHX. RELATION_O): Show When: CVDFHX.RELATION = 99														
Page-6-618776	Numeric	0	A2. Approximate age at which this relative experienced their first occurrence of CVD	CVDFHX.AGE_CVD	Yes							3	0	
Page-7-618776	Radiolist	0	A3. Is this Relative alive today?	CVDFHX. ALIVE	Yes				cYNUNK					
Page-8-618776	Radiolist	1	A3a. Cause of Death	CVDFHX.DEATH_CAUSE	Yes				cDCAUSE					
-- Page Dynamics (CVDFHX. DEATH_CAUSE): Show When: CVDFHX.ALIVE = 0														
Page-9-618776	Numeric	1	A3b. Age at Death	CVDFHX.DEATH_AGE	Yes							3	0	
-- Page Dynamics (CVDFHX. DEATH_AGE): Show When: CVDFHX.ALIVE = 0														
Page-10-618776	Help Text Line	0	Does/Did the relative have a medical history of any of the following...											
Page-11-618776	Radiolist Horizontal	0	A4. Myocardial Infarction	CVDFHX. MI	Yes				cYNUNK					
Page-12-618776	Radiolist Horizontal	0	A5. Angina	CVDFHX.ANGINA	Yes				cYNUNK					

Page Information														
Page-13-618776	Radiolist Horizontal	0	A6. Stroke	CVDFHX.STROKE	Yes				cYNUNK					
Page-14-618776	Radiolist Horizontal	0	A7. Diabetes Mellitus	CVDFHX.DIABETES	Yes				cYNUNK					
Page-15-618776	Radiolist Horizontal	1	A7a.Type	CVDFHX.DIABTYPE	Yes				cDIABTYPE					
-- Page Dynamics (CVDFHX. DIABTYPE): Show When: CVDFHX.DIABETES = 1														
Page-16-618776	Radiolist Horizontal	0	A8. Fatty Liver Disease	CVDFHX. FLD	Yes				cYNUNK					
Page-17-618776	Radiolist Horizontal	1	A8a. Is the Fatty Liver Disease related to alcohol?	CVDFHX.FLDALC	Yes				cYNUNK					
-- Page Dynamics (CVDFHX. FLDALC): Show When: CVDFHX.FLD = 1														
Page-18-618776	Radiolist Horizontal	0	A9. CABG	CVDFHX. CABG	Yes				cYNUNK					
Page-19-618776	Radiolist Horizontal	0	A10. Coronary Artery Angioplasty	CVDFHX. ANGIO	Yes				cYNUNK					
Page-20-618776	Radiolist Horizontal	0	A11. Stent Placement	CVDFHX. STENT	Yes				cYNUNK					

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619023	SYSQ_4983	CVDFHX.DEATH_AGE	Other / Cross Page		CVDFHX.DEATH_AGE < CVDFHX.AGE_CVD	Age at Death is prior to Age of first occurrence of CVD. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619608	SYSQ_5333	CVDFHX.RELATION	Field Null		CVDFHX.RELATION IS NULL	"A1. Relationship to Participant" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619609	SYSQ_5334	CVDFHX.RELATION_O	Field Null		CVDFHX.RELATION_O IS NULL	"A1a. Specify other:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0

System Queries														
sysq-619610	SYSQ_5335	CVDFHX.AGE_CVD	Field Null		CVDFHX.AGE_CVD IS NULL	"A2. Approximate age at which this relative experienced their first occurrence of CVD" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619611	SYSQ_5336	CVDFHX.ALIVE	Field Null		CVDFHX.ALIVE IS NULL	"A3. Is this Relative alive today?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619612	SYSQ_5337	CVDFHX.DEATH_CAUSE	Field Null		CVDFHX.DEATH_CAUSE IS NULL	"A3a. Cause of Death" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619613	SYSQ_5338	CVDFHX.DEATH_AGE	Field Null		CVDFHX.DEATH_AGE IS NULL	"A3b. Age at Death" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619614	SYSQ_5339	CVDFHX.MI	Field Null		CVDFHX.MI IS NULL	"A4. Myocardial Infarction" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619615	SYSQ_5340	CVDFHX.ANGINA	Field Null		CVDFHX.ANGINA IS NULL	"A5. Angina" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619616	SYSQ_5341	CVDFHX.STROKE	Field Null		CVDFHX.STROKE IS NULL	"A6. Stroke" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619617	SYSQ_5342	CVDFHX.DIABETES	Field Null		CVDFHX.DIABETES IS NULL	"A7. Diabetes Mellitus" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619618	SYSQ_5343	CVDFHX.DIABTYPE	Field Null		CVDFHX.DIABTYPE IS NULL	"A7a.Type" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619619	SYSQ_5344	CVDFHX.FLD	Field Null		CVDFHX.FLD IS NULL	"A8. Fatty Liver Disease" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0

System Queries														
sysq-619620	SYSQ_5345	CVDFHX.FLDALC	Field Null		CVDFHX.FLDALC IS NULL	"A8a. Is the Fatty Liver Disease related to alcohol?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619621	SYSQ_5346	CVDFHX.CABG	Field Null		CVDFHX.CABG IS NULL	"A9. CABG" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619622	SYSQ_5347	CVDFHX.ANGIO	Field Null		CVDFHX.ANGIO IS NULL	"A10. Coronary Artery Angioplasty" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619623	SYSQ_5348	CVDFHX.STENT	Field Null		CVDFHX.STENT IS NULL	"A11. Stent Placement" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0

pDISPENSE

Page

(Visit ID = 618777, Page ID =)

Unique Identifier page-618777-618777-618777-

Section A: DRUG DISPENSE ORDER				
SDV	A1. Date drug was dispensed		DISPENSE. DISPDAT	
SDV	A2. Time drug was dispensed	:	DISPENSE. DISPTIM	(HH24:MI)
SDV	* A3. Number of bottles to dispense:		DISPENSE. DISPNUM	(format x)
	A4. Bottle IDs Dispensed			
SDV	A4a. Bottle ID dispensed		DISPENSE. BOTTLE1ID	
SDV	A4b. Bottle ID dispensed		DISPENSE. BOTTLE2ID	

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618777	Section Header	0	Section A: DRUG DISPENSE ORDER											
Page-2-618777	Date	0	A1. Date drug was dispensed	DISPENSE. DISPDAT	Yes									
Page-3-618777	Time	0	A2. Time drug was dispensed	DISPENSE. DISPTIM	Yes									

Page Information														
Page-4-618777	Numeric	0	A3. Number of bottles to dispense:	DISPENSE.DISPNUM	Yes							1	0	Please enter the number of bottles to dispense. You may dispense up to 2 bottles. 1 bottle is expected to be dispensed at the following visits: Visit 0 (Baseline upon randomization) 1 Month 3 Month 6 Month 9 Month 2 bottles are expected to be dispensed at the following visits: 12 Months 18 Months
Page-5-618777	Help Text Line	1	A4. Bottle IDs Dispensed											
Page-6-618777	Text Field	2	A4a. Bottle ID dispensed	DISPENSE.BOTTLE1ID	Yes					10	10			
Page-7-618777	Text Field	2	A4b. Bottle ID dispensed	DISPENSE.BOTTLE2ID	Yes					10	10			Leave blank if only 1 bottle was dispensed.

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-620076	SYSQ_5639	DISPENSE.DISPNUM	Field Null		DISPENSE.DISPNUM IS NULL	"A3. Number of bottles to dispense:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0

pDM

Page

(Visit ID = 618778, Page ID =)

Unique Identifier page-618778-618778-618778-

Section A: DEMOGRAPHICS				
SDV	* A1. Date of Birth		DM.BRTHDAT	
SDV	* A2. Sex	○ Male ○ Female	DM.SEX	
SDV	* A3. Ethnicity	○ Hispanic or Latino/Latina ○ Not Hispanic or Latino/Latina ○ Unknown	DM.ETHNIC	
	A4. Race Select all that apply. If race is unknown, select "Yes" for unknown and other race questions will be skipped.			
SDV	* A4a. Unknown	○ Yes ○ No	DM.UNK	
SDV	* A4b. American Indian or Alaska Native	○ Yes ○ No	DM.AI	
SDV	* A4c. Asian	○ Yes ○ No	DM.ASIAN	
SDV	* A4d. Black or African American	○ Yes ○ No	DM.BLACK	
SDV	* A4e. Native Hawaiian or Other Pacific Islander	○ Yes ○ No	DM.NHPI	
SDV	* A4f. White	○ Yes ○ No	DM.WHITE	
DM Only				
	Age at the time Informed Consent was signed	(auto calculated)	DM.AGE	(format xxx)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text

Page Information														
Page-1-618778	Section Header	0	Section A: DEMOGRAPHICS											
Page-2-618778	Date	0	A1. Date of Birth	DM.BRTHDAT	Yes									For Canada, or if exact day is unknown for any reason, please record '01' for birth day, followed by 3 letter month, and 4 digit year.
Page-3-618778	Radiolist Horizontal	0	A2. Sex	DM. SEX	Yes				cSEX					
Page-4-618778	Radiolist	0	A3. Ethnicity	DM. ETHNIC	Yes				cETHNICITY					
Page-5-618778	Help Text Line	0	A4. Race											
Page-6-618778	Help Text Line	0	Select all that apply. If race is unknown, select "Yes" for unknown and other race questions will be skipped.											
Page-7-618778	Radiolist Horizontal	1	A4a. Unknown	DM. UNK	Yes				cYN					
Page-8-618778	Radiolist Horizontal	1	A4b. American Indian or Alaska Native	DM. AI	Yes				cYN					
-- Page Dynamics (DM. AI): Enable When: DM.UNK <> 1														
Page-9-618778	Radiolist Horizontal	1	A4c. Asian	DM. ASIAN	Yes				cYN					
-- Page Dynamics (DM. ASIAN): Enable When: DM.UNK <> 1														
Page-10-618778	Radiolist Horizontal	1	A4d. Black or African American	DM. BLACK	Yes				cYN					
-- Page Dynamics (DM. BLACK): Enable When: DM.UNK <> 1														
Page-11-618778	Radiolist Horizontal	1	A4e. Native Hawaiian or Other Pacific Islander	DM. NHPI	Yes				cYN					
-- Page Dynamics (DM. NHPI): Enable When: DM.UNK <> 1														
Page-12-618778	Radiolist Horizontal	1	A4f. White	DM. WHITE	Yes				cYN					

Page Information														
-- Page Dynamics (DM. WHITE): Enable When: DM.UNK <> 1														
Page-13-618778	Section Header	0	DM Only											
-- Role Permissions (.): Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide														
Page-14-618778	Auto Calc Field	0	Age at the time Informed Consent was signed	DM.AGE								3	0	
-- Auto Calc Rule (DM.AGE): (DM.BRTHDAT IS NOT NULL)>>>USE: DIFF_DATES[DM.BRTHDAT, RemoteLookup[10.20-ICF.ICF_DT], YEARS]														
-- Role Permissions (DM. AGE): Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide														

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618905	SYSQ_4913	DM.BRTHDAT	Field Null		DM.BRTHDAT IS NULL	"A1. Date of Birth" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618908	SYSQ_4914	DM.BRTHDAT	Future Date		DM.BRTHDAT > Today	"A1. Date of Birth" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618910	SYSQ_4915	DM.SEX	Field Null		DM.SEX IS NULL	"A2. Sex" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618911	SYSQ_4916	DM.ETHNIC	Field Null		DM.ETHNIC IS NULL	"A3. Ethnicity" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618913	SYSQ_4917	DM.UNK	Field Null		DM.UNK IS NULL	"A4a. Unknown" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618916	SYSQ_4918	DM.AI	Field Null		DM.AI IS NULL	"A4b. American Indian or Alaska Native" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0

System Queries														
sysq-618917	SYSQ_4919	DM.ASIAN	Field Null		DM.ASIAN IS NULL	"A4c. Asian" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618920	SYSQ_4920	DM.BLACK	Field Null		DM.BLACK IS NULL	"A4d. Black or African American" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618921	SYSQ_4921	DM.NHPI	Field Null		DM.NHPI IS NULL	"A4e. Native Hawaiian or Other Pacific Islander" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618924	SYSQ_4922	DM.WHITE	Field Null		DM.WHITE IS NULL	"A4f. White" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618925	SYSQ_4923	DM.BRTHDAT	Other / Cross Page		((IsNotNull(Field[DM.BRTHDAT])) And (IsNotNull(RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT]))) And (((DateTimeDifference[Year](Field[DM.BRTHDAT], RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT])) < 10) Or ((DateTimeDifference[Year](Field[DM.BRTHDAT], RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT])) > 17))	The subject was not within the protocol age limits at the time the Informed Consent was signed. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0

pDM_4

Page

(Visit ID = 618779, Page ID =)

Unique Identifier page-618779-618779-618779-

Section A: DEMOGRAPHICS			
SDV	* A1. Date of Birth		DM.BRTHDAT
SDV	* A2. Sex	○ Male ○ Female	DM.SEX
SDV	* A3. Ethnicity	○ Hispanic or Latino/Latina ○ Not Hispanic or Latino/Latina ○ Unknown	DM.ETHNIC
	A4. Race Select all that apply. If race is unknown, select "Yes" for unknown and other race questions will be skipped.		
SDV	* A4a. Unknown	○ Yes ○ No	DM.UNK
SDV	* A4b. American Indian or Alaska Native	○ Yes ○ No	DM.AI
SDV	* A4c. Asian	○ Yes ○ No	DM.ASIAN
SDV	* A4d. Black or African American	○ Yes ○ No	DM.BLACK
SDV	* A4e. Native Hawaiian or Other Pacific Islander	○ Yes ○ No	DM.NHPI
SDV	* A4f. White	○ Yes ○ No	DM.WHITE
DM Only			
	Age at the time Informed Consent was signed	(auto calculated)	DM.AGE (format xxx)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text

Page Information														
Page-1-618779	Section Header	0	Section A: DEMOGRAPHICS											
Page-2-618779	Date	0	A1. Date of Birth	DM. BRTHDAT	Yes									For Canada, or if exact day is unknown for any reason, please record '01' for birth day, followed by 3 letter month, and 4 digit year.
Page-3-618779	Radiolist Horizontal	0	A2. Sex	DM. SEX	Yes				cSEX					
Page-4-618779	Radiolist	0	A3. Ethnicity	DM. ETHNIC	Yes				cETHNICITY					
Page-5-618779	Help Text Line	0	A4. Race											
Page-6-618779	Help Text Line	0	Select all that apply. If race is unknown, select "Yes" for unknown and other race questions will be skipped.											
Page-7-618779	Radiolist Horizontal	1	A4a. Unknown	DM. UNK	Yes				cYN					
Page-8-618779	Radiolist Horizontal	1	A4b. American Indian or Alaska Native	DM. AI	Yes				cYN					
-- Page Dynamics (DM. AI): Enable When: DM.UNK <> 1														
Page-9-618779	Radiolist Horizontal	1	A4c. Asian	DM. ASIAN	Yes				cYN					
-- Page Dynamics (DM. ASIAN): Enable When: DM.UNK <> 1														
Page-10-618779	Radiolist Horizontal	1	A4d. Black or African American	DM. BLACK	Yes				cYN					
-- Page Dynamics (DM. BLACK): Enable When: DM.UNK <> 1														
Page-11-618779	Radiolist Horizontal	1	A4e. Native Hawaiian or Other Pacific Islander	DM. NHPI	Yes				cYN					
-- Page Dynamics (DM. NHPI): Enable When: DM.UNK <> 1														
Page-12-618779	Radiolist Horizontal	1	A4f. White	DM. WHITE	Yes				cYN					

Page Information														
-- Page Dynamics (DM. WHITE): Enable When: DM.UNK <> 1														
Page-13-618779	Section Header	0	DM Only											
-- Role Permissions (.): Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide														
Page-14-618779	Auto Calc Field	0	Age at the time Informed Consent was signed	DM.AGE								3	0	
-- Auto Calc Rule (DM.AGE): (DM.BRTHDAT IS NOT NULL)>>>USE: DIFF_DATES[DM.BRTHDAT, RemoteLookup[10.20-ICF.ICF_DT], YEARS]														
-- Role Permissions (DM. AGE): Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide														

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618906	SYSQ_4913	DM.BRTHDAT	Field Null		DM.BRTHDAT IS NULL	"A1. Date of Birth" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618907	SYSQ_4914	DM.BRTHDAT	Future Date		DM.BRTHDAT > Today	"A1. Date of Birth" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618909	SYSQ_4915	DM.SEX	Field Null		DM.SEX IS NULL	"A2. Sex" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618912	SYSQ_4916	DM.ETHNIC	Field Null		DM.ETHNIC IS NULL	"A3. Ethnicity" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618914	SYSQ_4917	DM.UNK	Field Null		DM.UNK IS NULL	"A4a. Unknown" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618915	SYSQ_4918	DM.AI	Field Null		DM.AI IS NULL	"A4b. American Indian or Alaska Native" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0

System Queries														
sysq-618918	SYSQ_4919	DM.ASIAN	Field Null		DM.ASIAN IS NULL	"A4c. Asian" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618919	SYSQ_4920	DM.BLACK	Field Null		DM.BLACK IS NULL	"A4d. Black or African American" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618922	SYSQ_4921	DM.NHPI	Field Null		DM.NHPI IS NULL	"A4e. Native Hawaiian or Other Pacific Islander" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618923	SYSQ_4922	DM.WHITE	Field Null		DM.WHITE IS NULL	"A4f. White" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618926	SYSQ_4923	DM.BRTHDAT	Other / Cross Page		((IsNotNull(Field[DM.BRTHDAT])) And (IsNotNull(RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT]))) And (((DateTimeDifference[Year](Field[DM.BRTHDAT], RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT])) < 10) Or ((DateTimeDifference[Year](Field[DM.BRTHDAT], RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT])) > 17))	The subject was not within the protocol age limits at the time the Informed Consent was signed. Please review and confirm.		Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0

System Queries														
sysq-620484	SYSQ_5885	DM.BRTHDAT	Other / Cross Page	Updated for protocol v.5	((RemotePageField[visitID: 10; pageID: 20; ICF.ICFPROTV] < 5) And (((DateTimeDifference[Year](Field[DM.BRTHDAT], RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT])) < 10) Or ((DateTimeDifference[Year](Field[DM.BRTHDAT], RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT])) > 17))) Or ((RemotePageField[visitID: 10; pageID: 20; ICF.ICFPROTV] = 5) And (((DateTimeDifference[Year](Field[DM.BRTHDAT], RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT])) < 10) Or ((DateTimeDifference[Year](Field[DM.BRTHDAT], RemotePageField[visitID: 10; pageID: 20; ICF.ICF_DT])) > 18)))	The subject was not within the protocol age limits at the time the Informed Consent was signed. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

pDV

Page

(Visit ID = 618780, Page ID =)

Unique Identifier page-618780-618780-618780-

SECTION A: PROTOCOL DEVIATIONS			
	This form is only applicable for randomized subjects. Complete 1 form per study visit and selected category of deviation type.		
SDV	* A1. Date deviation occurred		DV.DVDAT
SDV	* A2. Study visit associated with deviation		DV.DVVISIT
SDV	* A3. Please indicate the category of deviation	○ Informed Consent ○ Inclusion criteria violation ○ Exclusion criteria violation ○ Randomization violation ○ Lab value violation ○ Clinical Assessment violation ○ Study medication compliance ○ Follow-up compliance ○ AE/SAE not reported within the protocol required reporting window ○ Other	DV.DVCAT
SDV	* A4. Provide a description of the specific deviation		DV.DVDESC
SDV	* A5. Was this deviation reported to the IRB?	○ Yes ○ No	DV.DVIRB

Page Information														
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618780	Section Header	0	SECTION A: PROTOCOL DEVIATIONS											
Page-2-618780	Help Text Line	0	This form is only applicable for <u>randomized subjects</u>. Complete 1 form per study visit and selected category of deviation type.											
Page-3-618780	Date	0	A1. Date deviation occurred	DV.DVDAT	Yes									Enter the date of the visit or assessment associated with the deviation
Page-4-618780	Dropdown	0	A2. Study visit associated with deviation	DV.DVVISIT	Yes				cVISITS					Select the study visit during which the deviation took place.
Page-5-618780	Radiolist	0	A3. Please indicate the category of deviation	DV.DVCAT	Yes				cDVCAT					Select the type of protocol deviation to be reported.
Page-6-618780	Comments	0	A4. Provide a description of the specific deviation	DV.DVDESC	Yes									Enter a description of the deviation and any corrective action taken
Page-7-618780	Radiolist Horizontal	0	A5. Was this deviation reported to the IRB?	DV.DVIRB	Yes				cYN					Indicate if the deviation was reported to your IRB

System Queries													
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph

System Queries														
sysq-619034	SYSQ_4990	DV.DVDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(10-20-ICF.ICF_DT, DV.DVDAT) < 0 OR FUNCTION-DATE_COMPARE(DV.DVDAT, 120-20-EOS.DATE) < 0	Date deviation occurred is prior to study entry (Inform Consent Date) or after date of study exit. Please clarify or update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-620077	SYSQ_5641	DV.DVDAT	Field Null		DV.DVDAT IS NULL	"A1. Date deviation occurred" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620078	SYSQ_5642	DV.DVDAT	Future Date		DV.DVDAT > Today	"A1. Date deviation occurred" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620079	SYSQ_5643	DV.DVVISIT	Field Null		DV.DVVISIT IS NULL	"A2. Study visit associated with deviation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620080	SYSQ_5644	DV.DVCAT	Field Null		DV.DVCAT IS NULL	"A3. Please indicate the category of deviation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620081	SYSQ_5645	DV.DVDESC	Field Null		DV.DVDESC IS NULL	"A4. Provide a description of the specific deviation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620082	SYSQ_5646	DV.DVIRB	Field Null		DV.DVIRB IS NULL	"A5. Was this deviation reported to the IRB?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0

pEOS

Page

(Visit ID = 618781, Page ID =)

Unique Identifier page-618781-618781-618781-

SDV	* A1. Date study status changed or Date of Death:		EOS.DATE	
SDV	* A2. Primary reason for status change:	○ Not Randomized ○ Study Completed ○ Lost to Follow-Up ○ Death ○ Other adverse event ○ Physician decision to withdraw subject ○ Subject/guardian decision to withdraw ○ Study Closed ○ Site Closed ○ Other	EOS.REASON	
SDV	* A2a. If Other adverse event, specify the AE ID Number:		EOS.AESPID	(format xxx)
SDV	* A2b. If Other, specify:		EOS.SPECIFY	
SDV	* A2c. If lost to follow-up please specify the date of last contact		EOS.LAST_CON_DT	
SDV	* A2d. Withdrawal disposition:	○ No further contact and no further data collection ○ Vital status contact only ○ Allow Medical Records Review	EOS.DISPO	
SDV	* A2e. Primary cause of death:		EOS.DTHCAUS	

SDV	* A2f. Last visit at which subject completed any study measures?	○ Screening ○ Baseline ○ 1 Month ○ 3 Month ○ 6 Month ○ 9 Month ○ 12 Month ○ 18 Month ○ 24 Month	EOS.LAST_VISIT
SDV	A3. Comments		EOS.COMMENT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618781	Date	0	A1. Date study status changed or Date of Death:	EOS.DATE	Yes									
Page-2-618781	Radiolist	0	A2. Primary reason for status change:	EOS.REASON	Yes				cstatus_RN					
Page-3-618781	Numeric	1	A2a. If Other adverse event, specify the AE ID Number:	EOS.AESPID	Yes							3	0	
-- Page Dynamics (EOS. AESPID): Show When: EOS.REASON = 10														
Page-4-618781	Text Field	1	A2b. If Other, specify:	EOS.SPECIFY	Yes					100	99			
-- Page Dynamics (EOS. SPECIFY): Show When: EOS.REASON = 99														
Page-5-618781	Date	1	A2c. If lost to follow-up please specify the date of last contact	EOS.LAST_CON_DT	Yes									
-- Page Dynamics (EOS. LAST_CON_DT): Show When: EOS.REASON = 3														
Page-6-618781	Radiolist	1	A2d. Withdrawal disposition:	EOS.DISPO	Yes				cWD_DISPO					
-- Page Dynamics (EOS. DISPO): Show When: EOS.REASON = 5 OR EOS.REASON = 6														

Page Information														
Page-7-618781	Text Field	1	A2e. Primary cause of death:	EOS.DTHCAUS	Yes					200	99			
-- Page Dynamics (EOS. DTHCAUS): Show When: EOS.REASON = 4														
Page-8-618781	Radiolist	1	A2f. Last visit at which subject completed any study measures?	EOS.LAST_VISIT	Yes				cVISITS					
-- Page Dynamics (EOS. LAST_VISIT): Show When: EOS.REASON <> 2 AND EOS.REASON IS NOT NULL														
Page-9-618781	Comments	0	A3. Comments	EOS.COMMENT	Yes									

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618881	SYSQ_4527	EOS.DATE	Field Null		EOS.DATE IS NULL	"B1. Date study status changed or Date of Death:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618882	SYSQ_4528	EOS.DATE	Future Date		EOS.DATE > Today	"B1. Date study status changed or Date of Death:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618883	SYSQ_4529	EOS.REASON	Field Null		EOS.REASON IS NULL	"B2. Primary reason for status change:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618884	SYSQ_4530	EOS.SPECIFY	Field Null		EOS.SPECIFY IS NULL	"B2a. If Other, specify:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618885	SYSQ_4531	EOS.LAST_CON_DT	Field Null		EOS.LAST_CON_DT IS NULL	"B2b. If lost to follow-up please specify the date of last contact" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618886	SYSQ_4532	EOS.LAST_CON_DT	Future Date		EOS.LAST_CON_DT > Today	"B2b. If lost to follow-up please specify the date of last contact" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0

System Queries														
sysq-618887	SYSQ_4533	EOS.DISPO	Field Null		EOS.DISPO IS NULL	"B2c. Withdrawal disposition:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618888	SYSQ_4534	EOS.LAST_VISIT	Field Null		EOS.LAST_VISIT IS NULL	"B3. Last visit at which subject completed any study measures?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-619035	SYSQ_4991	EOS.REASON	Other / Cross Page		EOS.REASON <> 1 AND (10-20-ICF.ICF_YN = 0 OR 10-30-INEX.ENROLL_YN IS NULL OR 20-140-RAND.RANDYN = 0)	Informed Consent, Inclusion/Exclusion and/or Randomization Confirmation form(s) report subject was ineligible/not randomized in the trial, however, the Primary reason for status change is not = Not Randomized. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619036	SYSQ_4992	EOS.REASON	Other / Cross Page		EOS.REASON = 1 AND 20-140-RAND.RANDYN = 1	Randomization Confirmation form reports that subject was randomized, however, the primary reason for status change is = Not Randomized. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619037	SYSQ_4993	EOS.DATE	Other / Cross Page		EOS.DATE IS NOT NULL AND 10-20-ICF.ICF_DT IS NOT NULL AND 10-20-ICF.ICF_DT > EOS.DATE	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619038	SYSQ_4994	EOS.LAST_CON_DT	Other / Cross Page		EOS.LAST_CON_DT IS NOT NULL AND 10-20-ICF.ICF_DT IS NOT NULL AND 10-20-ICF.ICF_DT > EOS.LAST_CON_DT	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-620083	SYSQ_5647	EOS.AESPID	Field Null		EOS.AESPID IS NULL	"A2a. If Other adverse event, specify the AE ID Number:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0

System Queries														
sysq-620084	SYSQ_5648	EOS.LAST_CON_DT	Field Compare		EOS.LAST_CON_DT < EOS.DATE	The date of last contact is prior to A1. Date study status changed or Date of Death. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620085	SYSQ_5649	EOS.DTHCAUS	Field Null		EOS.DTHCAUS IS NULL	"A2e. Primary cause of death:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0

pEXAM

Page

(Visit ID = 618782, Page ID =)

Unique Identifier page-618782-618782-618782-

Section A: ANTHROPOMORPHIC MEASUREMENTS				
SDV	* A1. Were anthropomorphic measurements collected?	○ Yes ○ No	EXAM.ANTHROP	
SDV	* A1a. Date measurements performed		EXAM.ANTHRDAT	
SDV	* A1b. Does the subject have acanthosis nigricans in the neck and/or axilla? Baseline Visit Only	○ Yes ○ No	EXAM.ANIGRYN	
SDV	* A1c. Relevant Height 1 (cm)		EXAM.HEIGHT1	(format xxx.xx)
SDV	* A1d. Relevant Height 2 (cm)		EXAM.HEIGHT2	(format xxx.xx)
	A1e. Height Average (calculated)	(auto calculated)	EXAM.HEIGHT_AV	(format xxx.xx)
SDV	* A1f. Height Percentile		EXAM.HEIGHTPCT	(format xxx.xx)
SDV	* A1g. Relevant Weight 1 (kg)		EXAM.WEIGHT1	(format xxx.xx)
SDV	* A1h. Relevant Weight 2 (kg)		EXAM.WEIGHT2	(format xxx.xx)
	A1i. Weight Average (calculated)	(auto calculated)	EXAM.WEIGHT_AV	(format xxx.xx)
	A1j. Body Mass Index (BMI) (calculated)	(auto calculated)	EXAM.BMI	(format xx.x)
SDV	* A1k. BMI Percentile		EXAM.BMIPCT	(format xxx.xx)
SDV	* A1l. Relevant Waist Circumference 1 (cm)		EXAM.WCIRCUM1	(format xxx.xx)
SDV	* A1m. Relevant Waist Circumference 2 (cm)		EXAM.WCIRCUM2	(format xxx.xx)
	A1n. Waist Circumference Average (calculated)	(auto calculated)	EXAM.WCIRCUM_AV	(format xxx.xx)
	A1o. Waist to Height Ratio (calculated)	(auto calculated)	EXAM.WH_RATIO	(format xxx.xx)
SECTION B: BLOOD PRESSURE MEASUREMENTS				
SDV	* B1. Were blood pressure measurements collected at this visit?	○ Yes ○ No	EXAM.VITALSYN	

SDV	* B1a. Date measurements performed		EXAM.VITALDAT	
SDV	* B1b. Final method used for measurements	○ oscillometric ○ ausculatory	EXAM.METHOD	
SDV	* B1c. Was the arm circumference re-measured at this visit?	○ Yes ○ No	EXAM.ARMCIRCM	
SDV	* B1c1. Arm circumference (cm) Screening Visit Only AND if the subject has a >5 cm change in waist circumference		EXAM.ARMCIRC	(format xxx.xx)
	The same arm cuff should be used for all study visits, unless there is a change in arm circumference that would necessitate a change in cuff size.			
SDV	* B1d. Blood pressure cuff width (cm)		EXAM.BP_CUFF_WIDTH	(format xxx.xx)
SDV	* B1e. Length of the bladder (cm)		EXAM.BP_CUFF_LENGTH	(format xxx.xx)
SDV	* B1f. Systolic Blood Pressure 1		EXAM.SYS_BP1	(format xxx)
SDV	* B1g. Diastolic Blood Pressure 1		EXAM.DYA_BP1	(format xxx)
SDV	* B1h. Systolic Blood Pressure 2		EXAM.SYS_BP2	(format xxx)
SDV	* B1i. Diastolic Blood Pressure 2		EXAM.DYA_BP2	(format xxx)
SDV	* B1j. Systolic Blood Pressure 3		EXAM.SYS_BP3	(format xxx)
SDV	* B1k. Diastolic Blood Pressure 3		EXAM.DYA_BP3	(format xxx)
	B1l. Systolic Blood Pressure Average	(auto calculated)	EXAM.SYSBPAVG	(format xxx.xx)
	B1m. Diastolic Blood Pressure Average	(auto calculated)	EXAM.DYABPAVG	(format xxx.xx)
SDV	* B1n. Age range of participant at the time of blood pressure measurements	○ Aged < 13 years ○ Aged ≥ 13 years	EXAM.BPAGE	

SDV	* B1n1. Systolic BP Category/Stage (for Children Aged < 13 y)	○ Normal SBP: <90th percentile ○ Elevated SBP:≥90th to <95th percentile, or 120mmHg to <95th percentile (whichever is lower) ○ Stage1 systolic HTN:≥95th to 95th percentile +12mmHg, or systolic 130 to 139mmHg(whichever is lower) ○ Stage2 systolic HTN:≥95th percentile + 12mmHg, or ≥140mmHg (whichever is lower)	EXAM.SBPAG1CAT
SDV	* B1n2. Systolic BP Category/Stage (for Children Aged ≥ 13 y)	○ Normal SBP: <120 mmHg ○ Elevated SBP: 120 to 129 mmHg ○ Stage1 systolic HTN: 130 to 139 mmHg ○ Stage2 systolic HTN: ≥140 mmHg	EXAM.SBPAG2CAT

SDV	* B1n3. Diastolic BP Category/Stage (for Children Aged < 13 y)	○ Normal DBP: <90th percentile ○ Elevated DBP:≥90th to <95th percentile, or systolic 80mmHg to <95th percentile (whichever is lower) ○ Stage1 diastolic HTN:≥95th to 95th percentile + 12mmHg,or diastolic 80 to 89mmHg(whichever is lower) ○ Stage2 diastolic HTN:≥95th percentile + 12mmHg, or ≥90mmHg(whichever is lower)	EXAM.DBPAG1CAT
SDV	* B1n4. Diastolic BP Category/Stage (for Children Aged ≥ 13 y)	○ Normal DBP: <80 mmHg ○ Stage1 diastolic HTN: 80 to 89 mmHg ○ Stage2 diastolic HTN: ≥90 mmHg	EXAM.DBPAG2CAT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618782	Section Header	0	Section A: ANTHROPOMORPHIC MEASUREMENTS											
Page-2-618782	Radiolist Horizontal	0	A1. Were anthropomorphic measurements collected?	EXAM.ANTHROP	Yes				cYN					
Page-3-618782	Date	1	A1a. Date measurements performed	EXAM.ANTHRDAT	Yes									
-- Page Dynamics (EXAM. ANTHRDAT): Show When: EXAM.ANTHROP = 1														

Page Information														
Page-4-618782	Radiolist Horizontal	1	A1b. Does the subject have acanthosis nigricans in the neck and/or axilla? Baseline Visit Only	EXAM.ANIGRYN	Yes				cYN					
-- Page Dynamics (EXAM. ANIGRYN): Show When: EXAM.ANTHROP = 1 AND VISITID = 20														
Page-5-618782	Numeric	1	A1c. Relevant Height 1 (cm)	EXAM.HEIGHT1	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.5 cm difference between them).
-- Page Dynamics (EXAM. HEIGHT1): Show When: EXAM.ANTHROP = 1														
Page-6-618782	Numeric	1	A1d. Relevant Height 2 (cm)	EXAM.HEIGHT2	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.5 cm difference between them).
-- Page Dynamics (EXAM. HEIGHT2): Show When: EXAM.ANTHROP = 1														
Page-7-618782	Auto Calc Field	1	A1e. Height Average (calculated)	EXAM.HEIGHT_AV								3	2	
-- Auto Calc Rule (EXAM.HEIGHT_AV): (EXAM.HEIGHT1 IS NOT NULL AND EXAM.HEIGHT2 IS NOT NULL)>>>USE: (EXAM.HEIGHT1 + EXAM.HEIGHT2) / 2 (EXAM.HEIGHT1 IS NOT NULL AND EXAM.HEIGHT2 IS NULL)>>>USE: EXAM.HEIGHT1 / 1 (EXAM.HEIGHT1 IS NULL AND EXAM.HEIGHT2 IS NOT NULL)>>>USE: EXAM.HEIGHT2 / 1														
-- Page Dynamics (EXAM. HEIGHT_AV): Show When: EXAM.ANTHROP = 1														
Page-8-618782	Numeric	1	A1f. Height Percentile	EXAM.HEIGHTPCT	Yes							3	2	From average height, use CDC growth charts to obtain height percentile.
-- Page Dynamics (EXAM. HEIGHTPCT): Show When: EXAM.ANTHROP = 1														
Page-9-618782	Numeric	1	A1g. Relevant Weight 1 (kg)	EXAM.WEIGHT1	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.2 kg difference between them).
-- Page Dynamics (EXAM. WEIGHT1): Show When: EXAM.ANTHROP = 1														

Page Information														
Page-10-618782	Numeric	1	A1h. Relevant Weight 2 (kg)	EXAM.WEIGHT2	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.2 kg difference between them).
-- Page Dynamics (EXAM. WEIGHT2): Show When: EXAM.ANTHROP = 1														
Page-11-618782	Auto Calc Field	1	A1i. Weight Average (calculated)	EXAM.WEIGHT_AV								3	2	
-- Auto Calc Rule (EXAM.WEIGHT_AV): (EXAM.WEIGHT1 IS NOT NULL AND EXAM.WEIGHT2 IS NOT NULL)>>>USE: (EXAM.WEIGHT1 + EXAM.WEIGHT2)/2 (EXAM.WEIGHT1 IS NULL AND EXAM.WEIGHT2 IS NOT NULL)>>>USE: EXAM.WEIGHT2 / 1 (EXAM.WEIGHT1 IS NOT NULL AND EXAM.WEIGHT2 IS NULL)>>>USE: EXAM.WEIGHT1 / 1														
-- Page Dynamics (EXAM. WEIGHT_AV): Show When: EXAM.ANTHROP = 1														
Page-12-618782	Auto Calc Field	1	A1j. Body Mass Index (BMI) (calculated)	EXAM.BMI								2	1	
-- Auto Calc Rule (EXAM.BMI): (EXAM.HEIGHT_AV IS NOT NULL AND EXAM.WEIGHT_AV IS NOT NULL) ALWAYS>>>USE: EXAM.WEIGHT_AV / (pow ((EXAM.HEIGHT_AV / 100), 2))														
-- Page Dynamics (EXAM. BMI): Show When: EXAM.ANTHROP = 1														
Page-13-618782	Numeric	1	A1k. BMI Percentile	EXAM.BMIPCT	Yes							3	2	BMI Percentile is BMI converted to age- and sex-matched percentiles based on data from the Centers for Disease Control (CDC; http://www.cdc.gov/nchs/data/series/sr_11/sru_246.pdf).
-- Page Dynamics (EXAM. BMIPCT): Show When: EXAM.ANTHROP = 1														
Page-14-618782	Numeric	1	A1l. Relevant Waist Circumference 1 (cm)	EXAM.WCIRCUM1	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.5 cm difference between them).
-- Page Dynamics (EXAM. WCIRCUM1): Show When: EXAM.ANTHROP = 1														

Page Information														
Page-15-618782	Numeric	1	A1m. Relevant Waist Circumference 2 (cm)	EXAM.WCIRCUM2	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.5 cm difference between them).
-- Page Dynamics (EXAM. WCIRCUM2): Show When: EXAM.ANTHROP = 1														
Page-16-618782	Auto Calc Field	1	A1n. Waist Circumference Average (calculated)	EXAM.WCIRCUM_AV								3	2	
-- Auto Calc Rule (EXAM.WCIRCUM_AV): (EXAM.WCIRCUM1 IS NOT NULL AND EXAM.WCIRCUM2 IS NOT NULL)>>>USE: (EXAM.WCIRCUM1 + EXAM.WCIRCUM2) / 2 (EXAM.WCIRCUM1 IS NOT NULL AND EXAM.WCIRCUM2 IS NULL)>>>USE: EXAM.WCIRCUM1 / 1 (EXAM.WCIRCUM1 IS NULL AND EXAM.WCIRCUM2 IS NOT NULL)>>>USE: EXAM.WCIRCUM2 / 1														
-- Page Dynamics (EXAM. WCIRCUM_AV): Show When: EXAM.ANTHROP = 1														
Page-17-618782	Auto Calc Field	1	A1o. Waist to Height Ratio (calculated)	EXAM.WH_RATIO								3	2	
-- Auto Calc Rule (EXAM.WH_RATIO): (EXAM.HEIGHT_AV IS NOT NULL AND EXAM.WCIRCUM_AV IS NOT NULL) ALWAYS>>>USE: (EXAM.WCIRCUM_AV / EXAM.HEIGHT_AV) * 100														
-- Page Dynamics (EXAM. WH_RATIO): Show When: EXAM.ANTHROP = 1														
Page-18-618782	Section Header	0	SECTION B: BLOOD PRESSURE MEASUREMENTS											
Page-19-618782	Radiolist Horizontal	0	B1. Were blood pressure measurements collected at this visit?	EXAM.VITALSYN	Yes				cYN					
Page-20-618782	Date	1	B1a. Date measurements performed	EXAM.VITALDAT	Yes									
-- Page Dynamics (EXAM. VITALDAT): Show When: EXAM.VITALSYN = 1														
Page-21-618782	Radiolist Horizontal	1	B1b. Final method used for measurements	EXAM.METHOD	Yes				cBPMETHOD					
-- Page Dynamics (EXAM. METHOD): Show When: EXAM.VITALSYN = 1														
Page-22-618782	Radiolist Horizontal	1	B1c. Was the arm circumference re-measured at this visit?	EXAM.ARMCIRCM	Yes				cYN					If there is a >5 cm change in waist circumference at any visit during the trial, the arm circumference should be re-measured.
-- Page Dynamics (EXAM. ARMCIRCM): Show When: EXAM.VITALSYN = 1 AND VISITID > 10														

Page Information													
Page-23-618782	Numeric	2	B1c1. Arm circumference (cm) Screening Visit Only AND if the subject has a >5 cm change in waist circumference	EXAM.ARMCIRC	Yes							3	2	Measure arm circumference mid between shoulder and elbow prominences with forearm 90 degree. Only need to measure and record at screening, and if there is a >5 cm change in waist circumference at any visit during the trial.
-- Page Dynamics (EXAM. ARMCIRC): Show When: (EXAM.VITALSYN = 1 AND VISITID > 10 AND EXAM.ARMCIRCM = 1) OR (EXAM.VITALSYN = 1 AND VISITID <= 10 AND EXAM.ARMCIRCM IS NULL)													
Page-24-618782	Help Text Line	0	The same arm cuff should be used for all study visits, unless there is a change in arm circumference that would necessitate a change in cuff size.											
-- Page Dynamics (.): Show When: EXAM.VITALSYN = 1													
Page-25-618782	Numeric	1	B1d. Blood pressure cuff width (cm)	EXAM.BP_CUFF_WIDTH	Yes							3	2	please enter the width of the blood pressure cuff in cm
-- Page Dynamics (EXAM. BP_CUFF_WIDTH): Show When: EXAM.VITALSYN = 1													
Page-26-618782	Numeric	1	B1e. Length of the bladder (cm)	EXAM.BP_CUFF_LENGTH	Yes							3	2	Please enter the Bladder Length in cm. The bladder length recommended by the AHA is 80 percent of the patient's arm circumference, and the ideal width is at least 40 percent.
-- Page Dynamics (EXAM. BP_CUFF_LENGTH): Show When: EXAM.VITALSYN = 1													
Page-27-618782	Numeric	1	B1f. Systolic Blood Pressure 1	EXAM.SYS_BP1	Yes							3	0	Record 3 Blood Pressure measurements. Each measurement should be 2 minutes apart.
-- Page Dynamics (EXAM. SYS_BP1): Show When: EXAM.VITALSYN = 1													
Page-28-618782	Numeric	1	B1g. Diastolic Blood Pressure 1	EXAM.DYA_BP1	Yes							3	0	
-- Page Dynamics (EXAM. DYA_BP1): Show When: EXAM.VITALSYN = 1													

Page Information														
Page-29-618782	Numeric	1	B1h. Systolic Blood Pressure 2	EXAM.SYS_BP2	Yes							3	0	
-- Page Dynamics (EXAM. SYS_BP2): Show When: EXAM.VITALSYN = 1														
Page-30-618782	Numeric	1	B1i. Diastolic Blood Pressure 2	EXAM.DYA_BP2	Yes							3	0	
-- Page Dynamics (EXAM. DYA_BP2): Show When: EXAM.VITALSYN = 1														
Page-31-618782	Numeric	1	B1j. Systolic Blood Pressure 3	EXAM.SYS_BP3	Yes							3	0	
-- Page Dynamics (EXAM. SYS_BP3): Show When: EXAM.VITALSYN = 1														
Page-32-618782	Numeric	1	B1k. Diastolic Blood Pressure 3	EXAM.DYA_BP3	Yes							3	0	
-- Page Dynamics (EXAM. DYA_BP3): Show When: EXAM.VITALSYN = 1														
Page-33-618782	Auto Calc Field	1	B1l. Systolic Blood Pressure Average	EXAM.SYSBPAVG								3	2	
-- Auto Calc Rule (EXAM.SYSBPAVG): (EXAM.SYS_BP1 IS NOT NULL AND EXAM.SYS_BP2 IS NOT NULL AND EXAM.SYS_BP3 IS NOT NULL)>>>USE: (EXAM.SYS_BP1 + EXAM.SYS_BP2 + EXAM.SYS_BP3) / 3 (EXAM.SYS_BP1 IS NULL AND EXAM.SYS_BP2 IS NOT NULL AND EXAM.SYS_BP3 IS NOT NULL)>>>USE: (EXAM.SYS_BP2 + EXAM.SYS_BP3) / 2 (EXAM.SYS_BP1 IS NOT NULL AND EXAM.SYS_BP2 IS NULL AND EXAM.SYS_BP3 IS NOT NULL)>>>USE: (EXAM.SYS_BP1 + EXAM.SYS_BP3) / 2 (EXAM.SYS_BP1 IS NOT NULL AND EXAM.SYS_BP2 IS NOT NULL AND EXAM.SYS_BP3 IS NULL)>>>USE: (EXAM.SYS_BP1 + EXAM.SYS_BP2) / 2 (EXAM.SYS_BP1 IS NULL AND EXAM.SYS_BP2 IS NULL AND EXAM.SYS_BP3 IS NOT NULL)>>>USE: EXAM.SYS_BP3 / 1 (EXAM.SYS_BP1 IS NOT NULL AND EXAM.SYS_BP2 IS NULL AND EXAM.SYS_BP3 IS NULL)>>>USE: EXAM.SYS_BP1 / 1 (EXAM.SYS_BP1 IS NULL AND EXAM.SYS_BP2 IS NOT NULL AND EXAM.SYS_BP3 IS NULL)>>>USE: EXAM.SYS_BP2 / 1														
-- Page Dynamics (EXAM. SYSBPAVG): Show When: EXAM.VITALSYN = 1														
Page-34-618782	Auto Calc Field	1	B1m. Diastolic Blood Pressure Average	EXAM.DYABPAVG								3	2	
-- Auto Calc Rule (EXAM.DYABPAVG): (EXAM.DYA_BP1 IS NOT NULL AND EXAM.DYA_BP2 IS NOT NULL AND EXAM.DYA_BP3 IS NOT NULL)>>>USE: (EXAM.DYA_BP1 + EXAM.DYA_BP2 + EXAM.DYA_BP3) / 3 (EXAM.DYA_BP1 IS NULL AND EXAM.DYA_BP2 IS NOT NULL AND EXAM.DYA_BP3 IS NOT NULL)>>>USE: (EXAM.DYA_BP2 + EXAM.DYA_BP3) / 2 (EXAM.DYA_BP1 IS NOT NULL AND EXAM.DYA_BP2 IS NULL AND EXAM.DYA_BP3 IS NOT NULL)>>>USE: (EXAM.DYA_BP1 + EXAM.DYA_BP3) / 2 (EXAM.DYA_BP1 IS NOT NULL AND EXAM.DYA_BP2 IS NOT NULL AND EXAM.DYA_BP3 IS NULL)>>>USE: (EXAM.DYA_BP1 + EXAM.DYA_BP2) / 2 (EXAM.DYA_BP1 IS NULL AND EXAM.DYA_BP2 IS NULL AND EXAM.DYA_BP3 IS NOT NULL)>>>USE: EXAM.DYA_BP3 / 1 (EXAM.DYA_BP1 IS NOT NULL AND EXAM.DYA_BP2 IS NULL AND EXAM.DYA_BP3 IS NULL)>>>USE: EXAM.DYA_BP1 / 1 (EXAM.DYA_BP1 IS NULL AND EXAM.DYA_BP2 IS NOT NULL AND EXAM.DYA_BP3 IS NULL)>>>USE: EXAM.DYA_BP2 / 1														
-- Page Dynamics (EXAM. DYABPAVG): Show When: EXAM.VITALSYN = 1														
Page-35-618782	Radiolist Horizontal	1	B1n. Age range of participant at the time of blood pressure measurements	EXAM.BPAGE	Yes				cBPAGE					
-- Page Dynamics (EXAM. BPAGE): Show When: EXAM.VITALSYN = 1														
Page-36-618782	Radiolist	2	B1n1. Systolic BP Category/Stage (for Children Aged < 13 y)	EXAM.SBPAG1CAT	Yes				cSBPAGE1CAT					

Page Information														
-- Page Dynamics (EXAM. SBPAG1CAT): Show When: EXAM.VITALSYN = 1 AND EXAM.BPAGE = 1														
Page-37-618782	Radiolist	2	B1n2. Systolic BP Category/Stage (for Children Aged ≥ 13 y)	EXAM.SBPAG2CAT	Yes				cSBPAGE2CAT					
-- Page Dynamics (EXAM. SBPAG2CAT): Show When: EXAM.VITALSYN = 1 AND EXAM.BPAGE = 2														
Page-38-618782	Radiolist	2	B1n3. Diastolic BP Category/Stage (for Children Aged < 13 y)	EXAM.DBPAG1CAT	Yes				cDBPAGE1CAT					
-- Page Dynamics (EXAM. DBPAG1CAT): Show When: EXAM.VITALSYN = 1 AND EXAM.BPAGE = 1														
Page-39-618782	Radiolist	2	B1n4. Diastolic BP Category/Stage (for Children Aged ≥ 13 y)	EXAM.DBPAG2CAT	Yes				cDBPAGE2CAT					Note that there is no category at this age for elevated diastolic BP
-- Page Dynamics (EXAM. DBPAG2CAT): Show When: EXAM.VITALSYN = 1 AND EXAM.BPAGE = 2														

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618928	SYSQ_4924	EXAM.ANTHROP	Field Null		EXAM.ANTHROP IS NULL	"A1. Were anthropomorphic measurements collected?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618930	SYSQ_4925	EXAM.ANTHRDAT	Field Null		EXAM.ANTHRDAT IS NULL	"A1a. Date measurements performed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618932	SYSQ_4926	EXAM.ANTHRDAT	Future Date		EXAM.ANTHRDAT > Today	"A1a. Date measurements performed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618934	SYSQ_4927	EXAM.ANIGRYN	Field Null		EXAM.ANIGRYN IS NULL	"A1b. Does the subject have acanthosis nigricans in the neck and/or axilla? cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618936	SYSQ_4928	EXAM.HEIGHT1	Field Null		EXAM.HEIGHT1 IS NULL	"A1c. Relevant Height 1 (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618938	SYSQ_4929	EXAM.HEIGHT2	Field Null		EXAM.HEIGHT2 IS NULL	"A1d. Relevant Height 2 (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0

System Queries														
sysq-618940	SYSQ_4930	EXAM.HEIGHTPCT	Field Null		EXAM.HEIGHTPCT IS NULL	"A1f. Height Percentile" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618941	SYSQ_4931	EXAM.WEIGHT1	Field Null		EXAM.WEIGHT1 IS NULL	"A1g. Relevant Weight 1 (kg)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618944	SYSQ_4932	EXAM.WEIGHT2	Field Null		EXAM.WEIGHT2 IS NULL	"A1h. Relevant Weight 2 (kg)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618945	SYSQ_4933	EXAM.BMIPCT	Field Null		EXAM.BMIPCT IS NULL	"A1k. BMI Percentile" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618948	SYSQ_4934	EXAM.WCIRCUM1	Field Null		EXAM.WCIRCUM1 IS NULL	"A1l. Relevant Waist Circumference 1 (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618950	SYSQ_4935	EXAM.WCIRCUM2	Field Null		EXAM.WCIRCUM2 IS NULL	"A1m. Relevant Waist Circumference 2 (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618951	SYSQ_4936	EXAM.VITALSYN	Field Null		EXAM.VITALSYN IS NULL	"B1. Were blood pressure measurements collected at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618953	SYSQ_4937	EXAM.VITALDAT	Field Null		EXAM.VITALDAT IS NULL	"B1a. Date measurements performed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618955	SYSQ_4938	EXAM.VITALDAT	Future Date		EXAM.VITALDAT > Today	"B1a. Date measurements performed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618957	SYSQ_4939	EXAM.METHOD	Field Null		EXAM.METHOD IS NULL	"B1b. Final method used for measurements" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0

System Queries														
sysq-618959	SYSQ_4940	EXAM.ARMCIRCM	Field Null		EXAM.ARMCIRCM IS NULL	"B1c. Was the arm circumference re-measured at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618961	SYSQ_4941	EXAM.ARMCIRC	Field Null		EXAM.ARMCIRC IS NULL	"B1c1. Arm circumference (cm) cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618964	SYSQ_4942	EXAM.BP_CUFF_WIDTH	Field Null		EXAM.BP_CUFF_WIDTH IS NULL	"B1d. Blood pressure cuff width (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618965	SYSQ_4943	EXAM.BP_CUFF_LENGTH	Field Null		EXAM.BP_CUFF_LENGTH IS NULL	"B1e. Length of the bladder (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618968	SYSQ_4944	EXAM.SYS_BP1	Field Null		EXAM.SYS_BP1 IS NULL	"B1f. Systolic Blood Pressure 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618970	SYSQ_4945	EXAM.DYA_BP1	Field Null		EXAM.DYA_BP1 IS NULL	"B1g. Diastolic Blood Pressure 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618971	SYSQ_4946	EXAM.SYS_BP2	Field Null		EXAM.SYS_BP2 IS NULL	"B1h. Systolic Blood Pressure 2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618973	SYSQ_4947	EXAM.DYA_BP2	Field Null		EXAM.DYA_BP2 IS NULL	"B1i. Diastolic Blood Pressure 2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618976	SYSQ_4948	EXAM.SYS_BP3	Field Null		EXAM.SYS_BP3 IS NULL	"B1j. Systolic Blood Pressure 3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618977	SYSQ_4949	EXAM.DYA_BP3	Field Null		EXAM.DYA_BP3 IS NULL	"B1k. Diastolic Blood Pressure 3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0

System Queries														
sysq-618979	SYSQ_4950	EXAM.BPAGE	Field Null		EXAM.BPAGE IS NULL	"B1n. Age range of participant at the time of blood pressure measurements" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618982	SYSQ_4953	EXAM.BMIPCT	Other / Cross Page		EXAM.BMIPCT < 95 AND VISITID = 10	BMI is not ≥ 95th percentile which is an Inclusion Criteria Violation. Please confirm and if confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618984	SYSQ_4954	EXAM.ANTHRDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(EXAM.ANTHRDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618985	SYSQ_4955	EXAM.VITALDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(EXAM.VITALDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619232	SYSQ_5076	EXAM.SBPAG1CAT	Field Null		EXAM.SBPAG1CAT IS NULL	"B1n1. Systolic BP Category/Stage (for Children Aged < 13 y)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619234	SYSQ_5077	EXAM.SBPAG2CAT	Field Null		EXAM.SBPAG2CAT IS NULL	"B1n2. Systolic BP Category/Stage (for Children Aged ≥ 13 y)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619236	SYSQ_5078	EXAM.DBPAG1CAT	Field Null		EXAM.DBPAG1CAT IS NULL	"B1n3. Diastolic BP Category/Stage (for Children Aged < 13 y)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619237	SYSQ_5079	EXAM.DBPAG2CAT	Field Null		EXAM.DBPAG2CAT IS NULL	"B1n4. Diastolic BP Category/Stage (for Children Aged ≥ 13 y)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619240	SYSQ_5080	EXAM.HEIGHT1	Range		EXAM.HEIGHT1 < 120.0 OR EXAM.HEIGHT1 > 200	"A1c. Relevant Height 1 (cm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0

System Queries														
sysq-619242	SYSQ_5081	EXAM.HEIGHT2	Range		EXAM.HEIGHT2 < 120.0 OR EXAM.HEIGHT2 > 200	"A1d. Relevant Height 2 (cm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619243	SYSQ_5082	EXAM.WEIGHT1	Range		EXAM.WEIGHT1 < 20 OR EXAM.WEIGHT1 > 135	"A1g. Relevant Weight 1 (kg)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619245	SYSQ_5083	EXAM.WEIGHT2	Range		EXAM.WEIGHT2 < 20 OR EXAM.WEIGHT2 > 135	"A1h. Relevant Weight 2 (kg)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619248	SYSQ_5084	EXAM.WCIRCUM1	Range		EXAM.WCIRCUM1 < 30 OR EXAM.WCIRCUM1 > 150	"A1l. Relevant Waist Circumference 1 (cm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619249	SYSQ_5085	EXAM.WCIRCUM2	Range		EXAM.WCIRCUM2 < 30 OR EXAM.WCIRCUM2 > 150	"A1m. Relevant Waist Circumference 2 (cm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619251	SYSQ_5086	EXAM.SBPAG1CAT	Other / Cross Page		EXAM.SBPAG1CAT = 4 AND VISITID = 10	Stage 2 hypertension (systolic or diastolic blood pressure > 95th percentile for age, sex and height percentile + 12 mmHg or >140/90, whichever is lower for subjects <13 years of age; is an exclusion violation. Please review and confirm. If confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619253	SYSQ_5087	EXAM.SBPAG2CAT	Other / Cross Page		EXAM.SBPAG2CAT = 4 AND VISITID = 10	Stage 2 hypertension (systolic or diastolic blood pressure) >140/90 for subjects >13 years of age. Please review and confirm. If confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619256	SYSQ_5088	EXAM.DBPAG1CAT	Other / Cross Page		EXAM.DBPAG1CAT = 4 AND VISITID = 10	Stage 2 hypertension (systolic or diastolic blood pressure > 95th percentile for age, sex and height percentile + 12 mmHg or >140/90, whichever is lower for subjects <13 years of age; is an exclusion violation. Please review and confirm. If confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0

System Queries														
sysq-619257	SYSQ_5089	EXAM.DBPAG2CAT	Other / Cross Page		EXAM.DBPAG2CAT = 3 AND VISITID = 10	Stage 2 hypertension (systolic or diastolic blood pressure) >140/90 for subjects >13 years of age. Please review and confirm. If confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619260	SYSQ_5090	EXAM.SYS_BP1	Range		EXAM.SYS_BP1 < 70 OR EXAM.SYS_BP1 > 220	"B1f. Systolic Blood Pressure 1" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619261	SYSQ_5091	EXAM.DYA_BP1	Range		EXAM.DYA_BP1 < 20 OR EXAM.DYA_BP1 > 175	"B1g. Diastolic Blood Pressure 1" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619264	SYSQ_5092	EXAM.SYS_BP2	Range		EXAM.SYS_BP2 < 70 OR EXAM.SYS_BP2 > 220	"B1h. Systolic Blood Pressure 2" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619265	SYSQ_5093	EXAM.DYA_BP2	Range		EXAM.DYA_BP2 < 20 OR EXAM.DYA_BP2 > 175	"B1i. Diastolic Blood Pressure 2" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619268	SYSQ_5094	EXAM.SYS_BP3	Range		EXAM.SYS_BP3 < 70 OR EXAM.SYS_BP3 > 220	"B1j. Systolic Blood Pressure 3" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619270	SYSQ_5095	EXAM.DYA_BP3	Range		EXAM.DYA_BP3 < 20 OR EXAM.DYA_BP3 > 175	"B1k. Diastolic Blood Pressure 3" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619605	SYSQ_5331	EXAM.ANTHROP	Other / Cross Page		EXAM.ANTHROP = 0 AND (VISITID = 20 OR VISITID = 40 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90)	Anthropometry is required at this visit. If not done, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0

System Queries														
sysq-619607	SYSQ_5332	EXAM.VITALSYN	Other / Cross Page		EXAM.VITALSYN = 0 AND (VISITID = 20 OR VISITID = 40 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90)	Blood Pressure Measurements are required at this visit. If not done, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0

pEXAM_4

Page

(Visit ID = 618783, Page ID =)

Unique Identifier page-618783-618783-618783-

Section A: ANTHROPOMORPHIC MEASUREMENTS				
SDV	* A1. Were anthropomorphic measurements collected?	○ Yes ○ No	EXAM.ANTHROP	
SDV	* A1a. Date measurements performed		EXAM.ANTHRDAT	
SDV	* A1b. Does the subject have acanthosis nigricans in the neck and/or axilla? Baseline Visit Only	○ Yes ○ No	EXAM.ANIGRYN	
SDV	* A1c. Relevant Height 1 (cm)		EXAM.HEIGHT1	(format xxx.xx)
SDV	* A1d. Relevant Height 2 (cm)		EXAM.HEIGHT2	(format xxx.xx)
	A1e. Height Average (calculated)	(auto calculated)	EXAM.HEIGHT_AV	(format xxx.xx)
SDV	* A1f. Height Percentile		EXAM.HEIGHTPCT	(format xxx.xx)
SDV	* A1g. Relevant Weight 1 (kg)		EXAM.WEIGHT1	(format xxx.xx)
SDV	* A1h. Relevant Weight 2 (kg)		EXAM.WEIGHT2	(format xxx.xx)
	A1i. Weight Average (calculated)	(auto calculated)	EXAM.WEIGHT_AV	(format xxx.xx)
	A1j. Body Mass Index (BMI) (calculated)	(auto calculated)	EXAM.BMI	(format xx.x)
SDV	* A1k. BMI Percentile		EXAM.BMIPCT	(format xxx.xx)
SDV	* A1l. Relevant Waist Circumference 1 (cm)		EXAM.WCIRCUM1	(format xxx.xx)
SDV	* A1m. Relevant Waist Circumference 2 (cm)		EXAM.WCIRCUM2	(format xxx.xx)
	A1n. Waist Circumference Average (calculated)	(auto calculated)	EXAM.WCIRCUM_AV	(format xxx.xx)
	A1o. Waist to Height Ratio (calculated)	(auto calculated)	EXAM.WH_RATIO	(format xxx.xx)
SECTION B: BLOOD PRESSURE MEASUREMENTS				
SDV	* B1. Were blood pressure measurements collected at this visit?	○ Yes ○ No	EXAM.VITALSYN	

SDV	* B1a. Date measurements performed		EXAM.VITALDAT	
SDV	* B1b. Final method used for measurements	○ oscillometric ○ ausculatory	EXAM.METHOD	
SDV	* B1c. Was the arm circumference re-measured at this visit?	○ Yes ○ No	EXAM.ARMCIRCM	
SDV	* B1c1. Arm circumference (cm) Screening Visit Only AND if the subject has a >5 cm change in waist circumference *The same arm cuff should be used for all study visits, unless there is a change in arm circumference that would necessitate a change in cuff size.*		EXAM.ARMCIRC	(format xxx.xx)
SDV	* B1d. Blood pressure cuff width (cm)		EXAM.BP_CUFF_WIDTH	(format xxx.xx)
SDV	* B1e. Length of the bladder (cm)		EXAM.BP_CUFF_LENGTH	(format xxx.xx)
SDV	* B1f. Systolic Blood Pressure 1		EXAM.SYS_BP1	(format xxx)
SDV	* B1g. Diastolic Blood Pressure 1		EXAM.DYA_BP1	(format xxx)
SDV	* B1h. Systolic Blood Pressure 2		EXAM.SYS_BP2	(format xxx)
SDV	* B1i. Diastolic Blood Pressure 2		EXAM.DYA_BP2	(format xxx)
SDV	* B1j. Systolic Blood Pressure 3		EXAM.SYS_BP3	(format xxx)
SDV	* B1k. Diastolic Blood Pressure 3		EXAM.DYA_BP3	(format xxx)
	B1l. Systolic Blood Pressure Average	(auto calculated)	EXAM.SYSBPAVG	(format xxx.xx)
	B1m. Diastolic Blood Pressure Average	(auto calculated)	EXAM.DYABPAVG	(format xxx.xx)
SDV	* B1n. Age range of participant at the time of blood pressure measurements	○ Aged < 13 years ○ Aged ≥ 13 years	EXAM.BPAGE	

SDV	* B1n1. Systolic BP Category/Stage (for Children Aged < 13 y)	○ Normal SBP: <90th percentile ○ Elevated SBP:≥90th to <95th percentile, or 120mmHg to <95th percentile (whichever is lower) ○ Stage1 systolic HTN:≥95th to 95th percentile +12mmHg, or systolic 130 to 139mmHg(whichever is lower) ○ Stage2 systolic HTN:≥95th percentile + 12mmHg, or ≥140mmHg (whichever is lower)	EXAM.SBPAG1CAT
SDV	* B1n2. Systolic BP Category/Stage (for Children Aged ≥ 13 y)	○ Normal SBP: <120 mmHg ○ Elevated SBP: 120 to 129 mmHg ○ Stage1 systolic HTN: 130 to 139 mmHg ○ Stage2 systolic HTN: ≥140 mmHg	EXAM.SBPAG2CAT

SDV	* B1n3. Diastolic BP Category/Stage (for Children Aged < 13 y)	○ Normal DBP: <90th percentile ○ Elevated DBP:≥90th to <95th percentile, or systolic 80mmHg to <95th percentile (whichever is lower) ○ Stage1 diastolic HTN:≥95th to 95th percentile + 12mmHg,or diastolic 80 to 89mmHg(whichever is lower) ○ Stage2 diastolic HTN:≥95th percentile + 12mmHg, or ≥90mmHg(whichever is lower)	EXAM.DBPAG1CAT
SDV	* B1n4. Diastolic BP Category/Stage (for Children Aged ≥ 13 y)	○ Normal DBP: <80 mmHg ○ Stage1 diastolic HTN: 80 to 89 mmHg ○ Stage2 diastolic HTN: ≥90 mmHg	EXAM.DBPAG2CAT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618783	Section Header	0	Section A: ANTHROPOMORPHIC MEASUREMENTS											
Page-2-618783	Radiolist Horizontal	0	A1. Were anthropomorphic measurements collected?	EXAM.ANTHROP	Yes				cYN					
Page-3-618783	Date	1	A1a. Date measurements performed	EXAM.ANTHRDAT	Yes									
-- Page Dynamics (EXAM. ANTHRDAT): Show When: EXAM.ANTHROP = 1														

Page Information														
Page-4-618783	Radiolist Horizontal	1	A1b. Does the subject have acanthosis nigricans in the neck and/or axilla? Baseline Visit Only	EXAM.ANIGRYN	Yes				cYN					
-- Page Dynamics (EXAM. ANIGRYN): Show When: EXAM.ANTHROP = 1 AND VISITID = 20														
Page-5-618783	Numeric	1	A1c. Relevant Height 1 (cm)	EXAM.HEIGHT1	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.5 cm difference between them).
-- Page Dynamics (EXAM. HEIGHT1): Show When: EXAM.ANTHROP = 1														
Page-6-618783	Numeric	1	A1d. Relevant Height 2 (cm)	EXAM.HEIGHT2	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.5 cm difference between them).
-- Page Dynamics (EXAM. HEIGHT2): Show When: EXAM.ANTHROP = 1														
Page-7-618783	Auto Calc Field	1	A1e. Height Average (calculated)	EXAM.HEIGHT_AV								3	2	
-- Auto Calc Rule (EXAM.HEIGHT_AV): (EXAM.HEIGHT1 IS NOT NULL AND EXAM.HEIGHT2 IS NOT NULL)>>>USE: (EXAM.HEIGHT1 + EXAM.HEIGHT2) / 2 (EXAM.HEIGHT1 IS NOT NULL AND EXAM.HEIGHT2 IS NULL)>>>USE: EXAM.HEIGHT1 / 1 (EXAM.HEIGHT1 IS NULL AND EXAM.HEIGHT2 IS NOT NULL)>>>USE: EXAM.HEIGHT2 / 1														
-- Page Dynamics (EXAM. HEIGHT_AV): Show When: EXAM.ANTHROP = 1														
Page-8-618783	Numeric	1	A1f. Height Percentile	EXAM.HEIGHTPCT	Yes							3	2	From average height, use CDC growth charts to obtain height percentile.
-- Page Dynamics (EXAM. HEIGHTPCT): Show When: EXAM.ANTHROP = 1														
Page-9-618783	Numeric	1	A1g. Relevant Weight 1 (kg)	EXAM.WEIGHT1	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.2 kg difference between them).
-- Page Dynamics (EXAM. WEIGHT1): Show When: EXAM.ANTHROP = 1														

Page Information														
Page-10-618783	Numeric	1	A1h. Relevant Weight 2 (kg)	EXAM.WEIGHT2	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.2 kg difference between them).
-- Page Dynamics (EXAM. WEIGHT2): Show When: EXAM.ANTHROP = 1														
Page-11-618783	Auto Calc Field	1	A1i. Weight Average (calculated)	EXAM.WEIGHT_AV								3	2	
-- Auto Calc Rule (EXAM.WEIGHT_AV): (EXAM.WEIGHT1 IS NOT NULL AND EXAM.WEIGHT2 IS NOT NULL)>>>USE: (EXAM.WEIGHT1 + EXAM.WEIGHT2)/2 (EXAM.WEIGHT1 IS NULL AND EXAM.WEIGHT2 IS NOT NULL)>>>USE: EXAM.WEIGHT2 / 1 (EXAM.WEIGHT1 IS NOT NULL AND EXAM.WEIGHT2 IS NULL)>>>USE: EXAM.WEIGHT1 / 1														
-- Page Dynamics (EXAM. WEIGHT_AV): Show When: EXAM.ANTHROP = 1														
Page-12-618783	Auto Calc Field	1	A1j. Body Mass Index (BMI) (calculated)	EXAM.BMI								2	1	
-- Auto Calc Rule (EXAM.BMI): (EXAM.HEIGHT_AV IS NOT NULL AND EXAM.WEIGHT_AV IS NOT NULL) ALWAYS>>>USE: EXAM.WEIGHT_AV / (pow ((EXAM.HEIGHT_AV / 100), 2))														
-- Page Dynamics (EXAM. BMI): Show When: EXAM.ANTHROP = 1														
Page-13-618783	Numeric	1	A1k. BMI Percentile	EXAM.BMIPCT	Yes							3	2	BMI Percentile is BMI converted to age- and sex-matched percentiles based on data from the Centers for Disease Control (CDC; http://www.cdc.gov/nchs/data/series/sr_11/sru_246.pdf).
-- Page Dynamics (EXAM. BMIPCT): Show When: EXAM.ANTHROP = 1														
Page-14-618783	Numeric	1	A1l. Relevant Waist Circumference 1 (cm)	EXAM.WCIRCUM1	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.5 cm difference between them).
-- Page Dynamics (EXAM. WCIRCUM1): Show When: EXAM.ANTHROP = 1														

Page Information														
Page-15-618783	Numeric	1	A1m. Relevant Waist Circumference 2 (cm)	EXAM.WCIRCUM2	Yes							3	2	If more than 2 measurements are taken, please enter only the 2 most relevant measurements (those with less than 0.5 cm difference between them).
-- Page Dynamics (EXAM. WCIRCUM2): Show When: EXAM.ANTHROP = 1														
Page-16-618783	Auto Calc Field	1	A1n. Waist Circumference Average (calculated)	EXAM.WCIRCUM_AV								3	2	
-- Auto Calc Rule (EXAM.WCIRCUM_AV): (EXAM.WCIRCUM1 IS NOT NULL AND EXAM.WCIRCUM2 IS NOT NULL)>>>USE: (EXAM.WCIRCUM1 + EXAM.WCIRCUM2) / 2 (EXAM.WCIRCUM1 IS NOT NULL AND EXAM.WCIRCUM2 IS NULL)>>>USE: EXAM.WCIRCUM1 / 1 (EXAM.WCIRCUM1 IS NULL AND EXAM.WCIRCUM2 IS NOT NULL)>>>USE: EXAM.WCIRCUM2 / 1														
-- Page Dynamics (EXAM. WCIRCUM_AV): Show When: EXAM.ANTHROP = 1														
Page-17-618783	Auto Calc Field	1	A1o. Waist to Height Ratio (calculated)	EXAM.WH_RATIO								3	2	
-- Auto Calc Rule (EXAM.WH_RATIO): (EXAM.HEIGHT_AV IS NOT NULL AND EXAM.WCIRCUM_AV IS NOT NULL) ALWAYS>>>USE: (EXAM.WCIRCUM_AV / EXAM.HEIGHT_AV) * 100														
-- Page Dynamics (EXAM. WH_RATIO): Show When: EXAM.ANTHROP = 1														
Page-18-618783	Section Header	0	SECTION B: BLOOD PRESSURE MEASUREMENTS											
Page-19-618783	Radiolist Horizontal	0	B1. Were blood pressure measurements collected at this visit?	EXAM.VITALSYN	Yes				cYN					
Page-20-618783	Date	1	B1a. Date measurements performed	EXAM.VITALDAT	Yes									
-- Page Dynamics (EXAM. VITALDAT): Show When: EXAM.VITALSYN = 1														
Page-21-618783	Radiolist Horizontal	1	B1b. Final method used for measurements	EXAM.METHOD	Yes				cBPMETHOD					
-- Page Dynamics (EXAM. METHOD): Show When: EXAM.VITALSYN = 1														
Page-22-618783	Radiolist Horizontal	1	B1c. Was the arm circumference re-measured at this visit?	EXAM.ARMCIRCM	Yes				cYN					If there is a >5 cm change in waist circumference at any visit during the trial, the arm circumference should be re-measured.
-- Page Dynamics (EXAM. ARMCIRCM): Show When: EXAM.VITALSYN = 1 AND VISITID > 10														

Page Information													
Page-23-618783	Numeric	2	B1c1. Arm circumference (cm) Screening Visit Only AND if the subject has a >5 cm change in waist circumference	EXAM.ARMCIRC	Yes							3	2	Measure arm circumference mid between shoulder and elbow prominences with forearm 90 degree. Only need to measure and record at screening, and if there is a >5 cm change in waist circumference at any visit during the trial.
-- Page Dynamics (EXAM. ARMCIRC): Show When: (EXAM.VITALSYN = 1 AND VISITID > 10 AND EXAM.ARMCIRCM = 1) OR (EXAM.VITALSYN = 1 AND VISITID <= 10 AND EXAM.ARMCIRCM IS NULL)													
Page-24-618783	Help Text Line	0	The same arm cuff should be used for all study visits, unless there is a change in arm circumference that would necessitate a change in cuff size.											
-- Page Dynamics (.): Show When: EXAM.VITALSYN = 1													
Page-25-618783	Numeric	1	B1d. Blood pressure cuff width (cm)	EXAM.BP_CUFF_WIDTH	Yes							3	2	please enter the width of the blood pressure cuff in cm
-- Page Dynamics (EXAM. BP_CUFF_WIDTH): Show When: EXAM.VITALSYN = 1													
Page-26-618783	Numeric	1	B1e. Length of the bladder (cm)	EXAM.BP_CUFF_LENGTH	Yes							3	2	Please enter the Bladder Length in cm. The bladder length recommended by the AHA is 80 percent of the patient's arm circumference, and the ideal width is at least 40 percent.
-- Page Dynamics (EXAM. BP_CUFF_LENGTH): Show When: EXAM.VITALSYN = 1													
Page-27-618783	Numeric	1	B1f. Systolic Blood Pressure 1	EXAM.SYS_BP1	Yes							3	0	Record 3 Blood Pressure measurements. Each measurement should be 2 minutes apart.
-- Page Dynamics (EXAM. SYS_BP1): Show When: EXAM.VITALSYN = 1													
Page-28-618783	Numeric	1	B1g. Diastolic Blood Pressure 1	EXAM.DYA_BP1	Yes							3	0	
-- Page Dynamics (EXAM. DYA_BP1): Show When: EXAM.VITALSYN = 1													

Page Information														
Page-29-618783	Numeric	1	B1h. Systolic Blood Pressure 2	EXAM.SYS_BP2	Yes							3	0	
-- Page Dynamics (EXAM. SYS_BP2): Show When: EXAM.VITALSYN = 1														
Page-30-618783	Numeric	1	B1i. Diastolic Blood Pressure 2	EXAM.DYA_BP2	Yes							3	0	
-- Page Dynamics (EXAM. DYA_BP2): Show When: EXAM.VITALSYN = 1														
Page-31-618783	Numeric	1	B1j. Systolic Blood Pressure 3	EXAM.SYS_BP3	Yes							3	0	
-- Page Dynamics (EXAM. SYS_BP3): Show When: EXAM.VITALSYN = 1														
Page-32-618783	Numeric	1	B1k. Diastolic Blood Pressure 3	EXAM.DYA_BP3	Yes							3	0	
-- Page Dynamics (EXAM. DYA_BP3): Show When: EXAM.VITALSYN = 1														
Page-33-618783	Auto Calc Field	1	B1l. Systolic Blood Pressure Average	EXAM.SYSBPAVG								3	2	
-- Auto Calc Rule (EXAM.SYSBPAVG): (EXAM.SYS_BP1 IS NOT NULL AND EXAM.SYS_BP2 IS NOT NULL AND EXAM.SYS_BP3 IS NOT NULL)>>>USE: (EXAM.SYS_BP1 + EXAM.SYS_BP2 + EXAM.SYS_BP3) / 3 (EXAM.SYS_BP1 IS NULL AND EXAM.SYS_BP2 IS NOT NULL AND EXAM.SYS_BP3 IS NOT NULL)>>>USE: (EXAM.SYS_BP2 + EXAM.SYS_BP3) / 2 (EXAM.SYS_BP1 IS NOT NULL AND EXAM.SYS_BP2 IS NULL AND EXAM.SYS_BP3 IS NOT NULL)>>>USE: (EXAM.SYS_BP1 + EXAM.SYS_BP3) / 2 (EXAM.SYS_BP1 IS NOT NULL AND EXAM.SYS_BP2 IS NOT NULL AND EXAM.SYS_BP3 IS NULL)>>>USE: (EXAM.SYS_BP1 + EXAM.SYS_BP2) / 2 (EXAM.SYS_BP1 IS NULL AND EXAM.SYS_BP2 IS NULL AND EXAM.SYS_BP3 IS NOT NULL)>>>USE: EXAM.SYS_BP3 / 1 (EXAM.SYS_BP1 IS NOT NULL AND EXAM.SYS_BP2 IS NULL AND EXAM.SYS_BP3 IS NULL)>>>USE: EXAM.SYS_BP1 / 1 (EXAM.SYS_BP1 IS NULL AND EXAM.SYS_BP2 IS NOT NULL AND EXAM.SYS_BP3 IS NULL)>>>USE: EXAM.SYS_BP2 / 1														
-- Page Dynamics (EXAM. SYSBPAVG): Show When: EXAM.VITALSYN = 1														
Page-34-618783	Auto Calc Field	1	B1m. Diastolic Blood Pressure Average	EXAM.DYABPAVG								3	2	
-- Auto Calc Rule (EXAM.DYABPAVG): (EXAM.DYA_BP1 IS NOT NULL AND EXAM.DYA_BP2 IS NOT NULL AND EXAM.DYA_BP3 IS NOT NULL)>>>USE: (EXAM.DYA_BP1 + EXAM.DYA_BP2 + EXAM.DYA_BP3) / 3 (EXAM.DYA_BP1 IS NULL AND EXAM.DYA_BP2 IS NOT NULL AND EXAM.DYA_BP3 IS NOT NULL)>>>USE: (EXAM.DYA_BP2 + EXAM.DYA_BP3) / 2 (EXAM.DYA_BP1 IS NOT NULL AND EXAM.DYA_BP2 IS NULL AND EXAM.DYA_BP3 IS NOT NULL)>>>USE: (EXAM.DYA_BP1 + EXAM.DYA_BP3) / 2 (EXAM.DYA_BP1 IS NOT NULL AND EXAM.DYA_BP2 IS NOT NULL AND EXAM.DYA_BP3 IS NULL)>>>USE: (EXAM.DYA_BP1 + EXAM.DYA_BP2) / 2 (EXAM.DYA_BP1 IS NULL AND EXAM.DYA_BP2 IS NULL AND EXAM.DYA_BP3 IS NOT NULL)>>>USE: EXAM.DYA_BP3 / 1 (EXAM.DYA_BP1 IS NOT NULL AND EXAM.DYA_BP2 IS NULL AND EXAM.DYA_BP3 IS NULL)>>>USE: EXAM.DYA_BP1 / 1 (EXAM.DYA_BP1 IS NULL AND EXAM.DYA_BP2 IS NOT NULL AND EXAM.DYA_BP3 IS NULL)>>>USE: EXAM.DYA_BP2 / 1														
-- Page Dynamics (EXAM. DYABPAVG): Show When: EXAM.VITALSYN = 1														
Page-35-618783	Radiolist Horizontal	1	B1n. Age range of participant at the time of blood pressure measurements	EXAM.BPAGE	Yes				cBPAGE					
-- Page Dynamics (EXAM. BPAGE): Show When: EXAM.VITALSYN = 1														
Page-36-618783	Radiolist	2	B1n1. Systolic BP Category/Stage (for Children Aged < 13 y)	EXAM.SBPAG1CAT	Yes				cSBPAGE1CAT					

Page Information														
-- Page Dynamics (EXAM. SBPAG1CAT): Show When: EXAM.VITALSYN = 1 AND EXAM.BPAGE = 1														
Page-37-618783	Radiolist	2	B1n2. Systolic BP Category/Stage (for Children Aged ≥ 13 y)	EXAM.SBPAG2CAT	Yes				cSBPAGE2CAT					
-- Page Dynamics (EXAM. SBPAG2CAT): Show When: EXAM.VITALSYN = 1 AND EXAM.BPAGE = 2														
Page-38-618783	Radiolist	2	B1n3. Diastolic BP Category/Stage (for Children Aged < 13 y)	EXAM.DBPAG1CAT	Yes				cDBPAGE1CAT					
-- Page Dynamics (EXAM. DBPAG1CAT): Show When: EXAM.VITALSYN = 1 AND EXAM.BPAGE = 1														
Page-39-618783	Radiolist	2	B1n4. Diastolic BP Category/Stage (for Children Aged ≥ 13 y)	EXAM.DBPAG2CAT	Yes				cDBPAGE2CAT					Note that there is no category at this age for elevated diastolic BP
-- Page Dynamics (EXAM. DBPAG2CAT): Show When: EXAM.VITALSYN = 1 AND EXAM.BPAGE = 2														

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618927	SYSQ_4924	EXAM.ANTHROP	Field Null		EXAM.ANTHROP IS NULL	"A1. Were anthropomorphic measurements collected?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618929	SYSQ_4925	EXAM.ANTHRDAT	Field Null		EXAM.ANTHRDAT IS NULL	"A1a. Date measurements performed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618931	SYSQ_4926	EXAM.ANTHRDAT	Future Date		EXAM.ANTHRDAT > Today	"A1a. Date measurements performed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618933	SYSQ_4927	EXAM.ANIGRYN	Field Null		EXAM.ANIGRYN IS NULL	"A1b. Does the subject have acanthosis nigricans in the neck and/or axilla? cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618935	SYSQ_4928	EXAM.HEIGHT1	Field Null		EXAM.HEIGHT1 IS NULL	"A1c. Relevant Height 1 (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618937	SYSQ_4929	EXAM.HEIGHT2	Field Null		EXAM.HEIGHT2 IS NULL	"A1d. Relevant Height 2 (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0

System Queries														
sysq-618939	SYSQ_4930	EXAM.HEIGHTPCT	Field Null		EXAM.HEIGHTPCT IS NULL	"A1f. Height Percentile" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618942	SYSQ_4931	EXAM.WEIGHT1	Field Null		EXAM.WEIGHT1 IS NULL	"A1g. Relevant Weight 1 (kg)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618943	SYSQ_4932	EXAM.WEIGHT2	Field Null		EXAM.WEIGHT2 IS NULL	"A1h. Relevant Weight 2 (kg)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618946	SYSQ_4933	EXAM.BMIPCT	Field Null		EXAM.BMIPCT IS NULL	"A1k. BMI Percentile" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618947	SYSQ_4934	EXAM.WCIRCUM1	Field Null		EXAM.WCIRCUM1 IS NULL	"A1l. Relevant Waist Circumference 1 (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618949	SYSQ_4935	EXAM.WCIRCUM2	Field Null		EXAM.WCIRCUM2 IS NULL	"A1m. Relevant Waist Circumference 2 (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618952	SYSQ_4936	EXAM.VITALSYN	Field Null		EXAM.VITALSYN IS NULL	"B1. Were blood pressure measurements collected at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618954	SYSQ_4937	EXAM.VITALDAT	Field Null		EXAM.VITALDAT IS NULL	"B1a. Date measurements performed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:10	0	0	0	0	0	0
sysq-618956	SYSQ_4938	EXAM.VITALDAT	Future Date		EXAM.VITALDAT > Today	"B1a. Date measurements performed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618958	SYSQ_4939	EXAM.METHOD	Field Null		EXAM.METHOD IS NULL	"B1b. Final method used for measurements" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0

System Queries														
sysq-618960	SYSQ_4940	EXAM.ARMCIRCM	Field Null		EXAM.ARMCIRCM IS NULL	"B1c. Was the arm circumference re-measured at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618962	SYSQ_4941	EXAM.ARMCIRC	Field Null		EXAM.ARMCIRC IS NULL	"B1c1. Arm circumference (cm) cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618963	SYSQ_4942	EXAM.BP_CUFF_WIDTH	Field Null		EXAM.BP_CUFF_WIDTH IS NULL	"B1d. Blood pressure cuff width (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618966	SYSQ_4943	EXAM.BP_CUFF_LENGTH	Field Null		EXAM.BP_CUFF_LENGTH IS NULL	"B1e. Length of the bladder (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618967	SYSQ_4944	EXAM.SYS_BP1	Field Null		EXAM.SYS_BP1 IS NULL	"B1f. Systolic Blood Pressure 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618969	SYSQ_4945	EXAM.DYA_BP1	Field Null		EXAM.DYA_BP1 IS NULL	"B1g. Diastolic Blood Pressure 1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618972	SYSQ_4946	EXAM.SYS_BP2	Field Null		EXAM.SYS_BP2 IS NULL	"B1h. Systolic Blood Pressure 2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618974	SYSQ_4947	EXAM.DYA_BP2	Field Null		EXAM.DYA_BP2 IS NULL	"B1i. Diastolic Blood Pressure 2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618975	SYSQ_4948	EXAM.SYS_BP3	Field Null		EXAM.SYS_BP3 IS NULL	"B1j. Systolic Blood Pressure 3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618978	SYSQ_4949	EXAM.DYA_BP3	Field Null		EXAM.DYA_BP3 IS NULL	"B1k. Diastolic Blood Pressure 3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0

System Queries														
sysq-618980	SYSQ_4950	EXAM.BPAGE	Field Null		EXAM.BPAGE IS NULL	"B1n. Age range of participant at the time of blood pressure measurements" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618981	SYSQ_4953	EXAM.BMIPCT	Other / Cross Page		EXAM.BMIPCT < 95 AND VISITID = 10	BMI is not ≥ 95th percentile which is an Inclusion Criteria Violation. Please confirm and if confirmed, subject is not eligible.		Horng, Dunstan [DES] 14-SEP-20 14:38:11	0	0	0	0	0	0
sysq-618983	SYSQ_4954	EXAM.ANTHRDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(EXAM.ANTHRDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618986	SYSQ_4955	EXAM.VITALDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(EXAM.VITALDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619231	SYSQ_5076	EXAM.SBPAG1CAT	Field Null		EXAM.SBPAG1CAT IS NULL	"B1n1. Systolic BP Category/Stage (for Children Aged < 13 y)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619233	SYSQ_5077	EXAM.SBPAG2CAT	Field Null		EXAM.SBPAG2CAT IS NULL	"B1n2. Systolic BP Category/Stage (for Children Aged ≥ 13 y)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619235	SYSQ_5078	EXAM.DBPAG1CAT	Field Null		EXAM.DBPAG1CAT IS NULL	"B1n3. Diastolic BP Category/Stage (for Children Aged < 13 y)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619238	SYSQ_5079	EXAM.DBPAG2CAT	Field Null		EXAM.DBPAG2CAT IS NULL	"B1n4. Diastolic BP Category/Stage (for Children Aged ≥ 13 y)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619239	SYSQ_5080	EXAM.HEIGHT1	Range		EXAM.HEIGHT1 < 120.0 OR EXAM.HEIGHT1 > 200	"A1c. Relevant Height 1 (cm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0

System Queries														
sysq-619241	SYSQ_5081	EXAM.HEIGHT2	Range		EXAM.HEIGHT2 < 120.0 OR EXAM.HEIGHT2 > 200	"A1d. Relevant Height 2 (cm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619244	SYSQ_5082	EXAM.WEIGHT1	Range		EXAM.WEIGHT1 < 20 OR EXAM.WEIGHT1 > 135	"A1g. Relevant Weight 1 (kg)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619246	SYSQ_5083	EXAM.WEIGHT2	Range		EXAM.WEIGHT2 < 20 OR EXAM.WEIGHT2 > 135	"A1h. Relevant Weight 2 (kg)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619247	SYSQ_5084	EXAM.WCIRCUM1	Range		EXAM.WCIRCUM1 < 30 OR EXAM.WCIRCUM1 > 150	"A1l. Relevant Waist Circumference 1 (cm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619250	SYSQ_5085	EXAM.WCIRCUM2	Range		EXAM.WCIRCUM2 < 30 OR EXAM.WCIRCUM2 > 150	"A1m. Relevant Waist Circumference 2 (cm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619252	SYSQ_5086	EXAM.SBPAG1CAT	Other / Cross Page		EXAM.SBPAG1CAT = 4 AND VISITID = 10	Stage 2 hypertension (systolic or diastolic blood pressure > 95th percentile for age, sex and height percentile + 12 mmHg or >140/90, whichever is lower for subjects <13 years of age; is an exclusion violation. Please review and confirm. If confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619254	SYSQ_5087	EXAM.SBPAG2CAT	Other / Cross Page		EXAM.SBPAG2CAT = 4 AND VISITID = 10	Stage 2 hypertension (systolic or diastolic blood pressure) >140/90 for subjects >13 years of age. Please review and confirm. If confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619255	SYSQ_5088	EXAM.DBPAG1CAT	Other / Cross Page		EXAM.DBPAG1CAT = 4 AND VISITID = 10	Stage 2 hypertension (systolic or diastolic blood pressure > 95th percentile for age, sex and height percentile + 12 mmHg or >140/90, whichever is lower for subjects <13 years of age; is an exclusion violation. Please review and confirm. If confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0

System Queries														
sysq-619258	SYSQ_5089	EXAM.DBPAG2CAT	Other / Cross Page		EXAM.DBPAG2CAT = 3 AND VISITID = 10	Stage 2 hypertension (systolic or diastolic blood pressure) >140/90 for subjects >13 years of age. Please review and confirm. If confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619259	SYSQ_5090	EXAM.SYS_BP1	Range		EXAM.SYS_BP1 < 70 OR EXAM.SYS_BP1 > 220	"B1f. Systolic Blood Pressure 1" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619262	SYSQ_5091	EXAM.DYA_BP1	Range		EXAM.DYA_BP1 < 20 OR EXAM.DYA_BP1 > 175	"B1g. Diastolic Blood Pressure 1" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619263	SYSQ_5092	EXAM.SYS_BP2	Range		EXAM.SYS_BP2 < 70 OR EXAM.SYS_BP2 > 220	"B1h. Systolic Blood Pressure 2" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:21	0	0	0	0	0	0
sysq-619266	SYSQ_5093	EXAM.DYA_BP2	Range		EXAM.DYA_BP2 < 20 OR EXAM.DYA_BP2 > 175	"B1i. Diastolic Blood Pressure 2" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619267	SYSQ_5094	EXAM.SYS_BP3	Range		EXAM.SYS_BP3 < 70 OR EXAM.SYS_BP3 > 220	"B1j. Systolic Blood Pressure 3" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619269	SYSQ_5095	EXAM.DYA_BP3	Range		EXAM.DYA_BP3 < 20 OR EXAM.DYA_BP3 > 175	"B1k. Diastolic Blood Pressure 3" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619604	SYSQ_5331	EXAM.ANTHROP	Other / Cross Page		EXAM.ANTHROP = 0 AND (VISITID = 20 OR VISITID = 40 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90)	Anthropometry is required at this visit. If not done, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0

System Queries														
sysq-619606	SYSQ_5332	EXAM.VITALSYN	Other / Cross Page		EXAM.VITALSYN = 0 AND (VISITID = 20 OR VISITID = 40 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90)	Blood Pressure Measurements are required at this visit. If not done, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-620485	SYSQ_5886	EXAM.BMIPCT	Other / Cross Page	Protocol 5.0 updates	(10-20-ICF.ICFPROTV < 5 AND EXAM.BMIPCT < 95 AND VISITID = 10) OR (10-20-ICF.ICFPROTV = 5 AND EXAM.BMIPCT < 85 AND VISITID = 10)	BMI Percentile does not meet inclusion criteria. Please confirm and if confirmed, subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

pFBIT

Page

(Visit ID = 618784, Page ID =)

Unique Identifier page-618784-618784-618784-

Fitbit Data Recordings

* A1. Was the Fitbit worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit?	○ Yes ○ No	FBIT.FBITYN

Access the Fitbit application or your web account to obtain the following data points.

For each data point, record the average of 7 days.

* A2. Resting heart rate (bpm)		FBIT.FBHR	(format xxx)
* A3. Fitness score		FBIT.FBFITSCR	(format xx.x)
* A4. Daily steps		FBIT.FBSTEPS	(format xxxxxxx)
* A5. Number of days of exercise /7		FBIT.FBEXDAYS	(format x.x)

Daily time in exercise zones

	Hours		*Minutes*	
A6a. fat burn	(xx) FBIT.FBFATHRS		(xx) FBIT.FBFATMIN	
A6b. cardio	(xx) FBIT.FBCARDHRS		(xx) FBIT.FBCARDMIN	
A6c. peak	(xx) FBIT.FBPEAKHRS		(xx) FBIT.FBPEAKMIN	

Sleep and Bedtime

	Hours		*Minutes*	
A7. Average sleep time / 7	(xx) FBIT.FBSLPHRS		(xx) FBIT.FBSLPMIN	
A8. Average bedtime (week, weekend)	: (HH24:MI) FBIT.FBBEDTIM			

Page Information														
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618784	Section Header	0	Fitbit Data Recordings											
Page-2-618784	Radiolist Horizontal	0	A1. Was the Fitbit worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit?	FBIT.FBITYN					cYN					
Page-3-618784	Help Text Line	0	Access the Fitbit application or your web account to obtain the following data points. For each data point, record the <u>average of 7 days</u>.											
Page-4-618784	Numeric	0	A2. Resting heart rate (bpm)	FBIT.FBHR								3	0	
Page-5-618784	Numeric	0	A3. Fitness score	FBIT.FBFITSCR								2	1	
Page-6-618784	Numeric	0	A4. Daily steps	FBIT.FBSTEPS								7	0	
Page-7-618784	Numeric	0	A5. Number of days of exercise /7	FBIT.FBEXDAYS								1	1	
Page-8-618784	Section Header	0	Daily time in exercise zones											
Page-9-618784	Row Start/End	0												
Page-10-618784	Help Text Line	0												
Page-11-618784	Help Text Line	0	Hours											
Page-12-618784	Help Text Line	0	Minutes											

Page Information														
Page-13-618784	Row Start/End	0												
Page-14-618784	Row Start/End	0												
Page-15-618784	Help Text Line	0	A6a. fat burn											
Page-16-618784	Numeric	0	Hours	FBIT.FBFATHRS								2	0	
Page-17-618784	Numeric	0	Minutes	FBIT.FBFATMIN								2	0	
Page-18-618784	Row Start/End	0												
Page-19-618784	Row Start/End	0												
Page-20-618784	Help Text Line	0	A6b.cardio											
Page-21-618784	Numeric	0	Hours	FBIT.FBCARDHRS								2	0	
Page-22-618784	Numeric	0	Minutes	FBIT.FBCARDMIN								2	0	
Page-23-618784	Row Start/End	0												
Page-24-618784	Row Start/End	0												
Page-25-618784	Help Text Line	1	A6c.peak											
Page-26-618784	Numeric	0	Hours	FBIT.FBPEAKHRS								2	0	
Page-27-618784	Numeric	0	Minutes	FBIT.FBPEAKMIN								2	0	

Page Information														
Page-28-618784	Row Start/End	0												
Page-29-618784	Section Header	0	Sleep and Bedtime											
Page-30-618784	Row Start/End	0												
Page-31-618784	Help Text Line	0	 											
Page-32-618784	Help Text Line	0	Hours											
Page-33-618784	Help Text Line	0	Minutes											
Page-34-618784	Row Start/End	0												
Page-35-618784	Row Start/End	0												
Page-36-618784	Help Text Line	0	A7. Average sleep time / 7											
Page-37-618784	Numeric	1	A7a. Hours	FBIT.FBSLPHRS								2	0	Sleep time in "Hours"
Page-38-618784	Numeric	1	A7b. Minutes	FBIT.FBSLPMIN								2	0	Sleep time in "Minutes"
Page-39-618784	Row Start/End	0												
Page-40-618784	Row Start/End	0												
Page-41-618784	Help Text Line	0	A8. Average bedtime (week, weekend)											
Page-42-618784	Time	0	A8. Average bedtime (week, weekend)	FBIT.FBBEDTIM										

Page Information														
Page-43-618784	Help Text Line	0												
Page-44-618784	Row Start/End	0												

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619575	SYSQ_5316	FBIT.FBITYN	Field Null		FBIT.FBITYN IS NULL	"A1. Was the Fitbit worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619577	SYSQ_5317	FBIT.FBHR	Field Null		FBIT.FBHR IS NULL	"A2. Resting heart rate (bpm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619579	SYSQ_5318	FBIT.FBHR	Range		FBIT.FBHR < 60 OR FBIT.FBHR > 100	"A2. Resting heart rate (bpm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619580	SYSQ_5319	FBIT.FBFITSCR	Field Null		FBIT.FBFITSCR IS NULL	"A3. Fitness score" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619582	SYSQ_5320	FBIT.FBSTEPS	Field Null		FBIT.FBSTEPS IS NULL	"A4. Daily steps" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619585	SYSQ_5321	FBIT.FBEXDAYS	Field Null		FBIT.FBEXDAYS IS NULL	"A5. Number of days of exercise /7" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619586	SYSQ_5322	FBIT.FBFATHRS	Field Null		FBIT.FBFATHRS IS NULL	"Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619589	SYSQ_5323	FBIT.FBFATMIN	Field Null		FBIT.FBFATMIN IS NULL	"Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0

System Queries														
sysq-619591	SYSQ_5324	FBIT.FBCARDHRS	Field Null		FBIT.FBCARDHRS IS NULL	"Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619593	SYSQ_5325	FBIT.FBCARDMIN	Field Null		FBIT.FBCARDMIN IS NULL	"Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619595	SYSQ_5326	FBIT.FBPEAKHRS	Field Null		FBIT.FBPEAKHRS IS NULL	"Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619596	SYSQ_5327	FBIT.FBPEAKMIN	Field Null		FBIT.FBPEAKMIN IS NULL	"Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619599	SYSQ_5328	FBIT.FBSLPHRS	Field Null		FBIT.FBSLPHRS IS NULL	"A7a. Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619600	SYSQ_5329	FBIT.FBSLPMIN	Field Null		FBIT.FBSLPMIN IS NULL	"A7b. Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619603	SYSQ_5330	FBIT.FBBEDTIM	Field Null		FBIT.FBBEDTIM IS NULL	"A8. Average bedtime (week, weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0

pFBIT_2

Page

(Visit ID = 618785, Page ID =)

Unique Identifier page-618785-618785-618785-

Fitbit Data Recordings			
* A1. Was the Fitbit worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit?	○ Yes ○ No	FBIT.FBITYN	
* A1a. Was adequate data able to be obtained from the Fitbit?	○ Yes ○ No	FBIT.FBDATAYN	
* A1b. If No, specify the reason(s):		FBIT.FBDNOREAS	
Access the Fitbit application or your web account to obtain the following data points. *For each data point, record the average of 7 days.*			
* A2. Resting heart rate (bpm)		FBIT.FBHR	(format xxx)
* A3. Fitness score		FBIT.FBFITSCR	(format xx.x)
* A4. Daily steps		FBIT.FBSTEPS	(format xxxxxxx)
* A5. Number of days of exercise /7		FBIT.FBEXDAYS	(format x.x)

Daily time in exercise zones

	Hours		*Minutes*	
A6a. fat burn		(xx) FBIT.FBFATHRS		(xx) FBIT.FBFATMIN
A6b. cardio		(xx) FBIT.FBCARDHRS		(xx) FBIT.FBCARDMIN
A6c. peak		(xx) FBIT.FBPEAKHRS		(xx) FBIT.FBPEAKMIN

Sleep and Bedtime

	Hours		Minutes	
A7. Average sleep time / 7		(xx)		(xx)
	FBIT.FBSLPHRS		FBIT.FBSLPMIN	
A8. Average bedtime (week, weekend)	:	(HH24:MI)		
	FBIT.FBBEDTIM			

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618785	Section Header	0	Fitbit Data Recordings											
Page-2-618785	Radiolist Horizontal	0	A1. Was the Fitbit worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit?	FBIT.FBITYN					cYN					
Page-3-618785	Radiolist Horizontal	1	A1a. Was adequate data able to be obtained from the Fitbit?	FBIT.FBDATAYN					cYN					
-- Page Dynamics (FBIT. FBDATAYN): Show When: FBIT.FBITYN = 1														
Page-4-618785	Text Field	1	A1b. If No, specify the reason(s):	FBIT.FBDNOREAS						200	99			
-- Page Dynamics (FBIT. FBDNOREAS): Show When: FBIT.FBITYN = 0 OR FBIT.FBDATAYN = 0														
Page-5-618785	Help Text Line	0	Access the Fitbit application or your web account to obtain the following data points. For each data point, record the <u>average of 7 days</u>.											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-6-618785	Numeric	0	A2. Resting heart rate (bpm)	FBIT.FBHR								3	0	
-- Page Dynamics (FBIT. FBHR): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-7-618785	Numeric	0	A3. Fitness score	FBIT.FBFITSCR								2	1	

Page Information														
-- Page Dynamics (FBIT. FBFITSCR): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-8-618785	Numeric	0	A4. Daily steps	FBIT.FBSTEPS								7	0	
-- Page Dynamics (FBIT. FBSTEPS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-9-618785	Numeric	0	A5. Number of days of exercise /7	FBIT.FBEXDAYS								1	1	
-- Page Dynamics (FBIT. FBEXDAYS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-10-618785	Section Header	0	Daily time in exercise zones											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-11-618785	Row Start/End	0												
Page-12-618785	Help Text Line	0												
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-13-618785	Help Text Line	0	Hours											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-14-618785	Help Text Line	0	Minutes											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-15-618785	Row Start/End	0												
Page-16-618785	Row Start/End	0												
Page-17-618785	Help Text Line	0	A6a. fat burn											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														

Page Information														
Page-18-618785	Numeric	0	Hours	FBIT.FBFATHRS								2	0	
-- Page Dynamics (FBIT. FBFATHRS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-19-618785	Numeric	0	Minutes	FBIT.FBFATMIN								2	0	
-- Page Dynamics (FBIT. FBFATMIN): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-20-618785	Row Start/End	0												
Page-21-618785	Row Start/End	0												
Page-22-618785	Help Text Line	0	A6b.cardio											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-23-618785	Numeric	0	Hours	FBIT.FBCARDHRS								2	0	
-- Page Dynamics (FBIT. FBCARDHRS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-24-618785	Numeric	0	Minutes	FBIT.FBCARDMIN								2	0	
-- Page Dynamics (FBIT. FBCARDMIN): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-25-618785	Row Start/End	0												
Page-26-618785	Row Start/End	0												
Page-27-618785	Help Text Line	1	A6c.peak											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-28-618785	Numeric	0	Hours	FBIT.FBPEAKHRS								2	0	
-- Page Dynamics (FBIT. FBPEAKHRS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														

Page Information														
Page-29-618785	Numeric	0	Minutes	FBIT.FBPEAKMIN								2	0	
-- Page Dynamics (FBIT. FBPEAKMIN): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-30-618785	Row Start/End	0												
Page-31-618785	Section Header	0	Sleep and Bedtime											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-32-618785	Row Start/End	0												
Page-33-618785	Help Text Line	0	 											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-34-618785	Help Text Line	0	Hours											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-35-618785	Help Text Line	0	Minutes											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-36-618785	Row Start/End	0												
Page-37-618785	Row Start/End	0												
Page-38-618785	Help Text Line	0	A7. Average sleep time / 7											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-39-618785	Numeric	1	A7a. Hours	FBIT.FBSLPHRS								2	0	Sleep time in "Hours"
-- Page Dynamics (FBIT. FBSLPHRS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														

Page Information														
Page-40-618785	Numeric	1	A7b. Minutes	FBIT.FBSLPMIN								2	0	Sleep time in "Minutes"
-- Page Dynamics (FBIT. FBSLPMIN): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-41-618785	Row Start/End	0												
Page-42-618785	Row Start/End	0												
Page-43-618785	Help Text Line	0	A8. Average bedtime (week, weekend)											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-44-618785	Time	0	A8. Average bedtime (week, weekend)	FBIT.FBBEDTIM										
-- Page Dynamics (FBIT. FBBEDTIM): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-45-618785	Help Text Line	0												
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-46-618785	Row Start/End	0												

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619574	SYSQ_5316	FBIT.FBITYN	Field Null		FBIT.FBITYN IS NULL	"A1. Was the Fitbit worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619576	SYSQ_5317	FBIT.FBHR	Field Null		FBIT.FBHR IS NULL	"A2. Resting heart rate (bpm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619578	SYSQ_5318	FBIT.FBHR	Range		FBIT.FBHR < 60 OR FBIT.FBHR > 100	"A2. Resting heart rate (bpm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0

System Queries														
sysq-619581	SYSQ_5319	FBIT.FBFITSCR	Field Null		FBIT.FBFITSCR IS NULL	"A3. Fitness score" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619583	SYSQ_5320	FBIT.FBSTEPS	Field Null		FBIT.FBSTEPS IS NULL	"A4. Daily steps" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619584	SYSQ_5321	FBIT.FBEXDAYS	Field Null		FBIT.FBEXDAYS IS NULL	"A5. Number of days of exercise /7" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619587	SYSQ_5322	FBIT.FBFATHRS	Field Null		FBIT.FBFATHRS IS NULL	"Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619588	SYSQ_5323	FBIT.FBFATMIN	Field Null		FBIT.FBFATMIN IS NULL	"Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619590	SYSQ_5324	FBIT.FBCARDHRS	Field Null		FBIT.FBCARDHRS IS NULL	"Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619592	SYSQ_5325	FBIT.FBCARDMIN	Field Null		FBIT.FBCARDMIN IS NULL	"Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619594	SYSQ_5326	FBIT.FBPEAKHRS	Field Null		FBIT.FBPEAKHRS IS NULL	"Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619597	SYSQ_5327	FBIT.FBPEAKMIN	Field Null		FBIT.FBPEAKMIN IS NULL	"Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619598	SYSQ_5328	FBIT.FBSLPHRS	Field Null		FBIT.FBSLPHRS IS NULL	"A7a. Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0

System Queries														
sysq-619601	SYSQ_5329	FBIT.FBSLPMIN	Field Null		FBIT.FBSLPMIN IS NULL	"A7b. Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619602	SYSQ_5330	FBIT.FBBEDTIM	Field Null		FBIT.FBBEDTIM IS NULL	"A8. Average bedtime (week, weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-620431	SYSQ_5844	FBIT.FBDATAYN	Field Null		FBIT.FBDATAYN IS NULL	"A1a. Was adequate data able to be obtained from the Fitbit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620432	SYSQ_5845	FBIT.FBDNOREAS	Field Null		FBIT.FBDNOREAS IS NULL	"A1b. If No, specify the reason(s):" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0

pFBIT_8

Page

(Visit ID = 627101, Page ID =)

Unique Identifier page-627101-627101-627101-

Fitbit Data Recordings

* A1. Was the Fitbit worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit?	○ Yes ○ No	FBIT.FBITYN
* A1a. Was adequate data able to be obtained from the Fitbit?	○ Yes ○ No	FBIT.FBDATAYN
* A1b. If No, specify the reason(s):		FBIT.FBDNOREAS

Access the Fitbit application or your web account to obtain the following data points.

For each data point, record the average of 7 days.

* A2. Resting heart rate (bpm)	FBIT.FBHR	(format xxx)
A3a. Fitness Score 1	FBIT.FBFITSCR1	(format xx.x)
A3b. Fitness Score 2	FBIT.FBFITSCR2	(format xx.x)
* A4. Daily steps	FBIT.FBSTEPS	(format xxxxxxx)
* A5. Number of days of exercise /7	FBIT.FBEXDAYS	(format x.x)

Daily time in exercise zones

	Hours	*Minutes*
A6a. fat burn	(xx) FBIT.FBFATHRS	(xx) FBIT.FBFATMIN
A6b. cardio	(xx) FBIT.FBCARDHRS	(xx) FBIT.FBCARDMIN
A6c. peak	(xx) FBIT.FBPEAKHRS	(xx) FBIT.FBPEAKMIN

Sleep and Bedtime

	Hours	*Minutes*
A7. Average sleep time / 7	(xx) FBIT.FBSLPHRS	(xx) FBIT.FBSLPMIN

A8. Bedtime (week, weekend)

A8a. Monday Bedtime		FBIT.BEDMON	(HH24:MI)
A8b. Tuesday Bedtime		FBIT.BEDTUES	(HH24:MI)
A8c. Wednesday Bedtime		FBIT.BEDWED	(HH24:MI)
A8d. Thursday Bedtime		FBIT.BEDTHURS	(HH24:MI)
A8e. Friday Bedtime		FBIT.BEDFRI	(HH24:MI)
A8f. Saturday Bedtime		FBIT.BEDSAT	(HH24:MI)
A8g. Sunday Bedtime		FBIT.BEDSUN	(HH24:MI)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-627101	Section Header	0	Fitbit Data Recordings											
Page-2-627101	Radiolist Horizontal	0	A1. Was the Fitbit worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit?	FBIT.FBITYN					cYN					
Page-3-627101	Radiolist Horizontal	0	A1a. Was adequate data able to be obtained from the Fitbit?	FBIT.FBDATAYN					cYN					
-- Page Dynamics (FBIT. FBDATAYN): Show When: FBIT.FBITYN = 1														
Page-4-627101	Text Field	0	A1b. If No, specify the reason(s):	FBIT.FBDNOREAS						200	99			
-- Page Dynamics (FBIT. FBDNOREAS): Show When: FBIT.FBITYN = 0 OR FBIT.FBDATAYN = 0														
Page-5-627101	Help Text Line	0	Access the Fitbit application or your web account to obtain the following data points. For each data point, record the <u>average of 7 days</u>.											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														

Page Information														
Page-6-627101	Numeric	0	A2. Resting heart rate (bpm)	FBIT.FBHR								3	0	
-- Page Dynamics (FBIT. FBHR): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-7-627101	Numeric	1	A3a. Fitness Score 1	FBIT.FBFITSCR1								2	1	
Page-8-627101	Numeric	1	A3b. Fitness Score 2	FBIT.FBFITSCR2								2	1	
Page-9-627101	Numeric	0	A4. Daily steps	FBIT.FBSTEPS								7	0	
-- Page Dynamics (FBIT. FBSTEPS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-10-627101	Numeric	0	A5. Number of days of exercise /7	FBIT.FBEXDAYS								1	1	
-- Page Dynamics (FBIT. FBEXDAYS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-11-627101	Section Header	0	Daily time in exercise zones											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-12-627101	Row Start/End	0												
Page-13-627101	Help Text Line	0												
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-14-627101	Help Text Line	0	Hours											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-15-627101	Help Text Line	0	Minutes											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-16-627101	Row Start/End	0												

Page Information														
Page-17-627101	Row Start/End	0												
Page-18-627101	Help Text Line	0	A6a. fat burn											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-19-627101	Numeric	0	Hours	FBIT.FBFATHRS								2	0	
-- Page Dynamics (FBIT. FBFATHRS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-20-627101	Numeric	0	Minutes	FBIT.FBFATMIN								2	0	
-- Page Dynamics (FBIT. FBFATMIN): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-21-627101	Row Start/End	0												
Page-22-627101	Row Start/End	0												
Page-23-627101	Help Text Line	0	A6b.cardio											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-24-627101	Numeric	0	Hours	FBIT.FBCARDHRS								2	0	
-- Page Dynamics (FBIT. FBCARDHRS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-25-627101	Numeric	0	Minutes	FBIT.FBCARDMIN								2	0	
-- Page Dynamics (FBIT. FBCARDMIN): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-26-627101	Row Start/End	0												
Page-27-627101	Row Start/End	0												

Page Information														
Page-28-627101	Help Text Line	1	A6c.peak											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-29-627101	Numeric	0	Hours	FBIT.FBPEAKHRS								2	0	
-- Page Dynamics (FBIT. FBPEAKHRS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-30-627101	Numeric	0	Minutes	FBIT.FBPEAKMIN								2	0	
-- Page Dynamics (FBIT. FBPEAKMIN): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-31-627101	Row Start/End	0												
Page-32-627101	Section Header	0	Sleep and Bedtime											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-33-627101	Row Start/End	0												
Page-34-627101	Help Text Line	0	 											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-35-627101	Help Text Line	0	Hours											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-36-627101	Help Text Line	0	Minutes											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-37-627101	Row Start/End	0												
Page-38-627101	Row Start/End	0												

Page Information														
Page-39-627101	Help Text Line	0	A7. Average sleep time / 7											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-40-627101	Numeric	1	A7a. Hours	FBIT.FBSLPHRS								2	0	Sleep time in "Hours"
-- Page Dynamics (FBIT. FBSLPHRS): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-41-627101	Numeric	1	A7b. Minutes	FBIT.FBSLPMIN								2	0	Sleep time in "Minutes"
-- Page Dynamics (FBIT. FBSLPMIN): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-42-627101	Row Start/End	0												
Page-43-627101	Help Text Line	0	A8. Bedtime (week, weekend)											
-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)														
Page-44-627101	Time	0	A8a. Monday Bedtime	FBIT.BEDMON										
Page-45-627101	Time	0	A8b. Tuesday Bedtime	FBIT.BEDTUES										
Page-46-627101	Time	0	A8c. Wednesday Bedtime	FBIT.BEDWED										
Page-47-627101	Time	0	A8d. Thursday Bedtime	FBIT.BEDTHURS										
Page-48-627101	Time	0	A8e. Friday Bedtime	FBIT.BEDFRI										
Page-49-627101	Time	0	A8f. Saturday Bedtime	FBIT.BEDSAT										
Page-50-627101	Time	0	A8g. Sunday Bedtime	FBIT.BEDSUN										
Page-51-627101	Help Text Line	0												

Page Information

-- Page Dynamics (.): Show When: (FBIT.FBITYN = 1 AND FBIT.FBDATAYN = 1) OR (FBIT.FBITYN = 1 AND FBIT.FBDATAYN IS NULL) OR (FBIT.FBITYN IS NULL AND FBIT.FBDATAYN IS NULL)

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-627102	SYSQ_5316	FBIT.FBITYN	Field Null		FBIT.FBITYN IS NULL	"A1. Was the Fitbit worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627103	SYSQ_5317	FBIT.FBHR	Field Null		FBIT.FBHR IS NULL	"A2. Resting heart rate (bpm)" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627104	SYSQ_5318	FBIT.FBHR	Range		FBIT.FBHR < 60 OR FBIT.FBHR > 100	"A2. Resting heart rate (bpm)" is not within expected range. Please confirm.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627105	SYSQ_5319	.	Field Null		FBIT.FBFITSCR IS NULL	"A3. Fitness score" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627106	SYSQ_5320	FBIT.FBSTEPS	Field Null		FBIT.FBSTEPS IS NULL	"A4. Daily steps" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627107	SYSQ_5321	FBIT.FBEXDAYS	Field Null		FBIT.FBEXDAYS IS NULL	"A5. Number of days of exercise /7" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627108	SYSQ_5322	FBIT.FBFATHRS	Field Null		FBIT.FBFATHRS IS NULL	"Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627109	SYSQ_5323	FBIT.FBFATMIN	Field Null		FBIT.FBFATMIN IS NULL	"Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627110	SYSQ_5324	FBIT.FBCARDHRS	Field Null		FBIT.FBCARDHRS IS NULL	"Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0

System Queries														
sysq-627111	SYSQ_5325	FBIT.FBCARDMIN	Field Null		FBIT.FBCARDMIN IS NULL	"Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627112	SYSQ_5326	FBIT.FBPEAKHRS	Field Null		FBIT.FBPEAKHRS IS NULL	"Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627113	SYSQ_5327	FBIT.FBPEAKMIN	Field Null		FBIT.FBPEAKMIN IS NULL	"Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627114	SYSQ_5328	FBIT.FBSLPHRS	Field Null		FBIT.FBSLPHRS IS NULL	"A7a. Hours" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627115	SYSQ_5329	FBIT.FBSLPMIN	Field Null		FBIT.FBSLPMIN IS NULL	"A7b. Minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627116	SYSQ_5330	.	Field Null		FBIT.FBBEDTIM IS NULL	"A8. Average bedtime (week, weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627117	SYSQ_5844	FBIT.FBDATAYN	Field Null		FBIT.FBDATAYN IS NULL	"A1a. Was adequate data able to be obtained from the Fitbit?" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0
sysq-627118	SYSQ_5845	FBIT.FBDNOREAS	Field Null		FBIT.FBDNOREAS IS NULL	"A1b. If No, specify the reason(s):" cannot be empty.	Yes	Horng, Dunstan [DES] 12-OCT-20 15:03:16	0	0	0	0	0	0

pICF

Page

(Visit ID = 618786, Page ID =)

Unique Identifier page-618786-618786-618786-

SECTION A: Informed Consent			
SDV	* A1. Was the informed consent form (ICF) signed for screening and potential enrollment in Dyslipidemia of Obesity Intervention study?	○ Yes ○ No	ICF.ICF_YN
SDV	* A1a. Protocol version		ICF.ICFPROTV (format xx.x)
SDV	* A1b. Informed consent was signed by:	○ Patient ○ Parent ○ Legal guardian	ICF.ICF_WHO
SDV	* A1c. Date informed consent signed:		ICF.ICF_DT
SECTION B: Informed Assent			
SDV	* B1. Did the patient sign the informed assent?	○ Yes ○ No	ICF.ASSENT
SDV	* B1a. Date assent signed		ICF.ASSENT_DT
SECTION C: Repository Consent:			
SDV	* C1. Did the patient, parent or legal guardian consent to blood sample collection for DNA analysis?	○ Yes ○ No	ICF.DNA_CON
SDV	* C1a. If yes, Date of consent:		ICF.DNA_CON_DT
SDV	* C2. Did the patient, parent or legal guardian consent to the plasma/serum banking samples for future analysis?	○ Yes ○ No	ICF.BLOOD_CON
SDV	* C2a. If yes, Date of consent:		ICF.BLOOD_CON_DT
SDV	* C3. Did the patient, parent or legal guardian consent to the Urine banking samples for future analyses?	○ Yes ○ No	ICF.URINE_CON
SDV	* C3a. If yes, Date of consent:		ICF.URINE_CON_DT
	IF participant consent is "No" OR both parental/guardian consent and participant assent are "No", Please contact the DCC as Subject is not eligible.		

Page Information														
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618786	Section Header	0	SECTION A: Informed Consent											
Page-2-618786	Radiolist Horizontal	0	A1. Was the informed consent form (ICF) signed for screening and potential enrollment in Dyslipidemia of Obesity Intervention study?	ICF. ICF_YN	Yes				cYN					
Page-3-618786	Numeric	1	A1a. Protocol version	ICF. ICFPROTV	Yes							2	1	Enter the Protocol Version which was in effect when the informed consent and assent (if applicable) were signed.
-- Page Dynamics (ICF. ICFPROTV): Show When: ICF.ICF_YN = 1														
Page-4-618786	Radiolist Horizontal	1	A1b. Informed consent was signed by:	ICF. ICF_WHO	Yes				cICF_Signer					If Patient, Parent or Legal guardian sign the informed consent, collection of Demographic, Birth Date and Diagnosis information can occur.
-- Page Dynamics (ICF. ICF_WHO): Show When: ICF.ICF_YN = 1														
Page-5-618786	Date	1	A1c. Date informed consent signed:	ICF. ICF_DT	Yes									
-- Page Dynamics (ICF. ICF_DT): Show When: ICF.ICF_YN = 1														
Page-6-618786	Section Header	0	SECTION B: Informed Assent											
-- Page Dynamics (.): Show When: ICF.ICF_WHO = 2 OR ICF.ICF_WHO = 3														
Page-7-618786	Radiolist Horizontal	0	B1. Did the patient sign the informed assent?	ICF. ASSENT	Yes				cYN					
-- Page Dynamics (ICF. ASSENT): Show When: ICF.ICF_WHO = 2 OR ICF.ICF_WHO = 3														
Page-8-618786	Date	1	B1a. Date assent signed	ICF. ASSENT_DT	Yes									
-- Page Dynamics (ICF. ASSENT_DT): Show When: (ICF.ICF_WHO = 2 OR ICF.ICF_WHO = 3) AND ICF.ASSENT = 1														

Page Information														
Page-9-618786	Section Header	0	SECTION C: Repository Consent:											
Page-10-618786	Radiolist Horizontal	0	C1. Did the patient, parent or legal guardian consent to blood sample collection for DNA analysis?	ICF.DNA_CON	Yes				cYN					
Page-11-618786	Date	1	C1a. If yes, Date of consent:	ICF.DNA_CON_DT	Yes									
-- Page Dynamics (ICF. DNA_CON_DT): Show When: ICF.DNA_CON = 1														
Page-12-618786	Radiolist Horizontal	0	C2. Did the patient, parent or legal guardian consent to the plasma/serum banking samples for future analysis?	ICF.BLOOD_CON	Yes				cYN					
Page-13-618786	Date	1	C2a. If yes, Date of consent:	ICF.BLOOD_CON_DT	Yes									
-- Page Dynamics (ICF. BLOOD_CON_DT): Show When: ICF.BLOOD_CON = 1														
Page-14-618786	Radiolist Horizontal	0	C3. Did the patient, parent or legal guardian consent to the Urine banking samples for future analyses?	ICF.URINE_CON	Yes				cYN					
Page-15-618786	Date	1	C3a. If yes, Date of consent:	ICF.URINE_CON_DT	Yes									
-- Page Dynamics (ICF. URINE_CON_DT): Show When: ICF.URINE_CON = 1														
Page-16-618786	Help Text Line	0	IF participant consent is "No" OR both parental/guardian consent and participant assent are "No", Please contact the DCC as Subject is not eligible.											

System Queries													
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618903	SYSQ_4907	ICF.ICF_YN	Other / Cross Page		ICF.ASSENT = 0 OR ICF.ICF_YN = 0	Participant consent OR parental/guardian consent and participant assent is required. If not obtained, the participant is not eligible to participate in this study. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0

System Queries														
sysq-619043	SYSQ_4997	ICF.ICF_YN	Field Null		ICF.ICF_YN IS NULL	"A1. Was the informed consent form (ICF) signed for screening and potential enrollment in Dyslipidemia of Obesity Intervention study?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619046	SYSQ_4998	ICF.ICFPROTV	Field Null		ICF.ICFPROTV IS NULL	"A1a. Protocol version" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619048	SYSQ_4999	ICF.ICF_WHO	Field Null		ICF.ICF_WHO IS NULL	"A1b. Informed consent was signed by:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619050	SYSQ_5000	ICF.ICF_DT	Field Null		ICF.ICF_DT IS NULL	"A1c. Date informed consent signed:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619051	SYSQ_5001	ICF.ICF_DT	Future Date		ICF.ICF_DT > Today	"A1c. Date informed consent signed:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619053	SYSQ_5002	ICF.ASSENT	Field Null		ICF.ASSENT IS NULL	"B1. Did the patient sign the informed assent?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619056	SYSQ_5003	ICF.ASSENT_DT	Field Null		ICF.ASSENT_DT IS NULL	"B1a. Date assent signed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619057	SYSQ_5004	ICF.ASSENT_DT	Future Date		ICF.ASSENT_DT > Today	"B1a. Date assent signed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619060	SYSQ_5005	ICF.DNA_CON	Field Null		ICF.DNA_CON IS NULL	"C1. Did the patient, parent or legal guardian consent to blood sample collection for DNA analysis?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619061	SYSQ_5006	ICF.DNA_CON_DT	Field Null		ICF.DNA_CON_DT IS NULL	"C1a. If yes, Date of consent:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0

System Queries														
sysq-619064	SYSQ_5007	ICF.DNA_CON_DT	Future Date		ICF.DNA_CON_DT > Today	"C1a. If yes, Date of consent:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619066	SYSQ_5008	ICF.BLOOD_CON	Field Null		ICF.BLOOD_CON IS NULL	"C2. Did the patient, parent or legal guardian consent to the plasma/serum banking samples for future analysis?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619067	SYSQ_5009	ICF.BLOOD_CON_DT	Field Null		ICF.BLOOD_CON_DT IS NULL	"C2a. If yes, Date of consent:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619069	SYSQ_5010	ICF.BLOOD_CON_DT	Future Date		ICF.BLOOD_CON_DT > Today	"C2a. If yes, Date of consent:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619071	SYSQ_5011	ICF.URINE_CON	Field Null		ICF.URINE_CON IS NULL	"C3. Did the patient, parent or legal guardian consent to the Urine banking samples for future analyses?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619073	SYSQ_5012	ICF.URINE_CON_DT	Field Null		ICF.URINE_CON_DT IS NULL	"C3a. If yes, Date of consent:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619076	SYSQ_5013	ICF.URINE_CON_DT	Future Date		ICF.URINE_CON_DT > Today	"C3a. If yes, Date of consent:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0

pICF_3

Page

(Visit ID = 618787, Page ID =)

Unique Identifier page-618787-618787-618787-

SECTION A: Informed Consent			
SDV	* A1. Was the informed consent form (ICF) signed for screening and potential enrollment in Dyslipidemia of Obesity Intervention study?	○ Yes ○ No	ICF.ICF_YN
SDV	* A1a. Protocol version		ICF.ICFPROTV (format xx.x)
SDV	* A1b. Informed consent was signed by:	○ Patient ○ Parent ○ Legal guardian	ICF.ICF_WHO
SDV	* A1c. Date informed consent signed:		ICF.ICF_DT
SECTION B: Informed Assent			
SDV	* B1. Did the patient sign the informed assent?	○ Yes ○ No	ICF.ASSENT
SDV	* B1a. Date assent signed		ICF.ASSENT_DT
SECTION C: Repository Consent:			
SDV	* C1. Did the patient, parent or legal guardian consent to blood sample collection for DNA analysis?	○ Yes ○ No	ICF.DNA_CON
SDV	* C1a. If yes, Date of consent:		ICF.DNA_CON_DT
SDV	* C2. Did the patient, parent or legal guardian consent to the plasma/serum banking samples for future analysis?	○ Yes ○ No	ICF.BLOOD_CON
SDV	* C2a. If yes, Date of consent:		ICF.BLOOD_CON_DT
SDV	* C3. Did the patient, parent or legal guardian consent to the Urine banking samples for future analyses?	○ Yes ○ No	ICF.URINE_CON
SDV	* C3a. If yes, Date of consent:		ICF.URINE_CON_DT
	IF participant consent is "No" OR both parental/guardian consent and participant assent are "No", Please contact the DCC as Subject is not eligible.		
Section D: Re-Screening (if Applicable)			

SDV	D1. Check if participant was previously screened for the DO-IT Study and failed eligibility criteria. Note: This only applies to participants who were previously consented and entered into eCOS.	☐	ICF.PRIORSCRN
SDV	* D1a. Enter the DO-IT Subject ID (xxx-xxx) from the previous screening.		ICF.PRIORSUBID

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618787	Section Header	0	SECTION A: Informed Consent											
Page-2-618787	Radiolist Horizontal	0	A1. Was the informed consent form (ICF) signed for screening and potential enrollment in Dyslipidemia of Obesity Intervention study?	ICF.ICF_YN	Yes				cYN					
Page-3-618787	Numeric	1	A1a. Protocol version	ICF.ICFPROTV	Yes							2	1	Enter the Protocol Version which was in effect when the informed consent and assent (if applicable) were signed.
-- Page Dynamics (ICF. ICFPROTV): Show When: ICF.ICF_YN = 1														
Page-4-618787	Radiolist Horizontal	1	A1b. Informed consent was signed by:	ICF.ICF_WHO	Yes				cICF_Signer					If Patient, Parent or Legal guardian sign the informed consent, collection of Demographic, Birth Date and Diagnosis information can occur.
-- Page Dynamics (ICF. ICF_WHO): Show When: ICF.ICF_YN = 1														
Page-5-618787	Date	1	A1c. Date informed consent signed:	ICF.ICF_DT	Yes									

Page Information														
-- Page Dynamics (ICF. ICF_DT): Show When: ICF.ICF_YN = 1														
Page-6-618787	Section Header	0	SECTION B: Informed Assent											
-- Page Dynamics (.): Show When: ICF.ICF_WHO = 2 OR ICF.ICF_WHO = 3														
Page-7-618787	Radiolist Horizontal	0	B1. Did the patient sign the informed assent?	ICF.ASSENT	Yes				cYN					
-- Page Dynamics (ICF. ASSENT): Show When: ICF.ICF_WHO = 2 OR ICF.ICF_WHO = 3														
Page-8-618787	Date	1	B1a. Date assent signed	ICF.ASSENT_DT	Yes									
-- Page Dynamics (ICF. ASSENT_DT): Show When: (ICF.ICF_WHO = 2 OR ICF.ICF_WHO = 3) AND ICF.ASSENT = 1														
Page-9-618787	Section Header	0	SECTION C: Repository Consent:											
Page-10-618787	Radiolist Horizontal	0	C1. Did the patient, parent or legal guardian consent to blood sample collection for DNA analysis?	ICF.DNA_CON	Yes				cYN					
Page-11-618787	Date	1	C1a. If yes, Date of consent:	ICF.DNA_CON_DT	Yes									
-- Page Dynamics (ICF. DNA_CON_DT): Show When: ICF.DNA_CON = 1														
Page-12-618787	Radiolist Horizontal	0	C2. Did the patient, parent or legal guardian consent to the plasma/serum banking samples for future analysis?	ICF.BLOOD_CON	Yes				cYN					
Page-13-618787	Date	1	C2a. If yes, Date of consent:	ICF.BLOOD_CON_DT	Yes									
-- Page Dynamics (ICF. BLOOD_CON_DT): Show When: ICF.BLOOD_CON = 1														
Page-14-618787	Radiolist Horizontal	0	C3. Did the patient, parent or legal guardian consent to the Urine banking samples for future analyses?	ICF.URINE_CON	Yes				cYN					
Page-15-618787	Date	1	C3a. If yes, Date of consent:	ICF.URINE_CON_DT	Yes									
-- Page Dynamics (ICF. URINE_CON_DT): Show When: ICF.URINE_CON = 1														
Page-16-618787	Help Text Line	0	IF participant consent is "No" OR both parental/guardian consent and participant assent are "No", Please contact the DCC as Subject is not eligible.											

Page Information														
Page-17-618787	Section Header	0	Section D: Re-Screening (if Applicable)											
Page-18-618787	Check Box	0	D1. Check if participant was previously screened for the DO-IT Study and failed eligibility criteria. <u>Note: </u> This only applies to participants who were previously consented and entered into eCOS.	ICF.PRIORSCRN	Yes									
Page-19-618787	Text Field	1	D1a. Enter the DO-IT Subject ID (xxx-xxx) from the previous screening.	ICF.PRIORSUBID	Yes					7	7			
-- Page Dynamics (ICF. PRIORSUBID): Show When: ICF.PRIORSCRN IS NOT NULL														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618904	SYSQ_4907	ICF.ICF_YN	Other / Cross Page		ICF.ASSENT = 0 OR ICF.ICF_YN = 0	Participant consent OR parental/guardian consent and participant assent is required. If not obtained, the participant is not eligible to participate in this study. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-619044	SYSQ_4997	ICF.ICF_YN	Field Null		ICF.ICF_YN IS NULL	"A1. Was the informed consent form (ICF) signed for screening and potential enrollment in Dyslipidemia of Obesity Intervention study?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619045	SYSQ_4998	ICF.ICFPROTV	Field Null		ICF.ICFPROTV IS NULL	"A1a. Protocol version" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619047	SYSQ_4999	ICF.ICF_WHO	Field Null		ICF.ICF_WHO IS NULL	"A1b. Informed consent was signed by:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619049	SYSQ_5000	ICF.ICF_DT	Field Null		ICF.ICF_DT IS NULL	"A1c. Date informed consent signed:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0

System Queries														
sysq-619052	SYSQ_5001	ICF.ICF_DT	Future Date		ICF.ICF_DT > Today	"A1c. Date informed consent signed:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619054	SYSQ_5002	ICF.ASSENT	Field Null		ICF.ASSENT IS NULL	"B1. Did the patient sign the informed assent?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619055	SYSQ_5003	ICF.ASSENT_DT	Field Null		ICF.ASSENT_DT IS NULL	"B1a. Date assent signed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619058	SYSQ_5004	ICF.ASSENT_DT	Future Date		ICF.ASSENT_DT > Today	"B1a. Date assent signed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619059	SYSQ_5005	ICF.DNA_CON	Field Null		ICF.DNA_CON IS NULL	"C1. Did the patient, parent or legal guardian consent to blood sample collection for DNA analysis?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619062	SYSQ_5006	ICF.DNA_CON_DT	Field Null		ICF.DNA_CON_DT IS NULL	"C1a. If yes, Date of consent:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619063	SYSQ_5007	ICF.DNA_CON_DT	Future Date		ICF.DNA_CON_DT > Today	"C1a. If yes, Date of consent:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619065	SYSQ_5008	ICF.BLOOD_CON	Field Null		ICF.BLOOD_CON IS NULL	"C2. Did the patient, parent or legal guardian consent to the plasma/serum banking samples for future analysis?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619068	SYSQ_5009	ICF.BLOOD_CON_DT	Field Null		ICF.BLOOD_CON_DT IS NULL	"C2a. If yes, Date of consent:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619070	SYSQ_5010	ICF.BLOOD_CON_DT	Future Date		ICF.BLOOD_CON_DT > Today	"C2a. If yes, Date of consent:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0

System Queries														
sysq-619072	SYSQ_5011	ICF.URINE_CON	Field Null		ICF.URINE_CON IS NULL	"C3. Did the patient, parent or legal guardian consent to the Urine banking samples for future analyses?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619074	SYSQ_5012	ICF.URINE_CON_DT	Field Null		ICF.URINE_CON_DT IS NULL	"C3a. If yes, Date of consent:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619075	SYSQ_5013	ICF.URINE_CON_DT	Future Date		ICF.URINE_CON_DT > Today	"C3a. If yes, Date of consent:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-620434	SYSQ_5847	ICF.PRIORSUBID	Field Null		ICF.PRIORSUBID IS NULL	"D1a. Enter the DO-IT Subject ID (xxx-xxx) from the previous screening." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620435	SYSQ_5848	ICF.PRIORSUBID	Other / Cross Page		Not (Field[ICF.PRIORSUBID] MatchRegex '^(\d){3}-(\d){3}')	The prior subject ID is not in the correct format (a 3-digit site number followed by a dash '-' and a 3-digit subject number; example: 110-002). Please correct.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0

pINEX

Page

(Visit ID = 618788, Page ID =)

Unique Identifier page-618788-618788-618788-

Section A: Inclusion Criteria			
SDV	* A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE
SDV	* A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	○ Yes ○ No	INEX.BMI
SDV	* A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL	○ Yes ○ No	INEX.FLP1
SDV	* A4. Participant consent, or parental/guardian consent and participant assent obtained	○ Yes ○ No	INEX.FLP1_IC
SDV	* A5. Is the subject fluent in English?	○ Yes ○ No	INEX.ENGLISH
	Inclusion Criteria met?	(auto calculated)	INEX.INCL_MET (format x)
Section B: Exclusion Criteria			

SDV	* B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	○ Yes ○ No	INEX.MEDS
SDV	* B2. Known allergy or hypersensitivity to statin	○ Yes ○ No	INEX.ALLERGY
SDV	* B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	○ Yes ○ No	INEX.PREG
SDV	* B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for subjects <13 years of age; ≥140/90 for subjects ≥13 years of age) confirmed after an appropriate evaluation)	○ Yes ○ No	INEX.HYPERT
SDV	* B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	○ Yes ○ No	INEX.DIABETES
SDV	* B6. Use of insulin sensitizing therapy	○ Yes ○ No	INEX.PD_PCS
SDV	* B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	○ Yes ○ No	INEX.RENAL

SDV	* B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical of other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	○ Yes ○ No	INEX.THYROID
SDV	* B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	○ Yes ○ No	INEX.PROTEIN
SDV	* B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	○ Yes ○ No	INEX.NEURO
SDV	* B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	○ Yes ○ No	INEX.LIVER
SDV	* B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	○ Yes ○ No	INEX.CREATINE
SDV	* B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	○ Yes ○ No	INEX.LEAVE
SDV	* B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	○ Yes ○ No	INEX.UNSTABLE
SDV	* B15. Admits to current smoking, current alcohol consumption	○ Yes ○ No	INEX.FLP1_SMOK
	Exclusion Criteria met?	(auto calculated)	INEX.EXCL_MET (format x)
	ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study.		

SECTION C: Eligibility Determination		
Is subject eligible for Randomization?	(auto calculated)	INEX.ENROLL_YN (format x)

Page Information														
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618788	Section Header	0	Section A: Inclusion Criteria											
Page-2-618788	Radiolist Horizontal	0	A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	INEX.AGE	Yes				cYN					
Page-3-618788	Radiolist Horizontal	0	A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	INEX.BMI	Yes				cYN					
Page-4-618788	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥100 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥145 mg/dL	INEX.FLP1	Yes				cYN					Please enter the fasting lipid profile results on the LIPS (Fasting Lipid Profile) Form in the Screening visit.
Page-5-618788	Radiolist Horizontal	0	A4. Participant consent, or parental/guardian consent and participant assent obtained	INEX.FLP1_IC	Yes				cYN					
Page-6-618788	Radiolist Horizontal	0	A5. Is the subject fluent in English?	INEX.ENGLISH	Yes				cYN					
Page-7-618788	Auto Calc Field	0	Inclusion Criteria met?	INEX.INCL_MET								1	0	
-- Auto Calc Rule (INEX.INCL_MET): INEX.AGE = 1 AND INEX.BMI = 1 AND INEX.FLP1 = 1 AND INEX.ENGLISH = 1 AND INEX.FLP1_IC = 1>>>USE: 1														
Page-8-618788	Section Header	0	Section B: Exclusion Criteria											

Page Information															
Page-9-618788	Radiolist Horizontal	0	B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	INEX. MEDS	Yes				cYN					
Page-10-618788	Radiolist Horizontal	0	B2. Known allergy or hypersensitivity to statin	INEX. ALLERGY	Yes				cYN					
Page-11-618788	Radiolist Horizontal	0	B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	INEX. PREG	Yes				cYN					
Page-12-618788	Radiolist Horizontal	0	B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for subjects <13 years of age; ≥140/90 for subjects ≥13 years of age) confirmed after an appropriate evaluation)	INEX. HYPERT	Yes				cYN					
Page-13-618788	Radiolist Horizontal	0	B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	INEX. DIABETES	Yes				cYN					Glucose conversion: mg/dL x 0.0555 = mmol/L
Page-14-618788	Radiolist Horizontal	0	B6. Use of insulin sensitizing therapy	INEX. PD_PCS	Yes				cYN					
Page-15-618788	Radiolist Horizontal	0	B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	INEX. RENAL	Yes				cYN					

Page Information															
Page-16-618788	Radiolist Horizontal	0	B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical of other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	INEX.THYROID	Yes				cYN					
Page-17-618788	Radiolist Horizontal	0	B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	INEX.PROTEIN	Yes				cYN					
Page-18-618788	Radiolist Horizontal	0	B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	INEX.NEURO	Yes				cYN					
Page-19-618788	Radiolist Horizontal	0	B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	INEX.LIVER	Yes				cYN					
Page-20-618788	Radiolist Horizontal	0	B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	INEX.CREATINE	Yes				cYN					
Page-21-618788	Radiolist Horizontal	0	B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	INEX.LEAVE	Yes				cYN					
Page-22-618788	Radiolist Horizontal	0	B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	INEX.UNSTABLE	Yes				cYN					
Page-23-618788	Radiolist Horizontal	0	B15. Admits to current smoking, current alcohol consumption	INEX.FLP1_SMOK	Yes				cYN					
Page-24-618788	Auto Calc Field	0	Exclusion Criteria met?	INEX.EXCL_MET								1	0	
-- Auto Calc Rule (INEX.EXCL_MET): INEX.MEDS = 0 AND INEX.PREG = 0 AND INEX.ALLERGY = 0 AND INEX.HYPERT = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN = 0 AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0>>>USE: 0														

Page Information														
Page-25-618788	Help Text Line	0	ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study. 											
Page-26-618788	Section Header	0	SECTION C: Eligibility Determination											
Page-27-618788	Auto Calc Field	0	Is subject eligible for Randomization?	INEX.ENROLL_YN								1	0	If Yes, the Baseline Visit will be triggered. Please complete all forms in the Baseline Visit and Randomize the subject.
-- Auto Calc Rule (INEX.ENROLL_YN): INEX.INCL_MET = 1 AND INEX.EXCL_MET = 0>>>USE: 1														

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619078	SYSQ_5014	INEX.AGE	Field Null		INEX.AGE IS NULL	"A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619084	SYSQ_5015	INEX.BMI	Field Null		INEX.BMI IS NULL	"A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619088	SYSQ_5016	INEX.FLP1	Field Null		INEX.FLP1 IS NULL	"A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619089	SYSQ_5017	INEX.FLP1_IC	Field Null		INEX.FLP1_IC IS NULL	"A4. Participant consent, or parental/guardian consent and participant assent obtained" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0

System Queries														
sysq-619096	SYSQ_5018	INEX.ENGLISH	Field Null		INEX.ENGLISH IS NULL	"A5. Is the subject fluent in English?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619098	SYSQ_5019	INEX.MEDS	Field Null		INEX.MEDS IS NULL	"B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619103	SYSQ_5020	INEX.ALLERGY	Field Null		INEX.ALLERGY IS NULL	"B2. Known allergy or hypersensitivity to statin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619108	SYSQ_5021	INEX.PREG	Field Null		INEX.PREG IS NULL	"B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619111	SYSQ_5022	INEX.HYPERT	Field Null		INEX.HYPERT IS NULL	"B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for subjects <13 years of age; ≥140/90 for subjects ≥13 years of age) confirmed after an appropriate evaluation)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619114	SYSQ_5023	INEX.DIABETES	Field Null		INEX.DIABETES IS NULL	"B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0

System Queries														
sysq-619120	SYSQ_5024	INEX.PD_PCS	Field Null		INEX.PD_PCS IS NULL	"B6. Use of insulin sensitizing therapy" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619124	SYSQ_5025	INEX.RENAL	Field Null		INEX.RENAL IS NULL	"B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619128	SYSQ_5026	INEX.THYROID	Field Null		INEX.THYROID IS NULL	"B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical of other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619131	SYSQ_5027	INEX.PROTEIN	Field Null		INEX.PROTEIN IS NULL	"B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619133	SYSQ_5028	INEX.NEURO	Field Null		INEX.NEURO IS NULL	"B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619140	SYSQ_5029	INEX.LIVER	Field Null		INEX.LIVER IS NULL	"B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619144	SYSQ_5030	INEX.CREATINE	Field Null		INEX.CREATINE IS NULL	"B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619145	SYSQ_5031	INEX.LEAVE	Field Null		INEX.LEAVE IS NULL	"B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0

System Queries														
sysq-619151	SYSQ_5032	INEX.UNSTABLE	Field Null		INEX.UNSTABLE IS NULL	"B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619155	SYSQ_5033	INEX.FLP1_SMOK	Field Null		INEX.FLP1_SMOK IS NULL	"B15. Admits to current smoking, current alcohol consumption" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0

System Queries														
sysq-619157	SYSQ_5034	INEX.ENROLL_YN	Other / Cross Page		(Field[INEX.AGE] = '0') Or ((Field[INEX.BMI] = '0') Or ((Field[INEX.FLP1] = '0') Or ((Field[INEX.FLP1_IC] = '0') Or ((Field[INEX.ENGLISH] = '0') Or ((Field[INEX.MEDS] = '1') Or ((Field[INEX.ALLERGY] = '1') Or ((Field[INEX.PREG] = '1') Or ((Field[INEX.HYPERT] = '1') Or ((Field[INEX.DIABETES] = '1') Or ((Field[INEX.PD_PCS] = '1') Or ((Field[INEX.RENAL] = '1') Or ((Field[INEX.THYROID] = '1') Or ((Field[INEX.PROTEIN] = '1') Or ((Field[INEX.NEURO] = '1') Or ((Field[INEX.LIVER] = '1') Or ((Field[INEX.CREATINE] = '1') Or ((Field[INEX.LEAVE] = '1') Or ((Field[INEX.UNSTABLE] = '1') Or (Field[INEX.FLP1_SMOK] = '1'))))))))))))))))	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0

pINEX_4

Page

(Visit ID = 618789, Page ID =)

Unique Identifier page-618789-618789-618789-

Section A: Inclusion Criteria			
SDV	* A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE
SDV	* A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE_5V
SDV	* A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	○ Yes ○ No	INEX.BMI
SDV	* A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?	○ Yes ○ No	INEX.BMI_5V
SDV	* A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL	○ Yes ○ No	INEX.FLP1

SDV	* A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL	○ Yes ○ No	INEX.FLP1_5V
SDV	* A4. Participant consent, or parental/guardian consent and participant assent obtained	○ Yes ○ No	INEX.FLP1_IC
SDV	* A5. Is the subject fluent in English?	○ Yes ○ No	INEX.ENGLISH
	Inclusion Criteria met?	(auto calculated)	INEX.INCL_MET (format x)
Section B: Exclusion Criteria			
SDV	* B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	○ Yes ○ No	INEX.MEDS
SDV	* B2. Known allergy or hypersensitivity to statin	○ Yes ○ No	INEX.ALLERGY
SDV	* B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial	○ Yes ○ No	INEX.BARISURG
SDV	* B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	○ Yes ○ No	INEX.PREG

SDV	* B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	○ Yes ○ No	INEX.HYPERT
SDV	* B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	○ Yes ○ No	INEX.DIABETES
SDV	* B6. Use of insulin sensitizing therapy	○ Yes ○ No	INEX.PD_PCS
SDV	* B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	○ Yes ○ No	INEX.RENAL
SDV	* B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	○ Yes ○ No	INEX.THYROID
SDV	* B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	○ Yes ○ No	INEX.PROTEIN
SDV	* B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)	○ Yes ○ No	INEX.PROTEIN_5V
SDV	* B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	○ Yes ○ No	INEX.NEURO

SDV	* B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	○ Yes ○ No	INEX.LIVER
SDV	* B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	○ Yes ○ No	INEX.CREATINE
SDV	* B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	○ Yes ○ No	INEX.LEAVE
SDV	* B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	○ Yes ○ No	INEX.UNSTABLE
SDV	* B15. Admits to current smoking, current alcohol consumption	○ Yes ○ No	INEX.FLP1_SMOK
	Exclusion Criteria met?	(auto calculated)	INEX.EXCL_MET (format x)

ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study.

SECTION C: Eligibility Determination

	Is subject eligible for Randomization?	(auto calculated)	INEX.ENROLL_YN (format x)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618789	Section Header	0	Section A: Inclusion Criteria											
Page-2-618789	Radiolist Horizontal	0	A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	INEX.AGE	Yes				cYN					

-- Page Dynamics (INEX. AGE): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0

Page Information														
Page-3-618789	Radiolist Horizontal	0	A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?	INEX.AGE_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. AGE_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND (10-20-ICF.ICFPROTV = 5 OR 10-20-ICF.ICFPROTV = 5.0)														
Page-4-618789	Radiolist Horizontal	0	A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	INEX.BMI	Yes				cYN					
-- Page Dynamics (INEX. BMI): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-5-618789	Radiolist Horizontal	0	A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?	INEX.BMI_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. BMI_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND (10-20-ICF.ICFPROTV = 5 OR 10-20-ICF.ICFPROTV = 5.0)														
Page-6-618789	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥100 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥145 mg/dL	INEX.FLP1	Yes				cYN					Please enter the fasting lipid profile results on the LIPS (Fasting Lipid Profile) Form in the Screening visit.
-- Page Dynamics (INEX. FLP1): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-7-618789	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥90 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥125 mg/dL	INEX.FLP1_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. FLP1_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND (10-20-ICF.ICFPROTV = 5 OR 10-20-ICF.ICFPROTV = 5.0)														
Page-8-618789	Radiolist Horizontal	0	A4. Participant consent, or parental/guardian consent and participant assent obtained	INEX.FLP1_IC	Yes				cYN					
Page-9-618789	Radiolist Horizontal	0	A5. Is the subject fluent in English?	INEX.ENGLISH	Yes				cYN					
-- Page Dynamics (INEX. ENGLISH): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-10-618789	Auto Calc Field	0	Inclusion Criteria met?	INEX.INCL_MET								1	0	
-- Auto Calc Rule (INEX.INCL_MET): ((INEX.AGE = 1 AND INEX.AGE_5V IS NULL AND INEX.BMI = 1 AND INEX.BMI_5V IS NULL AND INEX.FLP1 = 1 AND INEX.FLP1_5V IS NULL AND INEX.FLP1_IC = 1 AND INEX.ENGLISH = 1) OR (INEX.AGE IS NULL AND INEX.AGE_5V = 1 AND INEX.BMI IS NULL AND INEX.BMI_5V = 1 AND INEX.FLP1 IS NULL AND INEX.FLP1_5V = 1 AND INEX.FLP1_IC = 1 AND INEX.ENGLISH IS NULL))>>>USE: 1														

Page Information														
Page-11-618789	Section Header	0	Section B: Exclusion Criteria											
Page-12-618789	Radiolist Horizontal	0	B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	INEX.MEDS	Yes				cYN					
Page-13-618789	Radiolist Horizontal	0	B2. Known allergy or hypersensitivity to statin	INEX.ALLERGY	Yes				cYN					
Page-14-618789	Radiolist Horizontal	0	B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial	INEX.BARISURG	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. BARISURG): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND (10-20-ICF.ICFPROTV = 5 OR 10-20-ICF.ICFPROTV = 5.0)														
Page-15-618789	Radiolist Horizontal	0	B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	INEX.PREG	Yes				cYN					
Page-16-618789	Radiolist Horizontal	0	B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	INEX.HYPERT	Yes				cYN					
Page-17-618789	Radiolist Horizontal	0	B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	INEX.DIABETES	Yes				cYN					Glucose conversion: mg/dL x 0.0555 = mmol/L
Page-18-618789	Radiolist Horizontal	0	B6. Use of insulin sensitizing therapy	INEX.PD_PCS	Yes				cYN					

Page Information															
Page-19-618789	Radiolist Horizontal	0	B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	INEX. RENAL	Yes				cYN					
Page-20-618789	Radiolist Horizontal	0	B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	INEX. THYROID	Yes				cYN					
Page-21-618789	Radiolist Horizontal	0	B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	INEX. PROTEIN	Yes				cYN					
-- Page Dynamics (INEX. PROTEIN): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0															
Page-22-618789	Radiolist Horizontal	0	B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)	INEX. PROTEIN_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. PROTEIN_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND (10-20-ICF.ICFPROTV = 5 OR 10-20-ICF.ICFPROTV = 5.0)															
Page-23-618789	Radiolist Horizontal	0	B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	INEX. NEURO	Yes				cYN					
Page-24-618789	Radiolist Horizontal	0	B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	INEX. LIVER	Yes				cYN					
Page-25-618789	Radiolist Horizontal	0	B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	INEX. CREATINE	Yes				cYN					
Page-26-618789	Radiolist Horizontal	0	B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	INEX. LEAVE	Yes				cYN					
Page-27-618789	Radiolist Horizontal	0	B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	INEX. UNSTABLE	Yes				cYN					

Page Information															
Page-28-618789	Radiolist Horizontal	0	B15. Admits to current smoking, current alcohol consumption	INEX.FLP1_SMOK	Yes				cYN						
Page-29-618789	Auto Calc Field	0	Exclusion Criteria met?	INEX.EXCL_MET								1	0		
-- Auto Calc Rule (INEX.EXCL_MET): ((INEX.MEDS = 0 AND INEX.ALLERGY = 0 AND INEX.BARISURG IS NULL AND INEX.PREG = 0 AND INEX.HYPERT = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN = 0 AND INEX.PROTEIN_5V IS NULL AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0) OR (INEX.MEDS = 0 AND INEX.ALLERGY = 0 AND INEX.BARISURG = 0 AND INEX.PREG = 0 AND INEX.HYPERT = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN IS NULL AND INEX.PROTEIN_5V = 0 AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0))>>>USE: 0															
Page-30-618789	Help Text Line	0	ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study. 												
Page-31-618789	Section Header	0	SECTION C: Eligibility Determination												
Page-32-618789	Auto Calc Field	0	Is subject eligible for Randomization?	INEX.ENROLL_YN								1	0	If Yes, the Baseline Visit will be triggered. Please complete all forms in the Baseline Visit and Randomize the subject.	
-- Auto Calc Rule (INEX.ENROLL_YN): INEX.INCL_MET = 1 AND INEX.EXCL_MET = 0>>>USE: 1															

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619079	SYSQ_5014	INEX.AGE	Field Null		INEX.AGE IS NULL	"A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619083	SYSQ_5015	INEX.BMI	Field Null		INEX.BMI IS NULL	"A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0

System Queries														
sysq-619087	SYSQ_5016	INEX.FLP1	Field Null		INEX.FLP1 IS NULL	"A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619091	SYSQ_5017	INEX.FLP1_IC	Field Null		INEX.FLP1_IC IS NULL	"A4. Participant consent, or parental/guardian consent and participant assent obtained" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619093	SYSQ_5018	INEX.ENGLISH	Field Null		INEX.ENGLISH IS NULL	"A5. Is the subject fluent in English?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619100	SYSQ_5019	INEX.MEDS	Field Null		INEX.MEDS IS NULL	"B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619102	SYSQ_5020	INEX.ALLERGY	Field Null		INEX.ALLERGY IS NULL	"B2. Known allergy or hypersensitivity to statin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619105	SYSQ_5021	INEX.PREG	Field Null		INEX.PREG IS NULL	"B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0

System Queries														
sysq-619110	SYSQ_5022	INEX.HYPERT	Field Null		INEX.HYPERT IS NULL	"B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619113	SYSQ_5023	INEX.DIABETES	Field Null		INEX.DIABETES IS NULL	"B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619117	SYSQ_5024	INEX.PD_PCS	Field Null		INEX.PD_PCS IS NULL	"B6. Use of insulin sensitizing therapy" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619122	SYSQ_5025	INEX.RENAL	Field Null		INEX.RENAL IS NULL	"B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619126	SYSQ_5026	INEX.THYROID	Field Null		INEX.THYROID IS NULL	"B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619129	SYSQ_5027	INEX.PROTEIN	Field Null		INEX.PROTEIN IS NULL	"B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619136	SYSQ_5028	INEX.NEURO	Field Null		INEX.NEURO IS NULL	"B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0

System Queries														
sysq-619139	SYSQ_5029	INEX.LIVER	Field Null		INEX.LIVER IS NULL	"B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619142	SYSQ_5030	INEX.CREATINE	Field Null		INEX.CREATINE IS NULL	"B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619147	SYSQ_5031	INEX.LEAVE	Field Null		INEX.LEAVE IS NULL	"B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619152	SYSQ_5032	INEX.UNSTABLE	Field Null		INEX.UNSTABLE IS NULL	"B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619153	SYSQ_5033	INEX.FLP1_SMOK	Field Null		INEX.FLP1_SMOK IS NULL	"B15. Admits to current smoking, current alcohol consumption" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0

System Queries														
sysq-619158	SYSQ_5034	INEX.ENROLL_YN	Other / Cross Page		(Field[INEX.AGE] = '0') Or ((Field[INEX.BMI] = '0') Or ((Field[INEX.FLP1] = '0') Or ((Field[INEX.FLP1_IC] = '0') Or ((Field[INEX.ENGLISH] = '0') Or ((Field[INEX.MEDS] = '1') Or ((Field[INEX.ALLERGY] = '1') Or ((Field[INEX.PREG] = '1') Or ((Field[INEX.HYPERT] = '1') Or ((Field[INEX.DIABETES] = '1') Or ((Field[INEX.PD_PCS] = '1') Or ((Field[INEX.RENAL] = '1') Or ((Field[INEX.THYROID] = '1') Or ((Field[INEX.PROTEIN] = '1') Or ((Field[INEX.NEURO] = '1') Or ((Field[INEX.LIVER] = '1') Or ((Field[INEX.CREATINE] = '1') Or ((Field[INEX.LEAVE] = '1') Or ((Field[INEX.UNSTABLE] = '1') Or (Field[INEX.FLP1_SMOK] = '1'))))))))))))))))	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.		Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0

System Queries														
sysq-620466	SYSQ_5879	INEX.AGE_5V	Field Null		INEX.AGE_5V IS NULL	"A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620470	SYSQ_5880	INEX.BMI_5V	Field Null		INEX.BMI_5V IS NULL	"A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620474	SYSQ_5881	INEX.FLP1_5V	Field Null		INEX.FLP1_5V IS NULL	"A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620475	SYSQ_5882	INEX.BARISURG	Field Null		INEX.BARISURG IS NULL	"B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620479	SYSQ_5883	INEX.PROTEIN_5V	Field Null		INEX.PROTEIN_5V IS NULL	"B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
sysq-620483	SYSQ_5884	INEX.ENROLL_YN	Other / Cross Page	Updated to Protocol v5.0	(Field[INEX.AGE] = '0') Or ((Field[INEX.AGE_5V] = '0') Or ((Field[INEX.BMI] = '0') Or ((Field[INEX.BMI_5V] = '0') Or ((Field[INEX.FLP1] = '0') Or ((Field[INEX.FLP1_5V] = '0') Or ((Field[INEX.FLP1_IC] = '0') Or ((Field[INEX.ENGLISH] = '0') Or ((Field[INEX.MEDS] = '1') Or ((Field[INEX.ALLERGY] = '1') Or ((Field[INEX.BARISURG] = '1') Or ((Field[INEX.PREG] = '1') Or ((Field[INEX.HYPERT] = '1') Or ((Field[INEX.DIABETES] = '1') Or ((Field[INEX.PD_PCS] = '1') Or ((Field[INEX.RENAL] = '1') Or ((Field[INEX.THYROID] = '1') Or ((Field[INEX.PROTEIN] = '1') Or ((Field[INEX.PROTEIN_5V] = '1') Or ((Field[INEX.NEURO] = '1') Or ((Field[INEX.LIVER] = '1') Or ((Field[INEX.CREATINE] = '1') Or ((Field[INEX.	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
					LEAVE] = '1') Or ((Field[INEX.UNSTABLE] = '1') Or (Field[INEX.FLP1_SMOK] = '1'))))))))))))))))									

pINEX_6

Page

(Visit ID = 618790, Page ID =)

Unique Identifier page-618790-618790-618790-

Section A: Inclusion Criteria			
SDV	* A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE
SDV	* A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE_5V
SDV	* A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	○ Yes ○ No	INEX.BMI
SDV	* A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?	○ Yes ○ No	INEX.BMI_5V
SDV	* A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL	○ Yes ○ No	INEX.FLP1

SDV	* A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL	○ Yes ○ No	INEX.FLP1_5V
SDV	* A4. Participant consent, or parental/guardian consent and participant assent obtained	○ Yes ○ No	INEX.FLP1_IC
SDV	* A5. Is the subject fluent in English?	○ Yes ○ No	INEX.ENGLISH
	Inclusion Criteria met?	(auto calculated)	INEX.INCL_MET (format x)
Section B: Exclusion Criteria			
SDV	* B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	○ Yes ○ No	INEX.MEDS
SDV	* B2. Known allergy or hypersensitivity to statin	○ Yes ○ No	INEX.ALLERGY
SDV	* B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial	○ Yes ○ No	INEX.BARISURG
SDV	* B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	○ Yes ○ No	INEX.PREG

SDV	* B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	○ Yes ○ No	INEX.HYPERT
SDV	* B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	○ Yes ○ No	INEX.DIABETES
SDV	* B6. Use of insulin sensitizing therapy	○ Yes ○ No	INEX.PD_PCS
SDV	* B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	○ Yes ○ No	INEX.RENAL
SDV	* B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	○ Yes ○ No	INEX.THYROID
SDV	* B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	○ Yes ○ No	INEX.PROTEIN
SDV	* B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)	○ Yes ○ No	INEX.PROTEIN_5V
SDV	* B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	○ Yes ○ No	INEX.NEURO

SDV	* B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	○ Yes ○ No	INEX.LIVER
SDV	* B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	○ Yes ○ No	INEX.CREATINE
SDV	* B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	○ Yes ○ No	INEX.LEAVE
SDV	* B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	○ Yes ○ No	INEX.UNSTABLE
SDV	* B15. Admits to current smoking, current alcohol consumption	○ Yes ○ No	INEX.FLP1_SMOK
	Exclusion Criteria met?	(auto calculated)	INEX.EXCL_MET (format x)

ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study.

SECTION C: Eligibility Determination

	Is subject eligible for Randomization?	(auto calculated)	INEX.ENROLL_YN (format x)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618790	Section Header	0	Section A: Inclusion Criteria											
Page-2-618790	Radiolist Horizontal	0	A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	INEX.AGE	Yes				cYN					

-- Page Dynamics (INEX. AGE): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0

Page Information														
Page-3-618790	Radiolist Horizontal	0	A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?	INEX.AGE_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. AGE_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														
Page-4-618790	Radiolist Horizontal	0	A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	INEX.BMI	Yes				cYN					
-- Page Dynamics (INEX. BMI): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-5-618790	Radiolist Horizontal	0	A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?	INEX.BMI_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. BMI_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														
Page-6-618790	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥100 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥145 mg/dL	INEX.FLP1	Yes				cYN					Please enter the fasting lipid profile results on the LIPS (Fasting Lipid Profile) Form in the Screening visit.
-- Page Dynamics (INEX. FLP1): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-7-618790	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥90 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥125 mg/dL	INEX.FLP1_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. FLP1_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														
Page-8-618790	Radiolist Horizontal	0	A4. Participant consent, or parental/guardian consent and participant assent obtained	INEX.FLP1_IC	Yes				cYN					
Page-9-618790	Radiolist Horizontal	0	A5. Is the subject fluent in English?	INEX.ENGLISH	Yes				cYN					
-- Page Dynamics (INEX. ENGLISH): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-10-618790	Auto Calc Field	0	Inclusion Criteria met?	INEX.INCL_MET								1	0	
-- Auto Calc Rule (INEX.INCL_MET): ((INEX.AGE = 1 AND INEX.AGE_5V IS NULL AND INEX.BMI = 1 AND INEX.BMI_5V IS NULL AND INEX.FLP1 = 1 AND INEX.FLP1_5V IS NULL AND INEX.FLP1_IC = 1 AND INEX.ENGLISH = 1) OR (INEX.AGE IS NULL AND INEX.AGE_5V = 1 AND INEX.BMI IS NULL AND INEX.BMI_5V = 1 AND INEX.FLP1 IS NULL AND INEX.FLP1_5V = 1 AND INEX.FLP1_IC = 1 AND INEX.ENGLISH IS NULL))>>>USE: 1														

Page Information														
Page-11-618790	Section Header	0	Section B: Exclusion Criteria											
Page-12-618790	Radiolist Horizontal	0	B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	INEX.MEDS	Yes				cYN					
Page-13-618790	Radiolist Horizontal	0	B2. Known allergy or hypersensitivity to statin	INEX.ALLERGY	Yes				cYN					
Page-14-618790	Radiolist Horizontal	0	B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial	INEX.BARISURG	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. BARISURG): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														
Page-15-618790	Radiolist Horizontal	0	B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	INEX.PREG	Yes				cYN					
Page-16-618790	Radiolist Horizontal	0	B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	INEX.HYPERT	Yes				cYN					
Page-17-618790	Radiolist Horizontal	0	B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	INEX.DIABETES	Yes				cYN					Glucose conversion: mg/dL x 0.0555 = mmol/L
Page-18-618790	Radiolist Horizontal	0	B6. Use of insulin sensitizing therapy	INEX.PD_PCS	Yes				cYN					

Page Information															
Page-19-618790	Radiolist Horizontal	0	B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	INEX. RENAL	Yes				cYN					
Page-20-618790	Radiolist Horizontal	0	B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	INEX. THYROID	Yes				cYN					
Page-21-618790	Radiolist Horizontal	0	B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	INEX. PROTEIN	Yes				cYN					
-- Page Dynamics (INEX. PROTEIN): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0															
Page-22-618790	Radiolist Horizontal	0	B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)	INEX. PROTEIN_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. PROTEIN_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0															
Page-23-618790	Radiolist Horizontal	0	B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	INEX. NEURO	Yes				cYN					
Page-24-618790	Radiolist Horizontal	0	B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	INEX. LIVER	Yes				cYN					
Page-25-618790	Radiolist Horizontal	0	B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	INEX. CREATINE	Yes				cYN					
Page-26-618790	Radiolist Horizontal	0	B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	INEX. LEAVE	Yes				cYN					
Page-27-618790	Radiolist Horizontal	0	B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	INEX. UNSTABLE	Yes				cYN					

Page Information															
Page-28-618790	Radiolist Horizontal	0	B15. Admits to current smoking, current alcohol consumption	INEX.FLP1_SMOK	Yes				cYN						
Page-29-618790	Auto Calc Field	0	Exclusion Criteria met?	INEX.EXCL_MET								1	0		
-- Auto Calc Rule (INEX.EXCL_MET): ((INEX.MEDS = 0 AND INEX.ALLERGY = 0 AND INEX.BARISURG IS NULL AND INEX.PREG = 0 AND INEX.HYPERT = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN = 0 AND INEX.PROTEIN_5V IS NULL AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0) OR (INEX.MEDS = 0 AND INEX.ALLERGY = 0 AND INEX.BARISURG = 0 AND INEX.PREG = 0 AND INEX.HYPERT = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN IS NULL AND INEX.PROTEIN_5V = 0 AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0))>>>USE: 0															
Page-30-618790	Help Text Line	0	ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study. 												
Page-31-618790	Section Header	0	SECTION C: Eligibility Determination												
Page-32-618790	Auto Calc Field	0	Is subject eligible for Randomization?	INEX.ENROLL_YN								1	0	If Yes, the Baseline Visit will be triggered. Please complete all forms in the Baseline Visit and Randomize the subject.	
-- Auto Calc Rule (INEX.ENROLL_YN): INEX.INCL_MET = 1 AND INEX.EXCL_MET = 0>>>USE: 1															

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619080	SYSQ_5014	INEX.AGE	Field Null		INEX.AGE IS NULL	"A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619081	SYSQ_5015	INEX.BMI	Field Null		INEX.BMI IS NULL	"A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0

System Queries														
sysq-619085	SYSQ_5016	INEX.FLP1	Field Null		INEX.FLP1 IS NULL	"A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619092	SYSQ_5017	INEX.FLP1_IC	Field Null		INEX.FLP1_IC IS NULL	"A4. Participant consent, or parental/guardian consent and participant assent obtained" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619095	SYSQ_5018	INEX.ENGLISH	Field Null		INEX.ENGLISH IS NULL	"A5. Is the subject fluent in English?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619097	SYSQ_5019	INEX.MEDS	Field Null		INEX.MEDS IS NULL	"B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619101	SYSQ_5020	INEX.ALLERGY	Field Null		INEX.ALLERGY IS NULL	"B2. Known allergy or hypersensitivity to statin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619107	SYSQ_5021	INEX.PREG	Field Null		INEX.PREG IS NULL	"B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0

System Queries														
sysq-619112	SYSQ_5022	INEX.HYPERT	Field Null		INEX.HYPERT IS NULL	"B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619116	SYSQ_5023	INEX.DIABETES	Field Null		INEX.DIABETES IS NULL	"B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619119	SYSQ_5024	INEX.PD_PCS	Field Null		INEX.PD_PCS IS NULL	"B6. Use of insulin sensitizing therapy" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619123	SYSQ_5025	INEX.RENAL	Field Null		INEX.RENAL IS NULL	"B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619125	SYSQ_5026	INEX.THYROID	Field Null		INEX.THYROID IS NULL	"B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619132	SYSQ_5027	INEX.PROTEIN	Field Null		INEX.PROTEIN IS NULL	"B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619134	SYSQ_5028	INEX.NEURO	Field Null		INEX.NEURO IS NULL	"B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0

System Queries														
sysq-619138	SYSQ_5029	INEX.LIVER	Field Null		INEX.LIVER IS NULL	"B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619143	SYSQ_5030	INEX.CREATINE	Field Null		INEX.CREATINE IS NULL	"B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619146	SYSQ_5031	INEX.LEAVE	Field Null		INEX.LEAVE IS NULL	"B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619150	SYSQ_5032	INEX.UNSTABLE	Field Null		INEX.UNSTABLE IS NULL	"B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619156	SYSQ_5033	INEX.FLP1_SMOK	Field Null		INEX.FLP1_SMOK IS NULL	"B15. Admits to current smoking, current alcohol consumption" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0

System Queries														
sysq-619160	SYSQ_5034	INEX.ENROLL_YN	Other / Cross Page		(Field[INEX.AGE] = '0') Or ((Field[INEX.BMI] = '0') Or ((Field[INEX.FLP1] = '0') Or ((Field[INEX.FLP1_IC] = '0') Or ((Field[INEX.ENGLISH] = '0') Or ((Field[INEX.MEDS] = '1') Or ((Field[INEX.ALLERGY] = '1') Or ((Field[INEX.PREG] = '1') Or ((Field[INEX.HYPERT] = '1') Or ((Field[INEX.DIABETES] = '1') Or ((Field[INEX.PD_PCS] = '1') Or ((Field[INEX.RENAL] = '1') Or ((Field[INEX.THYROID] = '1') Or ((Field[INEX.PROTEIN] = '1') Or ((Field[INEX.NEURO] = '1') Or ((Field[INEX.LIVER] = '1') Or ((Field[INEX.CREATINE] = '1') Or ((Field[INEX.LEAVE] = '1') Or ((Field[INEX.UNSTABLE] = '1') Or (Field[INEX.FLP1_SMOK] = '1'))))))))))))))))	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.		Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0

System Queries														
sysq-620467	SYSQ_5879	INEX.AGE_5V	Field Null		INEX.AGE_5V IS NULL	"A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620469	SYSQ_5880	INEX.BMI_5V	Field Null		INEX.BMI_5V IS NULL	"A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620472	SYSQ_5881	INEX.FLP1_5V	Field Null		INEX.FLP1_5V IS NULL	"A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620476	SYSQ_5882	INEX.BARISURG	Field Null		INEX.BARISURG IS NULL	"B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620478	SYSQ_5883	INEX.PROTEIN_5V	Field Null		INEX.PROTEIN_5V IS NULL	"B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
sysq-620481	SYSQ_5884	INEX.ENROLL_YN	Other / Cross Page		(Field[INEX.AGE] = '0') Or ((Field[INEX.AGE_5V] = '0') Or ((Field[INEX.BMI] = '0') Or ((Field[INEX.BMI_5V] = '0') Or ((Field[INEX.FLP1] = '0') Or ((Field[INEX.FLP1_5V] = '0') Or ((Field[INEX.FLP1_IC] = '0') Or ((Field[INEX.ENGLISH] = '0') Or ((Field[INEX.MEDS] = '1') Or ((Field[INEX.ALLERGY] = '1') Or ((Field[INEX.BARISURG] = '1') Or ((Field[INEX.PREG] = '1') Or ((Field[INEX.HYPERT] = '1') Or ((Field[INEX.DIABETES] = '1') Or ((Field[INEX.PD_PCS] = '1') Or ((Field[INEX.RENAL] = '1') Or ((Field[INEX.THYROID] = '1') Or ((Field[INEX.PROTEIN] = '1') Or ((Field[INEX.PROTEIN_5V] = '1') Or ((Field[INEX.NEURO] = '1') Or ((Field[INEX.LIVER] = '1') Or ((Field[INEX.CREATINE] = '1') Or ((Field[INEX.	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
					LEAVE] = '1') Or ((Field[INEX.UNSTABLE] = '1') Or (Field[INEX.FLP1_SMOK] = '1'))))))))))))))))									

pINEX_7

Page

(Visit ID = 618791, Page ID =)

Unique Identifier page-618791-618791-618791-

Section A: Inclusion Criteria			
SDV	* A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE
SDV	* A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE_5V
SDV	* A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	○ Yes ○ No	INEX.BMI
SDV	* A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?	○ Yes ○ No	INEX.BMI_5V
SDV	* A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL	○ Yes ○ No	INEX.FLP1

SDV	* A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL	○ Yes ○ No	INEX.FLP1_5V
SDV	* A4. Participant consent, or parental/guardian consent and participant assent obtained	○ Yes ○ No	INEX.FLP1_IC
SDV	* A5. Is the subject fluent in English?	○ Yes ○ No	INEX.ENGLISH
	Inclusion Criteria met?	(auto calculated)	INEX.INCL_MET (format x)
Section B: Exclusion Criteria			
SDV	* B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	○ Yes ○ No	INEX.MEDS
SDV	* B2. Known allergy or hypersensitivity to statin	○ Yes ○ No	INEX.ALLERGY
SDV	* B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial	○ Yes ○ No	INEX.BARISURG
SDV	* B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	○ Yes ○ No	INEX.PREG

SDV	* B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	○ Yes ○ No	INEX.HYPERT
SDV	* B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	○ Yes ○ No	INEX.DIABETES
SDV	* B6. Use of insulin sensitizing therapy	○ Yes ○ No	INEX.PD_PCS
SDV	* B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	○ Yes ○ No	INEX.RENAL
SDV	* B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	○ Yes ○ No	INEX.THYROID
SDV	* B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	○ Yes ○ No	INEX.PROTEIN
SDV	* B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)	○ Yes ○ No	INEX.PROTEIN_5V
SDV	* B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	○ Yes ○ No	INEX.NEURO

SDV	* B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	○ Yes ○ No	INEX.LIVER
SDV	* B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	○ Yes ○ No	INEX.CREATINE
SDV	* B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	○ Yes ○ No	INEX.LEAVE
SDV	* B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	○ Yes ○ No	INEX.UNSTABLE
SDV	* B15. Admits to current smoking, current alcohol consumption	○ Yes ○ No	INEX.FLP1_SMOK
	Exclusion Criteria met?	(auto calculated)	INEX.EXCL_MET (format x)
	ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study.		
SECTION C: Eligibility Determination			
	Is subject eligible for Randomization?	(auto calculated)	INEX.ENROLL_YN (format x)
SECTION D: Re-Screening Visit			
	* D1. Did participant complete a Re-Screening Visit?	○ Yes ○ No	INEX.RESCRN_YN
	* D2. Rescreening Date		INEX.RESCRN_DT
	* D3. Does participant still meet all non-lab-related exclusion per protocol?	○ Yes ○ No	INEX.EXCLPROT
	* D3a. If no, select the exclusion criteria no longer met	Codelist Choices Here	INEX.EXCL
	* D4. Does participant still meet BMI per protocol (Inclusion criteria except age/FLP)?	○ Yes ○ No	INEX.BMIFLX

* D5. Was a second set of screening FLP drawn?	○ Yes ○ No	INEX.SECFLP
* D5a. Does participant have a second screening FLP that meets the current protocol's criteria or the 10% flex FLP criteria (specified below)?	○ Yes, second FLP meets original ranges specified in current protocol ○ Yes, second FLP meets 10% flex criteria ○ No, second FLP does not meet eligibility requirements	INEX.SECFLPCR

10% Flex Criteria
*LDL-C < 160 mg/dL, and >= 81 mg/dL, and
*TG < 500 mg/dL, and
*TG/HDL-C ratio >= 2.25, OR HDL-C < 49.5 mg/dL for boys or HDL-C < 55 mg/dL, for girls
*non-HDL-C >= 112.5 mg/dL

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618791	Section Header	0	Section A: Inclusion Criteria											
Page-2-618791	Radiolist Horizontal	0	A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	INEX.AGE	Yes				cYN					
-- Page Dynamics (INEX. AGE): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-3-618791	Radiolist Horizontal	0	A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?	INEX.AGE_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. AGE_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														
Page-4-618791	Radiolist Horizontal	0	A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	INEX.BMI	Yes				cYN					
-- Page Dynamics (INEX. BMI): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-5-618791	Radiolist Horizontal	0	A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?	INEX.BMI_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. BMI_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														

Page Information														
Page-6-618791	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥100 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥145 mg/dL	INEX.FLP1	Yes				cYN					Please enter the fasting lipid profile results on the LIPS (Fasting Lipid Profile) Form in the Screening visit.
-- Page Dynamics (INEX. FLP1): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-7-618791	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥90 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥125 mg/dL	INEX.FLP1_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. FLP1_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														
Page-8-618791	Radiolist Horizontal	0	A4. Participant consent, or parental/guardian consent and participant assent obtained	INEX.FLP1_IC	Yes				cYN					
Page-9-618791	Radiolist Horizontal	0	A5. Is the subject fluent in English?	INEX.ENGLISH	Yes				cYN					
-- Page Dynamics (INEX. ENGLISH): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-10-618791	Auto Calc Field	0	Inclusion Criteria met?	INEX.INCL_MET								1	0	
-- Auto Calc Rule (INEX.INCL_MET): ((INEX.AGE = 1 AND INEX.AGE_5V IS NULL AND INEX.BMI = 1 AND INEX.BMI_5V IS NULL AND INEX.FLP1 = 1 AND INEX.FLP1_5V IS NULL AND INEX.FLP1_IC = 1 AND INEX.ENGLISH = 1) OR (INEX.AGE IS NULL AND INEX.AGE_5V = 1 AND INEX.BMI IS NULL AND INEX.BMI_5V = 1 AND INEX.FLP1 IS NULL AND INEX.FLP1_5V = 1 AND INEX.FLP1_IC = 1 AND INEX.ENGLISH IS NULL) OR (INEX.AGE IS NULL AND INEX.AGE_5V = 1 AND INEX.FLP1_IC = 1 AND INEX.ENGLISH IS NULL AND INEX.RESCRN_YN = 1 AND INEX.EXCLPROT = 1 AND INEX.BMIFLX = 1 AND INEX.SECFLP = 1 AND (INEX.SECFLPCR = 1 OR INEX.SECFLPCR = 2)))>>>USE: 1														
Page-11-618791	Section Header	0	Section B: Exclusion Criteria											

Page Information														
Page-12-618791	Radiolist Horizontal	0	B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	INEX. MEDS	Yes				cYN					
Page-13-618791	Radiolist Horizontal	0	B2. Known allergy or hypersensitivity to statin	INEX. ALLERGY	Yes				cYN					
Page-14-618791	Radiolist Horizontal	0	B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial	INEX. BARISURG	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. BARISURG): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														
Page-15-618791	Radiolist Horizontal	0	B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	INEX. PREG	Yes				cYN					
Page-16-618791	Radiolist Horizontal	0	B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	INEX. HYPERT	Yes				cYN					
Page-17-618791	Radiolist Horizontal	0	B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	INEX. DIABETES	Yes				cYN					Glucose conversion: mg/dL x 0.0555 = mmol/L
Page-18-618791	Radiolist Horizontal	0	B6. Use of insulin sensitizing therapy	INEX. PD_PCS	Yes				cYN					

Page Information															
Page-19-618791	Radiolist Horizontal	0	B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	INEX. RENAL	Yes				cYN					
Page-20-618791	Radiolist Horizontal	0	B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	INEX. THYROID	Yes				cYN					
Page-21-618791	Radiolist Horizontal	0	B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	INEX. PROTEIN	Yes				cYN					
-- Page Dynamics (INEX. PROTEIN): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0															
Page-22-618791	Radiolist Horizontal	0	B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)	INEX. PROTEIN_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. PROTEIN_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0															
Page-23-618791	Radiolist Horizontal	0	B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	INEX. NEURO	Yes				cYN					
Page-24-618791	Radiolist Horizontal	0	B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	INEX. LIVER	Yes				cYN					
Page-25-618791	Radiolist Horizontal	0	B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	INEX. CREATINE	Yes				cYN					
Page-26-618791	Radiolist Horizontal	0	B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	INEX. LEAVE	Yes				cYN					
Page-27-618791	Radiolist Horizontal	0	B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	INEX. UNSTABLE	Yes				cYN					

Page Information															
Page-28-618791	Radiolist Horizontal	0	B15. Admits to current smoking, current alcohol consumption	INEX.FLP1_SMOK	Yes				cYN						
Page-29-618791	Auto Calc Field	0	Exclusion Criteria met?	INEX.EXCL_MET								1	0		
-- Auto Calc Rule (INEX.EXCL_MET): ((INEX.MEDS = 0 AND INEX.ALLERGY = 0 AND INEX.BARISURG IS NULL AND INEX.PREG = 0 AND INEX.HYPERT = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN = 0 AND INEX.PROTEIN_5V IS NULL AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0) OR (INEX.MEDS = 0 AND INEX.ALLERGY = 0 AND INEX.BARISURG = 0 AND INEX.PREG = 0 AND INEX.HYPERT = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN IS NULL AND INEX.PROTEIN_5V = 0 AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0))>>>USE: 0															
Page-30-618791	Help Text Line	0	ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study. 												
Page-31-618791	Section Header	0	SECTION C: Eligibility Determination												
Page-32-618791	Auto Calc Field	0	Is subject eligible for Randomization?	INEX.ENROLL_YN								1	0	If Yes, the Baseline Visit will be triggered. Please complete all forms in the Baseline Visit and Randomize the subject.
-- Auto Calc Rule (INEX.ENROLL_YN): INEX.INCL_MET = 1 AND INEX.EXCL_MET = 0>>>USE: 1															
Page-33-618791	Section Header	0	SECTION D: Re-Screening Visit												
Page-34-618791	Radiolist Horizontal	0	D1. Did participant complete a Re-Screening Visit?	INEX.RESCRN_YN					cYN						
Page-35-618791	Date	0	D2. Rescreening Date	INEX.RESCRN_DT											
-- Page Dynamics (INEX. RESCRN_DT): Show When: INEX.RESCRN_YN = 1															
Page-36-618791	Radiolist Horizontal	0	D3. Does participant still meet all non-lab-related exclusion per protocol?	INEX.EXCLPROT					cYN						
-- Page Dynamics (INEX. EXCLPROT): Show When: INEX.RESCRN_YN = 1															
Page-37-618791	Multi Select	1	D3a. If no, select the exclusion criteria no longer met	INEX.EXCL					cEXCL						
-- Page Dynamics (INEX. EXCL): Show When: INEX.EXCLPROT = 0															

Page Information															
Page-38-618791	Radiolist Horizontal	0	D4. Does participant still meet BMI per protocol (Inclusion criteria except age/FLP)?	INEX.BMIFLX					cYN					
-- Page Dynamics (INEX. BMIFLX): Show When: INEX.RESCRN_YN = 1															
Page-39-618791	Radiolist Horizontal	0	D5. Was a second set of screening FLP drawn?	INEX.SECFLP					cYN					
-- Page Dynamics (INEX. SECFLP): Show When: INEX.RESCRN_YN = 1															
Page-40-618791	Radiolist	1	D5a. Does participant have a second screening FLP that meets the current protocol's criteria or the 10% flex FLP criteria (specified below)?	INEX.SECFLPCR					cYNFLP					
-- Page Dynamics (INEX. SECFLPCR): Show When: INEX.SECFLP = 1															
Page-41-618791	Help Text Line	0	10% Flex Criteria *LDL-C < 160 mg/dL, and >= 81 mg/dL, and *TG < 500 mg/dL, and *TG/HDL-C ratio >= 2.25, OR HDL-C < 49.5 mg/dL for boys or HDL-C < 55 mg/dL, for girls *non-HDL-C >= 112.5 mg/dL											

System Queries													
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619077	SYSQ_5014	INEX.AGE	Field Null		INEX.AGE IS NULL	"A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619082	SYSQ_5015	INEX.BMI	Field Null		INEX.BMI IS NULL	"A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0

System Queries														
sysq-619086	SYSQ_5016	INEX.FLP1	Field Null		INEX.FLP1 IS NULL	"A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619090	SYSQ_5017	INEX.FLP1_IC	Field Null		INEX.FLP1_IC IS NULL	"A4. Participant consent, or parental/guardian consent and participant assent obtained" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:15	0	0	0	0	0	0
sysq-619094	SYSQ_5018	INEX.ENGLISH	Field Null		INEX.ENGLISH IS NULL	"A5. Is the subject fluent in English?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619099	SYSQ_5019	INEX.MEDS	Field Null		INEX.MEDS IS NULL	"B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619104	SYSQ_5020	INEX.ALLERGY	Field Null		INEX.ALLERGY IS NULL	"B2. Known allergy or hypersensitivity to statin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619106	SYSQ_5021	INEX.PREG	Field Null		INEX.PREG IS NULL	"B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0

System Queries														
sysq-619109	SYSQ_5022	INEX.HYPERT	Field Null		INEX.HYPERT IS NULL	"B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619115	SYSQ_5023	INEX.DIABETES	Field Null		INEX.DIABETES IS NULL	"B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619118	SYSQ_5024	INEX.PD_PCS	Field Null		INEX.PD_PCS IS NULL	"B6. Use of insulin sensitizing therapy" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619121	SYSQ_5025	INEX.RENAL	Field Null		INEX.RENAL IS NULL	"B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:16	0	0	0	0	0	0
sysq-619127	SYSQ_5026	INEX.THYROID	Field Null		INEX.THYROID IS NULL	"B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619130	SYSQ_5027	INEX.PROTEIN	Field Null		INEX.PROTEIN IS NULL	"B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619135	SYSQ_5028	INEX.NEURO	Field Null		INEX.NEURO IS NULL	"B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0

System Queries														
sysq-619137	SYSQ_5029	INEX.LIVER	Field Null		INEX.LIVER IS NULL	"B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619141	SYSQ_5030	INEX.CREATINE	Field Null		INEX.CREATINE IS NULL	"B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619148	SYSQ_5031	INEX.LEAVE	Field Null		INEX.LEAVE IS NULL	"B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619149	SYSQ_5032	INEX.UNSTABLE	Field Null		INEX.UNSTABLE IS NULL	"B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0
sysq-619154	SYSQ_5033	INEX.FLP1_SMOK	Field Null		INEX.FLP1_SMOK IS NULL	"B15. Admits to current smoking, current alcohol consumption" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:17	0	0	0	0	0	0

System Queries														
sysq-619159	SYSQ_5034	INEX.ENROLL_YN	Other / Cross Page		(Field[INEX.AGE] = '0') Or ((Field[INEX.BMI] = '0') Or ((Field[INEX.FLP1] = '0') Or ((Field[INEX.FLP1_IC] = '0') Or ((Field[INEX.ENGLISH] = '0') Or ((Field[INEX.MEDS] = '1') Or ((Field[INEX.ALLERGY] = '1') Or ((Field[INEX.PREG] = '1') Or ((Field[INEX.HYPERT] = '1') Or ((Field[INEX.DIABETES] = '1') Or ((Field[INEX.PD_PCS] = '1') Or ((Field[INEX.RENAL] = '1') Or ((Field[INEX.THYROID] = '1') Or ((Field[INEX.PROTEIN] = '1') Or ((Field[INEX.NEURO] = '1') Or ((Field[INEX.LIVER] = '1') Or ((Field[INEX.CREATINE] = '1') Or ((Field[INEX.LEAVE] = '1') Or ((Field[INEX.UNSTABLE] = '1') Or (Field[INEX.FLP1_SMOK] = '1'))))))))))))))))	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.		Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0

System Queries														
sysq-620468	SYSQ_5879	INEX.AGE_5V	Field Null		INEX.AGE_5V IS NULL	"A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620471	SYSQ_5880	INEX.BMI_5V	Field Null		INEX.BMI_5V IS NULL	"A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:02	0	0	0	0	0	0
sysq-620473	SYSQ_5881	INEX.FLP1_5V	Field Null		INEX.FLP1_5V IS NULL	"A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620477	SYSQ_5882	INEX.BARISURG	Field Null		INEX.BARISURG IS NULL	"B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620480	SYSQ_5883	INEX.PROTEIN_5V	Field Null		INEX.PROTEIN_5V IS NULL	"B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
sysq-620482	SYSQ_5884	INEX.ENROLL_YN	Other / Cross Page		(Field[INEX.AGE] = '0') Or ((Field[INEX.AGE_5V] = '0') Or ((Field[INEX.BMI] = '0') Or ((Field[INEX.BMI_5V] = '0') Or ((Field[INEX.FLP1] = '0') Or ((Field[INEX.FLP1_5V] = '0') Or ((Field[INEX.FLP1_IC] = '0') Or ((Field[INEX.ENGLISH] = '0') Or ((Field[INEX.MEDS] = '1') Or ((Field[INEX.ALLERGY] = '1') Or ((Field[INEX.BARISURG] = '1') Or ((Field[INEX.PREG] = '1') Or ((Field[INEX.HYPERT] = '1') Or ((Field[INEX.DIABETES] = '1') Or ((Field[INEX.PD_PCS] = '1') Or ((Field[INEX.RENAL] = '1') Or ((Field[INEX.THYROID] = '1') Or ((Field[INEX.PROTEIN] = '1') Or ((Field[INEX.PROTEIN_5V] = '1') Or ((Field[INEX.NEURO] = '1') Or ((Field[INEX.LIVER] = '1') Or ((Field[INEX.CREATINE] = '1') Or ((Field[INEX.	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
					LEAVE] = '1') Or ((Field[INEX.UNSTABLE] = '1') Or (Field[INEX.FLP1_SMOK] = '1'))))))))))))))))									
sysq-620535	SYSQ_5936	INEX.RESCRN_YN	Field Null		INEX.RESCRN_YN IS NULL	"D1. Did participant complete a Re-Screening Visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620536	SYSQ_5937	INEX.RESCRN_DT	Field Null		INEX.RESCRN_DT IS NULL	"D2. Rescreening Date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620537	SYSQ_5938	INEX.RESCRN_DT	Future Date		INEX.RESCRN_DT > Today	"D2. Rescreening Date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620538	SYSQ_5939	INEX.EXCLPROT	Field Null		INEX.EXCLPROT IS NULL	"D3. Does participant still meet all non-lab-related exclusion per protocol?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620539	SYSQ_5940	INEX.EXCL	Field Null		INEX.EXCL IS NULL	"D3a. If no, select the exclusion criteria no longer met" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620540	SYSQ_5941	INEX.BMIFLX	Field Null		INEX.BMIFLX IS NULL	"D4. Does participant still meet BMI per protocol (Inclusion criteria except age/FLP)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620541	SYSQ_5942	INEX.SECFLP	Field Null		INEX.SECFLP IS NULL	"D5. Was a second set of screening FLP drawn?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620542	SYSQ_5943	INEX.SECFLPCR	Field Null		INEX.SECFLPCR IS NULL	"D5a. Does participant have a second screening FLP that meets the current protocol's criteria or the 10% flex FLP criteria (specified below)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:05	0	0	0	0	0	0

pINEX_8

Page

(Visit ID = 620547, Page ID =)

Unique Identifier page-620547-620547-620547-

Section A: Inclusion Criteria			
SDV	* A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE
SDV	* A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE_5V
SDV	A1. Is the subject aged 10 to 19 years (with 2 year availability for study participation)?	○ Yes ○ No	INEX.AGE_7V
SDV	* A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	○ Yes ○ No	INEX.BMI
SDV	* A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?	○ Yes ○ No	INEX.BMI_5V
SDV	* A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL	○ Yes ○ No	INEX.FLP1

SDV	* A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL	○ Yes ○ No	INEX.FLP1_5V
SDV	A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥120 mg/dL	○ Yes ○ No	INEX.FLP1_7V
SDV	* A4. Participant consent, or parental/guardian consent and participant assent obtained	○ Yes ○ No	INEX.FLP1_IC
SDV	* A5. Is the subject fluent in English?	○ Yes ○ No	INEX.ENGLISH
	Inclusion Criteria met?	(auto calculated)	INEX.INCL_MET (format x)
Section B: Exclusion Criteria			
SDV	* B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	○ Yes ○ No	INEX.MEDS

SDV	B1. Current use of lipid lowering medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy and antihypertensive medication will be accepted	○ Yes ○ No	INEX.MEDS_7V
SDV	* B2. Known allergy or hypersensitivity to statin	○ Yes ○ No	INEX.ALLERGY
SDV	* B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial	○ Yes ○ No	INEX.BARISURG
SDV	* B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	○ Yes ○ No	INEX.PREG
SDV	* B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	○ Yes ○ No	INEX.HYPERT
SDV	B4. Uncontrolled Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	○ Yes ○ No	INEX.HYPERT_7V

SDV	* B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	○ Yes ○ No	INEX.DIABETES
SDV	* B6. Use of insulin sensitizing therapy	○ Yes ○ No	INEX.PD_PCS
SDV	* B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	○ Yes ○ No	INEX.RENAL
SDV	* B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	○ Yes ○ No	INEX.THYROID
SDV	* B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	○ Yes ○ No	INEX.PROTEIN
SDV	* B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)	○ Yes ○ No	INEX.PROTEIN_5V
SDV	* B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	○ Yes ○ No	INEX.NEURO
SDV	* B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	○ Yes ○ No	INEX.LIVER
SDV	* B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	○ Yes ○ No	INEX.CREATINE

SDV	* B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	○ Yes ○ No	INEX.LEAVE
SDV	* B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	○ Yes ○ No	INEX.UNSTABLE
SDV	* B15. Admits to current smoking, current alcohol consumption	○ Yes ○ No	INEX.FLP1_SMOK
	Exclusion Criteria met?	(auto calculated)	INEX.EXCL_MET (format x)
	ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study.		
SECTION C: Eligibility Determination			
	* Is subject eligible for Randomization?	(auto calculated)	INEX.ENROLL_YN (format x)
SECTION D: Re-Screening Visit			
	* D1. Did participant complete a Re-Screening Visit?	○ Yes ○ No	INEX.RESCRN_YN
	* D2. Rescreening Date		INEX.RESCRN_DT
	* D3. Does participant still meet all non-lab-related exclusion per protocol?	○ Yes ○ No	INEX.EXCLPROT
	* D3a. If no, select the exclusion criteria no longer met	Codelist Choices Here	INEX.EXCL
	* D4. Does participant still meet BMI per protocol (Inclusion criteria except age/FLP)?	○ Yes ○ No	INEX.BMIFLX
	* D5. Was a second set of screening FLP drawn?	○ Yes ○ No	INEX.SECFLP

* D5a. Does participant have a second screening FLP that meets the current protocol's criteria or the 10% flex FLP criteria (specified below)?	○ Yes, second FLP meets original ranges specified in current protocol ○ Yes, second FLP meets 10% flex criteria ○ No, second FLP does not meet eligibility requirements	INEX.SECFL PCR

10% Flex Criteria
*LDL-C < 160 mg/dL, and >= 81 mg/dL, and
*TG < 500 mg/dL, and
*TG/HDL-C ratio >= 2.25, OR HDL-C < 49.5 mg/dL for boys or HDL-C < 55 mg/dL, for girls
*non-HDL-C >= 112.5 mg/dL

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-620547	Section Header	0	Section A: Inclusion Criteria											
Page-2-620547	Radiolist Horizontal	0	A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?	INEX.AGE	Yes				cYN					
-- Page Dynamics (INEX.AGE): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-3-620547	Radiolist Horizontal	0	A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?	INEX.AGE_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX.AGE_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0 AND 10-20-ICF.ICFPROTV < 7.0														
Page-4-620547	Radiolist Horizontal	0	A1. Is the subject aged 10 to 19 years (with 2 year availability for study participation)?	INEX.AGE_7V	Yes				cYN					
-- Page Dynamics (INEX.AGE_7V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 7.0														
Page-5-620547	Radiolist Horizontal	0	A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?	INEX.BMI	Yes				cYN					
-- Page Dynamics (INEX.BMI): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														

Page Information														
Page-6-620547	Radiolist Horizontal	0	A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?	INEX. BMI_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. BMI_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														
Page-7-620547	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥100 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥145 mg/dL	INEX. FLP1	Yes				cYN					Please enter the fasting lipid profile results on the LIPS (Fasting Lipid Profile) Form in the Screening visit.
-- Page Dynamics (INEX. FLP1): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-8-620547	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥90 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥125 mg/dL	INEX. FLP1_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. FLP1_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0 AND 10-20-ICF.ICFPROTV < 7.0														
Page-9-620547	Radiolist Horizontal	0	A3. Fasting lipid profile x2 each with all of the following: •LDL-C <160 mg/dL and ≥90 mg/dL, and •TG <500 mg/dL, and •TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and •non-HDL-C ≥120 mg/dL	INEX. FLP1_7V	Yes				cYN					Protocol version 7.0
-- Page Dynamics (INEX. FLP1_7V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 7.0														
Page-10-620547	Radiolist Horizontal	0	A4. Participant consent, or parental/guardian consent and participant assent obtained	INEX. FLP1_IC	Yes				cYN					
Page-11-620547	Radiolist Horizontal	0	A5. Is the subject fluent in English?	INEX. ENGLISH	Yes				cYN					
-- Page Dynamics (INEX. ENGLISH): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0														
Page-12-620547	Auto Calc Field	0	Inclusion Criteria met?	INEX. INCL_MET								1	0	

Page Information														
-- Auto Calc Rule (INEX.INCL_MET): (INEX.AGE = 1 AND INEX.BMI = 1 AND INEX.FLP1 = 1 AND INEX.FLP1_IC = 1 AND INEX.AGE_5V IS NULL AND INEX.AGE_7V IS NULL AND INEX.BMI_5V IS NULL AND INEX.FLP1_5V IS NULL AND INEX.FLP1_7V IS NULL AND INEX.ENGLISH = 1) OR (INEX.AGE_5V = 1 AND INEX.BMI_5V = 1 AND INEX.FLP1_5V = 1 AND INEX.FLP1_IC = 1 AND INEX.AGE IS NULL AND INEX.AGE_7V IS NULL AND INEX.BMI IS NULL AND INEX.FLP1 IS NULL AND INEX.FLP1_7V IS NULL AND INEX.ENGLISH IS NULL) OR (INEX.EXCLPROT = 1 AND INEX.BMIFLX = 1 AND INEX.AGE_5V = 1 AND INEX.FLP1_IC = 1 AND INEX.RESCRN_YN = 1 AND INEX.SECFLP = 1 AND INEX.AGE IS NULL AND INEX.AGE_7V IS NULL AND INEX.ENGLISH IS NULL AND (INEX.SECFLPCR = 1 OR INEX.SECFLPCR = 2)) OR (INEX.AGE_7V = 1 AND INEX.BMI_5V = 1 AND INEX.FLP1_7V = 1 AND INEX.FLP1_IC = 1 AND INEX.AGE IS NULL AND INEX.AGE_5V IS NULL AND INEX.BMI IS NULL AND INEX.FLP1 IS NULL AND INEX.FLP1_5V IS NULL AND INEX.ENGLISH IS NULL) OR (INEX.AGE_7V = 1 AND INEX.FLP1_IC = 1 AND INEX.RESCRN_YN = 1 AND INEX.EXCLPROT = 1 AND INEX.BMIFLX = 1 AND INEX.SECFLP = 1 AND INEX.AGE_5V IS NULL AND INEX.AGE IS NULL AND INEX.ENGLISH IS NULL AND (INEX.SECFLPCR = 1 OR INEX.SECFLPCR = 2))>>>USE: 1														
Page-13-620547	Section Header	0	Section B: Exclusion Criteria											
Page-14-620547	Radiolist Horizontal	0	B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted	INEX. MEDS	Yes				cYN					
-- Page Dynamics (INEX. MEDS): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 7.0														
Page-15-620547	Radiolist Horizontal	0	B1. Current use of lipid lowering medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy and antihypertensive medication will be accepted	INEX. MEDS_7V	Yes				cYN					Protocol version 7.0
-- Page Dynamics (INEX. MEDS_7V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 7.0														
Page-16-620547	Radiolist Horizontal	0	B2. Known allergy or hypersensitivity to statin	INEX. ALLERGY	Yes				cYN					
Page-17-620547	Radiolist Horizontal	0	B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial	INEX. BARISURG	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. BARISURG): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0														

Page Information															
Page-18-620547	Radiolist Horizontal	0	B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception	INEX. PREG	Yes				cYN						
Page-19-620547	Radiolist Horizontal	0	B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	INEX. HYPERT	Yes				cYN						
-- Page Dynamics (INEX. HYPERT): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 7.0															
Page-20-620547	Radiolist Horizontal	0	B4. Uncontrolled Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)	INEX. HYPERT_7V	Yes				cYN						Protocol version 7.0
-- Page Dynamics (INEX. HYPERT_7V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 7.0															
Page-21-620547	Radiolist Horizontal	0	B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)	INEX. DIABETES	Yes				cYN						Glucose conversion: mg/dL x 0.0555 = mmol/L
Page-22-620547	Radiolist Horizontal	0	B6. Use of insulin sensitizing therapy	INEX. PD_PCS	Yes				cYN						
Page-23-620547	Radiolist Horizontal	0	B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)	INEX. RENAL	Yes				cYN						

Page Information															
Page-24-620547	Radiolist Horizontal	0	B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)	INEX.THYROID	Yes				cYN					
Page-25-620547	Radiolist Horizontal	0	B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)	INEX.PROTEIN	Yes				cYN					
-- Page Dynamics (INEX. PROTEIN): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV < 5.0															
Page-26-620547	Radiolist Horizontal	0	B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)	INEX.PROTEIN_5V	Yes				cYN					Protocol version 5.0
-- Page Dynamics (INEX. PROTEIN_5V): Show When: 10-20-ICF.ICFPROTV IS NOT NULL AND 10-20-ICF.ICFPROTV >= 5.0															
Page-27-620547	Radiolist Horizontal	0	B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug	INEX.NEURO	Yes				cYN					
Page-28-620547	Radiolist Horizontal	0	B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L	INEX.LIVER	Yes				cYN					
Page-29-620547	Radiolist Horizontal	0	B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal	INEX.CREATINE	Yes				cYN					
Page-30-620547	Radiolist Horizontal	0	B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation	INEX.LEAVE	Yes				cYN					
Page-31-620547	Radiolist Horizontal	0	B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement	INEX.UNSTABLE	Yes				cYN					
Page-32-620547	Radiolist Horizontal	0	B15. Admits to current smoking, current alcohol consumption	INEX.FLP1_SMOK	Yes				cYN					

Page Information														
Page-33-620547	Auto Calc Field	0	Exclusion Criteria met?	INEX.EXCL_MET								1	0	
-- Auto Calc Rule (INEX.EXCL_MET): ((INEX.MEDS = 0 AND INEX.ALLERGY = 0 AND INEX.BARISURG IS NULL AND INEX.PREG = 0 AND INEX.HYPERT = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN = 0 AND INEX.PROTEIN_5V IS NULL AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0 AND INEX.MEDS_7V IS NULL AND INEX.HYPERT_7V IS NULL) OR (INEX.MEDS = 0 AND INEX.ALLERGY = 0 AND INEX.BARISURG = 0 AND INEX.PREG = 0 AND INEX.HYPERT = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN IS NULL AND INEX.PROTEIN_5V = 0 AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0 AND INEX.MEDS_7V IS NULL AND INEX.HYPERT_7V IS NULL) OR (INEX.MEDS IS NULL AND INEX.MEDS_7V = 0 AND INEX.ALLERGY = 0 AND INEX.BARISURG = 0 AND INEX.PREG = 0 AND INEX.HYPERT IS NULL AND INEX.HYPERT_7V = 0 AND INEX.DIABETES = 0 AND INEX.PD_PCS = 0 AND INEX.RENAL = 0 AND INEX.THYROID = 0 AND INEX.PROTEIN IS NULL AND INEX.PROTEIN_5V = 0 AND INEX.NEURO = 0 AND INEX.LIVER = 0 AND INEX.CREATINE = 0 AND INEX.LEAVE = 0 AND INEX.UNSTABLE = 0 AND INEX.FLP1_SMOK = 0))>>>USE: 0													
Page-34-620547	Help Text Line	0	ALERT: Please verify all INCLUSION criteria and no EXCLUSION criteria are met by Subject, to continue in the DO IT study. 											
Page-35-620547	Section Header	0	SECTION C: Eligibility Determination											
Page-36-620547	Auto Calc Field	0	Is subject eligible for Randomization?	INEX.ENROLL_YN								1	0	If Yes, the Baseline Visit will be triggered. Please complete all forms in the Baseline Visit and Randomize the subject.
-- Auto Calc Rule (INEX.ENROLL_YN): INEX.INCL_MET = 1 AND INEX.EXCL_MET = 0>>>USE: 1														
Page-37-620547	Section Header	0	SECTION D: Re-Screening Visit											
Page-38-620547	Radiolist Horizontal	0	D1. Did participant complete a Re-Screening Visit?	INEX.RESCRN_YN					cYN					
Page-39-620547	Date	0	D2. Rescreening Date	INEX.RESCRN_DT										
-- Page Dynamics (INEX. RESCRN_DT): Show When: INEX.RESCRN_YN = 1														
Page-40-620547	Radiolist Horizontal	0	D3. Does participant still meet all non-lab-related exclusion per protocol?	INEX.EXCLPROT					cYN					
-- Page Dynamics (INEX. EXCLPROT): Show When: INEX.RESCRN_YN = 1														
Page-41-620547	Multi Select	1	D3a. If no, select the exclusion criteria no longer met	INEX.EXCL					cEXCL					

Page Information														
-- Page Dynamics (INEX. EXCL): Show When: INEX.EXCLPROT = 0														
Page-42-620547	Radiolist Horizontal	0	D4. Does participant still meet BMI per protocol (Inclusion criteria except age/FLP)?	INEX.BMIFLX					cYN					
-- Page Dynamics (INEX. BMIFLX): Show When: INEX.RESCRN_YN = 1														
Page-43-620547	Radiolist Horizontal	0	D5. Was a second set of screening FLP drawn?	INEX.SECFLP					cYN					
-- Page Dynamics (INEX. SECFLP): Show When: INEX.RESCRN_YN = 1														
Page-44-620547	Radiolist	1	D5a. Does participant have a second screening FLP that meets the current protocol's criteria or the 10% flex FLP criteria (specified below)?	INEX.SECFLPCR					cYNFLP					
-- Page Dynamics (INEX. SECFLPCR): Show When: INEX.SECFLP = 1														
Page-45-620547	Help Text Line	0	10% Flex Criteria *LDL-C < 160 mg/dL, and >= 81 mg/dL, and *TG < 500 mg/dL, and *TG/HDL-C ratio >= 2.25, OR HDL-C < 49.5 mg/dL for boys or HDL-C < 55 mg/dL, for girls *non-HDL-C >= 112.5 mg/dL											

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-620548	SYSQ_5014	INEX.AGE	Field Null		INEX.AGE IS NULL	"A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620549	SYSQ_5015	INEX.BMI	Field Null		INEX.BMI IS NULL	"A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0

System Queries														
sysq-620550	SYSQ_5016	INEX.FLP1	Field Null		INEX.FLP1 IS NULL	"A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620551	SYSQ_5017	INEX.FLP1_IC	Field Null		INEX.FLP1_IC IS NULL	"A4. Participant consent, or parental/guardian consent and participant assent obtained" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620552	SYSQ_5018	INEX.ENGLISH	Field Null		INEX.ENGLISH IS NULL	"A5. Is the subject fluent in English?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620553	SYSQ_5019	INEX.MEDS	Field Null		INEX.MEDS IS NULL	"B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulant or antidepressant therapy will be accepted" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620554	SYSQ_5020	INEX.ALLERGY	Field Null		INEX.ALLERGY IS NULL	"B2. Known allergy or hypersensitivity to statin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620555	SYSQ_5021	INEX.PREG	Field Null		INEX.PREG IS NULL	"B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0

System Queries														
sysq-620556	SYSQ_5022	INEX.HYPERT	Field Null		INEX.HYPERT IS NULL	"B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) confirmed after an appropriate evaluation)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620557	SYSQ_5023	INEX.DIABETES	Field Null		INEX.DIABETES IS NULL	"B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620558	SYSQ_5024	INEX.PD_PCS	Field Null		INEX.PD_PCS IS NULL	"B6. Use of insulin sensitizing therapy" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620559	SYSQ_5025	INEX.RENAL	Field Null		INEX.RENAL IS NULL	"B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620560	SYSQ_5026	INEX.THYROID	Field Null		INEX.THYROID IS NULL	"B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical or other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620561	SYSQ_5027	INEX.PROTEIN	Field Null		INEX.PROTEIN IS NULL	"B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620562	SYSQ_5028	INEX.NEURO	Field Null		INEX.NEURO IS NULL	"B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0

System Queries														
sysq-620563	SYSQ_5029	INEX.LIVER	Field Null		INEX.LIVER IS NULL	"B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620564	SYSQ_5030	INEX.CREATINE	Field Null		INEX.CREATINE IS NULL	"B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620565	SYSQ_5031	INEX.LEAVE	Field Null		INEX.LEAVE IS NULL	"B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620566	SYSQ_5032	INEX.UNSTABLE	Field Null		INEX.UNSTABLE IS NULL	"B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620567	SYSQ_5033	INEX.FLP1_SMOK	Field Null		INEX.FLP1_SMOK IS NULL	"B15. Admits to current smoking, current alcohol consumption" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0

System Queries														
sysq-620568	SYSQ_5034	INEX.ENROLL_YN	Other / Cross Page		(Field[INEX.AGE] = '0') Or ((Field[INEX.BMI] = '0') Or ((Field[INEX.FLP1] = '0') Or ((Field[INEX.FLP1_IC] = '0') Or ((Field[INEX.ENGLISH] = '0') Or ((Field[INEX.MEDS] = '1') Or ((Field[INEX.ALLERGY] = '1') Or ((Field[INEX.PREG] = '1') Or ((Field[INEX.HYPERT] = '1') Or ((Field[INEX.DIABETES] = '1') Or ((Field[INEX.PD_PCS] = '1') Or ((Field[INEX.RENAL] = '1') Or ((Field[INEX.THYROID] = '1') Or ((Field[INEX.PROTEIN] = '1') Or ((Field[INEX.NEURO] = '1') Or ((Field[INEX.LIVER] = '1') Or ((Field[INEX.CREATINE] = '1') Or ((Field[INEX.LEAVE] = '1') Or ((Field[INEX.UNSTABLE] = '1') Or (Field[INEX.FLP1_SMOK] = '1'))))))))))))))))	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.		Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0

System Queries														
sysq-620569	SYSQ_5879	INEX.AGE_5V	Field Null		INEX.AGE_5V IS NULL	"A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:16	0	0	0	0	0	0
sysq-620570	SYSQ_5880	INEX.BMI_5V	Field Null		INEX.BMI_5V IS NULL	"A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620571	SYSQ_5881	INEX.FLP1_5V	Field Null		INEX.FLP1_5V IS NULL	"A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620572	SYSQ_5882	INEX.BARISURG	Field Null		INEX.BARISURG IS NULL	"B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620573	SYSQ_5883	INEX.PROTEIN_5V	Field Null		INEX.PROTEIN_5V IS NULL	"B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0

System Queries														
sysq-620574	SYSQ_5884	INEX.ENROLL_YN	Other / Cross Page		(Field[INEX.AGE] = '0') Or ((Field[INEX.AGE_5V] = '0') Or ((Field[INEX.BMI] = '0') Or ((Field[INEX.BMI_5V] = '0') Or ((Field[INEX.FLP1] = '0') Or ((Field[INEX.FLP1_5V] = '0') Or ((Field[INEX.FLP1_IC] = '0') Or ((Field[INEX.ENGLISH] = '0') Or ((Field[INEX.MEDS] = '1') Or ((Field[INEX.ALLERGY] = '1') Or ((Field[INEX.BARISURG] = '1') Or ((Field[INEX.PREG] = '1') Or ((Field[INEX.HYPERT] = '1') Or ((Field[INEX.DIABETES] = '1') Or ((Field[INEX.PD_PCS] = '1') Or ((Field[INEX.RENAL] = '1') Or ((Field[INEX.THYROID] = '1') Or ((Field[INEX.PROTEIN] = '1') Or ((Field[INEX.PROTEIN_5V] = '1') Or ((Field[INEX.NEURO] = '1') Or ((Field[INEX.LIVER] = '1') Or ((Field[INEX.CREATINE] = '1') Or ((Field[INEX.	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.		Horng, Dunstan [DES] 12-OCT-20 21:26:56	0	0	0	0	0	0

System Queries														
					LEAVE] = '1') Or ((Field[INEX.UNSTABLE] = '1') Or (Field[INEX.FLP1_SMOK] = '1'))))))))))))))))									
sysq-620575	SYSQ_5936	INEX.RESCRN_YN	Field Null		INEX.RESCRN_YN IS NULL	"D1. Did participant complete a Re-Screening Visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620576	SYSQ_5937	INEX.RESCRN_DT	Field Null		INEX.RESCRN_DT IS NULL	"D2. Rescreening Date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620577	SYSQ_5938	INEX.RESCRN_DT	Future Date		INEX.RESCRN_DT > Today	"D2. Rescreening Date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620578	SYSQ_5939	INEX.EXCLPROT	Field Null		INEX.EXCLPROT IS NULL	"D3. Does participant still meet all non-lab-related exclusion per protocol?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620579	SYSQ_5940	INEX.EXCL	Field Null		INEX.EXCL IS NULL	"D3a. If no, select the exclusion criteria no longer met" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620580	SYSQ_5941	INEX.BMIFLX	Field Null		INEX.BMIFLX IS NULL	"D4. Does participant still meet BMI per protocol (Inclusion criteria except age/FLP)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620581	SYSQ_5942	INEX.SECFLP	Field Null		INEX.SECFLP IS NULL	"D5. Was a second set of screening FLP drawn?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0
sysq-620582	SYSQ_5943	INEX.SECFLPCR	Field Null		INEX.SECFLPCR IS NULL	"D5a. Does participant have a second screening FLP that meets the current protocol's criteria or the 10% flex FLP criteria (specified below)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:41:17	0	0	0	0	0	0

System Queries														
sysq-627123	SYSQ_5948	INEX.ENROLL_YN	Other / Cross Page		INEX.ENROLL_YN IS NULL	STOP! either all Inclusion criteria are not met or Exclusion criteria was met. Please confirm your responses and if confirmed, subject is not eligible to continue with randomization and an End of Study form should be completed.	Yes	Horng, Dunstan [DES] 13-OCT-20 13:20:36	0	0	0	0	0	0

pLBA

Page

(Visit ID = 618792, Page ID =)

Unique Identifier page-618792-618792-618792-

SECTION A. COMPLETE BLOOD COUNT (CBC) RESULTS			
	Complete Blood Count (CBC) is required at Screening and Month 24.		
SDV	* A1. Were Complete Blood Count (CBC) Results obtained?	○ Yes ○ No	LBA.CBCPERF
SDV	* A1a. Date of sample collection		LBA.CBCDAT

Test Name	Result		Unit
A1b. White Blood Cell Count (WBC)	SDV LBA.WBCRES	(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L LBA.WBCUNT
A1c. Red Blood Cell Count (RBC)	SDV LBA.RBCRES	(xx.xx)	SDV ○ 10^6uL ○ 10^12/L LBA.RBCUNT
A1d. Hemoglobin	SDV LBA.HGBRES	(xxx.xx)	SDV ○ g/dL ○ g/L LBA.HGBUNT
A1e. Hematocrit (HCT)	SDV LBA.HCTRES	(xxx.xx)	SDV ○ % ○ Proportion of 1.0 LBA.HCTUNT
A1f. Mean Cell Volume (MCV)	SDV LBA.MCVRES	(xxx.xx)	**fL**
A1g. Mean Corpuscular Hemoglobin (MCHb)	SDV LBA.MCHBRES	(xxx.xx)	**pg**
A1h. Mean Corpuscular Hemoglobin (MCHb) Conc	SDV LBA.MCHBCRES	(xxxx.xx)	SDV ○ g/dL ○ g/L LBA.MCHBCUNT
A1i. RDW - Red Blood Cell Distribution Width (%)	SDV LBA.RDWRES	(xxx.xx)	**%**
A1j. Platelet Count	SDV LBA.PLTRES	(xxxxxx.xx)	SDV ○ 10^3/uL ○ 10^9/L LBA.PLT_UNT
A1k. Was a CBC differential done? Please only report the absolute count of each cell type.	SDV ○ Yes ○ No LBA.CBCDPERF		
A1k1. Neutrophils-segmented	SDV LBA.NEUTSRES	(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L LBA.NEUTSUNT
A1k2. Neutrophils-bands	SDV	(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L

	LBA.NEUTBRES			LBA.NEUTBUNT
A1k3. Lymphocytes	SDV		(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L
	LBA.LYMPRES			LBA.LYMPUNT
A1k4. Monocytes	SDV		(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L
	LBA.MONORES			LBA.MONOUNT
A1k5. Eosinophils	SDV		(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L
	LBA.EOSRES			LBA.EOSUNT
A1k6. Basophils	SDV		(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L
	LBA.BASORES			LBA.BASOUNT
SECTION B: BLOOD CHEMISTRY PANEL				
SDV	* B1. Were Blood Chemistry Results obtained?	○ Yes ○ No		LBA.CHEMPERF
SDV	* B1a. Date of Blood Chemistry Panel			LBA.CHEMDAT

Test Name	Result		Unit
B1b. Glucose	SDV LBA.GLUCRES	(xxxx.xx)	SDV ○ mg/dL ○ mmol/L LBA.GLUCUNT
B1c. Calcium	SDV LBA.CALRES	(xx.xx)	SDV ○ mg/dL ○ mmol/L LBA.CALUNT
B1d. Albumin	SDV LBA.ALBUMRES	(xxx.xx)	SDV ○ g/dL ○ g/L LBA.ALBUMUNT
B1e. Total protein	SDV LBA.PROTRES	(xxx.xx)	SDV ○ g/dL ○ g/L LBA.PROTUNT
B1f. Sodium	SDV LBA.SODIUMRES	(xxx.xx)	SDV ○ mEq/L ○ mmol/L LBA.SODIUMUNT
B1g. Potassium	SDV LBA.POTASRES	(xx.xx)	SDV ○ mEq/L ○ mmol/L LBA.POTASUNT
B1h. Bicarbonate	SDV LBA.CO2RES	(xxx.xx)	SDV ○ mEq/L ○ mmol/L LBA.CO2UNT
B1i. Chloride	SDV LBA.CHLORRES	(xxx.xx)	SDV ○ mEq/L ○ mmol/L LBA.CHLORUNT
B1j. BUN	SDV LBA.BUNRES	(xxx.xx)	SDV ○ mg/dL ○ mmol/L LBA.BUNUNT
B1k. Creatinine	SDV LBA.CREATRES	(xxx.xx)	SDV ○ mg/dL ○ µmol/L LBA.CREATUNT
GFR	(auto calculated) LBA.GFRCALC	(xxx.xx)	
B1l. Alkaline phosphatase	SDV LBA.ALPRES	(xxxx.xx)	SDV ○ U/L ○ IU/L LBA.ALPUNT

B1m. ALT	SDV	LBA.ALTRES	(xxx.xx)	SDV ○ U/L ○ IU/L LBA.ALTUNT
B1n. AST	SDV	LBA.ASTRES	(xxx.xx)	SDV ○ U/L ○ IU/L LBA.ASTUNT
B1o. Total bilirubin	SDV	LBA.BILIRRES	(xxx.xx)	SDV ○ mg/dL ○ µmol/L LBA.BILIRUNT

SECTION C: Creatine Kinase (CK)			
	* C1. Was Creatine Kinase (CK) done?	○ Yes ○ No	LBA.CKYN
	* C1a. Date of blood draw		LBA.CKDAT
SDV	* C1b. Result		LBA.CKRES (format xxxx.xx)
	* C1c. Unit	○ U/L ○ IU/L	LBA.CKUNT
SECTION D: Hemoglobin A1c			
	* D1. Was Hemoglobin A1c done?	○ Yes ○ No	LBA.HBA1CYN
	* D1a. Date of blood draw		LBA.HBA1CDAT
SDV	* D1b. Result (%)		LBA.HBA1CRES (format xx.xx)
SECTION E: URINALYSIS			
	Urinalysis is required at Screening ONLY.		
SDV	E1. Was urine sample acquired for urinalysis?	○ Yes ○ No	LBA.URINPERF
SDV	E1a. Date of urine sample collection		LBA.URINDAT
SDV	E1b. Glucose	○ Normal ○ Abnormal ○ Not Done	LBA.URGLURES
SDV	E1c. Protein	○ Normal ○ Abnormal ○ Not Done	LBA.URPRORES
SDV	E2. Was a urine albumin: urine creatinine ratio obtained?	○ Yes ○ No	LBA.URCRPERF
	E2a. Check if urine sample collection date for albumin:urine creatinine ratio was different	☐	LBA.URCRDIFF

SDV	E2a1. Date of urine sample collection		LBA.URCREDAT
SDV	E2b. Result		LBA.URCRERES (format xxx.xx)
SDV	E2c. Unit	○ mg/g ○ mg/mmol	LBA.URCREUNT
SECTION F: PREGNANCY TEST			
SDV	* F1. Was a urine pregnancy test done at this visit?	○ Yes ○ No ○ Not Applicable	LBA.PREGPERF
SDV	* F1a. Date of Pregnancy Test		LBA.PREGDAT
SDV	* F1b. Result of Pregnancy Test	○ Positive ○ Negative	LBA.PREGRES
SECTION G: THYROID STIMULATING HORMONE (TSH)			
	Thyroid Stimulating Hormone (TSH) is required at Screening ONLY.		
SDV	* G1. Was a TSH sample collected	○ Yes ○ No	LBA.TSHPERF
SDV	* G1a. Date sample collected		LBA.TSHDAT
SDV	* G1b. Time of TSH sample collection	:	LBA.TSHTIM (HH24:MI)
SDV	* G1c. TSH (µIU/mL)		LBA.TSHRES (format xx.xx)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618792	Section Header	0	SECTION A. COMPLETE BLOOD COUNT (CBC) RESULTS											
Page-2-618792	Help Text Line	0	Complete Blood Count (CBC) is required at Screening and Month 24.											
Page-3-618792	Radiolist Horizontal	0	A1. Were Complete Blood Count (CBC) Results obtained?	LBA.CBCPERF	Yes				cYN					
Page-4-618792	Date	1	A1a. Date of sample collection	LBA.CBCDAT	Yes									
-- Page Dynamics (LBA. CBCDAT): Show When: LBA.CBCPERF = 1														

Page Information														
Page-5-618792	Row Start/End	0												
Page-6-618792	Section Header	0	Test Name											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-7-618792	Section Header	0	Result											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-8-618792	Section Header	0	Unit											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-9-618792	Row Start/End	0												
Page-10-618792	Row Start/End	0												
Page-11-618792	Help Text Line	0	A1b. White Blood Cell Count (WBC)											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-12-618792	Numeric	0	White Blood Cell Count (WBC)	LBA.WBCRES	Yes							2	2	Normal Range: 3.5 - 12.0 (10^3/uL) 3.5 - 12.0 (10^9/L)
-- Page Dynamics (LBA. WBCRES): Show When: LBA.CBCPERF = 1														
Page-13-618792	Radiolist Horizontal	0	White Blood Cell Count (WBC)	LBA.WBCUNT	Yes				cUNIT_103UL_109L					If reporting unit is mm3 (i.e. 3500-12,000/mm3), WBC value should be reported as 3.5 - 12.0 with either unit 10^3/uL or 10^9/L.
-- Page Dynamics (LBA. WBCUNT): Show When: LBA.CBCPERF = 1 AND LBA.WBCRES IS NOT NULL														
Page-14-618792	Row Start/End	0												
Page-15-618792	Row Start/End	0												

Page Information														
Page-16-618792	Help Text Line	0	A1c. Red Blood Cell Count (RBC)											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-17-618792	Numeric	0	Red Blood Cell Count (RBC)	LBA.RBCRES	Yes							2	2	Normal Range: 3.9 - 6.0 (10^6uL) 3.9 - 6.0 (10^12/L)
-- Page Dynamics (LBA. RBCRES): Show When: LBA.CBCPERF = 1														
Page-18-618792	Radiolist Horizontal	0	Red Blood Cell Count (RBC)	LBA.RBCUNT	Yes				cUNIT_106UL_1012L					
-- Page Dynamics (LBA. RBCUNT): Show When: LBA.CBCPERF = 1 AND LBA.RBCRES IS NOT NULL														
Page-19-618792	Row Start/End	0												
Page-20-618792	Row Start/End	0												
Page-21-618792	Help Text Line	0	A1d. Hemoglobin											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-22-618792	Numeric	0	Hemoglobin	LBA.HGBRES	Yes							3	2	Normal Range: 11.2 - 18.0 (g/dL) 112 - 180 (g/L)
-- Page Dynamics (LBA. HGBRES): Show When: LBA.CBCPERF = 1														
Page-23-618792	Radiolist Horizontal	0	Hemoglobin	LBA.HGBUNT	Yes				cUNIT_GDL_GL					
-- Page Dynamics (LBA. HGBUNT): Show When: LBA.CBCPERF = 1 AND LBA.HGBRES IS NOT NULL														
Page-24-618792	Row Start/End	0												
Page-25-618792	Row Start/End	0												
Page-26-618792	Help Text Line	0	A1e. Hematocrit (HCT)											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														

Page Information														
Page-27-618792	Numeric	0	Hematocrit (HCT)	LBA.HCTRES	Yes							3	2	Normal Range: 35 - 54 (%) 0.35 - 0.54 (Proportion of 1.0)
-- Page Dynamics (LBA. HCTRES): Show When: LBA.CBCPERF = 1														
Page-28-618792	Radiolist Horizontal	0	Hematocrit (HCT)	LBA.HCTUNT	Yes				cUNIT_PROP1_PERC					
-- Page Dynamics (LBA. HCTUNT): Show When: LBA.CBCPERF = 1 AND LBA.HCTRES IS NOT NULL														
Page-29-618792	Row Start/End	0												
Page-30-618792	Row Start/End	0												
Page-31-618792	Help Text Line	0	A1f. Mean Cell Volume (MCV)											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-32-618792	Numeric	0	Mean Cell Volume (MCV)	LBA.MCVRES	Yes							3	2	Normal Range: 76-100 (fL) Note (if reporting unit is µm3): 1fL is the same as 1µm3
-- Page Dynamics (LBA. MCVRES): Show When: LBA.CBCPERF = 1														
Page-33-618792	Help Text Line	0	fL											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-34-618792	Row Start/End	0												
Page-35-618792	Row Start/End	0												
Page-36-618792	Help Text Line	0	A1g. Mean Corpuscular Hemoglobin (MCHb)											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-37-618792	Numeric	0	Mean Corpuscular Hemoglobin (MCHb)	LBA.MCHBRES	Yes							3	2	Normal Range: 24 - 35 (pg/cell)
-- Page Dynamics (LBA. MCHBRES): Show When: LBA.CBCPERF = 1														

Page Information														
Page-38-618792	Help Text Line	0	pg											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-39-618792	Row Start/End	0												
Page-40-618792	Row Start/End	0												
Page-41-618792	Help Text Line	0	A1h. Mean Corpuscular Hemoglobin (MCHb) Conc											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-42-618792	Numeric	0	Mean Corpuscular Hemoglobin (MCHb) Conc	LBA.MCHBCRES	Yes							4	2	Normal Range: 31 - 37 (g/dL) 310 - 370 (g/L)
-- Page Dynamics (LBA. MCHBCRES): Show When: LBA.CBCPERF = 1														
Page-43-618792	Radiolist Horizontal	0	Mean Corpuscular Hemoglobin (MCHb) Conc	LBA.MCHBCUNT	Yes				cUNIT_GDL_GL					
-- Page Dynamics (LBA. MCHBCUNT): Show When: LBA.CBCPERF = 1 AND LBA.MCHBCRES IS NOT NULL														
Page-44-618792	Row Start/End	0												
Page-45-618792	Row Start/End	0												
Page-46-618792	Help Text Line	0	A1i. RDW - Red Blood Cell Distribution Width (%)											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-47-618792	Numeric	0	RDW - Red Blood Cell Distribution Width	LBA.RDWRES	Yes							3	2	Normal Range: 11.0 - 15.6 (%)
-- Page Dynamics (LBA. RDWRES): Show When: LBA.CBCPERF = 1														
Page-48-618792	Help Text Line	0	%											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-49-618792	Row Start/End	0												

Page Information														
Page-50-618792	Row Start/End	0												
Page-51-618792	Help Text Line	0	A1j. Platelet Count											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-52-618792	Numeric	0	Platelet Count	LBA.PLTRES	Yes							6	2	Normal Range: 150-450 x (10^9/L) 150-450 x (10^3/uL)
-- Page Dynamics (LBA. PLTRES): Show When: LBA.CBCPERF = 1														
Page-53-618792	Radiolist Horizontal	0	Platelet Count	LBA.PLT_UNT	Yes				cUNIT_103UL_109L					If reporting unit is mm3 (i.e. 150,000-450,000/mm3), PLT value should be reported as 150 - 450 with either unit 10^3/uL or 10^9/L.
-- Page Dynamics (LBA. PLT_UNT): Show When: LBA.CBCPERF = 1 AND LBA.PLTRES IS NOT NULL														
Page-54-618792	Row Start/End	0												
Page-55-618792	Row Start/End	0												
Page-56-618792	Help Text Line	0	A1k. Was a CBC differential done? Please only report the <u>absolute count of each cell type</u>.											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														
Page-57-618792	Radiolist Horizontal	0	Was a CBC differential done?	LBA.CBCDPERF	Yes				cYN					CBC differential must include absolute counts of both segmented and band neutrophils.
-- Page Dynamics (LBA. CBCDPERF): Show When: LBA.CBCPERF = 1														
Page-58-618792	Help Text Line	0												
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1														

Page Information														
Page-59-618792	Row Start/End	0												
Page-60-618792	Row Start/End	0												
Page-61-618792	Help Text Line	0	A1k1. Neutrophils-segmented											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-62-618792	Numeric	0	Neutrophils-segmented	LBA.NEUTSRES	Yes							2	2	Normal Range: 1.5 - 8.0 x (10^9/L) 1.5 - 8.0 x (10^3/uL)
-- Page Dynamics (LBA. NEUTSRES): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-63-618792	Radiolist Horizontal	0	Neutrophils-segmented	LBA.NEUTSUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBA. NEUTSUNT): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1 AND LBA.NEUTSRES IS NOT NULL														
Page-64-618792	Row Start/End	0												
Page-65-618792	Row Start/End	0												
Page-66-618792	Help Text Line	0	A1k2. Neutrophils-bands											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-67-618792	Numeric	0	Neutrophils-bands	LBA.NEUTBRES	Yes							2	2	Normal Range: 0 - 0.70 x (10^9/L) 0 - 0.70 x (10^3/uL)
-- Page Dynamics (LBA. NEUTBRES): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-68-618792	Radiolist Horizontal	0	Neutrophils-bands	LBA.NEUTBUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBA. NEUTBUNT): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1 AND LBA.NEUTBRES IS NOT NULL														
Page-69-618792	Row Start/End	0												

Page Information														
Page-70-618792	Row Start/End	0												
Page-71-618792	Help Text Line	0	A1k3. Lymphocytes											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-72-618792	Numeric	0	Lymphocytes	LBA.LYMPRES	Yes							2	2	Normal Range: 1.0 - 6.5 x (10^9/L) 1.0 - 6.5 x (10^3/uL)
-- Page Dynamics (LBA. LYMPRES): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-73-618792	Radiolist Horizontal	0	Lymphocytes	LBA.LYMPUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBA. LYMPUNT): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1 AND LBA.LYMPRES IS NOT NULL														
Page-74-618792	Row Start/End	0												
Page-75-618792	Row Start/End	0												
Page-76-618792	Help Text Line	0	A1k4. Monocytes											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-77-618792	Numeric	0	Monocytes	LBA.MONORES	Yes							2	2	Normal Range: 0.00 - 0.90 x (10^9/L) 0.00 - 0.90 x (10^3/uL)
-- Page Dynamics (LBA. MONORES): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-78-618792	Radiolist Horizontal	0	Monocytes	LBA.MONOUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBA. MONOUNT): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1 AND LBA.MONORES IS NOT NULL														
Page-79-618792	Row Start/End	0												
Page-80-618792	Row Start/End	0												

Page Information														
Page-81-618792	Help Text Line	0	A1k5. Eosinophils											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-82-618792	Numeric	0	Eosinophils	LBA.EOSRES	Yes							2	2	Normal Range: 0.00 - 0.50 x (10^9/L) 0.00 - 0.50 x (10^3/uL)
-- Page Dynamics (LBA. EOSRES): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-83-618792	Radiolist Horizontal	0	Eosinophils	LBA.EOSUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBA. EOSUNT): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1 AND LBA.EOSRES IS NOT NULL														
Page-84-618792	Row Start/End	0												
Page-85-618792	Row Start/End	0												
Page-86-618792	Help Text Line	0	A1k6. Basophils											
-- Page Dynamics (.): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-87-618792	Numeric	0	Basophils	LBA.BASORES	Yes							2	2	Normal Range: 0.00 - 0.30 x (10^9/L) 0.00 - 0.30 x (10^3/uL)
-- Page Dynamics (LBA. BASORES): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1														
Page-88-618792	Radiolist Horizontal	0	Basophils	LBA.BASOUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBA. BASOUNT): Show When: LBA.CBCPERF = 1 AND LBA.CBCDPERF = 1 AND LBA.BASORES IS NOT NULL														
Page-89-618792	Row Start/End	0												
Page-90-618792	Section Header	0	SECTION B: BLOOD CHEMISTRY PANEL											
Page-91-618792	Radiolist Horizontal	0	B1. Were Blood Chemistry Results obtained?	LBA.CHEMPERF	Yes				cYN					

Page Information														
Page-92-618792	Date	1	B1a. Date of Blood Chemistry Panel	LBA.CHEMDAT	Yes									
-- Page Dynamics (LBA. CHEMDAT): Show When: LBA.CHEMPERF = 1														
Page-93-618792	Row Start/End	0												
Page-94-618792	Section Header	0	Test Name											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-95-618792	Section Header	0	Result											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-96-618792	Section Header	0	Unit											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-97-618792	Row Start/End	0												
Page-98-618792	Row Start/End	0												
Page-99-618792	Help Text Line	0	B1b. Glucose											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-100-618792	Numeric	0	Glucose	LBA.GLUCRES	Yes							4	2	Normal Range: 70 - 110 (mg/dL) 3.9 - 6.1 (mmol/L)
-- Page Dynamics (LBA. GLUCRES): Show When: LBA.CHEMPERF = 1														
Page-101-618792	Radiolist Horizontal	0	Glucose	LBA.GLUCUNT	Yes				cUNIT_MGDL_MMOLL					mg/dl x 0.0555 = mmol/L
-- Page Dynamics (LBA. GLUCUNT): Show When: LBA.CHEMPERF = 1 AND LBA.GLUCRES IS NOT NULL														
Page-102-618792	Row Start/End	0												
Page-103-618792	Row Start/End	0												

Page Information														
Page-104-618792	Help Text Line	0	B1c. Calcium											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-105-618792	Numeric	0	Calcium	LBA.CALRES	Yes							2	2	Normal Range: 8.2 - 10.2 (mg/dL) 2.05 - 2.55 (mmol/L)
-- Page Dynamics (LBA. CALRES): Show When: LBA.CHEMPERF = 1														
Page-106-618792	Radiolist Horizontal	0	Calcium	LBA.CALUNT	Yes				cUNIT_MGDL_MMOLL					mg/dl x 0.25 = mmol/L
-- Page Dynamics (LBA. CALUNT): Show When: LBA.CHEMPERF = 1 AND LBA.CALRES IS NOT NULL														
Page-107-618792	Row Start/End	0												
Page-108-618792	Row Start/End	0												
Page-109-618792	Help Text Line	0	B1d. Albumin											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-110-618792	Numeric	0	Albumin	LBA.ALBUMRES	Yes							3	2	Normal Range: 3.5 - 5.0 g/dL 35 - 50 g/L
-- Page Dynamics (LBA. ALBUMRES): Show When: LBA.CHEMPERF = 1														
Page-111-618792	Radiolist Horizontal	0	Albumin	LBA.ALBUMUNT	Yes				cUNIT_GDL_GL					
-- Page Dynamics (LBA. ALBUMUNT): Show When: LBA.CHEMPERF = 1 AND LBA.ALBUMRES IS NOT NULL														
Page-112-618792	Row Start/End	0												
Page-113-618792	Row Start/End	0												
Page-114-618792	Help Text Line	0	B1e. Total protein											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-115-618792	Numeric	0	Total protein	LBA.PROTRES	Yes							3	2	Normal Range: 6.0 - 8.0 g/dL 60 - 80 g/L

Page Information														
-- Page Dynamics (LBA. PROTRES): Show When: LBA.CHEMPERF = 1														
Page-116-618792	Radiolist Horizontal	0	Total protein	LBA.PROTUNT	Yes				cUNIT_GDL_GL					
-- Page Dynamics (LBA. PROTUNT): Show When: LBA.CHEMPERF = 1 AND LBA.PROTRES IS NOT NULL														
Page-117-618792	Row Start/End	0												
Page-118-618792	Row Start/End	0												
Page-119-618792	Help Text Line	0	B1f. Sodium											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-120-618792	Numeric	0	Sodium	LBA.SODIUMRES	Yes							3	2	Normal Range: 135-145 mEq/L 135-145 mmol/L
-- Page Dynamics (LBA. SODIUMRES): Show When: LBA.CHEMPERF = 1														
Page-121-618792	Radiolist Horizontal	0	Sodium	LBA.SODIUMUNT	Yes				cUNIT_MEQL_MMOLL					
-- Page Dynamics (LBA. SODIUMUNT): Show When: LBA.CHEMPERF = 1 AND LBA.SODIUMRES IS NOT NULL														
Page-122-618792	Row Start/End	0												
Page-123-618792	Row Start/End	0												
Page-124-618792	Help Text Line	0	B1g. Potassium											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-125-618792	Numeric	0	Potassium	LBA.POTASRES	Yes							2	2	Normal Range: 3.4 - 5.2 mEq/L 3.4 - 5.2 mmol/L
-- Page Dynamics (LBA. POTASRES): Show When: LBA.CHEMPERF = 1														
Page-126-618792	Radiolist Horizontal	0	Potassium	LBA.POTASUNT	Yes				cUNIT_MEQL_MMOLL					
-- Page Dynamics (LBA. POTASUNT): Show When: LBA.CHEMPERF = 1 AND LBA.POTASRES IS NOT NULL														
Page-127-618792	Row Start/End	0												

Page Information														
Page-128-618792	Row Start/End	0												
Page-129-618792	Help Text Line	0	B1h. Bicarbonate											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-130-618792	Numeric	0	Bicarbonate	LBA.CO2RES	Yes							3	2	Normal Range: 21 - 29 mEq/L 21 - 29 mmol/L
-- Page Dynamics (LBA. CO2RES): Show When: LBA.CHEMPERF = 1														
Page-131-618792	Radiolist Horizontal	0	Bicarbonate	LBA.CO2UNT	Yes				cUNIT_MEQL_MMOLL					
-- Page Dynamics (LBA. CO2UNT): Show When: LBA.CHEMPERF = 1 AND LBA.CO2RES IS NOT NULL														
Page-132-618792	Row Start/End	0												
Page-133-618792	Row Start/End	0												
Page-134-618792	Help Text Line	0	B1i. Chloride											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-135-618792	Numeric	0	Chloride	LBA.CHLORRES	Yes							3	2	Normal Range: 96 - 106 mEq/L 96 - 106 mmol/L
-- Page Dynamics (LBA. CHLORRES): Show When: LBA.CHEMPERF = 1														
Page-136-618792	Radiolist Horizontal	0	Chloride	LBA.CHLORUNT	Yes				cUNIT_MEQL_MMOLL					
-- Page Dynamics (LBA. CHLORUNT): Show When: LBA.CHEMPERF = 1 AND LBA.CHLORRES IS NOT NULL														
Page-137-618792	Row Start/End	0												
Page-138-618792	Row Start/End	0												
Page-139-618792	Help Text Line	0	B1j. BUN											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														

Page Information														
Page-140-618792	Numeric	0	BUN	LBA.BUNRES	Yes							3	2	Normal Range: 8.0 - 23.0 (mg/dL) 2.9 - 8.2 (mmol/L)
-- Page Dynamics (LBA. BUNRES): Show When: LBA.CHEMPERF = 1														
Page-141-618792	Radiolist Horizontal	0	BUN	LBA.BUNUNT	Yes				cUNIT_MGDL_MMOLL					mg/dL x 0.357 = mmol/L
-- Page Dynamics (LBA. BUNUNT): Show When: LBA.CHEMPERF = 1 AND LBA.BUNRES IS NOT NULL														
Page-142-618792	Row Start/End	0												
Page-143-618792	Row Start/End	0												
Page-144-618792	Help Text Line	0	B1k. Creatinine											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-145-618792	Numeric	0	Creatinine	LBA.CREATRES	Yes							3	2	Normal Range: 0.6 - 1.2 (mg/dL) 53 - 106 (µmol/L)
-- Page Dynamics (LBA. CREATRES): Show When: LBA.CHEMPERF = 1														
Page-146-618792	Radiolist Horizontal	0	Creatinine	LBA.CREATUNT	Yes				cUNIT_MGDL_UMOLL					mg/dL x 88.4 = µmol/L
-- Page Dynamics (LBA. CREATUNT): Show When: LBA.CHEMPERF = 1 AND LBA.CREATRES IS NOT NULL														
Page-147-618792	Row Start/End	0												
Page-148-618792	Row Start/End	0												
Page-149-618792	Help Text Line	0	GFR											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1 AND LBA.CREATRES IS NOT NULL														
Page-150-618792	Auto Calc Field	0	GFR	LBA.GFRCALC								3	2	
-- Auto Calc Rule (LBA.GFRCALC): (LBA.CREATRES IS NOT NULL AND LBA.CREATUNT IS NOT NULL AND LBA.CREATUNT = 1)>>>USE: (RemoteLookup[10.50-EXAM.HEIGHT_AV] * 0.41) / LBA.CREATRES (LBA.CREATRES IS NOT NULL AND LBA.CREATUNT IS NOT NULL AND LBA.CREATUNT = 2)>>>USE: ((RemoteLookup[10.50-EXAM.HEIGHT_AV] * 0.41) / (LBA.CREATRES * 0.0113))														
-- Page Dynamics (LBA. GFRCALC): Show When: LBA.CHEMPERF = 1 AND LBA.CREATRES IS NOT NULL														

Page Information														
Page-151-618792	Help Text Line	0												
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1 AND LBA.CREATRES IS NOT NULL														
Page-152-618792	Row Start/End	0												
Page-153-618792	Row Start/End	0												
Page-154-618792	Help Text Line	0	B1l. Alkaline phosphatase											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-155-618792	Numeric	0	Alkaline phosphatase	LBA.ALPRES	Yes							4	2	Normal Range: 40 - 160 (U/L) 40 - 160 (IU/L)
-- Page Dynamics (LBA. ALPRES): Show When: LBA.CHEMPERF = 1														
Page-156-618792	Radiolist Horizontal	0	Alkaline phosphatase	LBA.ALPUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
-- Page Dynamics (LBA. ALPUNT): Show When: LBA.CHEMPERF = 1 AND LBA.ALPRES IS NOT NULL														
Page-157-618792	Row Start/End	0												
Page-158-618792	Row Start/End	0												
Page-159-618792	Help Text Line	0	B1m. ALT											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-160-618792	Numeric	0	ALT	LBA.ALTRES	Yes							3	2	Normal Range: 5.0 - 35.0 (U/L) 5.0 - 35.0 (IU/L)
-- Page Dynamics (LBA. ALTRES): Show When: LBA.CHEMPERF = 1														
Page-161-618792	Radiolist Horizontal	0	ALT	LBA.ALTUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
-- Page Dynamics (LBA. ALTUNT): Show When: LBA.CHEMPERF = 1 AND LBA.ALTRES IS NOT NULL														
Page-162-618792	Row Start/End	0												

Page Information														
Page-163-618792	Row Start/End	0												
Page-164-618792	Help Text Line	0	B1n. AST											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-165-618792	Numeric	0	AST	LBA.ASTRES	Yes							3	2	Normal Range: 7.0 - 40.0 (U/L) 7.0 - 40.0 (IU/L)
-- Page Dynamics (LBA. ASTRES): Show When: LBA.CHEMPERF = 1														
Page-166-618792	Radiolist Horizontal	0	AST	LBA.ASTUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
-- Page Dynamics (LBA. ASTUNT): Show When: LBA.CHEMPERF = 1 AND LBA.ASTRES IS NOT NULL														
Page-167-618792	Row Start/End	0												
Page-168-618792	Row Start/End	0												
Page-169-618792	Help Text Line	0	B1o. Total bilirubin											
-- Page Dynamics (.): Show When: LBA.CHEMPERF = 1														
Page-170-618792	Numeric	0	Total bilirubin	LBA.BILIRRES	Yes							3	2	Normal Range: 0.3 - 1.2 (mg/dL) 5.0 - 21.0 (µmol/L)
-- Page Dynamics (LBA. BILIRRES): Show When: LBA.CHEMPERF = 1														
Page-171-618792	Radiolist Horizontal	0	Total bilirubin	LBA.BILIRUNT	Yes				cUNIT_MGDL_UMOLL					mg/dL x 17.104 = µmol/L
-- Page Dynamics (LBA. BILIRUNT): Show When: LBA.CHEMPERF = 1 AND LBA.BILIRRES IS NOT NULL														
Page-172-618792	Row Start/End	0												
Page-173-618792	Section Header	0	SECTION C: Creatine Kinase (CK)											
Page-174-618792	Radiolist Horizontal	0	C1. Was Creatine Kinase (CK) done?	LBA.CKYN					cYN					

Page Information														
Page-175-618792	Date	1	C1a. Date of blood draw	LBA.CKDAT										
-- Page Dynamics (LBA. CKDAT): Show When: LBA.CKYN = 1														
Page-176-618792	Numeric	1	C1b. Result	LBA.CKRES	Yes							4	2	Normal Range: 20.0 - 215 (U/L) 20.0 - 215 (IU/L)
-- Page Dynamics (LBA. CKRES): Show When: LBA.CKYN = 1														
Page-177-618792	Radiolist Horizontal	1	C1c. Unit	LBA.CKUNT					cUNIT_UL_IUL					
-- Page Dynamics (LBA. CKUNT): Show When: LBA.CKYN = 1														
Page-178-618792	Section Header	0	SECTION D: Hemoglobin A1c											
Page-179-618792	Radiolist Horizontal	0	D1. Was Hemoglobin A1c done?	LBA.HBA1CYN					cYN					HbA1c must be done at a site lab and not point of care.
Page-180-618792	Date	1	D1a. Date of blood draw	LBA.HBA1CDAT										
-- Page Dynamics (LBA. HBA1CDAT): Show When: LBA.HBA1CYN = 1														
Page-181-618792	Numeric	1	D1b. Result (%)	LBA.HBA1CRES	Yes							2	2	Normal Range: 4.0 - 6.0 (%)
-- Page Dynamics (LBA. HBA1CRES): Show When: LBA.HBA1CYN = 1														
Page-182-618792	Section Header	0	SECTION E: URINALYSIS											
-- Role Permissions (.): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page-183-618792	Help Text Line	0	Urinalysis is required at Screening ONLY.											
-- Role Permissions (.): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page-184-618792	Radiolist Horizontal	0	E1. Was urine sample acquired for urinalysis?	LBA.URINPERF	Yes				cYN					
-- Role Permissions (LBA. URINPERF): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														

Page Information														
Page -185-618792	Date	1	E1a. Date of urine sample collection	LBA.URINDAT	Yes									Indicate the date the sample was collected. The date should be in Enter in DD/MMM/YYYY date format.
-- Page Dynamics (LBA. URINDAT): Show When: LBA.URINPERF = 1														
-- Role Permissions (LBA. URINDAT): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page -186-618792	Radiolist	1	E1b. Glucose	LBA.URGLURES	Yes				cURINE_RES					Normal is Negative or Trace amounts of Glucose
-- Page Dynamics (LBA. URGLURES): Show When: LBA.URINPERF = 1														
-- Role Permissions (LBA. URGLURES): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page -187-618792	Radiolist	1	E1c. Protein	LBA.URPRORES	Yes				cURINE_RES					Normal is Negative or Trace amounts of Protein
-- Page Dynamics (LBA. URPRORES): Show When: LBA.URINPERF = 1														
-- Role Permissions (LBA. URPRORES): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page -188-618792	Radiolist Horizontal	0	E2. Was a urine albumin: urine creatinine ratio obtained?	LBA.URCRPERF	Yes				cYN					
-- Role Permissions (LBA. URCRPERF): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page -189-618792	Check Box	1	E2a. Check if urine sample collection date for albumin:urine creatinine ratio was different	LBA.URCRDIFF										
-- Page Dynamics (LBA. URCRDIFF): Show When: LBA.URCRPERF = 1														
-- Role Permissions (LBA. URCRDIFF): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page -190-618792	Date	2	E2a1. Date of urine sample collection	LBA.URCREDAT	Yes									
-- Page Dynamics (LBA. URCREDAT): Show When: LBA.URCRPERF = 1 AND LBA.URCRDIFF IS NOT NULL														
-- Role Permissions (LBA. URCREDAT): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page -191-618792	Numeric	1	E2b. Result	LBA.URCRERES	Yes							3	2	Normal Range: <30 (mg/g) <3.5 (mg/mmol)
-- Page Dynamics (LBA. URCRERES): Show When: LBA.URCRPERF = 1														

Page Information														
-- Role Permissions (LBA. URCRERES): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page-192-618792	Radiolist Horizontal	1	E2c. Unit	LBA.URCREUNT	Yes				cUNIT_MGG_MGMMOL					mg/g x 0.113 = mg/mmol mg/mmol x 8.85 = mg/g
-- Page Dynamics (LBA. URCREUNT): Show When: LBA.URCRPERF = 1														
-- Role Permissions (LBA. URCREUNT): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page-193-618792	Section Header	0	SECTION F: PREGNANCY TEST											
-- Page Dynamics (.): Show When: 10-40-DM.SEX = 2														
Page-194-618792	Radiolist Horizontal	0	F1. Was a urine pregnancy test done at this visit?	LBA.PREGPERF	Yes				cYNNA					
-- Page Dynamics (LBA. PREGPERF): Show When: 10-40-DM.SEX = 2														
Page-195-618792	Date	1	F1a. Date of Pregnancy Test	LBA.PREGDAT	Yes									
-- Page Dynamics (LBA. PREGDAT): Show When: 10-40-DM.SEX = 2 AND LBA.PREGPERF = 1														
Page-196-618792	Radiolist Horizontal	1	F1b. Result of Pregnancy Test	LBA.PREGRES	Yes				cPOS_NEG					
-- Page Dynamics (LBA. PREGRES): Show When: 10-40-DM.SEX = 2 AND LBA.PREGPERF = 1														
Page-197-618792	Section Header	0	SECTION G: THYROID STIMULATING HORMONE (TSH)											
Page-198-618792	Help Text Line	0	Thyroid Stimulating Hormone (TSH) is required at Screening ONLY.											
Page-199-618792	Radiolist Horizontal	0	G1. Was a TSH sample collected	LBA.TSHPERF	Yes				cYN					
Page-200-618792	Date	1	G1a. Date sample collected	LBA.TSHDAT	Yes									
-- Page Dynamics (LBA. TSHDAT): Show When: LBA.TSHPERF = 1														
Page-201-618792	Time	1	G1b. Time of TSH sample collection	LBA.TSHTIM	Yes									
-- Page Dynamics (LBA. TSHTIM): Show When: LBA.TSHPERF = 1														
Page-202-618792	Numeric	1	G1c. TSH (µIU/mL)	LBA.TSHRES	Yes							2	2	Normal Range: 0.45 – 4.80 µIU/mL

Page Information
-- Page Dynamics (LBA. TSHRES): Show When: LBA.TSHPERF = 1

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618987	SYSQ_4958	LBA.CBCDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(LBA.CBCDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618988	SYSQ_4959	LBA.CHEMDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(LBA.CHEMDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618989	SYSQ_4960	LBA.URINDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(LBA.URINDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.		Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618990	SYSQ_4961	LBA.URCREDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(LBA.URCREDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.		Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618991	SYSQ_4962	LBA.PREGDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(LBA.PREGDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618992	SYSQ_4963	LBA.TSHDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(LBA.TSHDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0

System Queries														
sysq-618993	SYSQ_4966	LBA.URCRERES	Other / Cross Page		(VISITID = 10 AND LBA.URCRERES > 0.2 AND LBA.URCREUNT = 2) OR (VISITID = 10 AND LBA.URCRERES > 1.77 AND LBA.URCREUNT = 1)	ACR is > 0.2 mg/mmol or > 1.77 mg/g. Please confirm exclusion criteria "Proteinuria suggestive of renal disease (urine protein: creatinine >0.2)" was not met.		Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619271	SYSQ_5096	LBA.HBA1CRES	Other / Cross Page		LBA.HBA1CRES >= 6.5 AND VISITID = 10	Diabetes (type 1 or 2) by ADA criteria which includes a hemoglobin A1c (HbA1c) level of 6.5% or higher, is an exclusion criteria violation. Please review and confirm. If confirmed subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619272	SYSQ_5097	LBA.GLUCRES	Other / Cross Page		((LBA.GLUCRES >= 126 AND LBA.GLUCUNT = 1) OR (LBA.GLUCRES >= 7 AND LBA.GLUCUNT = 2) AND VISITID = 10)	Diabetes (type 1 or 2) by ADA criteria which includes fasting glucose 126 mg/dL (7 mmol/L) or higher, is an exclusion criteria violation. Please review and confirm value. If confirmed subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619273	SYSQ_5098	LBA.GFRCALC	Other / Cross Page		LBA.GFRCALC < 60	Estimated GFR (calculated using the Bedside IDMS-traceable Schwartz calculator for children) is < 60 mL/min/1.73m^2) which is an exclusion criteria violation. Please confirm creatinine value.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619274	SYSQ_5099	LBA.CBCPERF	Field Null		LBA.CBCPERF IS NULL	"A1. Were Complete Blood Count (CBC) Results obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619275	SYSQ_5100	LBA.CBCDAT	Field Null		LBA.CBCDAT IS NULL	"A1a. Date of sample collection" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0

System Queries														
sysq-619276	SYSQ_5101	LBA.CBCDAT	Future Date		LBA.CBCDAT > Today	"A1a. Date of sample collection" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619277	SYSQ_5102	LBA.WBCRES	Field Null		LBA.WBCRES IS NULL	"White Blood Cell Count (WBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619278	SYSQ_5103	LBA.WBCUNT	Field Null		LBA.WBCUNT IS NULL	"White Blood Cell Count (WBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619279	SYSQ_5104	LBA.RBCRES	Field Null		LBA.RBCRES IS NULL	"Red Blood Cell Count (RBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619280	SYSQ_5105	LBA.RBCUNT	Field Null		LBA.RBCUNT IS NULL	"Red Blood Cell Count (RBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619281	SYSQ_5106	LBA.HGBRES	Field Null		LBA.HGBRES IS NULL	"Hemoglobin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619282	SYSQ_5107	LBA.HGBUNT	Field Null		LBA.HGBUNT IS NULL	"Hemoglobin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619283	SYSQ_5108	LBA.HCTRES	Field Null		LBA.HCTRES IS NULL	"Hematocrit (HCT)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619284	SYSQ_5109	LBA.HCTUNT	Field Null		LBA.HCTUNT IS NULL	"Hematocrit (HCT)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619285	SYSQ_5110	LBA.MCVRES	Field Null		LBA.MCVRES IS NULL	"Mean Cell Volume (MCV)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0

System Queries														
sysq-619286	SYSQ_5111	LBA.MCHBRES	Field Null		LBA.MCHBRES IS NULL	"Mean Corpuscular Hemoglobin (MCHb)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619287	SYSQ_5112	LBA.MCHBCRES	Field Null		LBA.MCHBCRES IS NULL	"Mean Corpuscular Hemoglobin (MCHb) Conc" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619288	SYSQ_5113	LBA.MCHBCUNT	Field Null		LBA.MCHBCUNT IS NULL	"Mean Corpuscular Hemoglobin (MCHb) Conc" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619289	SYSQ_5114	LBA.RDWRES	Field Null		LBA.RDWRES IS NULL	"RDW - Red Blood Cell Distribution Width" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:22	0	0	0	0	0	0
sysq-619290	SYSQ_5115	LBA.PLTRES	Field Null		LBA.PLTRES IS NULL	"Platelet Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619291	SYSQ_5116	LBA.PLT_UNT	Field Null		LBA.PLT_UNT IS NULL	"Platelet Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619292	SYSQ_5117	LBA.CBCDPERF	Field Null		LBA.CBCDPERF IS NULL	"Was a CBC differential done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619293	SYSQ_5118	LBA.NEUTSRES	Field Null		LBA.NEUTSRES IS NULL	"Neutrophils-segmented" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619294	SYSQ_5119	LBA.NEUTSUNT	Field Null		LBA.NEUTSUNT IS NULL	"Neutrophils-segmented" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619295	SYSQ_5120	LBA.NEUTBRES	Field Null		LBA.NEUTBRES IS NULL	"Neutrophils-bands" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0

System Queries														
sysq-619296	SYSQ_5121	LBA.NEUTBUNT	Field Null		LBA.NEUTBUNT IS NULL	"Neutrophils-bands" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619297	SYSQ_5122	LBA.LYMPRES	Field Null		LBA.LYMPRES IS NULL	"Lymphocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619298	SYSQ_5123	LBA.LYMPUNT	Field Null		LBA.LYMPUNT IS NULL	"Lymphocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619299	SYSQ_5124	LBA.MONORES	Field Null		LBA.MONORES IS NULL	"Monocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619300	SYSQ_5125	LBA.MONOUNT	Field Null		LBA.MONOUNT IS NULL	"Monocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619301	SYSQ_5126	LBA.EOSRES	Field Null		LBA.EOSRES IS NULL	"Eosinophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619302	SYSQ_5127	LBA.EOSUNT	Field Null		LBA.EOSUNT IS NULL	"Eosinophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619303	SYSQ_5128	LBA.BASORES	Field Null		LBA.BASORES IS NULL	"Basophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619304	SYSQ_5129	LBA.BASOUNT	Field Null		LBA.BASOUNT IS NULL	"Basophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619305	SYSQ_5130	LBA.CHEMPERF	Field Null		LBA.CHEMPERF IS NULL	"B1. Were Blood Chemistry/CK Results obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0

System Queries														
sysq-619306	SYSQ_5131	LBA.CHEMDAT	Field Null		LBA.CHEMDAT IS NULL	"B1a. Date of Blood Chemistry Panel" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619307	SYSQ_5132	LBA.CHEMDAT	Future Date		LBA.CHEMDAT > Today	"B1a. Date of Blood Chemistry Panel" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619308	SYSQ_5133	LBA.GLUCRES	Field Null		LBA.GLUCRES IS NULL	"Glucose" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619309	SYSQ_5134	LBA.GLUCUNT	Field Null		LBA.GLUCUNT IS NULL	"Glucose" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619310	SYSQ_5136	LBA.CALRES	Field Null		LBA.CALRES IS NULL	"Calcium" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619311	SYSQ_5137	LBA.CALUNT	Field Null		LBA.CALUNT IS NULL	"Calcium" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619312	SYSQ_5138	LBA.ALBUMRES	Field Null		LBA.ALBUMRES IS NULL	"Albumin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619313	SYSQ_5139	LBA.ALBUMUNT	Field Null		LBA.ALBUMUNT IS NULL	"Albumin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619314	SYSQ_5140	LBA.PROTRES	Field Null		LBA.PROTRES IS NULL	"Total protein" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619315	SYSQ_5141	LBA.PROTUNT	Field Null		LBA.PROTUNT IS NULL	"Total protein" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0

System Queries														
sysq-619316	SYSQ_5142	LBA.SODIUMRES	Field Null		LBA.SODIUMRES IS NULL	"Sodium" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619317	SYSQ_5143	LBA.SODIUMUNT	Field Null		LBA.SODIUMUNT IS NULL	"Sodium" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619318	SYSQ_5144	LBA.POTASRES	Field Null		LBA.POTASRES IS NULL	"Potassium" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619319	SYSQ_5145	LBA.POTASUNT	Field Null		LBA.POTASUNT IS NULL	"Potassium" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619320	SYSQ_5146	LBA.CO2RES	Field Null		LBA.CO2RES IS NULL	"Bicarbonate" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619321	SYSQ_5147	LBA.CO2UNT	Field Null		LBA.CO2UNT IS NULL	"Bicarbonate" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:23	0	0	0	0	0	0
sysq-619322	SYSQ_5148	LBA.CHLORRES	Field Null		LBA.CHLORRES IS NULL	"Chloride" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619323	SYSQ_5149	LBA.CHLORUNT	Field Null		LBA.CHLORUNT IS NULL	"Chloride" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619324	SYSQ_5150	LBA.BUNRES	Field Null		LBA.BUNRES IS NULL	"BUN" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619325	SYSQ_5151	LBA.BUNUNT	Field Null		LBA.BUNUNT IS NULL	"BUN" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0

System Queries														
sysq-619326	SYSQ_5152	LBA.CREATRES	Field Null		LBA.CREATRES IS NULL	"Creatinine" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619327	SYSQ_5153	LBA.CREATUNT	Field Null		LBA.CREATUNT IS NULL	"Creatinine" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619328	SYSQ_5154	LBA.ALPRES	Field Null		LBA.ALPRES IS NULL	"Alkaline phosphatase" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619329	SYSQ_5155	LBA.ALPUNT	Field Null		LBA.ALPUNT IS NULL	"Alkaline phosphatase" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619330	SYSQ_5156	LBA.ALTRES	Field Null		LBA.ALTRES IS NULL	"ALT" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619331	SYSQ_5157	LBA.ALTUNT	Field Null		LBA.ALTUNT IS NULL	"ALT" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619332	SYSQ_5158	LBA.ASTRES	Field Null		LBA.ASTRES IS NULL	"AST" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619333	SYSQ_5159	LBA.ASTUNT	Field Null		LBA.ASTUNT IS NULL	"AST" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619334	SYSQ_5160	LBA.BILIRRES	Field Null		LBA.BILIRRES IS NULL	"Total bilirubin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619335	SYSQ_5161	LBA.BILIRUNT	Field Null		LBA.BILIRUNT IS NULL	"Total bilirubin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0

System Queries														
sysq-619336	SYSQ_5162	LBA.CKRES	Field Null		LBA.CKRES IS NULL	"Creatine Kinase (CK)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619337	SYSQ_5164	LBA.URINPERF	Field Null		LBA.URINPERF IS NULL	"C1. Was urine sample acquired for urinalysis?" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619338	SYSQ_5165	LBA.URINDAT	Field Null		LBA.URINDAT IS NULL	"C1a. Date of urine sample collection" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619339	SYSQ_5166	LBA.URINDAT	Future Date		LBA.URINDAT > Today	"C1a. Date of urine sample collection" cannot be in the future.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619340	SYSQ_5167	LBA.URGLURES	Field Null		LBA.URGLURES IS NULL	"C1b. Glucose" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619341	SYSQ_5168	LBA.URPRORES	Field Null		LBA.URPRORES IS NULL	"C1c. Protein" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619342	SYSQ_5169	LBA.URCRPERF	Field Null		LBA.URCRPERF IS NULL	"C2. Was a urine albumin: urine creatinine ratio obtained?" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619343	SYSQ_5170	LBA.URCREDAT	Field Null		LBA.URCREDAT IS NULL	"C2a1. Date of urine sample collection" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619344	SYSQ_5171	LBA.URCREDAT	Future Date		LBA.URCREDAT > Today	"C2a1. Date of urine sample collection" cannot be in the future.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619345	SYSQ_5172	LBA.URCRERES	Field Null		LBA.URCRERES IS NULL	"C2b. Result" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0

System Queries														
sysq-619346	SYSQ_5173	LBA.URCREUNT	Field Null		LBA.URCREUNT IS NULL	"C2c. Unit" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619347	SYSQ_5174	LBA.PREGPERF	Field Null		LBA.PREGPERF IS NULL	"D1. Was a urine pregnancy test done at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619348	SYSQ_5175	LBA.PREGDAT	Field Null		LBA.PREGDAT IS NULL	"D1a. Date of Pregnancy Test" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619349	SYSQ_5176	LBA.PREGDAT	Future Date		LBA.PREGDAT > Today	"D1a. Date of Pregnancy Test" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619350	SYSQ_5177	LBA.PREGRES	Field Null		LBA.PREGRES IS NULL	"D1b. Result of Pregnancy Test" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619351	SYSQ_5178	LBA.TSHPERF	Field Null		LBA.TSHPERF IS NULL	"E1. Was a TSH sample collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619352	SYSQ_5179	LBA.TSHDAT	Field Null		LBA.TSHDAT IS NULL	"E1a. Date sample collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619353	SYSQ_5180	LBA.TSHDAT	Future Date		LBA.TSHDAT > Today	"E1a. Date sample collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619354	SYSQ_5181	LBA.TSHTIM	Field Null		LBA.TSHTIM IS NULL	"E1b. Time of TSH sample collection" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619355	SYSQ_5182	LBA.TSHRES	Field Null		LBA.TSHRES IS NULL	"E1c. TSH (uU/ml)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0

System Queries														
sysq-620282	SYSQ_5754	LBA.CKYN	Field Null		LBA.CKYN IS NULL	"C1. Was Creatine Kinase (CK) done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620283	SYSQ_5755	LBA.CKDAT	Field Null		LBA.CKDAT IS NULL	"C1a. Date of blood draw" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620284	SYSQ_5756	LBA.CKDAT	Future Date		LBA.CKDAT > Today	"C1a. Date of blood draw" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620285	SYSQ_5757	LBA.CKUNT	Field Null		LBA.CKUNT IS NULL	"C1c. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620286	SYSQ_5758	LBA.HBA1CYN	Field Null		LBA.HBA1CYN IS NULL	"D1. Was Hemoglobin A1c done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620287	SYSQ_5759	LBA.HBA1CDAT	Field Null		LBA.HBA1CDAT IS NULL	"D1a. Date of blood draw" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620288	SYSQ_5760	LBA.HBA1CDAT	Future Date		LBA.HBA1CDAT > Today	"D1a. Date of blood draw" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620289	SYSQ_5761	LBA.HBA1CRES	Field Null		LBA.HBA1CRES IS NULL	"D1b. Result (%)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620290	SYSQ_5762	LBA.CKDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(LBA.CKDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0

System Queries														
sysq-620291	SYSQ_5763	LBA.HBA1CDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(LBA.HBA1CDAT, 10-20-ICF.ICF_DT) > 0 AND VISITID = 10	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0

pLBALT

Page

(Visit ID = 618793, Page ID =)

Unique Identifier page-618793-618793-618793-

SECTION A: REPEATED ALT ASSESSMENTS

For subjects without known liver disease (other than NAFLD) or ALT elevation at randomization, increases in ALT will be verified by repeat assessment within 48-72 hours, together with a bilirubin + INR. Subjects with persistent ALT abnormalities, abnormal bilirubin or INR, or symptoms will be further assessed by the site's gastroenterologist /hepatologist, and the results of any additional evaluation will be recorded and reported.

SDV	* A1. Date of blood draw		LBALT.ALTDAT	
SDV	* A1a. ALT Result		LBALT.ALTRES	(format xxx.xx)
SDV	* A1b. Unit	○ U/L ○ IU/L	LBALT.ALTUNT	
SDV	* A1c. ULN		LBALT.ALTULN	(format xxx.xx)
SDV	* A1d. Was the ALT result normal?	○ Yes ○ No	LBALT.ALTNORM	
SDV	* A2. Did subject have any symptoms of liver disease?	○ Yes ○ No	LBALT.ALTGISYM	

If Yes, please ensure all symptoms are reported on the Visit Form in this visit.

SDV	* A3. Was INR measurement obtained?	○ Yes ○ No	LBALT.INRYN	
SDV	* A3a. Result		LBALT.INRRES	(format x.x)
SDV	* A3b. ULN		LBALT.INRULN	(format x.x)
SDV	* A3c. Was the INR result normal?	○ Yes ○ No	LBALT.INRNORMYN	
SDV	* A4. Was bilirubin measurement obtained?	○ Yes ○ No	LBALT.BILIYN	
SDV	* A4a. Result		LBALT.BILIRES	(format xxx.xx)
SDV	* A4b. Unit	○ mg/dL ○ µmol/L	LBALT.BILIUNT	
SDV	* A4c. ULN		LBALT.BILIULN	(format xxx.xx)
SDV	* A4d. Was the bilirubin result normal?	○ Yes ○ No	LBALT.BILNORMYN	

SDV	* A5. Was an additional evaluation performed by the site's gastroenterologist /hepatologist?	○ Yes ○ No	LBALT.ADD EVALYN
SDV	* A5a. Please provide the results of the additional evaluation		LBALT.ADD EVRES

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618793	Section Header	0	SECTION A: REPEATED ALT ASSESSMENTS											
Page-2-618793	Help Text Line	0	For subjects without known liver disease (other than NAFLD) or ALT elevation at randomization, increases in ALT will be verified by repeat assessment within 48-72 hours, together with a bilirubin + INR. Subjects with persistent ALT abnormalities, abnormal bilirubin or INR, or symptoms will be further assessed by the site's gastroenterologist /hepatologist, and the results of any additional evaluation will be recorded and reported.											
Page-3-618793	Date	0	A1. Date of blood draw	LBALT.ALTDAT	Yes									
Page-4-618793	Numeric	0	A1a. ALT Result	LBALT.ALTRES	Yes							3	2	Normal Range: 5.0 - 35.0 (U/L) 5.0 - 35.0 (IU/L)
Page-5-618793	Radiolist Horizontal	0	A1b. Unit	LBALT.ALTUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
Page-6-618793	Numeric	0	A1c. ULN	LBALT.ALTULN	Yes							3	2	

Page Information														
Page-7-618793	Radiolist Horizontal	0	A1d. Was the ALT result normal?	LBALT.ALTNORM	Yes				cYN					
Page-8-618793	Radiolist Horizontal	0	A2. Did subject have any symptoms of liver disease?	LBALT.ALTGISYM	Yes				cYN					
Page-9-618793	Help Text Line	1	If Yes, please ensure all symptoms are reported on the Visit Form in this visit.											
-- Page Dynamics (.): Show When: LBALT.ALTGISYM = 1														
Page-10-618793	Radiolist Horizontal	0	A3. Was INR measurement obtained?	LBALT.INRYN	Yes				cYN					
Page-11-618793	Numeric	1	A3a. Result	LBALT.INRRES	Yes							1	1	Normal Range: 0.80 - 1.20
-- Page Dynamics (LBALT. INRRES): Show When: LBALT.INRYN = 1														
Page-12-618793	Numeric	1	A3b. ULN	LBALT.INRULN	Yes							1	1	
-- Page Dynamics (LBALT. INRULN): Show When: LBALT.INRYN = 1														
Page-13-618793	Radiolist Horizontal	1	A3c. Was the INR result normal?	LBALT.INRNORMYN	Yes				cYN					
-- Page Dynamics (LBALT. INRNORMYN): Show When: LBALT.INRYN = 1														
Page-14-618793	Radiolist Horizontal	0	A4. Was bilirubin measurement obtained?	LBALT.BILIYN	Yes				cYN					
Page-15-618793	Numeric	1	A4a. Result	LBALT.BILIRES	Yes							3	2	Normal Range: 0.3 - 1.2 (mg/dL) 5.0 - 21.0 (µmol/L)
-- Page Dynamics (LBALT. BILIRES): Show When: LBALT.BILIYN = 1														
Page-16-618793	Radiolist Horizontal	1	A4b. Unit	LBALT.BILIUNT	Yes				cUNIT_MGDL_UMOLL					mg/dL x 17.104 = µmol/L
-- Page Dynamics (LBALT. BILIUNT): Show When: LBALT.BILIYN = 1														
Page-17-618793	Numeric	1	A4c. ULN	LBALT.BILIULN	Yes							3	2	
-- Page Dynamics (LBALT. BILIULN): Show When: LBALT.BILIYN = 1														
Page-18-618793	Radiolist Horizontal	1	A4d. Was the bilirubin result normal?	LBALT.BILNORMYN	Yes				cYN					
-- Page Dynamics (LBALT. BILNORMYN): Show When: LBALT.BILIYN = 1														

Page Information															
Page-19-618793	Radiolist Horizontal	0	A5. Was an additional evaluation performed by the site's gastroenterologist /hepatologist?	LBALT.ADDEVALYN	Yes				cYN					
Page-20-618793	Text Field	1	A5a. Please provide the results of the additional evaluation	LBALT.ADDEVRES	Yes					200	99			
-- Page Dynamics (LBALT. ADDEVRES): Show When: LBALT.ADDEVALYN = 1															

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619778	SYSQ_5427	LBALT.ALTDAT	Field Null		LBALT.ALTDAT IS NULL	"A1. Date of blood draw" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619779	SYSQ_5428	LBALT.ALTDAT	Future Date		LBALT.ALTDAT > Today	"A1. Date of blood draw" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619780	SYSQ_5430	LBALT.ALTUNT	Field Null		LBALT.ALTUNT IS NULL	"A1b. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619781	SYSQ_5431	LBALT.ALTULN	Field Null		LBALT.ALTULN IS NULL	"A1c. ULN" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619782	SYSQ_5432	LBALT.ALTNORM	Field Null		LBALT.ALTNORM IS NULL	"A1d. Was the ALT result normal?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619783	SYSQ_5433	LBALT.ALTGISYM	Field Null		LBALT.ALTGISYM IS NULL	"A2. Did subject have any symptoms of liver disease?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619784	SYSQ_5434	LBALT.INRYN	Field Null		LBALT.INRYN IS NULL	"A3. Was INR measurement obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0

System Queries														
sysq-619785	SYSQ_5435	LBALT.INRRES	Field Null		LBALT.INRRES IS NULL	"A3a. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619786	SYSQ_5436	LBALT.INRULN	Field Null		LBALT.INRULN IS NULL	"A3b. ULN" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619787	SYSQ_5437	LBALT.INRNORMYN	Field Null		LBALT.INRNORMYN IS NULL	"A3c. Was the INR result normal?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619788	SYSQ_5438	LBALT.BILIYN	Field Null		LBALT.BILIYN IS NULL	"A4. Was bilirubin measurement obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619789	SYSQ_5439	LBALT.BILIRES	Field Null		LBALT.BILIRES IS NULL	"A4a. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619790	SYSQ_5440	LBALT.BILIUNT	Field Null		LBALT.BILIUNT IS NULL	"A4b. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619791	SYSQ_5441	LBALT.BILIULN	Field Null		LBALT.BILIULN IS NULL	"A4c. ULN" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619792	SYSQ_5442	LBALT.BILNORMYN	Field Null		LBALT.BILNORMYN IS NULL	"A4d. Was the bilirubin result normal?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619793	SYSQ_5443	LBALT.ADDEVALYN	Field Null		LBALT.ADDEVALYN IS NULL	"A5. Was an additional evaluation performed by the site's gastroenterologist /hepatologist?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619794	SYSQ_5444	LBALT.ADDEVRES	Field Null		LBALT.ADDEVRES IS NULL	"A5a. Please provide the results of the additional evaluation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0

System Queries														
sysq-620086	SYSQ_5650	LBALT.ALTRES	Field Null		LBALT.ALTRES IS NULL	"A1a. ALT Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0

pLBB

Page

(Visit ID = 618794, Page ID =)

Unique Identifier page-618794-618794-618794-

SECTION A: AST, ALT and CK			
SDV	* A1. Was AST done?	○ Yes ○ No	LBB.ASTYN
SDV	* A1a. Date of blood draw		LBB.ASTDAT
SDV	* A1b. Result		LBB.ASTRES (format xxx.xx)
SDV	* A1c. Unit	○ U/L ○ IU/L	LBB.ASTUNT
SDV	* A2. Was ALT done?	○ Yes ○ No	LBB.ALTYN
SDV	* A2a. Date of blood draw		LBB.ALTDAT
SDV	* A2b. Result		LBB.ALTRES (format xxx.xx)
SDV	* A2c. Unit	○ U/L ○ IU/L	LBB.ALTUNT
SDV	* A2d. ALT result category Baseline Only	○ ALT is < 40 U/L ○ ALT is 40 -79 U/L ○ ALT is 80 – 199 U/L with NAFLD	LBB.ALTBCAT
	Baseline ALT Result (read-only)	(remote value)	
	Baseline ALT Category (read-only)	(remote value)	
SDV	* A2e. ALT result category Follow-up Only	○ ALT is ≥ 80 U/L ○ ALT is ≥ 2 times the baseline ALT result ○ Other	LBB.ALTFCAT
	COMPLETE Questions below IF... Baseline ALT was < 40 U/L AND Result is ≥ 80 U/L OR Baseline ALT was 40 -79 AND Result is ≥ 2 times the baseline ALT result OR Baseline ALT was 80 – 199 with NAFLD AND Result is ≥ 2 times the baseline ALT result		
SDV	* A2f. Was an assessment by GI done?	○ Yes ○ No	LBB.ALTGIYN

SDV	* A2f1. Did the assessment confirm no liver disease other than NAFLD present?	○ Yes ○ No	LBB.ALTGIRES	
SDV	* A2f2. Did subject have any symptoms of liver disease?	○ Yes ○ No	LBB.ALTGISYM	
	If Yes, please ensure all symptoms are reported on the Visit Form in this visit.			
SDV	* A2g. Was INR measurement obtained?	○ Yes ○ No	LBB.INRYN	
SDV	* A2g1. Result		LBB.INRRES	(format x.x)
SDV	* A2g2. ULN		LBB.INRULN	(format x.x)
SDV	* A2g3. Was the INR result normal?	○ Yes ○ No	LBB.INRNORMYN	
SDV	* A2h. Was bilirubin measurement obtained?	○ Yes ○ No	LBB.BILIYN	
SDV	* A2h1. Result		LBB.BILIRES	(format xxx.xx)
SDV	* A2h2. Unit	○ mg/dL ○ µmol/L	LBB.BILIUNT	
SDV	* A2h3. ULN		LBB.BILIULN	(format xxx.xx)
SDV	* A2h4. Was the bilirubin result normal?	○ Yes ○ No	LBB.BILNORMYN	
SDV	* A2i. Were any increases in ALT (if applicable) verified by repeat assessment(s)?	○ Yes ○ No ○ Not Applicable	LBB.ALTREP	
SDV	* A3. Was CK done?	○ Yes ○ No	LBB.CKYN	
SDV	* A3a. Date of blood draw		LBB.CKDAT	
SDV	* A3b. Result		LBB.CKRES	(format xxxx.xx)
SDV	* A3c. Unit	○ U/L ○ IU/L	LBB.CKUNT	
SECTION B: GLUCOSE HOMEOSTASIS - FASTING GLUCOSE, HBA1C				
SDV	* B1. Was a fasting blood sample obtained?	○ Yes ○ No	LBB.FASTGLYN	
SDV	* B1a. Date sample collected		LBB.FASTGLDAT	
SDV	* B1b. Fasting glucose result		LBB.FASTGLRES	(format xxxx.xx)
SDV	* B1c. Unit	○ mg/dL ○ mmol/L	LBB.FASTGLUNT	

SDV	* B2. Was a hemoglobin A1c result obtained	○ Yes ○ No	LBB.HBA1C YN
SDV	* B2a. Date sample collected		LBB.HBA1C DAT
SDV	* B2b. Hemoglobin A1c (%)		LBB.HBA1C RES (format xx.xx)

SECTION C: PREGNANCY TEST

Required at Screening and Baseline. After screening and baseline, urine pregnancy tests may be performed at subsequent times at the discretion of site study personnel.

SDV	* C1. Was a urine pregnancy test done at this visit?	○ Yes ○ No ○ Not Applicable	LBB.PREGPERF
SDV	* C1a. Date of Pregnancy Test		LBB.PREGDAT
SDV	* C1b. Result of Pregnancy Test	○ Positive ○ Negative	LBB.PREGRES

SECTION D. COMPLETE BLOOD COUNT (CBC) RESULTS

SDV	* D1. Were Complete Blood Count (CBC) Results obtained?	○ Yes ○ No	LBB.CBCPERF

Complete Blood Count (CBC) is required at Screening and Month 24.

SDV	* D1a. Date of sample collection		LBB.CBCDAT

Test Name	Result		Unit
D1b. White Blood Cell Count (WBC)	SDV LBB.WBCRES	(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L LBB.WBCUNT
D1c. Red Blood Cell Count (RBC)	SDV LBB.RBCRES	(xx.xx)	SDV ○ 10^6uL ○ 10^12/L LBB.RBCUNT
D1d. Hemoglobin	SDV LBB.HGBRES	(xxx.xx)	SDV ○ g/dL ○ g/L LBB.HGBUNT
D1e. Hematocrit (HCT)	SDV LBB.HCTRES	(xxx.xx)	SDV ○ % ○ Proportion of 1.0 LBB.HCTUNT
D1f. Mean Cell Volume (MCV)	SDV LBB.MCVRES	(xxx.xx)	**fL**
D1g. Mean Corpuscular Hemoglobin (MCHb)	SDV LBB.MCHBRES	(xxx.xx)	**pg**
D1h. Mean Corpuscular Hemoglobin (MCHb) Conc	SDV LBB.MCHBCRES	(xxxx.xx)	SDV ○ g/dL ○ g/L LBB.MCHBCUNT
D1i. RDW - Red Blood Cell Distribution Width (%)	SDV LBB.RDWRES	(xxx.xx)	**%**
D1j. Platelet Count	SDV LBB.PLTRES	(xxxxxx.xx)	SDV ○ 10^3/uL ○ 10^9/L LBB.PLTUNT
D1k. Was a CBC differential done? Please only report the absolute count of each cell type.	SDV ○ Yes ○ No LBB.CBCDIFYN		
D1k1. Neutrophils-segmented	SDV LBB.NEUTSRES	(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L LBB.NEUTSUNT
D1k2. Neutrophils-bands	SDV	(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L

	LBB.NEUTBRES		LBB.NEUTBUNT
D1k3. Lymphocytes	SDV	(xx.xx)	SDV 10^3/uL 10^9/L
	LBB.LYMPRES		LBB.LYMPUNT
D1k4. Monocytes	SDV	(xx.xx)	SDV 10^3/uL 10^9/L
	LBB.MONORES		LBB.MONOUNT
D1k5. Eosinophils	SDV	(xx.xx)	SDV 10^3/uL 10^9/L
	LBB.EOSRES		LBB.EOSUNT
D1k6. Basophils	SDV	(xx.xx)	SDV 10^3/uL 10^9/L
	LBB.BASORES		LBB.BASOUNT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618794	Section Header	0	SECTION A: AST, ALT and CK											
Page-2-618794	Radiolist Horizontal	0	A1. Was AST done?	LBB.ASTYN	Yes				cYN					
Page-3-618794	Date	1	A1a. Date of blood draw	LBB.ASTDAT	Yes									
-- Page Dynamics (LBB.ASTDAT): Show When: LBB.ASTYN = 1														
Page-4-618794	Numeric	1	A1b. Result	LBB.ASTRES	Yes							3	2	Normal Range: 7.0 - 40.0 (U/L) 7.0 - 40.0 (IU/L)
-- Page Dynamics (LBB.ASTRES): Show When: LBB.ASTYN = 1														
Page-5-618794	Radiolist Horizontal	1	A1c. Unit	LBB.ASTUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
-- Page Dynamics (LBB.ASTUNT): Show When: LBB.ASTYN = 1														
Page-6-618794	Radiolist Horizontal	0	A2. Was ALT done?	LBB.ALTYN	Yes				cYN					

Page Information														
Page-7-618794	Date	1	A2a. Date of blood draw	LBB.ALTDAT	Yes									
-- Page Dynamics (LBB. ALTDAT): Show When: LBB.ALTYN = 1														
Page-8-618794	Numeric	1	A2b. Result	LBB.ALTRES	Yes							3	2	Normal Range: 5.0 - 35.0 (U/L) 5.0 - 35.0 (IU/L)
-- Page Dynamics (LBB. ALTRES): Show When: LBB.ALTYN = 1														
Page-9-618794	Radiolist Horizontal	1	A2c. Unit	LBB.ALTUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
-- Page Dynamics (LBB. ALTUNT): Show When: LBB.ALTYN = 1														
Page-10-618794	Radiolist	1	A2d. ALT result category Baseline Only	LBB.ALTBCAT	Yes				cALTBASECAT					
-- Page Dynamics (LBB. ALTBCAT): Show When: LBB.ALTYN = 1 AND VISITID = 20														
Page-11-618794	Remote Value	1	Baseline ALT Result (read-only)											
-- Remote Value: field at visit:20, page:50, table.column:LBB.ALTRES														
-- Page Dynamics (.): Show When: LBB.ALTYN = 1 AND VISITID > 20														
Page-12-618794	Remote Value	1	Baseline ALT Category (read-only)											
-- Remote Value: field at visit:20, page:50, table.column:LBB.ALTBCAT														
-- Page Dynamics (.): Show When: LBB.ALTYN = 1 AND VISITID > 20														
Page-13-618794	Radiolist	1	A2e. ALT result category Follow-up Only	LBB.ALTFCAT	Yes				cALTFUPCAT					
-- Page Dynamics (LBB. ALTFCAT): Show When: LBB.ALTYN = 1 AND VISITID > 20														
Page-14-618794	Help Text Line	1	COMPLETE Questions below IF... <u>Baseline ALT was < 40 U/L</u> AND Result is ≥ 80 U/L OR <u>Baseline ALT was 40 -79</u> AND Result is ≥ 2 times the baseline ALT result OR <u>Baseline ALT was 80 – 199 with NAFLD</u> AND Result is ≥ 2 times the baseline ALT result											
-- Page Dynamics (.): Show When: LBB.ALTYN = 1 AND (LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2) AND VISITID > 20														
Page-15-618794	Radiolist Horizontal	1	A2f. Was an assessment by GI done?	LBB.ALTGIYN	Yes				cYN					

Page Information														
-- Page Dynamics (LBB. ALTGIYN): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-16-618794	Radiolist Horizontal	2	A2f1. Did the assessment confirm no liver disease other than NAFLD present?	LBB.ALTGIRES	Yes				cYN					
-- Page Dynamics (LBB. ALTGIRES): Show When: LBB.ALTGIYN = 1														
Page-17-618794	Radiolist Horizontal	2	A2f2. Did subject have any symptoms of liver disease?	LBB.ALTGISYM	Yes				cYN					
-- Page Dynamics (LBB. ALTGISYM): Show When: LBB.ALTGIYN = 1														
Page-18-618794	Help Text Line	1	If Yes, please ensure all symptoms are reported on the Visit Form in this visit.											
-- Page Dynamics (.): Show When: LBB.ALTGIYN = 1 AND LBB.ALTGISYM = 1														
Page-19-618794	Radiolist Horizontal	1	A2g. Was INR measurement obtained?	LBB.INRYN	Yes				cYN					
-- Page Dynamics (LBB. INRYN): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-20-618794	Numeric	2	A2g1. Result	LBB.INRRES	Yes							1	1	Normal Range: 0.80 - 1.20
-- Page Dynamics (LBB. INRRES): Show When: LBB.INRYN = 1														
Page-21-618794	Numeric	2	A2g2. ULN	LBB.INRULN	Yes							1	1	
-- Page Dynamics (LBB. INRULN): Show When: LBB.INRYN = 1														
Page-22-618794	Radiolist Horizontal	2	A2g3. Was the INR result normal?	LBB.INRNORMYN	Yes				cYN					
-- Page Dynamics (LBB. INRNORMYN): Show When: LBB.INRYN = 1														
Page-23-618794	Radiolist Horizontal	1	A2h. Was bilirubin measurement obtained?	LBB.BILIYN	Yes				cYN					
-- Page Dynamics (LBB. BILIYN): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-24-618794	Numeric	2	A2h1. Result	LBB.BILIRES	Yes							3	2	Normal Range: 0.3 - 1.2 (mg/dL) 5.0 - 21.0 (µmol/L)
-- Page Dynamics (LBB. BILIRES): Show When: LBB.BILIYN = 1														
Page-25-618794	Radiolist Horizontal	2	A2h2. Unit	LBB.BILIUNT	Yes				cUNIT_MGDL_UMOLL					mg/dL x 17.104 = µmol/L
-- Page Dynamics (LBB. BILIUNT): Show When: LBB.BILIYN = 1														

Page Information														
Page-26-618794	Numeric	2	A2h3. ULN	LBB.BILIULN	Yes							3	2	
-- Page Dynamics (LBB. BILIULN): Show When: LBB.BILIYN = 1														
Page-27-618794	Radiolist Horizontal	2	A2h4. Was the bilirubin result normal?	LBB.BILNORMYN	Yes				cYN					
-- Page Dynamics (LBB. BILNORMYN): Show When: LBB.BILIYN = 1														
Page-28-618794	Radiolist Horizontal	1	A2i. Were any increases in ALT (if applicable) verified by repeat assessment(s)?	LBB.ALTREP	Yes				cYNNA					For subjects without known liver disease (other than NAFLD) or ALT elevation at randomization, increases in ALT will be verified by repeat assessment within 48-72 hours, together with a bilirubin + INR. Subjects with persistent ALT abnormalities, abnormal bilirubin or INR, or symptoms will be further assessed by the site's gastroenterologist /hepatologist, and the results of any additional evaluation will be recorded and reported.
-- Page Dynamics (LBB. ALTREP): Show When: LBB.ALTYN = 1														
Page-29-618794	Radiolist Horizontal	0	A3. Was CK done?	LBB.CKYN	Yes				cYN					
Page-30-618794	Date	1	A3a. Date of blood draw	LBB.CKDAT	Yes									
-- Page Dynamics (LBB. CKDAT): Show When: LBB.CKYN = 1														
Page-31-618794	Numeric	1	A3b. Result	LBB.CKRES	Yes							4	2	Normal Range: 20.0 - 215 (U/L) 20.0 - 215 (IU/L)
-- Page Dynamics (LBB. CKRES): Show When: LBB.CKYN = 1														

Page Information														
Page-32-618794	Radiolist Horizontal	1	A3c. Unit	LBB.CKUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
-- Page Dynamics (LBB. CKUNT): Show When: LBB.CKYN = 1														
Page-33-618794	Section Header	0	SECTION B: GLUCOSE HOMEOSTASIS - FASTING GLUCOSE, HBA1C											
Page-34-618794	Radiolist Horizontal	0	B1. Was a fasting blood sample obtained?	LBB.FASTGLYN	Yes				cYN					
Page-35-618794	Date	1	B1a. Date sample collected	LBB.FASTGLDAT	Yes									Enter the date the sample was taken in DD/MMM/YYYY date format.
-- Page Dynamics (LBB. FASTGLDAT): Show When: LBB.FASTGLYN = 1														
Page-36-618794	Numeric	1	B1b. Fasting glucose result	LBB.FASTGLRES	Yes							4	2	Normal Range: 70 - 110 (mg/dL) 3.9 - 6.1 (mmol/L)
-- Page Dynamics (LBB. FASTGLRES): Show When: LBB.FASTGLYN = 1														
Page-37-618794	Radiolist Horizontal	1	B1c. Unit	LBB.FASTGLUNT	Yes				cUNIT_MGDL_MMOLL					mg/dl x 0.0555 = mmol/L
-- Page Dynamics (LBB. FASTGLUNT): Show When: LBB.FASTGLYN = 1														
Page-38-618794	Radiolist Horizontal	0	B2. Was a hemoglobin A1c result obtained	LBB.HBA1CYN	Yes				cYN					
Page-39-618794	Date	1	B2a. Date sample collected	LBB.HBA1CDAT	Yes									
-- Page Dynamics (LBB. HBA1CDAT): Show When: LBB.HBA1CYN = 1														
Page-40-618794	Numeric	1	B2b. Hemoglobin A1c (%)	LBB.HBA1CRES	Yes							2	2	Normal Range: 4.0 - 6.0 (%)
-- Page Dynamics (LBB. HBA1CRES): Show When: LBB.HBA1CYN = 1														
Page-41-618794	Section Header	0	SECTION C: PREGNANCY TEST											
-- Page Dynamics (.): Show When: 10-40-DM.SEX = 2														
Page-42-618794	Help Text Line	0	Required at Screening and Baseline. After screening and baseline, urine pregnancy tests may be performed at subsequent times at the discretion of site study personnel.											
-- Page Dynamics (.): Show When: 10-40-DM.SEX = 2														

Page Information														
Page-43-618794	Radiolist Horizontal	0	C1. Was a urine pregnancy test done at this visit?	LBB.PREGPERF	Yes				cYNNA					
-- Page Dynamics (LBB.PREGPERF): Show When: 10-40-DM.SEX = 2														
Page-44-618794	Date	1	C1a. Date of Pregnancy Test	LBB.PREGDAT	Yes									
-- Page Dynamics (LBB.PREGDAT): Show When: 10-40-DM.SEX = 2 AND LBB.PREGPERF = 1														
Page-45-618794	Radiolist Horizontal	1	C1b. Result of Pregnancy Test	LBB.PREGRES	Yes				cPOS_NEG					
-- Page Dynamics (LBB.PREGRES): Show When: 10-40-DM.SEX = 2 AND LBB.PREGPERF = 1														
Page-46-618794	Section Header	0	SECTION D. COMPLETE BLOOD COUNT (CBC) RESULTS											
-- Page Dynamics (.): Show When: VISITID = 90 OR VISITID = 140														
Page-47-618794	Radiolist Horizontal	0	D1. Were Complete Blood Count (CBC) Results obtained?	LBB.CBCPERF	Yes				cYN					
-- Page Dynamics (LBB.CBCPERF): Show When: VISITID = 90 OR VISITID = 140														
Page-48-618794	Help Text Line	0	Complete Blood Count (CBC) is required at Screening and Month 24.											
-- Page Dynamics (.): Show When: VISITID = 90 OR VISITID = 140														
Page-49-618794	Date	1	D1a. Date of sample collection	LBB.CBCDAT	Yes									
-- Page Dynamics (LBB.CBCDAT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-50-618794	Row Start/End	0												
Page-51-618794	Section Header	0	Test Name											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-52-618794	Section Header	0	Result											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-53-618794	Section Header	0	Unit											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-54-618794	Row Start/End	0												

Page Information														
Page-55-618794	Row Start/End	0												
Page-56-618794	Help Text Line	0	D1b. White Blood Cell Count (WBC)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-57-618794	Numeric	0	White Blood Cell Count (WBC)	LBB.WBCRES	Yes							2	2	Normal Range: 3.5 - 12.0 (10^3/uL) 3.5 - 12.0 (10^9/L)
-- Page Dynamics (LBB. WBCRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-58-618794	Radiolist Horizontal	0	White Blood Cell Count (WBC)	LBB.WBCUNT	Yes				cUNIT_103UL_109L					If reporting unit is mm3 (i.e. 3500-12,000/mm3), WBC value should be reported as 3.5 - 12.0 with either unit 10^3/uL or 10^9/L.
-- Page Dynamics (LBB. WBCUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.WBCRES IS NOT NULL														
Page-59-618794	Row Start/End	0												
Page-60-618794	Row Start/End	0												
Page-61-618794	Help Text Line	0	D1c. Red Blood Cell Count (RBC)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-62-618794	Numeric	0	Red Blood Cell Count (RBC)	LBB.RBCRES	Yes							2	2	Normal Range: 3.9 - 6.0 (10^6uL) 3.9 - 6.0 (10^12/L)
-- Page Dynamics (LBB. RBCRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-63-618794	Radiolist Horizontal	0	Red Blood Cell Count (RBC)	LBB.RBCUNT	Yes				cUNIT_106UL_1012L					
-- Page Dynamics (LBB. RBCUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.RBCRES IS NOT NULL														
Page-64-618794	Row Start/End	0												

Page Information														
Page-65-618794	Row Start/End	0												
Page-66-618794	Help Text Line	0	D1d. Hemoglobin											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-67-618794	Numeric	0	Hemoglobin	LBB.HGBRES	Yes							3	2	Normal Range: 11.2 - 18.0 (g/dL) 112 - 180 (g/L)
-- Page Dynamics (LBB. HGBRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-68-618794	Radiolist Horizontal	0	Hemoglobin	LBB.HGBUNT	Yes				cUNIT_GDL_GL					
-- Page Dynamics (LBB. HGBUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.HGBRES IS NOT NULL														
Page-69-618794	Row Start/End	0												
Page-70-618794	Row Start/End	0												
Page-71-618794	Help Text Line	0	D1e. Hematocrit (HCT)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-72-618794	Numeric	0	Hematocrit (HCT)	LBB.HCTRES	Yes							3	2	Normal Range: 35 - 54 (%) 0.35 - 0.54 (Proportion of 1.0)
-- Page Dynamics (LBB. HCTRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-73-618794	Radiolist Horizontal	0	Hematocrit (HCT)	LBB.HCTUNT	Yes				cUNIT_PROP1_PERC					
-- Page Dynamics (LBB. HCTUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.HCTRES IS NOT NULL														
Page-74-618794	Row Start/End	0												
Page-75-618794	Row Start/End	0												

Page Information														
Page-76-618794	Help Text Line	0	D1f. Mean Cell Volume (MCV)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-77-618794	Numeric	0	Mean Cell Volume (MCV)	LBB.MCVRES	Yes							3	2	Normal Range: 76-100 (fL) Note (if reporting unit is µm3): 1fL is the same as 1µm3
-- Page Dynamics (LBB. MCVRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-78-618794	Help Text Line	0	fL											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-79-618794	Row Start/End	0												
Page-80-618794	Row Start/End	0												
Page-81-618794	Help Text Line	0	D1g. Mean Corpuscular Hemoglobin (MCHb)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-82-618794	Numeric	0	Mean Corpuscular Hemoglobin (MCHb)	LBB.MCHBRES	Yes							3	2	Normal Range: 24 - 35 (pg/cell)
-- Page Dynamics (LBB. MCHBRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-83-618794	Help Text Line	0	pg											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-84-618794	Row Start/End	0												
Page-85-618794	Row Start/End	0												
Page-86-618794	Help Text Line	0	D1h. Mean Corpuscular Hemoglobin (MCHb) Conc											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														

Page Information														
Page-87-618794	Numeric	0	Mean Corpuscular Hemoglobin (MCHb) Conc	LBB.MCHBCRES	Yes							4	2	Normal Range: 31 - 37 (g/dL) 310 - 370 (g/L)
-- Page Dynamics (LBB. MCHBCRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-88-618794	Radiolist Horizontal	0	Mean Corpuscular Hemoglobin (MCHb) Conc	LBB.MCHBCUNT	Yes				cUNIT_GDL_GL					
-- Page Dynamics (LBB. MCHBCUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.MCHBCRES IS NOT NULL														
Page-89-618794	Row Start/End	0												
Page-90-618794	Row Start/End	0												
Page-91-618794	Help Text Line	0	D1i. RDW - Red Blood Cell Distribution Width (%)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-92-618794	Numeric	0	RDW - Red Blood Cell Distribution Width	LBB.RDWRES	Yes							3	2	Normal Range: 11.0 - 15.6 (%)
-- Page Dynamics (LBB. RDWRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-93-618794	Help Text Line	0	%											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-94-618794	Row Start/End	0												
Page-95-618794	Row Start/End	0												
Page-96-618794	Help Text Line	0	D1j. Platelet Count											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-97-618794	Numeric	0	Platelet Count	LBB.PLTRES	Yes							6	2	Normal Range: 150-450 x (10^9/L) 150-450 x (10^3/uL)
-- Page Dynamics (LBB. PLTRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														

Page Information														
Page-98-618794	Radiolist Horizontal	0	Platelet Count	LBB.PLTUNT	Yes				cUNIT_103UL_109L					If reporting unit is mm3 (i.e. 150,000-450,000/mm3), PLT value should be reported as 150 - 450 with either unit 10^3/uL or 10^9/L.
-- Page Dynamics (LBB. PLTUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.PLTRES IS NOT NULL														
Page-99-618794	Row Start/End	0												
Page-100-618794	Row Start/End	0												
Page-101-618794	Help Text Line	0	D1k. Was a CBC differential done? Please only report the <u>absolute count of each cell type</u>.											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-102-618794	Radiolist Horizontal	0	Was a CBC differential done?	LBB.CBCDIFYN	Yes				cYN					
-- Page Dynamics (LBB. CBCDIFYN): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-103-618794	Help Text Line	0												
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-104-618794	Row Start/End	0												
Page-105-618794	Row Start/End	0												
Page-106-618794	Help Text Line	0	D1k1. Neutrophils-segmented											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-107-618794	Numeric	0	Neutrophils-segmented	LBB.NEUTSRES	Yes							2	2	Normal Range: 1.5 - 8.0 x (10^9/L) 1.5 - 8.0 x (10^3/uL)
-- Page Dynamics (LBB. NEUTSRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														

Page Information														
Page-108-618794	Radiolist Horizontal	0	Neutrophils-segmented	LBB.NEUTSUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB.NEUTSUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.NEUTSRES IS NOT NULL														
Page-109-618794	Row Start/End	0												
Page-110-618794	Row Start/End	0												
Page-111-618794	Help Text Line	0	D1k2. Neutrophils-bands											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-112-618794	Numeric	0	Neutrophils-bands	LBB.NEUTBRES	Yes							2	2	Normal Range: 0 - 0.70 x (10^9/L) 0 - 0.70 x (10^3/uL)
-- Page Dynamics (LBB.NEUTBRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-113-618794	Radiolist Horizontal	0	Neutrophils-bands	LBB.NEUTBUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB.NEUTBUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.NEUTBRES IS NOT NULL														
Page-114-618794	Row Start/End	0												
Page-115-618794	Row Start/End	0												
Page-116-618794	Help Text Line	0	D1k3. Lymphocytes											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-117-618794	Numeric	0	Lymphocytes	LBB.LYMPRES	Yes							2	2	Normal Range: 1.0 - 6.5 x (10^9/L) 1.0 - 6.5 x (10^3/uL)
-- Page Dynamics (LBB.LYMPRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-118-618794	Radiolist Horizontal	0	Lymphocytes	LBB.LYMPUNT	Yes				cUNIT_103UL_109L					

Page Information														
-- Page Dynamics (LBB. LYMPUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.LYMPRES IS NOT NULL														
Page-119-618794	Row Start/End	0												
Page-120-618794	Row Start/End	0												
Page-121-618794	Help Text Line	0	D1k4. Monocytes											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-122-618794	Numeric	0	Monocytes	LBB.MONORES	Yes							2	2	Normal Range: 0.00 - 0.90 x (10^9/L) 0.00 - 0.90 x (10^3/uL)
-- Page Dynamics (LBB. MONORES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-123-618794	Radiolist Horizontal	0	Monocytes	LBB.MONOUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB. MONOUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.MONORES IS NOT NULL														
Page-124-618794	Row Start/End	0												
Page-125-618794	Row Start/End	0												
Page-126-618794	Help Text Line	0	D1k5. Eosinophils											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-127-618794	Numeric	0	Eosinophils	LBB.EOSRES	Yes							2	2	Normal Range: 0.00 - 0.50 x (10^9/L) 0.00 - 0.50 x (10^3/uL)
-- Page Dynamics (LBB. EOSRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-128-618794	Radiolist Horizontal	0	Eosinophils	LBB.EOSUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB. EOSUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.EOSRES IS NOT NULL														

Page Information														
Page-129-618794	Row Start/End	0												
Page-130-618794	Row Start/End	0												
Page-131-618794	Help Text Line	0	D1k6. Basophils											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-132-618794	Numeric	0	Basophils	LBB.BASORES	Yes							2	2	Normal Range: 0.00 - 0.30 x (10^9/L) 0.00 - 0.30 x (10^3/uL)
-- Page Dynamics (LBB. BASORES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-133-618794	Radiolist Horizontal	0	Basophils	LBB.BASOUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB. BASOUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.BASORES IS NOT NULL														
Page-134-618794	Row Start/End	0												

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619624	SYSQ_5349	LBB.ASTYN	Field Null		LBB.ASTYN IS NULL	"A1. Was AST done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619626	SYSQ_5350	LBB.ASTDAT	Field Null		LBB.ASTDAT IS NULL	"A1a. Date of blood draw" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619629	SYSQ_5351	LBB.ASTDAT	Future Date		LBB.ASTDAT > Today	"A1a. Date of blood draw" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619631	SYSQ_5352	LBB.ASTRES	Field Null		LBB.ASTRES IS NULL	"A1b. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0

System Queries														
sysq-619633	SYSQ_5353	LBB.ASTUNT	Field Null		LBB.ASTUNT IS NULL	"A1c. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619634	SYSQ_5354	LBB.ALTYN	Field Null		LBB.ALTYN IS NULL	"A2. Was ALT done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619637	SYSQ_5355	LBB.ALTDAT	Field Null		LBB.ALTDAT IS NULL	"A2a. Date of blood draw" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619638	SYSQ_5356	LBB.ALTDAT	Future Date		LBB.ALTDAT > Today	"A2a. Date of blood draw" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619640	SYSQ_5357	LBB.ALTRES	Field Null		LBB.ALTRES IS NULL	"A2b. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619643	SYSQ_5358	LBB.ALTUNT	Field Null		LBB.ALTUNT IS NULL	"A2c. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619645	SYSQ_5359	LBB.ALTBCAT	Field Null		LBB.ALTBCAT IS NULL	"A2d. ALT result category Baseline Only" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619646	SYSQ_5360	LBB.ALTFCAT	Field Null		LBB.ALTFCAT IS NULL	"A2e. ALT result category Follow-up Only" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619649	SYSQ_5361	LBB.ALTGIYN	Field Null		LBB.ALTGIYN IS NULL	"A2f. Was an assessment by GI done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619651	SYSQ_5362	LBB.ALTGIRES	Field Null		LBB.ALTGIRES IS NULL	"A2f1. Did the assessment confirm no liver disease other than NAFLD present?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0

System Queries														
sysq-619652	SYSQ_5363	LBB.ALTGISYM	Field Null		LBB.ALTGISYM IS NULL	"A2f2. Did subject have any symptoms of liver disease?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619655	SYSQ_5364	LBB.INRYN	Field Null		LBB.INRYN IS NULL	"A2g. Was INR measurement obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619656	SYSQ_5365	LBB.INRRES	Field Null		LBB.INRRES IS NULL	"A2g1. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619658	SYSQ_5366	LBB.INRULN	Field Null		LBB.INRULN IS NULL	"A2g2. ULN" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619661	SYSQ_5367	LBB.INRNORMYN	Field Null		LBB.INRNORMYN IS NULL	"A2g3. Was the INR result normal?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619663	SYSQ_5368	LBB.BILIYN	Field Null		LBB.BILIYN IS NULL	"A2h. Was bilirubin measurement obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619665	SYSQ_5369	LBB.BILIRES	Field Null		LBB.BILIRES IS NULL	"A2h1. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619666	SYSQ_5370	LBB.BILIUNT	Field Null		LBB.BILIUNT IS NULL	"A2h2. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619668	SYSQ_5371	LBB.BILIULN	Field Null		LBB.BILIULN IS NULL	"A2h3. ULN" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619671	SYSQ_5372	LBB.BILNORMYN	Field Null		LBB.BILNORMYN IS NULL	"A2h4. Was the bilirubin result normal?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0

System Queries														
sysq-619672	SYSQ_5373	LBB.ALTREP	Field Null		LBB.ALTREP IS NULL	"A2i. Were any increases in ALT (if applicable) verified by repeat assessment(s)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619674	SYSQ_5374	LBB.CKYN	Field Null		LBB.CKYN IS NULL	"A3. Was CK done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619677	SYSQ_5375	LBB.CKDAT	Field Null		LBB.CKDAT IS NULL	"A3a. Date of blood draw" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619679	SYSQ_5376	LBB.CKDAT	Future Date		LBB.CKDAT > Today	"A3a. Date of blood draw" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619680	SYSQ_5377	LBB.CKRES	Field Null		LBB.CKRES IS NULL	"A3b. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619682	SYSQ_5378	LBB.CKUNT	Field Null		LBB.CKUNT IS NULL	"A3c. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619684	SYSQ_5379	LBB.FASTGLYN	Field Null		LBB.FASTGLYN IS NULL	"B1. Was a fasting blood sample obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619686	SYSQ_5380	LBB.FASTGLDAT	Field Null		LBB.FASTGLDAT IS NULL	"B1a. Date sample collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619688	SYSQ_5381	LBB.FASTGLDAT	Future Date		LBB.FASTGLDAT > Today	"B1a. Date sample collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619690	SYSQ_5382	LBB.FASTGLRES	Field Null		LBB.FASTGLRES IS NULL	"B1b. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0

System Queries														
sysq-619693	SYSQ_5383	LBB.FASTGLUNT	Field Null		LBB.FASTGLUNT IS NULL	"B1c. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619694	SYSQ_5384	LBB.HBA1CYN	Field Null		LBB.HBA1CYN IS NULL	"B2. Was a hemoglobin A1c result obtained" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619697	SYSQ_5385	LBB.HBA1CDAT	Field Null		LBB.HBA1CDAT IS NULL	"B2a. Date sample collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619698	SYSQ_5386	LBB.HBA1CDAT	Future Date		LBB.HBA1CDAT > Today	"B2a. Date sample collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619700	SYSQ_5387	LBB.HBA1CRES	Field Null		LBB.HBA1CRES IS NULL	"B2b. Hemoglobin A1c (%)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619702	SYSQ_5388	LBB.PREGPERF	Field Null		LBB.PREGPERF IS NULL	"C1. Was a urine pregnancy test done at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619705	SYSQ_5389	LBB.PREGDAT	Field Null		LBB.PREGDAT IS NULL	"C1a. Date of Pregnancy Test" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619707	SYSQ_5390	LBB.PREGDAT	Future Date		LBB.PREGDAT > Today	"C1a. Date of Pregnancy Test" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619708	SYSQ_5391	LBB.PREGRES	Field Null		LBB.PREGRES IS NULL	"C1b. Result of Pregnancy Test" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619711	SYSQ_5392	LBB.CBCPERF	Field Null		LBB.CBCPERF IS NULL	"D1. Were Complete Blood Count (CBC) Results obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0

System Queries														
sysq-619712	SYSQ_5393	LBB.CBCDAT	Field Null		LBB.CBCDAT IS NULL	"D1a. Date of sample collection" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619715	SYSQ_5394	LBB.CBCDAT	Future Date		LBB.CBCDAT > Today	"D1a. Date of sample collection" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619716	SYSQ_5395	LBB.WBCRES	Field Null		LBB.WBCRES IS NULL	"White Blood Cell Count (WBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619719	SYSQ_5396	LBB.WBCUNT	Field Null		LBB.WBCUNT IS NULL	"White Blood Cell Count (WBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619720	SYSQ_5397	LBB.RBCRES	Field Null		LBB.RBCRES IS NULL	"Red Blood Cell Count (RBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619723	SYSQ_5398	LBB.RBCUNT	Field Null		LBB.RBCUNT IS NULL	"Red Blood Cell Count (RBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619724	SYSQ_5399	LBB.HGBRES	Field Null		LBB.HGBRES IS NULL	"Hemoglobin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619726	SYSQ_5400	LBB.HGBUNT	Field Null		LBB.HGBUNT IS NULL	"Hemoglobin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619728	SYSQ_5401	LBB.HCTRES	Field Null		LBB.HCTRES IS NULL	"Hematocrit (HCT)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619731	SYSQ_5402	LBB.HCTUNT	Field Null		LBB.HCTUNT IS NULL	"Hematocrit (HCT)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0

System Queries														
sysq-619733	SYSQ_5403	LBB.MCVRES	Field Null		LBB.MCVRES IS NULL	"Mean Cell Volume (MCV)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619734	SYSQ_5404	LBB.MCHBRES	Field Null		LBB.MCHBRES IS NULL	"Mean Corpuscular Hemoglobin (MCHb)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619736	SYSQ_5405	LBB.MCHBCRES	Field Null		LBB.MCHBCRES IS NULL	"Mean Corpuscular Hemoglobin (MCHb) Conc" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619738	SYSQ_5406	LBB.MCHBCUNT	Field Null		LBB.MCHBCUNT IS NULL	"Mean Corpuscular Hemoglobin (MCHb) Conc" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619741	SYSQ_5407	LBB.RDWRES	Field Null		LBB.RDWRES IS NULL	"RDW - Red Blood Cell Distribution Width" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619743	SYSQ_5408	LBB.PLTRES	Field Null		LBB.PLTRES IS NULL	"Platelet Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619745	SYSQ_5409	LBB.PLTUNT	Field Null		LBB.PLTUNT IS NULL	"Platelet Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619746	SYSQ_5410	LBB.CBCDIFYN	Field Null		LBB.CBCDIFYN IS NULL	"Was a CBC differential done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619748	SYSQ_5411	LBB.NEUTSRES	Field Null		LBB.NEUTSRES IS NULL	"Neutrophils-segmented" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619750	SYSQ_5412	LBB.NEUTSUNT	Field Null		LBB.NEUTSUNT IS NULL	"Neutrophils-segmented" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0

System Queries														
sysq-619752	SYSQ_5413	LBB.NEUTBRES	Field Null		LBB.NEUTBRES IS NULL	"Neutrophils-bands" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619754	SYSQ_5414	LBB.NEUTBUNT	Field Null		LBB.NEUTBUNT IS NULL	"Neutrophils-bands" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619756	SYSQ_5415	LBB.LYMPRES	Field Null		LBB.LYMPRES IS NULL	"Lymphocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619759	SYSQ_5416	LBB.LYMPUNT	Field Null		LBB.LYMPUNT IS NULL	"Lymphocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619761	SYSQ_5417	LBB.MONORES	Field Null		LBB.MONORES IS NULL	"Monocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619763	SYSQ_5418	LBB.MONOUNT	Field Null		LBB.MONOUNT IS NULL	"Monocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619765	SYSQ_5419	LBB.EOSRES	Field Null		LBB.EOSRES IS NULL	"Eosinophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619767	SYSQ_5420	LBB.EOSUNT	Field Null		LBB.EOSUNT IS NULL	"Eosinophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619769	SYSQ_5421	LBB.BASORES	Field Null		LBB.BASORES IS NULL	"Basophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619771	SYSQ_5422	LBB.BASOUNT	Field Null		LBB.BASOUNT IS NULL	"Basophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0

System Queries														
sysq-619773	SYSQ_5423	LBB.ASTYN	Other / Cross Page		(LBB.ASTYN <> 1 OR LBB.ALTYN <> 1 OR LBB.CKYN <> 1 OR LBB.FASTGLYN <> 1 OR LBB.HBA1CYN <> 1) AND 20-140-RAND.RANDYN = 1	1 or more Safety measures (AST, ALT, CK, Fasting Glucose and/or HbA1c) are/is reported as not done. Please confirm and if confirmed, complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619775	SYSQ_5425	LBB.PREGPERF	Other / Cross Page		LBB.PREGPERF = 0 AND 20-140-RAND.RANDYN = 1 AND VISITID = 20	A urine pregnancy test is required at baseline (if subject was randomized). If not done, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619776	SYSQ_5426	LBB.ALTREP	Other / Cross Page		LBB.ALTREP = 1	If Yes, please complete the LBALT (Laboratory Results - Repeat ALT Assessments) Form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0

pLBB_4

Page

(Visit ID = 618795, Page ID =)

Unique Identifier page-618795-618795-618795-

SECTION A: AST, ALT and CK			
SDV	* A1. Was AST done?	○ Yes ○ No	LBB.ASTYN
SDV	* A1a. Date of blood draw		LBB.ASTDAT
SDV	* A1b. Result		LBB.ASTRES (format xxx.xx)
SDV	* A1c. Unit	○ U/L ○ IU/L	LBB.ASTUNT
SDV	* A2. Was ALT done?	○ Yes ○ No	LBB.ALTYN
SDV	* A2a. Date of blood draw		LBB.ALTDAT
SDV	* A2b. Result		LBB.ALTRES (format xxx.xx)
SDV	* A2c. Unit	○ U/L ○ IU/L	LBB.ALTUNT
SDV	* A2d. ALT result category Baseline Only	○ ALT is < 40 U/L ○ ALT is 40 -79 U/L ○ ALT is 80 – 199 U/L with NAFLD	LBB.ALTBCAT
	Baseline ALT Result (read-only)	(remote value)	
	Baseline ALT Category (read-only)	(remote value)	
SDV	* A2e. ALT result category Follow-up Only	○ ALT is ≥ 80 U/L ○ ALT is ≥ 2 times the baseline ALT result ○ Other	LBB.ALTFCAT
	COMPLETE Questions below IF... Baseline ALT was < 40 U/L AND Result is ≥ 80 U/L OR Baseline ALT was 40 -79 AND Result is ≥ 2 times the baseline ALT result OR Baseline ALT was 80 – 199 with NAFLD AND Result is ≥ 2 times the baseline ALT result		
Assessment of elevations in ALT and other liver abnormalities			

SDV	* Were any increases in ALT (if applicable) verified by repeat assessment(s)?	○ Yes ○ No ○ Not Applicable	LBB.ALTREP	
SDV	* Was additional bloodwork performed?	○ Yes ○ No	LBB.BLODYN	
SDV	* Date of bloodwork		LBB.BLODAT	
SDV	* Was INR measurement obtained?	○ Yes ○ No	LBB.INRYN	
SDV	* Result		LBB.INRRES	(format x.x)
SDV	* ULN		LBB.INRULN	(format x.x)
SDV	* Was the INR result normal?	○ Yes ○ No	LBB.INRNORMYN	
SDV	* Was bilirubin measurement obtained?	○ Yes ○ No	LBB.BILIYN	
SDV	* Result		LBB.BILIRES	(format xxx.xx)
SDV	* Unit	○ mg/dL ○ µmol/L	LBB.BILIUNT	
SDV	* ULN		LBB.BILIULN	(format xxx.xx)
SDV	* Was the bilirubin result normal?	○ Yes ○ No	LBB.BILNORMYN	
SDV	* Were any other tests performed (blood, liver, ultrasound, etc.)?	○ Yes ○ No	LBB.OTHTSTYN	
SDV	* Please provide a description, date and result of each other test that was performed:		LBB.OTHTDESC	
SDV	* Did subject have any symptoms of liver disease?	○ Yes ○ No	LBB.ALTGISYM	
	If Yes, please ensure all symptoms are reported on the Visit Form in this visit.			
SDV	* Was an assessment by GI done?	○ Yes ○ No	LBB.ALTGIYN	
SDV	* Date of consult		LBB.ALTGIDAT	
SDV	* Result of consult		LBB.GIRES	
SDV	* Did the results of the further workup reveal any liver disease other than NAFLD?	○ Yes ○ No	LBB.ALTNAFLD	
SDV	* If Yes, please describe in detail		LBB.ALTNDESC	

SDV	A2f1. Did the assessment confirm no liver disease other than NAFLD present?	○ Yes ○ No	LBB.ALTGIRES
Creatine Kinase (CK) Test			
SDV	* A3. Was CK done?	○ Yes ○ No	LBB.CKYN
SDV	* A3a. Date of blood draw		LBB.CKDAT
SDV	* A3b. Result		LBB.CKRES (format xxxx.xx)
SDV	* A3c. Unit	○ U/L ○ IU/L	LBB.CKUNT
SECTION B: GLUCOSE HOMEOSTASIS - FASTING GLUCOSE, HBA1C			
SDV	* B1. Was a fasting blood sample obtained?	○ Yes ○ No	LBB.FASTGLYN
SDV	* B1a. Date sample collected		LBB.FASTGLDAT
SDV	* B1b. Fasting glucose result		LBB.FASTGLRES (format xxxx.xx)
SDV	* B1c. Unit	○ mg/dL ○ mmol/L	LBB.FASTGLUNT
SDV	* B2. Was a hemoglobin A1c result obtained	○ Yes ○ No	LBB.HBA1CYN
SDV	* B2a. Date sample collected		LBB.HBA1CDAT
SDV	* B2b. Hemoglobin A1c (%)		LBB.HBA1CRES (format xx.xx)
SECTION C: PREGNANCY TEST			
	Required at Screening and Baseline. After screening and baseline, urine pregnancy tests may be performed at subsequent times at the discretion of site study personnel.		
SDV	* C1. Was a urine pregnancy test done at this visit?	○ Yes ○ No ○ Not Applicable	LBB.PREGPERF
SDV	* C1a. Date of Pregnancy Test		LBB.PREGDAT
SDV	* C1b. Result of Pregnancy Test	○ Positive ○ Negative	LBB.PREGRES
SECTION D. COMPLETE BLOOD COUNT (CBC) RESULTS			
SDV	* D1. Were Complete Blood Count (CBC) Results obtained?	○ Yes ○ No	LBB.CBCPERF
	Complete Blood Count (CBC) is required at Screening and Month 24.		
SDV	* D1a. Date of sample collection		LBB.CBCDAT

Test Name	Result		Unit
D1b. White Blood Cell Count (WBC)	SDV LBB.WBCRES	(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L LBB.WBCUNT
D1c. Red Blood Cell Count (RBC)	SDV LBB.RBCRES	(xx.xx)	SDV ○ 10^6uL ○ 10^12/L LBB.RBCUNT
D1d. Hemoglobin	SDV LBB.HGBRES	(xxx.xx)	SDV ○ g/dL ○ g/L LBB.HGBUNT
D1e. Hematocrit (HCT)	SDV LBB.HCTRES	(xxx.xx)	SDV ○ % ○ Proportion of 1.0 LBB.HCTUNT
D1f. Mean Cell Volume (MCV)	SDV LBB.MCVRES	(xxx.xx)	**fL**
D1g. Mean Corpuscular Hemoglobin (MCHb)	SDV LBB.MCHBRES	(xxx.xx)	**pg**
D1h. Mean Corpuscular Hemoglobin (MCHb) Conc	SDV LBB.MCHBCRES	(xxxx.xx)	SDV ○ g/dL ○ g/L LBB.MCHBCUNT
D1i. RDW - Red Blood Cell Distribution Width (%)	SDV LBB.RDWRES	(xxx.xx)	**%**
D1j. Platelet Count	SDV LBB.PLTRES	(xxxxxx.xx)	SDV ○ 10^3/uL ○ 10^9/L LBB.PLTUNT
D1k. Was a CBC differential done? Please only report the absolute count of each cell type.	SDV ○ Yes ○ No LBB.CBCDIFYN		
D1k1. Neutrophils-segmented	SDV LBB.NEUTSRES	(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L LBB.NEUTSUNT
D1k2. Neutrophils-bands	SDV	(xx.xx)	SDV ○ 10^3/uL ○ 10^9/L

	LBB.NEUTBRES		LBB.NEUTBUNT
D1k3. Lymphocytes	SDV	(xx.xx)	SDV 10^3/uL 10^9/L
	LBB.LYMPRES		LBB.LYMPUNT
D1k4. Monocytes	SDV	(xx.xx)	SDV 10^3/uL 10^9/L
	LBB.MONORES		LBB.MONOUNT
D1k5. Eosinophils	SDV	(xx.xx)	SDV 10^3/uL 10^9/L
	LBB.EOSRES		LBB.EOSUNT
D1k6. Basophils	SDV	(xx.xx)	SDV 10^3/uL 10^9/L
	LBB.BASORES		LBB.BASOUNT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618795	Section Header	0	SECTION A: AST, ALT and CK											
Page-2-618795	Radiolist Horizontal	0	A1. Was AST done?	LBB.ASTYN	Yes				cYN					
Page-3-618795	Date	1	A1a. Date of blood draw	LBB.ASTDAT	Yes									
-- Page Dynamics (LBB.ASTDAT): Show When: LBB.ASTYN = 1														
Page-4-618795	Numeric	1	A1b. Result	LBB.ASTRES	Yes							3	2	Normal Range: 7.0 - 40.0 (U/L) 7.0 - 40.0 (IU/L)
-- Page Dynamics (LBB.ASTRES): Show When: LBB.ASTYN = 1														
Page-5-618795	Radiolist Horizontal	1	A1c. Unit	LBB.ASTUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
-- Page Dynamics (LBB.ASTUNT): Show When: LBB.ASTYN = 1														
Page-6-618795	Radiolist Horizontal	0	A2. Was ALT done?	LBB.ALTYN	Yes				cYN					

Page Information														
Page-7-618795	Date	1	A2a. Date of blood draw	LBB.ALTDAT	Yes									
-- Page Dynamics (LBB. ALTDAT): Show When: LBB.ALTYN = 1														
Page-8-618795	Numeric	1	A2b. Result	LBB.ALTRES	Yes							3	2	Normal Range: 5.0 - 35.0 (U/L) 5.0 - 35.0 (IU/L)
-- Page Dynamics (LBB. ALTRES): Show When: LBB.ALTYN = 1														
Page-9-618795	Radiolist Horizontal	1	A2c. Unit	LBB.ALTUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
-- Page Dynamics (LBB. ALTUNT): Show When: LBB.ALTYN = 1														
Page-10-618795	Radiolist	1	A2d. ALT result category Baseline Only	LBB.ALTBCAT	Yes				cALTBASECAT					
-- Page Dynamics (LBB. ALTBCAT): Show When: LBB.ALTYN = 1 AND VISITID = 20														
Page-11-618795	Remote Value	1	Baseline ALT Result (read-only)											
-- Remote Value: field at visit:20, page:50, table.column:LBB.ALTRES														
-- Page Dynamics (.): Show When: LBB.ALTYN = 1 AND VISITID > 20														
Page-12-618795	Remote Value	1	Baseline ALT Category (read-only)											
-- Remote Value: field at visit:20, page:50, table.column:LBB.ALTBCAT														
-- Page Dynamics (.): Show When: LBB.ALTYN = 1 AND VISITID > 20														
Page-13-618795	Radiolist	1	A2e. ALT result category Follow-up Only	LBB.ALTFCAT	Yes				cALTFUPCAT					
-- Page Dynamics (LBB. ALTFCAT): Show When: LBB.ALTYN = 1 AND VISITID > 20														
Page-14-618795	Help Text Line	1	COMPLETE Questions below IF... <u>Baseline ALT was < 40 U/L</u> AND Result is ≥ 80 U/L OR <u>Baseline ALT was 40 -79</u> AND Result is ≥ 2 times the baseline ALT result OR <u>Baseline ALT was 80 – 199 with NAFLD</u> AND Result is ≥ 2 times the baseline ALT result											
-- Page Dynamics (.): Show When: LBB.ALTYN = 1 AND (LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2) AND VISITID > 20														
Page-15-618795	Section Header	0	Assessment of elevations in ALT and other liver abnormalities											

Page Information														
-- Page Dynamics (.): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-16-618795	Radiolist Horizontal	1	Were any increases in ALT (if applicable) verified by repeat assessment(s)?	LBB.ALTREP	Yes				cYNNA					If Yes, please enter the results of the repeat ALT assessments on the Laboratory Results - Repeat ALT Assessments (LBALT) form
-- Page Dynamics (LBB. ALTREP): Show When: LBB.ALTYN = 1														
Page-17-618795	Radiolist Horizontal	1	Was additional bloodwork performed?	LBB.BLODYN	Yes				cYN					
-- Page Dynamics (LBB. BLODYN): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-18-618795	Date	2	Date of bloodwork	LBB.BLODAT	Yes									
-- Page Dynamics (LBB. BLODAT): Show When: LBB.BLODYN = 1														
Page-19-618795	Radiolist Horizontal	1	Was INR measurement obtained?	LBB.INRYN	Yes				cYN					
-- Page Dynamics (LBB. INRYN): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-20-618795	Numeric	2	Result	LBB.INRRES	Yes							1	1	Normal Range: 0.80 - 1.20
-- Page Dynamics (LBB. INRRES): Show When: LBB.INRYN = 1														
Page-21-618795	Numeric	2	ULN	LBB.INRULN	Yes							1	1	
-- Page Dynamics (LBB. INRULN): Show When: LBB.INRYN = 1														
Page-22-618795	Radiolist Horizontal	2	Was the INR result normal?	LBB.INRNORMYN	Yes				cYN					
-- Page Dynamics (LBB. INRNORMYN): Show When: LBB.INRYN = 1														
Page-23-618795	Radiolist Horizontal	1	Was bilirubin measurement obtained?	LBB.BILIYN	Yes				cYN					
-- Page Dynamics (LBB. BILIYN): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-24-618795	Numeric	2	Result	LBB.BILIRES	Yes							3	2	Normal Range: 0.3 - 1.2 (mg/dL) 5.0 - 21.0 (µmol/L)
-- Page Dynamics (LBB. BILIRES): Show When: LBB.BILIYN = 1														

Page Information														
Page-25-618795	Radiolist Horizontal	2	Unit	LBB.BILIUNT	Yes				cUNIT_MGDL_UMOLL					mg/dL x 17.104 = µmol/L
-- Page Dynamics (LBB.BILIUNT): Show When: LBB.BILIYN = 1														
Page-26-618795	Numeric	2	ULN	LBB.BILIULN	Yes							3	2	
-- Page Dynamics (LBB.BILIULN): Show When: LBB.BILIYN = 1														
Page-27-618795	Radiolist Horizontal	2	Was the bilirubin result normal?	LBB.BILNORMYN	Yes				cYN					
-- Page Dynamics (LBB.BILNORMYN): Show When: LBB.BILIYN = 1														
Page-28-618795	Radiolist Horizontal	1	Were any other tests performed (blood, liver, ultrasound, etc.)?	LBB.OTHTSTYN	Yes				cYN					
-- Page Dynamics (LBB.OTHTSTYN): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-29-618795	Text Field	2	Please provide a description, date and result of each other test that was performed:	LBB.OTHTDESC	Yes					500	99			
-- Page Dynamics (LBB.OTHTDESC): Show When: LBB.OTHTSTYN = 1														
Page-30-618795	Radiolist Horizontal	1	Did subject have any symptoms of liver disease?	LBB.ALTGISYM	Yes				cYN					
-- Page Dynamics (LBB.ALTGISYM): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-31-618795	Help Text Line	1	If Yes, please ensure all symptoms are reported on the Visit Form in this visit.											
-- Page Dynamics (.): Show When: LBB.ALTGISYM = 1														
Page-32-618795	Radiolist Horizontal	1	Was an assessment by GI done?	LBB.ALTGIYN	Yes				cYN					Indicate "Yes" if a GI consult was done at this visit or if it was done in the past.
-- Page Dynamics (LBB.ALTGIYN): Show When: LBB.ALTBCAT = 2 OR LBB.ALTBCAT = 3 OR LBB.ALTFCAT = 1 OR LBB.ALTFCAT = 2														
Page-33-618795	Date	2	Date of consult	LBB.ALTGIDAT	Yes									
-- Page Dynamics (LBB.ALTGIDAT): Show When: LBB.ALTGIYN = 1														
Page-34-618795	Text Field	2	Result of consult	LBB.GIRES	Yes					500	99			
-- Page Dynamics (LBB.GIRES): Show When: LBB.ALTGIYN = 1														

Page Information														
Page-35-618795	Radiolist Horizontal	1	Did the results of the further workup reveal any liver disease other than NAFLD?	LBB.ALTNAFLD	Yes				cYN					
-- Page Dynamics (LBB. ALTNAFLD): Show When: LBB.ALTGIYN = 1														
Page-36-618795	Text Field	2	If Yes, please describe in detail	LBB.ALTNDESC	Yes					500	99			
-- Page Dynamics (LBB. ALTNDESC): Show When: LBB.ALTNAFLD = 1														
Page-37-618795	Radiolist Horizontal	2	A2f1. Did the assessment confirm no liver disease other than NAFLD present?	LBB.ALTGIRES	Yes				cYN					
-- Page Dynamics (LBB. ALTGIRES): Show When: LBB.ALTGIYN = 1														
-- Role Permissions (LBB. ALTGIRES): Unblinded CDM: Hide , Clinical Research Associate: Hide , Site Coordinator: Hide , Site Principal Investigator: Hide , Medical Monitor: Hide , Project Manager: Hide , Sponsor: Hide , Statistician: Hide , Pharmacist: Hide , Coder: Hide , Clinical Data Manager: Hide , Site PI Read Only: Hide														
Page-38-618795	Section Header	0	Creatine Kinase (CK) Test											
Page-39-618795	Radiolist Horizontal	0	A3. Was CK done?	LBB.CKYN	Yes				cYN					
Page-40-618795	Date	1	A3a. Date of blood draw	LBB.CKDAT	Yes									
-- Page Dynamics (LBB. CKDAT): Show When: LBB.CKYN = 1														
Page-41-618795	Numeric	1	A3b. Result	LBB.CKRES	Yes							4	2	Normal Range: 20.0 - 215 (U/L) 20.0 - 215 (IU/L)
-- Page Dynamics (LBB. CKRES): Show When: LBB.CKYN = 1														
Page-42-618795	Radiolist Horizontal	1	A3c. Unit	LBB.CKUNT	Yes				cUNIT_UL_IUL					1 U/L = 1 IU/L
-- Page Dynamics (LBB. CKUNT): Show When: LBB.CKYN = 1														
Page-43-618795	Section Header	0	SECTION B: GLUCOSE HOMEOSTASIS - FASTING GLUCOSE, HBA1C											
Page-44-618795	Radiolist Horizontal	0	B1. Was a fasting blood sample obtained?	LBB.FASTGLYN	Yes				cYN					
Page-45-618795	Date	1	B1a. Date sample collected	LBB.FASTGLDAT	Yes									Enter the date the sample was taken in DD/MMM/YYYY date format.
-- Page Dynamics (LBB. FASTGLDAT): Show When: LBB.FASTGLYN = 1														

Page Information														
Page-46-618795	Numeric	1	B1b. Fasting glucose result	LBB.FASTGLRES	Yes							4	2	Normal Range: 70 - 110 (mg/dL) 3.9 - 6.1 (mmol/L)
-- Page Dynamics (LBB.FASTGLRES): Show When: LBB.FASTGLYN = 1														
Page-47-618795	Radiolist Horizontal	1	B1c. Unit	LBB.FASTGLUNT	Yes				cUNIT_MGDL_MMOLL					mg/dl x 0.0555 = mmol/L
-- Page Dynamics (LBB.FASTGLUNT): Show When: LBB.FASTGLYN = 1														
Page-48-618795	Radiolist Horizontal	0	B2. Was a hemoglobin A1c result obtained	LBB.HBA1CYN	Yes				cYN					HbA1c must be done at a site lab and not point of care.
Page-49-618795	Date	1	B2a. Date sample collected	LBB.HBA1CDAT	Yes									
-- Page Dynamics (LBB.HBA1CDAT): Show When: LBB.HBA1CYN = 1														
Page-50-618795	Numeric	1	B2b. Hemoglobin A1c (%)	LBB.HBA1CRES	Yes							2	2	Normal Range: 4.0 - 6.0 (%)
-- Page Dynamics (LBB.HBA1CRES): Show When: LBB.HBA1CYN = 1														
Page-51-618795	Section Header	0	SECTION C: PREGNANCY TEST											
-- Page Dynamics (.): Show When: 10-40-DM.SEX = 2														
Page-52-618795	Help Text Line	0	Required at Screening and Baseline. After screening and baseline, urine pregnancy tests may be performed at subsequent times at the discretion of site study personnel.											
-- Page Dynamics (.): Show When: 10-40-DM.SEX = 2														
Page-53-618795	Radiolist Horizontal	0	C1. Was a urine pregnancy test done at this visit?	LBB.PREGPERF	Yes				cYNNA					
-- Page Dynamics (LBB.PREGPERF): Show When: 10-40-DM.SEX = 2														
Page-54-618795	Date	1	C1a. Date of Pregnancy Test	LBB.PREGDAT	Yes									
-- Page Dynamics (LBB.PREGDAT): Show When: 10-40-DM.SEX = 2 AND LBB.PREGPERF = 1														
Page-55-618795	Radiolist Horizontal	1	C1b. Result of Pregnancy Test	LBB.PREGRES	Yes				cPOS_NEG					
-- Page Dynamics (LBB.PREGRES): Show When: 10-40-DM.SEX = 2 AND LBB.PREGPERF = 1														
Page-56-618795	Section Header	0	SECTION D. COMPLETE BLOOD COUNT (CBC) RESULTS											

Page Information														
-- Page Dynamics (.): Show When: VISITID = 90 OR VISITID = 140														
Page-57-618795	Radiolist Horizontal	0	D1. Were Complete Blood Count (CBC) Results obtained?	LBB.CBCPERF	Yes				cYN					
-- Page Dynamics (LBB. CBCPERF): Show When: VISITID = 90 OR VISITID = 140														
Page-58-618795	Help Text Line	0	Complete Blood Count (CBC) is required at Screening and Month 24.											
-- Page Dynamics (.): Show When: VISITID = 90 OR VISITID = 140														
Page-59-618795	Date	1	D1a. Date of sample collection	LBB.CBCDAT	Yes									
-- Page Dynamics (LBB. CBCDAT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-60-618795	Row Start/End	0												
Page-61-618795	Section Header	0	Test Name											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-62-618795	Section Header	0	Result											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-63-618795	Section Header	0	Unit											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-64-618795	Row Start/End	0												
Page-65-618795	Row Start/End	0												
Page-66-618795	Help Text Line	0	D1b. White Blood Cell Count (WBC)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-67-618795	Numeric	0	White Blood Cell Count (WBC)	LBB.WBCRES	Yes							2	2	Normal Range: 3.5 - 12.0 (10^3/uL) 3.5 - 12.0 (10^9/L)
-- Page Dynamics (LBB. WBCRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														

Page Information														
Page-68-618795	Radiolist Horizontal	0	White Blood Cell Count (WBC)	LBB.WBCUNT	Yes				cUNIT_103UL_109L					If reporting unit is mm3 (i.e. 3500-12,000/mm3), WBC value should be reported as 3.5 - 12.0 with either unit 10^3/uL or 10^9/L.
-- Page Dynamics (LBB. WBCUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.WBCRES IS NOT NULL														
Page-69-618795	Row Start/End	0												
Page-70-618795	Row Start/End	0												
Page-71-618795	Help Text Line	0	D1c. Red Blood Cell Count (RBC)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-72-618795	Numeric	0	Red Blood Cell Count (RBC)	LBB.RBCRES	Yes							2	2	Normal Range: 3.9 - 6.0 (10^6uL) 3.9 - 6.0 (10^12/L)
-- Page Dynamics (LBB. RBCRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-73-618795	Radiolist Horizontal	0	Red Blood Cell Count (RBC)	LBB.RBCUNT	Yes				cUNIT_106UL_1012L					
-- Page Dynamics (LBB. RBCUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.RBCRES IS NOT NULL														
Page-74-618795	Row Start/End	0												
Page-75-618795	Row Start/End	0												
Page-76-618795	Help Text Line	0	D1d. Hemoglobin											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-77-618795	Numeric	0	Hemoglobin	LBB.HGBRES	Yes							3	2	Normal Range: 11.2 - 18.0 (g/dL) 112 - 180 (g/L)
-- Page Dynamics (LBB. HGBRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														

Page Information														
Page-78-618795	Radiolist Horizontal	0	Hemoglobin	LBB.HGBUNT	Yes				cUNIT_GDL_GL					
-- Page Dynamics (LBB. HGBUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.HGBRES IS NOT NULL														
Page-79-618795	Row Start/End	0												
Page-80-618795	Row Start/End	0												
Page-81-618795	Help Text Line	0	D1e. Hematocrit (HCT)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-82-618795	Numeric	0	Hematocrit (HCT)	LBB.HCTRES	Yes							3	2	Normal Range: 35 - 54 (%) 0.35 - 0.54 (Proportion of 1.0)
-- Page Dynamics (LBB. HCTRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-83-618795	Radiolist Horizontal	0	Hematocrit (HCT)	LBB.HCTUNT	Yes				cUNIT_PROP1_PERC					
-- Page Dynamics (LBB. HCTUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.HCTRES IS NOT NULL														
Page-84-618795	Row Start/End	0												
Page-85-618795	Row Start/End	0												
Page-86-618795	Help Text Line	0	D1f. Mean Cell Volume (MCV)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-87-618795	Numeric	0	Mean Cell Volume (MCV)	LBB.MCVRES	Yes							3	2	Normal Range: 76-100 (fL) Note (if reporting unit is µm3): 1fL is the same as 1µm3
-- Page Dynamics (LBB. MCVRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-88-618795	Help Text Line	0	fL											

Page Information														
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-89-618795	Row Start/End	0												
Page-90-618795	Row Start/End	0												
Page-91-618795	Help Text Line	0	D1g. Mean Corpuscular Hemoglobin (MCHb)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-92-618795	Numeric	0	Mean Corpuscular Hemoglobin (MCHb)	LBB.MCHBRES	Yes							3	2	Normal Range: 24 - 35 (pg/cell)
-- Page Dynamics (LBB. MCHBRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-93-618795	Help Text Line	0	pg											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-94-618795	Row Start/End	0												
Page-95-618795	Row Start/End	0												
Page-96-618795	Help Text Line	0	D1h. Mean Corpuscular Hemoglobin (MCHb) Conc											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-97-618795	Numeric	0	Mean Corpuscular Hemoglobin (MCHb) Conc	LBB.MCHBCRES	Yes							4	2	Normal Range: 31 - 37 (g/dL) 310 - 370 (g/L)
-- Page Dynamics (LBB. MCHBCRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-98-618795	Radiolist Horizontal	0	Mean Corpuscular Hemoglobin (MCHb) Conc	LBB.MCHBCUNT	Yes				cUNIT_GDL_GL					
-- Page Dynamics (LBB. MCHBCUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.MCHBCRES IS NOT NULL														
Page-99-618795	Row Start/End	0												
Page-100-618795	Row Start/End	0												

Page Information														
Page-101-618795	Help Text Line	0	D1i. RDW - Red Blood Cell Distribution Width (%)											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-102-618795	Numeric	0	RDW - Red Blood Cell Distribution Width	LBB. RDWRES	Yes							3	2	Normal Range: 11.0 - 15.6 (%)
-- Page Dynamics (LBB. RDWRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-103-618795	Help Text Line	0	%											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-104-618795	Row Start/End	0												
Page-105-618795	Row Start/End	0												
Page-106-618795	Help Text Line	0	D1j. Platelet Count											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-107-618795	Numeric	0	Platelet Count	LBB. PLTRES	Yes							6	2	Normal Range: 150-450 x (10^9/L) 150-450 x (10^3/uL)
-- Page Dynamics (LBB. PLTRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-108-618795	Radiolist Horizontal	0	Platelet Count	LBB. PLTUNT	Yes				cUNIT_103UL_109L					If reporting unit is mm3 (i.e. 150,000-450,000/mm3), PLT value should be reported as 150 - 450 with either unit 10^3/uL or 10^9/L.
-- Page Dynamics (LBB. PLTUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.PLTRES IS NOT NULL														
Page-109-618795	Row Start/End	0												
Page-110-618795	Row Start/End	0												

Page Information														
Page-111-618795	Help Text Line	0	D1k. Was a CBC differential done? Please only report the <u>absolute count of each cell type</u>.											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-112-618795	Radiolist Horizontal	0	Was a CBC differential done?	LBB. CBCDIFYN	Yes				cYN					CBC differential must include absolute counts of both segmented and band neutrophils.
-- Page Dynamics (LBB. CBCDIFYN): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-113-618795	Help Text Line	0												
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1														
Page-114-618795	Row Start/End	0												
Page-115-618795	Row Start/End	0												
Page-116-618795	Help Text Line	0	D1k1. Neutrophils-segmented											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-117-618795	Numeric	0	Neutrophils-segmented	LBB. NEUTSRES	Yes							2	2	Normal Range: 1.5 - 8.0 x (10^9/L) 1.5 - 8.0 x (10^3/uL)
-- Page Dynamics (LBB. NEUTSRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-118-618795	Radiolist Horizontal	0	Neutrophils-segmented	LBB. NEUTSUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB. NEUTSUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.NEUTSRES IS NOT NULL														
Page-119-618795	Row Start/End	0												
Page-120-618795	Row Start/End	0												

Page Information														
Page-121-618795	Help Text Line	0	D1k2. Neutrophils-bands											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-122-618795	Numeric	0	Neutrophils-bands	LBB.NEUTBRES	Yes							2	2	Normal Range: 0 - 0.70 x (10^9/L) 0 - 0.70 x (10^3/uL)
-- Page Dynamics (LBB. NEUTBRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-123-618795	Radiolist Horizontal	0	Neutrophils-bands	LBB.NEUTBUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB. NEUTBUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.NEUTBRES IS NOT NULL														
Page-124-618795	Row Start/End	0												
Page-125-618795	Row Start/End	0												
Page-126-618795	Help Text Line	0	D1k3. Lymphocytes											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-127-618795	Numeric	0	Lymphocytes	LBB.LYMPRES	Yes							2	2	Normal Range: 1.0 - 6.5 x (10^9/L) 1.0 - 6.5 x (10^3/uL)
-- Page Dynamics (LBB. LYMPRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-128-618795	Radiolist Horizontal	0	Lymphocytes	LBB.LYMPUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB. LYMPUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.LYMPRES IS NOT NULL														
Page-129-618795	Row Start/End	0												
Page-130-618795	Row Start/End	0												
Page-131-618795	Help Text Line	0	D1k4. Monocytes											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														

Page Information														
Page-132-618795	Numeric	0	Monocytes	LBB.MONORES	Yes							2	2	Normal Range: 0.00 - 0.90 x (10^9/L) 0.00 - 0.90 x (10^3/uL)
-- Page Dynamics (LBB. MONORES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-133-618795	Radiolist Horizontal	0	Monocytes	LBB.MONOUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB. MONOUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.MONORES IS NOT NULL														
Page-134-618795	Row Start/End	0												
Page-135-618795	Row Start/End	0												
Page-136-618795	Help Text Line	0	D1k5. Eosinophils											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-137-618795	Numeric	0	Eosinophils	LBB.EOSRES	Yes							2	2	Normal Range: 0.00 - 0.50 x (10^9/L) 0.00 - 0.50 x (10^3/uL)
-- Page Dynamics (LBB. EOSRES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-138-618795	Radiolist Horizontal	0	Eosinophils	LBB.EOSUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB. EOSUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.EOSRES IS NOT NULL														
Page-139-618795	Row Start/End	0												
Page-140-618795	Row Start/End	0												
Page-141-618795	Help Text Line	0	D1k6. Basophils											
-- Page Dynamics (.): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page-142-618795	Numeric	0	Basophils	LBB.BASORES	Yes							2	2	Normal Range: 0.00 - 0.30 x (10^9/L) 0.00 - 0.30 x (10^3/uL)

Page Information														
-- Page Dynamics (LBB. BASORES): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1														
Page -143-618795	Radiolist Horizontal	0	Basophils	LBB. BASOUNT	Yes				cUNIT_103UL_109L					
-- Page Dynamics (LBB. BASOUNT): Show When: (VISITID = 90 OR VISITID = 140) AND LBB.CBCPERF = 1 AND LBB.CBCDIFYN = 1 AND LBB.BASORES IS NOT NULL														
Page -144-618795	Row Start/End	0												

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619625	SYSQ_5349	LBB. ASTYN	Field Null		LBB.ASTYN IS NULL	"A1. Was AST done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:33	0	0	0	0	0	0
sysq-619627	SYSQ_5350	LBB. ASTDAT	Field Null		LBB.ASTDAT IS NULL	"A1a. Date of blood draw" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619628	SYSQ_5351	LBB. ASTDAT	Future Date		LBB.ASTDAT > Today	"A1a. Date of blood draw" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619630	SYSQ_5352	LBB. ASTRES	Field Null		LBB.ASTRES IS NULL	"A1b. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619632	SYSQ_5353	LBB. ASTUNT	Field Null		LBB.ASTUNT IS NULL	"A1c. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619635	SYSQ_5354	LBB. ALTYN	Field Null		LBB.ALTYN IS NULL	"A2. Was ALT done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619636	SYSQ_5355	LBB. ALTDAT	Field Null		LBB.ALTDAT IS NULL	"A2a. Date of blood draw" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0

System Queries														
sysq-619639	SYSQ_5356	LBB.ALTDAT	Future Date		LBB.ALTDAT > Today	"A2a. Date of blood draw" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619641	SYSQ_5357	LBB.ALTRES	Field Null		LBB.ALTRES IS NULL	"A2b. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619642	SYSQ_5358	LBB.ALTUNT	Field Null		LBB.ALTUNT IS NULL	"A2c. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619644	SYSQ_5359	LBB.ALTBCAT	Field Null		LBB.ALTBCAT IS NULL	"A2d. ALT result category Baseline Only" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619647	SYSQ_5360	LBB.ALTFCAT	Field Null		LBB.ALTFCAT IS NULL	"A2e. ALT result category Follow-up Only" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619648	SYSQ_5361	LBB.ALTGIYN	Field Null		LBB.ALTGIYN IS NULL	Was an assessment by GI done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619650	SYSQ_5362	LBB.ALTGIRES	Field Null		LBB.ALTGIRES IS NULL	"A2f1. Did the assessment confirm no liver disease other than NAFLD present?" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619653	SYSQ_5363	LBB.ALTGISYM	Field Null		LBB.ALTGISYM IS NULL	"Did subject have any symptoms of liver disease?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619654	SYSQ_5364	LBB.INRYN	Field Null		LBB.INRYN IS NULL	"Was INR measurement obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619657	SYSQ_5365	LBB.INRRES	Field Null		LBB.INRRES IS NULL	INR "Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0

System Queries														
sysq-619659	SYSQ_5366	LBB.INRULN	Field Null		LBB.INRULN IS NULL	INR "ULN" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619660	SYSQ_5367	LBB.INRNORMYN	Field Null		LBB.INRNORMYN IS NULL	"Was the INR result normal?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:34	0	0	0	0	0	0
sysq-619662	SYSQ_5368	LBB.BILIYN	Field Null		LBB.BILIYN IS NULL	"Was bilirubin measurement obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619664	SYSQ_5369	LBB.BILIRES	Field Null		LBB.BILIRES IS NULL	Bilirubin "Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619667	SYSQ_5370	LBB.BILIUNT	Field Null		LBB.BILIUNT IS NULL	Bilirubin "Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619669	SYSQ_5371	LBB.BILIULN	Field Null		LBB.BILIULN IS NULL	Bilirubin "ULN" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619670	SYSQ_5372	LBB.BILNORMYN	Field Null		LBB.BILNORMYN IS NULL	"Was the bilirubin result normal?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619673	SYSQ_5373	LBB.ALTREP	Field Null		LBB.ALTREP IS NULL	"Were any increases in ALT (if applicable) verified by repeat assessment(s)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619675	SYSQ_5374	LBB.CKYN	Field Null		LBB.CKYN IS NULL	"A3. Was CK done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619676	SYSQ_5375	LBB.CKDAT	Field Null		LBB.CKDAT IS NULL	"A3a. Date of blood draw" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0

System Queries														
sysq-619678	SYSQ_5376	LBB.CKDAT	Future Date		LBB.CKDAT > Today	"A3a. Date of blood draw" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619681	SYSQ_5377	LBB.CKRES	Field Null		LBB.CKRES IS NULL	"A3b. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619683	SYSQ_5378	LBB.CKUNT	Field Null		LBB.CKUNT IS NULL	"A3c. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619685	SYSQ_5379	LBB.FASTGLYN	Field Null		LBB.FASTGLYN IS NULL	"B1. Was a fasting blood sample obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619687	SYSQ_5380	LBB.FASTGLDAT	Field Null		LBB.FASTGLDAT IS NULL	"B1a. Date sample collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619689	SYSQ_5381	LBB.FASTGLDAT	Future Date		LBB.FASTGLDAT > Today	"B1a. Date sample collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619691	SYSQ_5382	LBB.FASTGLRES	Field Null		LBB.FASTGLRES IS NULL	"B1b. Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619692	SYSQ_5383	LBB.FASTGLUNT	Field Null		LBB.FASTGLUNT IS NULL	"B1c. Unit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:35	0	0	0	0	0	0
sysq-619695	SYSQ_5384	LBB.HBA1CYN	Field Null		LBB.HBA1CYN IS NULL	"B2. Was a hemoglobin A1c result obtained" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619696	SYSQ_5385	LBB.HBA1CDAT	Field Null		LBB.HBA1CDAT IS NULL	"B2a. Date sample collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0

System Queries														
sysq-619699	SYSQ_5386	LBB.HBA1CDAT	Future Date		LBB.HBA1CDAT > Today	"B2a. Date sample collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619701	SYSQ_5387	LBB.HBA1CRES	Field Null		LBB.HBA1CRES IS NULL	"B2b. Hemoglobin A1c (%)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619703	SYSQ_5388	LBB.PREGPERF	Field Null		LBB.PREGPERF IS NULL	"C1. Was a urine pregnancy test done at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619704	SYSQ_5389	LBB.PREGDAT	Field Null		LBB.PREGDAT IS NULL	"C1a. Date of Pregnancy Test" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619706	SYSQ_5390	LBB.PREGDAT	Future Date		LBB.PREGDAT > Today	"C1a. Date of Pregnancy Test" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619709	SYSQ_5391	LBB.PREGRES	Field Null		LBB.PREGRES IS NULL	"C1b. Result of Pregnancy Test" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619710	SYSQ_5392	LBB.CBCPERF	Field Null		LBB.CBCPERF IS NULL	"D1. Were Complete Blood Count (CBC) Results obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619713	SYSQ_5393	LBB.CBCDAT	Field Null		LBB.CBCDAT IS NULL	"D1a. Date of sample collection" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619714	SYSQ_5394	LBB.CBCDAT	Future Date		LBB.CBCDAT > Today	"D1a. Date of sample collection" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619717	SYSQ_5395	LBB.WBCRES	Field Null		LBB.WBCRES IS NULL	"White Blood Cell Count (WBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0

System Queries														
sysq-619718	SYSQ_5396	LBB.WBCUNT	Field Null		LBB.WBCUNT IS NULL	"White Blood Cell Count (WBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619721	SYSQ_5397	LBB.RBCRES	Field Null		LBB.RBCRES IS NULL	"Red Blood Cell Count (RBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619722	SYSQ_5398	LBB.RBCUNT	Field Null		LBB.RBCUNT IS NULL	"Red Blood Cell Count (RBC)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619725	SYSQ_5399	LBB.HGBRES	Field Null		LBB.HGBRES IS NULL	"Hemoglobin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619727	SYSQ_5400	LBB.HGBUNT	Field Null		LBB.HGBUNT IS NULL	"Hemoglobin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619729	SYSQ_5401	LBB.HCTRES	Field Null		LBB.HCTRES IS NULL	"Hematocrit (HCT)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:36	0	0	0	0	0	0
sysq-619730	SYSQ_5402	LBB.HCTUNT	Field Null		LBB.HCTUNT IS NULL	"Hematocrit (HCT)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619732	SYSQ_5403	LBB.MCVRES	Field Null		LBB.MCVRES IS NULL	"Mean Cell Volume (MCV)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619735	SYSQ_5404	LBB.MCHBRES	Field Null		LBB.MCHBRES IS NULL	"Mean Corpuscular Hemoglobin (MCHb)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619737	SYSQ_5405	LBB.MCHBCRES	Field Null		LBB.MCHBCRES IS NULL	"Mean Corpuscular Hemoglobin (MCHb) Conc" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0

System Queries														
sysq-619739	SYSQ_5406	LBB.MCHBCUNT	Field Null		LBB.MCHBCUNT IS NULL	"Mean Corpuscular Hemoglobin (MCHb) Conc" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619740	SYSQ_5407	LBB.RDWRES	Field Null		LBB.RDWRES IS NULL	"RDW - Red Blood Cell Distribution Width" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619742	SYSQ_5408	LBB.PLTRES	Field Null		LBB.PLTRES IS NULL	"Platelet Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619744	SYSQ_5409	LBB.PLTUNT	Field Null		LBB.PLTUNT IS NULL	"Platelet Count" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619747	SYSQ_5410	LBB.CBCDIFYN	Field Null		LBB.CBCDIFYN IS NULL	"Was a CBC differential done?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619749	SYSQ_5411	LBB.NEUTSRES	Field Null		LBB.NEUTSRES IS NULL	"Neutrophils-segmented" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619751	SYSQ_5412	LBB.NEUTSUNT	Field Null		LBB.NEUTSUNT IS NULL	"Neutrophils-segmented" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619753	SYSQ_5413	LBB.NEUTBRES	Field Null		LBB.NEUTBRES IS NULL	"Neutrophils-bands" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619755	SYSQ_5414	LBB.NEUTBUNT	Field Null		LBB.NEUTBUNT IS NULL	"Neutrophils-bands" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619757	SYSQ_5415	LBB.LYMPRES	Field Null		LBB.LYMPRES IS NULL	"Lymphocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0

System Queries														
sysq-619758	SYSQ_5416	LBB.LYMPUNT	Field Null		LBB.LYMPUNT IS NULL	"Lymphocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619760	SYSQ_5417	LBB.MONORES	Field Null		LBB.MONORES IS NULL	"Monocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619762	SYSQ_5418	LBB.MONOUNT	Field Null		LBB.MONOUNT IS NULL	"Monocytes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:37	0	0	0	0	0	0
sysq-619764	SYSQ_5419	LBB.EOSRES	Field Null		LBB.EOSRES IS NULL	"Eosinophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619766	SYSQ_5420	LBB.EOSUNT	Field Null		LBB.EOSUNT IS NULL	"Eosinophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619768	SYSQ_5421	LBB.BASORES	Field Null		LBB.BASORES IS NULL	"Basophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619770	SYSQ_5422	LBB.BASOUNT	Field Null		LBB.BASOUNT IS NULL	"Basophils" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619772	SYSQ_5423	LBB.ASTYN	Other / Cross Page		(LBB.ASTYN <> 1 OR LBB.ALTYN <> 1 OR LBB.CKYN <> 1 OR LBB.FASTGLYN <> 1 OR LBB.HBA1CYN <> 1) AND 20-140-RAND.RANDYN = 1	1 or more Safety measures (AST, ALT, CK, Fasting Glucose and/or HbA1c) are/is reported as not done. Please confirm and if confirmed, complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0

System Queries														
sysq-619774	SYSQ_5425	LBB.PREGPERF	Other / Cross Page		LBB.PREGPERF = 0 AND 20-140-RAND.RANDYN = 1 AND VISITID = 20	A urine pregnancy test is required at baseline (if subject was randomized). If not done, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-619777	SYSQ_5426	LBB.ALTREP	Other / Cross Page		LBB.ALTREP = 1	If Yes, please complete the LBALT (Laboratory Results - Repeat ALT Assessments) Form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:38	0	0	0	0	0	0
sysq-620504	SYSQ_5905	LBB.BLODYN	Field Null		LBB.BLODYN IS NULL	"Was additional bloodwork performed?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620505	SYSQ_5906	LBB.BLODAT	Field Null		LBB.BLODAT IS NULL	"Date of bloodwork" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620506	SYSQ_5907	LBB.BLODAT	Future Date		LBB.BLODAT > Today	"Date of bloodwork" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620507	SYSQ_5908	LBB.OTHTSTYN	Field Null		LBB.OTHTSTYN IS NULL	"Were any other tests performed (blood, liver, ultrasound, etc.)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620508	SYSQ_5909	LBB.OTHTDESC	Field Null		LBB.OTHTDESC IS NULL	"Please provide a description, date and result of each other test that was performed:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620509	SYSQ_5910	LBB.ALTGIDAT	Field Null		LBB.ALTGIDAT IS NULL	"Date of consult" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620510	SYSQ_5911	LBB.ALTGIDAT	Future Date		LBB.ALTGIDAT > Today	"Date of consult" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620511	SYSQ_5912	LBB.GIRES	Field Null		LBB.GIRES IS NULL	"Result of consult" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0

System Queries														
sysq-620512	SYSQ_5913	LBB.ALTNAFLD	Field Null		LBB.ALTNAFLD IS NULL	"Did the results of the further workup reveal any liver disease other than NAFLD?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620513	SYSQ_5914	LBB.ALTNDESC	Field Null		LBB.ALTNDESC IS NULL	"If Yes, please describe in detail" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0

pLIPS

Page

(Visit ID = 618796, Page ID =)

Unique Identifier page-618796-618796-618796-

Section A: Lipid Measures				
	Local Lipid results for Screening ONLY			
SDV	* A1. Was a fasting lipid profile obtained for screening purposes?	○ Yes ○ No	LIPS.LIPID_YN	
SDV	* A1a. Blood draw date		LIPS.LIPIDDAT	
SDV	* A1b. Date subject last ate		LIPS.MEALDAT	
SDV	* A1c. Time when subject last ate	:	LIPS.MEALTIM	(HH24:MI)
SDV	* A1d. Please describe what the subject last ate. Please include liquids as well as food.		LIPS.MEALCONTENT	
SDV	* A1e. Total Cholesterol Result (mg/dL)		LIPS.TOTAL_CHOL	(format xxxx.xx)
SDV	* A1f. Low density lipoprotein-c (LDL-C) Result (mg/dL)		LIPS.LDL	(format xxxx.xx)
SDV	* A1f1. Method for LDL-C Result	○ Direct ○ Calculated	LIPS.LDLMETH	
SDV	* A1g. High density lipoprotein-c (HDL-C) Result (mg/dL)		LIPS.HDL	(format xxxx.xx)
SDV	* A1h. Triglycerides Result (mg/dL)		LIPS.TRIGLYCERIDES	(format xxxx.xx)
	A1i. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	(auto calculated)	LIPS.NONHDLC	(format xxxx.xx)
	A1j. TG/HDL-C ratio	(auto calculated)	LIPS.TGHDLC	(format xxxx.xx)
SDV	* A2. Was a fasting lipid profile obtained prior to the screening lipid profile?	○ Yes ○ No ○ Unknown	LIPS.PRIOR_LIPID	
SDV	* A2a. Date of prior fasting lipid profile		LIPS.PRIOR_LIPID_DT	
SDV	* A2b. Total Cholesterol Result (mg/dL)		LIPS.PRIOR_CHOL	(format xxxx.xx)

SDV	* A2c. Low density lipoprotein-c (LDL-C) Result (mg/dL)		LIPS.PRIOR_LDL	(format xxxx.xx)
SDV	* A2c1. Method for LDL-C Result	○ Direct ○ Calculated	LIPS.PRIOR_LDLMETH	
SDV	* A2d. High density lipoprotein-c (HDL-C) Result (mg/dL)		LIPS.PRIOR_HDL	(format xxxx.xx)
SDV	* A2e. Triglycerides Result (mg/dL)		LIPS.PRIOR_TRIGLY	(format xxxx.xx)
	A2f. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	(auto calculated)	LIPS.PNONHDLC	(format xxxx.xx)
	A2g. TG/HDL-C ratio	(auto calculated)	LIPS.PTGHDLC	(format xxxx.xx)
SDV	* A3. Were physical measurements (Height, Weight, BMI, and BMI Percentile) obtained within the previous 6 months before being considered for screening?	○ Yes ○ No	LIPS.PRIOR_PHYMEAS	
SDV	* A3a. Date measurements performed		LIPS.PRIOR_SCRDAT	
SDV	* A3b. Height (cm)		LIPS.PRIOR_HT	(format xxx.xx)
SDV	* A3c. Weight (kg)		LIPS.PRIOR_WT	(format xxx.xx)
	A3d. BMI	(auto calculated)	LIPS.PRIOR_BMI	(format xx.x)
SDV	* A3e. BMI Percentile		LIPS.PRIOR_BMIP	(format xxx.xx)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618796	Section Header	0	Section A: Lipid Measures											
Page-2-618796	Help Text Line	0	Local Lipid results for Screening ONLY											

Page Information														
Page-3-618796	Radiolist Horizontal	0	A1. Was a fasting lipid profile obtained for screening purposes?	LIPS.LIPID_YN	Yes				cYN					
Page-4-618796	Date	1	A1a. Blood draw date	LIPS.LIPIDDAT	Yes									
-- Page Dynamics (LIPS. LIPIDDAT): Show When: LIPS.LIPID_YN = 1														
Page-5-618796	Date	1	A1b. Date subject last ate	LIPS.MEALDAT	Yes									Please enter the date the subject last ate
-- Page Dynamics (LIPS. MEALDAT): Show When: LIPS.LIPID_YN = 1														
Page-6-618796	Time	1	A1c. Time when subject last ate	LIPS.MEALTIM	Yes									Please enter the time the subject last ate
-- Page Dynamics (LIPS. MEALTIM): Show When: LIPS.LIPID_YN = 1														
Page-7-618796	Comments	1	A1d. Please describe what the subject last ate. Please include liquids as well as food.	LIPS.MEALCONTENT	Yes									
-- Page Dynamics (LIPS. MEALCONTENT): Show When: LIPS.LIPID_YN = 1														
Page-8-618796	Numeric	1	A1e. Total Cholesterol Result (mg/dL)	LIPS.TOTAL_CHOL	Yes							4	2	If Total Cholesterol is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 200 mg/dL
-- Page Dynamics (LIPS. TOTAL_CHOL): Show When: LIPS.LIPID_YN = 1														
Page-9-618796	Numeric	1	A1f. Low density lipoprotein-c (LDL-C) Result (mg/dL)	LIPS.LDL	Yes							4	2	If Low density lipoprotein-c (LDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 130 mg/dL
-- Page Dynamics (LIPS. LDL): Show When: LIPS.LIPID_YN = 1														

Page Information														
Page-10-618796	Radiolist Horizontal	2	A1f1. Method for LDL-C Result	LIPS.LDLMETH	Yes				cLDLMETHOD					Indicate whether LDL-C Result was obtained via direct measurement or calculated.
-- Page Dynamics (LIPS. LDLMETH): Show When: LIPS.LIPID_YN = 1 AND LIPS.LDL IS NOT NULL														
Page-11-618796	Numeric	1	A1g. High density lipoprotein-c (HDL-C) Result (mg/dL)	LIPS.HDL	Yes							4	2	If High density lipoprotein-c (HDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: > 35 mg/dL
-- Page Dynamics (LIPS. HDL): Show When: LIPS.LIPID_YN = 1														
Page-12-618796	Numeric	1	A1h. Triglycerides Result (mg/dL)	LIPS.TRIGLYCERIDES	Yes							4	2	If Triglycerides is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 88.57. Normal Range: 40-150 mg/dL
-- Page Dynamics (LIPS. TRIGLYCERIDES): Show When: LIPS.LIPID_YN = 1														
Page-13-618796	Auto Calc Field	1	A1i. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	LIPS.NONHDLC								4	2	
-- Auto Calc Rule (LIPS.NONHDLC): (LIPS.TOTAL_CHOL IS NOT NULL AND LIPS.HDL IS NOT NULL)>>>USE: LIPS.TOTAL_CHOL - LIPS.HDL														
-- Page Dynamics (LIPS. NONHDLC): Show When: LIPS.LIPID_YN = 1														
Page-14-618796	Auto Calc Field	1	A1j. TG/HDL-C ratio	LIPS.TGHDLC								4	2	
-- Auto Calc Rule (LIPS.TGHDLC): (LIPS.HDL IS NOT NULL AND LIPS.TRIGLYCERIDES IS NOT NULL)>>>USE: LIPS.TRIGLYCERIDES / LIPS.HDL														
-- Page Dynamics (LIPS. TGHDLC): Show When: LIPS.LIPID_YN = 1														

Page Information														
Page-15-618796	Radiolist Horizontal	0	A2. Was a fasting lipid profile obtained prior to the screening lipid profile?	LIPS.PRIOR_LIPID	Yes				cYNUNK					Per inclusion/exclusion criteria, a fasting lipid profile must have been done at the clinical site within 3 months of screening
Page-16-618796	Date	1	A2a. Date of prior fasting lipid profile	LIPS.PRIOR_LIPID_DT	Yes									
-- Page Dynamics (LIPS. PRIOR_LIPID_DT): Show When: LIPS.PRIOR_LIPID = 1														
Page-17-618796	Numeric	1	A2b. Total Cholesterol Result (mg/dL)	LIPS.PRIOR_CHOL	Yes							4	2	If Total Cholesterol is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 200 mg/dL
-- Page Dynamics (LIPS. PRIOR_CHOL): Show When: LIPS.PRIOR_LIPID = 1														
Page-18-618796	Numeric	1	A2c. Low density lipoprotein-c (LDL-C) Result (mg/dL)	LIPS.PRIOR_LDL	Yes							4	2	If Low density lipoprotein-c (LDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 130 mg/dL
-- Page Dynamics (LIPS. PRIOR_LDL): Show When: LIPS.PRIOR_LIPID = 1														
Page-19-618796	Radiolist Horizontal	2	A2c1. Method for LDL-C Result	LIPS.PRIOR_LDLMETH	Yes				cLDLMETHOD					Indicate whether LDL-C Result was obtained via direct measurement or calculated.
-- Page Dynamics (LIPS. PRIOR_LDLMETH): Show When: LIPS.PRIOR_LIPID = 1 AND LIPS.PRIOR_LDL IS NOT NULL														

Page Information														
Page-20-618796	Numeric	1	A2d. High density lipoprotein-c (HDL-C) Result (mg/dL)	LIPS.PRIOR_HDL	Yes							4	2	If High density lipoprotein-c (HDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: > 35 mg/dL
-- Page Dynamics (LIPS. PRIOR_HDL): Show When: LIPS.PRIOR_LIPID = 1														
Page-21-618796	Numeric	1	A2e. Triglycerides Result (mg/dL)	LIPS.PRIOR_TRIGLY	Yes							4	2	If Triglycerides is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 88.57. Normal Range: 40-150 mg/dL
-- Page Dynamics (LIPS. PRIOR_TRIGLY): Show When: LIPS.PRIOR_LIPID = 1														
Page-22-618796	Auto Calc Field	1	A2f. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	LIPS.PNONHDLC								4	2	
-- Auto Calc Rule (LIPS.PNONHDLC): (LIPS.PRIOR_CHOL IS NOT NULL AND LIPS.PRIOR_HDL IS NOT NULL)>>>USE: LIPS.PRIOR_CHOL - LIPS.PRIOR_HDL														
-- Page Dynamics (LIPS. PNONHDLC): Show When: LIPS.PRIOR_LIPID = 1														
Page-23-618796	Auto Calc Field	1	A2g. TG/HDL-C ratio	LIPS.PTGHDLC								4	2	
-- Auto Calc Rule (LIPS.PTGHDLC): (LIPS.PRIOR_HDL IS NOT NULL AND LIPS.PRIOR_TRIGLY IS NOT NULL)>>>USE: LIPS.PRIOR_TRIGLY / LIPS.PRIOR_HDL														
-- Page Dynamics (LIPS. PTGHDLC): Show When: LIPS.PRIOR_LIPID = 1														

Page Information														
Page-24-618796	Radiolist Horizontal	0	A3. Were physical measurements (Height, Weight, BMI, and BMI Percentile) obtained within the previous 6 months before being considered for screening?	LIPS.PRIOR_PHYMEAS	Yes				cYN					STEP 1: Potential participants will meet all of the following criteria based on medical record review or from a visit within the previous 6 months before being considered for screening (if known exclusion criteria, such as elevated AST, are noted at this step and cannot be clarified the patient will be excluded from STEP 2): * Boys and girls ages 10 to 17 years inclusive * BMI >95th%ile (CDC BMI charts)
Page-25-618796	Date	1	A3a. Date measurements performed	LIPS.PRIOR_SCRDAT	Yes									This can be the date of a visit done within the previous 6 months
-- Page Dynamics (LIPS. PRIOR_SCRDAT): Show When: LIPS.PRIOR_PHYMEAS = 1														
Page-26-618796	Numeric	1	A3b. Height (cm)	LIPS.PRIOR_HT	Yes							3	2	
-- Page Dynamics (LIPS. PRIOR_HT): Show When: LIPS.PRIOR_PHYMEAS = 1														
Page-27-618796	Numeric	1	A3c. Weight (kg)	LIPS.PRIOR_WT	Yes							3	2	
-- Page Dynamics (LIPS. PRIOR_WT): Show When: LIPS.PRIOR_PHYMEAS = 1														
Page-28-618796	Auto Calc Field	1	A3d. BMI	LIPS.PRIOR_BMI								2	1	
-- Auto Calc Rule (LIPS.PRIOR_BMI): (LIPS.PRIOR_HT IS NOT NULL AND LIPS.PRIOR_WT IS NOT NULL) ALWAYS>>>USE: LIPS.PRIOR_WT / (pow ((LIPS.PRIOR_HT / 100), 2))														
-- Page Dynamics (LIPS. PRIOR_BMI): Show When: LIPS.PRIOR_PHYMEAS = 1														
Page-29-618796	Numeric	1	A3e. BMI Percentile	LIPS.PRIOR_BMIP	Yes							3	2	
-- Page Dynamics (LIPS. PRIOR_BMIP): Show When: LIPS.PRIOR_PHYMEAS = 1														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619357	SYSQ_5183	LIPS.LIPID_YN	Field Null		LIPS.LIPID_YN IS NULL	"A1. Was a fasting lipid profile obtained for screening purposes?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619359	SYSQ_5184	LIPS.LIPIDDAT	Field Null		LIPS.LIPIDDAT IS NULL	"A1a. Blood draw date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619360	SYSQ_5185	LIPS.LIPIDDAT	Future Date		LIPS.LIPIDDAT > Today	"A1a. Blood draw date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619363	SYSQ_5186	LIPS.MEALDAT	Field Null		LIPS.MEALDAT IS NULL	"A1b. Date subject last ate" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619364	SYSQ_5187	LIPS.MEALDAT	Future Date		LIPS.MEALDAT > Today	"A1b. Date subject last ate" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619366	SYSQ_5188	LIPS.MEALTIM	Field Null		LIPS.MEALTIM IS NULL	"A1c. Time when subject last ate" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619369	SYSQ_5189	LIPS.MEALCONTENT	Field Null		LIPS.MEALCONTENT IS NULL	"A1d. Please describe what the subject last ate. Please include liquids as well as food." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619370	SYSQ_5190	LIPS.TOTAL_CHOL	Field Null		LIPS.TOTAL_CHOL IS NULL	"A1e. Total Cholesterol Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619372	SYSQ_5191	LIPS.LDL	Field Null		LIPS.LDL IS NULL	"A1f. Low density lipoprotein-c (LDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0

System Queries														
sysq-619375	SYSQ_5192	LIPS.HDL	Field Null		LIPS.HDL IS NULL	"A1g. High density lipoprotein-c (HDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619377	SYSQ_5193	LIPS.TRIGLYCERIDES	Field Null		LIPS.TRIGLYCERIDES IS NULL	"A1h. Triglycerides Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619378	SYSQ_5194	LIPS.PRIOR_LIPID	Field Null		LIPS.PRIOR_LIPID IS NULL	"A2. Was a fasting lipid profile obtained prior to the screening lipid profile?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619380	SYSQ_5195	LIPS.PRIOR_LIPID_DT	Field Null		LIPS.PRIOR_LIPID_DT IS NULL	"A2a. Date of prior fasting lipid profile" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619383	SYSQ_5196	LIPS.PRIOR_LIPID_DT	Future Date		LIPS.PRIOR_LIPID_DT > Today	"A2a. Date of prior fasting lipid profile" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619384	SYSQ_5197	LIPS.PRIOR_CHOL	Field Null		LIPS.PRIOR_CHOL IS NULL	"A2b. Total Cholesterol Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619386	SYSQ_5198	LIPS.PRIOR_LDL	Field Null		LIPS.PRIOR_LDL IS NULL	"A2c. Low density lipoprotein-c (LDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619388	SYSQ_5199	LIPS.PRIOR_HDL	Field Null		LIPS.PRIOR_HDL IS NULL	"A2d. High density lipoprotein-c (HDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619391	SYSQ_5200	LIPS.PRIOR_TRIGLY	Field Null		LIPS.PRIOR_TRIGLY IS NULL	"A2e. Triglycerides Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619392	SYSQ_5201	LIPS.PRIOR_PHYMEAS	Field Null		LIPS.PRIOR_PHYMEAS IS NULL	"A3. Were physical measurements (Height, Weight, BMI, and BMI Percentile) obtained within the previous 6 months before being considered for screening?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0

System Queries														
sysq-619394	SYSQ_5202	LIPS.PRIOR_HT	Field Null		LIPS.PRIOR_HT IS NULL	"A3a. Height (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619396	SYSQ_5203	LIPS.PRIOR_WT	Field Null		LIPS.PRIOR_WT IS NULL	"A3b. Weight (kg)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619398	SYSQ_5204	LIPS.PRIOR_BMIP	Field Null		LIPS.PRIOR_BMIP IS NULL	"A3d. BMI Percentile" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619400	SYSQ_5205	LIPS.PRIOR_HT	Range		LIPS.PRIOR_HT < 120 OR LIPS.PRIOR_HT > 200	"A3a. Height (cm)" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619402	SYSQ_5206	LIPS.PRIOR_WT	Range		LIPS.PRIOR_WT < 20 OR LIPS.PRIOR_WT > 135	"A3b. Weight (kg)" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619404	SYSQ_5207	LIPS.LIPIDDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(LIPS.LIPIDDAT, 10-20-ICF.ICF_DT) > 0	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619407	SYSQ_5208	LIPS.MEALDAT	Field Compare		LIPS.MEALDAT > LIPS.LIPIDDAT	"A1b. Date subject last ate" is after the "A1a. Blood draw date". Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619409	SYSQ_5209	LIPS.PRIOR_LIPID_DT	Field Compare		LIPS.PRIOR_LIPID_DT >= LIPS.LIPIDDAT	"A2a. Date of prior fasting lipid profile" is after or on the same date as screening lipid profile. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619411	SYSQ_5210	LIPS.LDL	Other / Cross Page		LIPS.LDL < 100 OR LIPS.LDL >= 160	The following Fasting Lipid Inclusion Criteria: LDL-C < 160 mg/dL and ≥ 100 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619412	SYSQ_5211	LIPS.TRIGLYCERIDES	Other / Cross Page		LIPS.TRIGLYCERIDES >= 500	The following Fasting Lipid Inclusion Criteria: TG < 500 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0

System Queries														
sysq-619416	SYSQ_5212	LIPS.NONHDLC	Other / Cross Page		LIPS.NONHDLC < 145	The following Fasting Lipid Inclusion Criteria: non-HDL-C ≥145 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619417	SYSQ_5213	LIPS.HDL	Other / Cross Page		(LIPS.TGHDLC < 3 AND LIPS.HDL >= 45 AND 10-40-DM.SEX = 1) OR (LIPS.TGHDLC < 3 AND LIPS.HDL >= 50 AND 10-40-DM.SEX = 2)	The following Fasting Lipid Inclusion Criteria: "TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls" was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619420	SYSQ_5214	LIPS.PRIOR_LDL	Other / Cross Page		LIPS.PRIOR_LDL < 100 OR LIPS.PRIOR_LDL >= 160	The following Fasting Lipid Inclusion Criteria: LDL-C < 160 mg/dL and ≥ 100 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619422	SYSQ_5215	LIPS.PRIOR_TRIGLY	Other / Cross Page		LIPS.PRIOR_TRIGLY >= 500	The following Fasting Lipid Inclusion Criteria: TG < 500 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619423	SYSQ_5216	LIPS.PNONHDLC	Other / Cross Page		LIPS.PNONHDLC < 145	The following Fasting Lipid Inclusion Criteria: non-HDL-C ≥145 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619426	SYSQ_5217	LIPS.PRIOR_HDL	Other / Cross Page		(LIPS.PTGHDLC < 3 AND LIPS.PRIOR_HDL >= 45 AND 10-40-DM.SEX = 1) OR (LIPS.PTGHDLC < 3 AND LIPS.PRIOR_HDL >= 50 AND 10-40-DM.SEX = 2)	The following Fasting Lipid Inclusion Criteria: "TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls" was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0

System Queries														
sysq-620398	SYSQ_5817	LIPS.LDLMETH	Field Null		LIPS.LDLMETH IS NULL	"A1f1. Method for LDL-C Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620400	SYSQ_5818	LIPS.PRIOR_LDLMETH	Field Null		LIPS.PRIOR_LDLMETH IS NULL	"A2c1. Method for LDL-C Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620402	SYSQ_5819	LIPS.PRIOR_SCRDAT	Field Null		LIPS.PRIOR_SCRDAT IS NULL	"A3a. Date measurements performed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620405	SYSQ_5820	LIPS.PRIOR_SCRDAT	Future Date		LIPS.PRIOR_SCRDAT > Today	"A3a. Date measurements performed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620407	SYSQ_5821	LIPS.PRIOR_SCRDAT	Other / Cross Page		(FUNCTION-DATE_COMPARE(LIPS.PRIOR_SCRDAT, 10-10-VIS.VISDAT) > 180 AND VISITID = 10) OR (FUNCTION-DATE_COMPARE(LIPS.PRIOR_SCRDAT, 10-10-VIS.VISDAT) < 0 AND VISITID = 10)	This date is not within 6 months of the screening visit. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0

System Queries														
sysq-620409	SYSQ_5822	LIPS.PRIOR_LIPID_DT	Other / Cross Page		(FUNCTION-DATE_COMPARE(LIPS.PRIOR_LIPID_DT, 10-10-VIS.VISDAT) > 90 AND VISITID = 10) OR (FUNCTION-DATE_COMPARE(LIPS.PRIOR_LIPID_DT, 10-10-VIS.VISDAT) < 0 AND VISITID = 10)	The date of the prior Fasting lipid profile (FLP) is not within 3 months of the screening visit. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0

pLIPSRE

Page

(Visit ID = 618797, Page ID =)

Unique Identifier page-618797-618797-618797-

Section A: Lipid Measures			
Local Lipid results for Screening ONLY			
* A1. Was a fasting lipid profile obtained for screening purposes?	○ Yes ○ No	LIPSRE.LIPID_YN	
* A1a. Blood draw date		LIPSRE.LIPIDDAT	
* A1b. Date subject last ate		LIPSRE.MEALDAT	
* A1c. Time when subject last ate		LIPSRE.MEALTIM	(HH24:MI)
* A1d. Please describe what the subject last ate. Please include liquids as well as food.		LIPSRE.MEALCONTENT	
* A1e. Total Cholesterol Result (mg/dL)		LIPSRE.TOTAL_CHOL	(format xxxx.xx)
* A1f. Low density lipoprotein-c (LDL-C) Result (mg/dL)		LIPSRE.LDL	(format xxxx.xx)
* A1f1. Method for LDL-C Result	○ Direct ○ Calculated	LIPSRE.LDLMETH	
* A1g. High density lipoprotein-c (HDL-C) Result (mg/dL)		LIPSRE.HDL	(format xxxx.xx)
* A1h. Triglycerides Result (mg/dL)		LIPSRE.TRIGLYCERIDES	(format xxxx.xx)
* A1i. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	(auto calculated)	LIPSRE.NONHDLC	(format xxxx.xx)
* A1j. TG/HDL-C ratio	(auto calculated)	LIPSRE.TGHDLC	(format xxxx.xx)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text

Page Information														
Page-1-618797	Section Header	0	Section A: Lipid Measures											
Page-2-618797	Help Text Line	0	Local Lipid results for Screening ONLY											
Page-3-618797	Radiolist Horizontal	0	A1. Was a fasting lipid profile obtained for screening purposes?	LIPSRE.LIPID_YN					cYN					
Page-4-618797	Date	1	A1a. Blood draw date	LIPSRE.LIPIDDAT										
-- Page Dynamics (LIPSRE. LIPIDDAT): Show When: LIPSRE.LIPID_YN = 1														
Page-5-618797	Date	1	A1b. Date subject last ate	LIPSRE.MEALDAT										Please enter the date the subject last ate
-- Page Dynamics (LIPSRE. MEALDAT): Show When: LIPSRE.LIPID_YN = 1														
Page-6-618797	Time	1	A1c. Time when subject last ate	LIPSRE.MEALTIM										Please enter the time the subject last ate
-- Page Dynamics (LIPSRE. MEALTIM): Show When: LIPSRE.LIPID_YN = 1														
Page-7-618797	Comments	1	A1d. Please describe what the subject last ate. Please include liquids as well as food.	LIPSRE.MEALCONTENT										
-- Page Dynamics (LIPSRE. MEALCONTENT): Show When: LIPSRE.LIPID_YN = 1														
Page-8-618797	Numeric	1	A1e. Total Cholesterol Result (mg/dL)	LIPSRE.TOTAL_CHOL								4	2	If Total Cholesterol is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 200 mg/dL
-- Page Dynamics (LIPSRE. TOTAL_CHOL): Show When: LIPSRE.LIPID_YN = 1														

Page Information														
Page-9-618797	Numeric	1	A1f. Low density lipoprotein-c (LDL-C) Result (mg/dL)	LIPSRE.LDL								4	2	If Low density lipoprotein-c (LDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 130 mg/dL
-- Page Dynamics (LIPSRE. LDL): Show When: LIPSRE.LIPID_YN = 1														
Page-10-618797	Radiolist Horizontal	2	A1f1. Method for LDL-C Result	LIPSRE.LDLMETH					cLDLMETHOD					Indicate whether LDL-C Result was obtained via direct measurement or calculated.
-- Page Dynamics (LIPSRE. LDLMETH): Show When: LIPSRE.LIPID_YN = 1 AND LIPSRE.LDL IS NOT NULL														
Page-11-618797	Numeric	1	A1g. High density lipoprotein-c (HDL-C) Result (mg/dL)	LIPSRE.HDL								4	2	If High density lipoprotein-c (HDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: > 35 mg/dL
-- Page Dynamics (LIPSRE. HDL): Show When: LIPSRE.LIPID_YN = 1														
Page-12-618797	Numeric	1	A1h. Triglycerides Result (mg/dL)	LIPSRE.TRIGLYCERIDES								4	2	If Triglycerides is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 88.57. Normal Range: 40 -150 mg/dL
-- Page Dynamics (LIPSRE. TRIGLYCERIDES): Show When: LIPSRE.LIPID_YN = 1														

Page Information															
Page-13-618797	Auto Calc Field	1	A1i. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	LIPSRE.NONHDLC								4	2		
-- Auto Calc Rule (LIPSRE.NONHDLC): (LIPSRE.TOTAL_CHOL IS NOT NULL AND LIPSRE.HDL IS NOT NULL)>>>USE: LIPSRE.TOTAL_CHOL - LIPSRE.HDL															
-- Page Dynamics (LIPSRE. NONHDLC): Show When: LIPSRE.LIPID_YN = 1															
Page-14-618797	Auto Calc Field	1	A1j. TG/HDL-C ratio	LIPSRE.TGHDLC								4	2		
-- Auto Calc Rule (LIPSRE.TGHDLC): (LIPSRE.HDL IS NOT NULL AND LIPSRE.TRIGLYCERIDES IS NOT NULL)>>>USE: LIPSRE.TRIGLYCERIDES / LIPSRE.HDL															
-- Page Dynamics (LIPSRE. TGHDLC): Show When: LIPSRE.LIPID_YN = 1															

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619414	SYSQ_5211	LIPSRE.TRIGLYCERIDES	Other / Cross Page		LIPSRE.TRIGLYCERIDES >= 500	The following Fasting Lipid Inclusion Criteria: TG < 500 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-620521	SYSQ_5922	LIPSRE.LIPID_YN	Field Null		LIPSRE.LIPID_YN IS NULL	"A1. Was a fasting lipid profile obtained for screening purposes?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620522	SYSQ_5923	LIPSRE.LIPIDDAT	Field Null		LIPSRE.LIPIDDAT IS NULL	"A1a. Blood draw date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620523	SYSQ_5924	LIPSRE.LIPIDDAT	Future Date		LIPSRE.LIPIDDAT > Today	"A1a. Blood draw date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620524	SYSQ_5925	LIPSRE.MEALDAT	Field Null		LIPSRE.MEALDAT IS NULL	"A1b. Date subject last ate" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620525	SYSQ_5926	LIPSRE.MEALDAT	Future Date		LIPSRE.MEALDAT > Today	"A1b. Date subject last ate" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0

System Queries														
sysq-620526	SYSQ_5927	LIPSRE.MEALTIM	Field Null		LIPSRE.MEALTIM IS NULL	"A1c. Time when subject last ate" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620527	SYSQ_5928	LIPSRE.MEALCONTENT	Field Null		LIPSRE.MEALCONTENT IS NULL	"A1d. Please describe what the subject last ate. Please include liquids as well as food." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620528	SYSQ_5929	LIPSRE.TOTAL_CHOL	Field Null		LIPSRE.TOTAL_CHOL IS NULL	"A1e. Total Cholesterol Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620529	SYSQ_5930	LIPSRE.LDL	Field Null		LIPSRE.LDL IS NULL	"A1f. Low density lipoprotein-c (LDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620530	SYSQ_5931	LIPSRE.LDLMETH	Field Null		LIPSRE.LDLMETH IS NULL	"A1f1. Method for LDL-C Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620531	SYSQ_5932	LIPSRE.HDL	Field Null		LIPSRE.HDL IS NULL	"A1g. High density lipoprotein-c (HDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620532	SYSQ_5933	LIPSRE.TRIGLYCERIDES	Field Null		LIPSRE.TRIGLYCERIDES IS NULL	"A1h. Triglycerides Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620533	SYSQ_5934	LIPSRE.NONHDLC	Field Null		LIPSRE.NONHDLC IS NULL	"A1i. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620534	SYSQ_5935	LIPSRE.TGHDLC	Field Null		LIPSRE.TGHDLC IS NULL	"A1j. TG/HDL-C ratio" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620543	SYSQ_5944	LIPSRE.NONHDLC	Other / Cross Page		LIPSRE.NONHDLC < 125	Fasting Lipid Inclusion Criteria for non-HDL was not met. Please confirm. If confirmed, the subject is not eligible	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:05	0	0	0	0	0	0

System Queries														
sysq-620544	SYSQ_59045	LIPSRE.LDL	Other / Cross Page		LIPSRE.LDL < 90 OR LIPSRE.LDL > 160	Fasting Lipid Inclusion Criteria for LDL-C was not met. Please confirm. If confirmed, the subject is not eligible	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:05	0	0	0	0	0	0
sysq-620545	SYSQ_59046	LIPSRE.TGHDLC	Other / Cross Page		10-40-DM.SEX = 1 AND (LIPSRE.HDL >= 45 OR LIPSRE.TGHDLC < 2.5)	Fasting Lipid Inclusion Criteria for TG/HDL-C ratio and/or HDL-C was not met. Please confirm. If confirmed, the subject is not eligible	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:05	0	0	0	0	0	0
sysq-620546	SYSQ_59047	LIPSRE.TGHDLC	Other / Cross Page		10-40-DM.SEX = 2 AND (LIPSRE.HDL >= 50 OR LIPSRE.TGHDLC < 2.5)	Fasting Lipid Inclusion Criteria for TG/HDL-C ratio and/or HDL-C was not met. Please confirm. If confirmed, the subject is not eligible	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:05	0	0	0	0	0	0

pLIPS_4

Page

(Visit ID = 618798, Page ID =)

Unique Identifier page-618798-618798-618798-

Section A: Lipid Measures				
	Local Lipid results for Screening ONLY			
SDV	* A1. Was a fasting lipid profile obtained for screening purposes?	○ Yes ○ No	LIPS.LIPID_YN	
SDV	* A1a. Blood draw date		LIPS.LIPIDDAT	
SDV	* A1b. Date subject last ate		LIPS.MEALDAT	
SDV	* A1c. Time when subject last ate		LIPS.MEALTIM	(HH24:MI)
SDV	* A1d. Please describe what the subject last ate. Please include liquids as well as food.		LIPS.MEALCONTENT	
SDV	* A1e. Total Cholesterol Result (mg/dL)		LIPS.TOTAL_CHOL	(format xxxx.xx)
SDV	* A1f. Low density lipoprotein-c (LDL-C) Result (mg/dL)		LIPS.LDL	(format xxxx.xx)
SDV	* A1f1. Method for LDL-C Result	○ Direct ○ Calculated	LIPS.LDLMETH	
SDV	* A1g. High density lipoprotein-c (HDL-C) Result (mg/dL)		LIPS.HDL	(format xxxx.xx)
SDV	* A1h. Triglycerides Result (mg/dL)		LIPS.TRIGLYCERIDES	(format xxxx.xx)
	A1i. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	(auto calculated)	LIPS.NONHDLC	(format xxxx.xx)
	A1j. TG/HDL-C ratio	(auto calculated)	LIPS.TGHDLC	(format xxxx.xx)
SDV	* A2. Was a fasting lipid profile obtained prior to the screening lipid profile?	○ Yes ○ No ○ Unknown	LIPS.PRIOR_LIPID	

(For Subjects enrolled under Protocol v5.0) As part of the pre-screening Inclusion criteria, a Fasting Lipid Profile (FLP) must be done within 6 months of screening at the clinical site or outside lab.

(For Subjects enrolled under Protocol v4.1) As part of the pre-screening Inclusion criteria, a Fasting Lipid Profile (FLP) must be done within 3 months of screening at the clinical site.

SDV	* A2a. Date of prior fasting lipid profile		LIPS.PRIOR_LIPID_DT	
SDV	* A2b. Total Cholesterol Result (mg/dL)		LIPS.PRIOR_CHOL	(format xxxx.xx)
SDV	* A2c. Low density lipoprotein-c (LDL-C) Result (mg/dL)		LIPS.PRIOR_LDL	(format xxxx.xx)
SDV	* A2c1. Method for LDL-C Result	○ Direct ○ Calculated	LIPS.PRIOR_LDLMETH	
SDV	* A2d. High density lipoprotein-c (HDL-C) Result (mg/dL)		LIPS.PRIOR_HDL	(format xxxx.xx)
SDV	* A2e. Triglycerides Result (mg/dL)		LIPS.PRIOR_TRIGLY	(format xxxx.xx)
	A2f. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	(auto calculated)	LIPS.PNONHDLC	(format xxxx.xx)
	A2g. TG/HDL-C ratio	(auto calculated)	LIPS.PTGHDLC	(format xxxx.xx)
SDV	* A3. Were physical measurements (Height, Weight, BMI, and BMI Percentile) obtained within the previous 6 months before being considered for screening?	○ Yes ○ No	LIPS.PRIOR_PHYMEAS	
	A3. HelpText: STEP 1: Potential participants will meet all of the following criteria based on medical record review or from a visit within the previous 6 months before being considered for screening (if known exclusion criteria, such as elevated AST, are noted at this step and cannot be clarified the patient will be excluded from STEP 2): * Boys and girls ages 10 to 17 years inclusive * BMI >95th%ile (CDC BMI charts)			
	A3. HelpText: STEP 1: Potential participants will meet all of the following criteria based on medical record review or from a visit within the previous 6 months before being considered for screening (if known exclusion criteria, such as elevated TSH, are noted at this step and cannot be clarified the patient will be excluded from STEP 2): * Boys and girls ages 10 to 18 years inclusive * BMI >85th%ile (CDC BMI charts)			
SDV	* A3a. Date measurements performed		LIPS.PRIOR_SCRDAT	
SDV	* A3b. Height (cm)		LIPS.PRIOR_HT	(format xxx.xx)
SDV	* A3c. Weight (kg)		LIPS.PRIOR_WT	(format xxx.xx)
	A3d. BMI	(auto calculated)	LIPS.PRIOR_BMI	(format xx.x)
SDV	* A3e. BMI Percentile		LIPS.PRIOR_BMIP	(format xxx.xx)

Page Information														
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618798	Section Header	0	Section A: Lipid Measures											
Page-2-618798	Help Text Line	0	Local Lipid results for Screening ONLY											
Page-3-618798	Radiolist Horizontal	0	A1. Was a fasting lipid profile obtained for screening purposes?	LIPS.LIPID_YN	Yes				cYN					
Page-4-618798	Date	1	A1a. Blood draw date	LIPS.LIPIDDAT	Yes									
-- Page Dynamics (LIPS.LIPIDDAT): Show When: LIPS.LIPID_YN = 1														
Page-5-618798	Date	1	A1b. Date subject last ate	LIPS.MEALDAT	Yes									Please enter the date the subject last ate
-- Page Dynamics (LIPS.MEALDAT): Show When: LIPS.LIPID_YN = 1														
Page-6-618798	Time	1	A1c. Time when subject last ate	LIPS.MEALTIM	Yes									Please enter the time the subject last ate
-- Page Dynamics (LIPS.MEALTIM): Show When: LIPS.LIPID_YN = 1														
Page-7-618798	Comments	1	A1d. Please describe what the subject last ate. Please include liquids as well as food.	LIPS.MEALCONTENT	Yes									
-- Page Dynamics (LIPS.MEALCONTENT): Show When: LIPS.LIPID_YN = 1														
Page-8-618798	Numeric	1	A1e. Total Cholesterol Result (mg/dL)	LIPS.TOTAL_CHOL	Yes							4	2	If Total Cholesterol is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 200 mg/dL

Page Information													
-- Page Dynamics (LIPS. TOTAL_CHOL): Show When: LIPS.LIPID_YN = 1													
Page-9-618798	Numeric	1	A1f. Low density lipoprotein-c (LDL-C) Result (mg/dL)	LIPS. LDL	Yes							4	2	If Low density lipoprotein-c (LDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 130 mg/dL
-- Page Dynamics (LIPS. LDL): Show When: LIPS.LIPID_YN = 1													
Page-10-618798	Radiolist Horizontal	2	A1f1. Method for LDL-C Result	LIPS. LDLMETH	Yes				cLDLMETHOD					Indicate whether LDL-C Result was obtained via direct measurement or calculated.
-- Page Dynamics (LIPS. LDLMETH): Show When: LIPS.LIPID_YN = 1 AND LIPS.LDL IS NOT NULL													
Page-11-618798	Numeric	1	A1g. High density lipoprotein-c (HDL-C) Result (mg/dL)	LIPS. HDL	Yes							4	2	If High density lipoprotein-c (HDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: > 35 mg/dL
-- Page Dynamics (LIPS. HDL): Show When: LIPS.LIPID_YN = 1													
Page-12-618798	Numeric	1	A1h. Triglycerides Result (mg/dL)	LIPS. TRIGLYCERIDES	Yes							4	2	If Triglycerides is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 88.57. Normal Range: 40 -150 mg/dL

Page Information														
-- Page Dynamics (LIPS. TRIGLYCERIDES): Show When: LIPS.LIPID_YN = 1														
Page-13-618798	Auto Calc Field	1	A1i. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	LIPS.NONHDLC								4	2	
-- Auto Calc Rule (LIPS.NONHDLC): (LIPS.TOTAL_CHOL IS NOT NULL AND LIPS.HDL IS NOT NULL)>>>USE: LIPS.TOTAL_CHOL - LIPS.HDL														
-- Page Dynamics (LIPS. NONHDLC): Show When: LIPS.LIPID_YN = 1														
Page-14-618798	Auto Calc Field	1	A1j. TG/HDL-C ratio	LIPS.TGHDLC								4	2	
-- Auto Calc Rule (LIPS.TGHDLC): (LIPS.HDL IS NOT NULL AND LIPS.TRIGLYCERIDES IS NOT NULL)>>>USE: LIPS.TRIGLYCERIDES / LIPS.HDL														
-- Page Dynamics (LIPS. TGHDLC): Show When: LIPS.LIPID_YN = 1														
Page-15-618798	Radiolist Horizontal	0	A2. Was a fasting lipid profile obtained prior to the screening lipid profile?	LIPS.PRIOR_LIPID	Yes				cYNUNK					
Page-16-618798	Help Text Line	0	(For Subjects enrolled under Protocol v5.0) As part of the pre-screening Inclusion criteria, a Fasting Lipid Profile (FLP) must be done within 6 months of screening at the clinical site or outside lab.											
-- Page Dynamics (.): Show When: 10-20-ICF.ICFPROTV = 5														
Page-17-618798	Help Text Line	0	(For Subjects enrolled under Protocol v4.1) As part of the pre-screening Inclusion criteria, a Fasting Lipid Profile (FLP) must be done within 3 months of screening at the clinical site.											
-- Page Dynamics (.): Show When: 10-20-ICF.ICFPROTV < 5														
Page-18-618798	Date	1	A2a. Date of prior fasting lipid profile	LIPS.PRIOR_LIPID_DT	Yes									
-- Page Dynamics (LIPS. PRIOR_LIPID_DT): Show When: LIPS.PRIOR_LIPID = 1														
Page-19-618798	Numeric	1	A2b. Total Cholesterol Result (mg/dL)	LIPS.PRIOR_CHOL	Yes							4	2	If Total Cholesterol is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 200 mg/dL

Page Information													
-- Page Dynamics (LIPS. PRIOR_CHOL): Show When: LIPS.PRIOR_LIPID = 1													
Page-20-618798	Numeric	1	A2c. Low density lipoprotein-c (LDL-C) Result (mg/dL)	LIPS. PRIOR_ LDL	Yes							4	2	If Low density lipoprotein-c (LDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: < 130 mg/dL
-- Page Dynamics (LIPS. PRIOR_LDL): Show When: LIPS.PRIOR_LIPID = 1													
Page-21-618798	Radiolist Horizontal	2	A2c1. Method for LDL-C Result	LIPS. PRIOR_ LDLMETH	Yes				cLDLMETHOD					Indicate whether LDL-C Result was obtained via direct measurement or calculated.
-- Page Dynamics (LIPS. PRIOR_LDLMETH): Show When: LIPS.PRIOR_LIPID = 1 AND LIPS.PRIOR_LDL IS NOT NULL													
Page-22-618798	Numeric	1	A2d. High density lipoprotein-c (HDL-C) Result (mg/dL)	LIPS. PRIOR_ HDL	Yes							4	2	If High density lipoprotein-c (HDL-C) is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 38.67. Normal Range: > 35 mg/dL
-- Page Dynamics (LIPS. PRIOR_HDL): Show When: LIPS.PRIOR_LIPID = 1													
Page-23-618798	Numeric	1	A2e. Triglycerides Result (mg/dL)	LIPS. PRIOR_ TRIGLY	Yes							4	2	If Triglycerides is reported in <u>mmol/L</u>, please convert to mg/dL when reporting. To get from SI units <u>(mmol/L) to mg/dL</u> multiply by 88.57. Normal Range: 40 -150 mg/dL

Page Information														
-- Page Dynamics (LIPS. PRIOR_TRIGLY): Show When: LIPS.PRIOR_LIPID = 1														
Page-24-618798	Auto Calc Field	1	A2f. Non-High Density Lipoprotein - Cholesterol (Non-HDL-C)	LIPS. PNONHDLC								4	2	
-- Auto Calc Rule (LIPS.PNONHDLC): (LIPS.PRIOR_CHOL IS NOT NULL AND LIPS.PRIOR_HDL IS NOT NULL)>>>USE: LIPS.PRIOR_CHOL - LIPS.PRIOR_HDL														
-- Page Dynamics (LIPS. PNONHDLC): Show When: LIPS.PRIOR_LIPID = 1														
Page-25-618798	Auto Calc Field	1	A2g. TG/HDL-C ratio	LIPS. PTGHDLC								4	2	
-- Auto Calc Rule (LIPS.PTGHDLC): (LIPS.PRIOR_HDL IS NOT NULL AND LIPS.PRIOR_TRIGLY IS NOT NULL)>>>USE: LIPS.PRIOR_TRIGLY / LIPS.PRIOR_HDL														
-- Page Dynamics (LIPS. PTGHDLC): Show When: LIPS.PRIOR_LIPID = 1														
Page-26-618798	Radiolist Horizontal	0	A3. Were physical measurements (Height, Weight, BMI, and BMI Percentile) obtained within the previous 6 months before being considered for screening?	LIPS. PRIOR_PHYMEAS	Yes				cYN					
Page-27-618798	Help Text Line	0	A3. HelpText: STEP 1: Potential participants will meet all of the following criteria based on medical record review or from a visit within the previous 6 months before being considered for screening (if known exclusion criteria, such as elevated AST, are noted at this step and cannot be clarified the patient will be excluded from STEP 2): * Boys and girls ages 10 to 17 years inclusive * BMI >95th%ile (CDC BMI charts)											
-- Page Dynamics (.): Show When: 10-20-ICF.ICFPROTV < 5														

Page Information														
Page-28-618798	Help Text Line	0	A3. HelpText: STEP 1: Potential participants will meet all of the following criteria based on medical record review or from a visit within the previous 6 months before being considered for screening (if known exclusion criteria, such as elevated TSH, are noted at this step and cannot be clarified the patient will be excluded from STEP 2): * Boys and girls ages 10 to 18 years inclusive * BMI >85th%ile (CDC BMI charts)											
-- Page Dynamics (.): Show When: 10-20-ICF.ICFPROTV = 5														
Page-29-618798	Date	1	A3a. Date measurements performed	LIPS.PRIOR_SCRDAT	Yes									This can be the date of a visit done within the previous 6 months
-- Page Dynamics (LIPS. PRIOR_SCRDAT): Show When: LIPS.PRIOR_PHYMEAS = 1														
Page-30-618798	Numeric	1	A3b. Height (cm)	LIPS.PRIOR_HT	Yes							3	2	
-- Page Dynamics (LIPS. PRIOR_HT): Show When: LIPS.PRIOR_PHYMEAS = 1														
Page-31-618798	Numeric	1	A3c. Weight (kg)	LIPS.PRIOR_WT	Yes							3	2	
-- Page Dynamics (LIPS. PRIOR_WT): Show When: LIPS.PRIOR_PHYMEAS = 1														
Page-32-618798	Auto Calc Field	1	A3d. BMI	LIPS.PRIOR_BMI								2	1	
-- Auto Calc Rule (LIPS.PRIOR_BMI): (LIPS.PRIOR_HT IS NOT NULL AND LIPS.PRIOR_WT IS NOT NULL) ALWAYS>>>USE: LIPS.PRIOR_WT / (pow ((LIPS.PRIOR_HT / 100), 2))														
-- Page Dynamics (LIPS. PRIOR_BMI): Show When: LIPS.PRIOR_PHYMEAS = 1														
Page-33-618798	Numeric	1	A3e. BMI Percentile	LIPS.PRIOR_BMIP	Yes							3	2	
-- Page Dynamics (LIPS. PRIOR_BMIP): Show When: LIPS.PRIOR_PHYMEAS = 1														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph

System Queries														
sysq-619356	SYSQ_5183	LIPS.LIPID_YN	Field Null		LIPS.LIPID_YN IS NULL	"A1. Was a fasting lipid profile obtained for screening purposes?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:24	0	0	0	0	0	0
sysq-619358	SYSQ_5184	LIPS.LIPIDDAT	Field Null		LIPS.LIPIDDAT IS NULL	"A1a. Blood draw date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619361	SYSQ_5185	LIPS.LIPIDDAT	Future Date		LIPS.LIPIDDAT > Today	"A1a. Blood draw date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619362	SYSQ_5186	LIPS.MEALDAT	Field Null		LIPS.MEALDAT IS NULL	"A1b. Date subject last ate" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619365	SYSQ_5187	LIPS.MEALDAT	Future Date		LIPS.MEALDAT > Today	"A1b. Date subject last ate" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619367	SYSQ_5188	LIPS.MEALTIM	Field Null		LIPS.MEALTIM IS NULL	"A1c. Time when subject last ate" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619368	SYSQ_5189	LIPS.MEALCONTENT	Field Null		LIPS.MEALCONTENT IS NULL	"A1d. Please describe what the subject last ate. Please include liquids as well as food." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619371	SYSQ_5190	LIPS.TOTAL_CHOL	Field Null		LIPS.TOTAL_CHOL IS NULL	"A1e. Total Cholesterol Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619373	SYSQ_5191	LIPS.LDL	Field Null		LIPS.LDL IS NULL	"A1f. Low density lipoprotein-c (LDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619374	SYSQ_5192	LIPS.HDL	Field Null		LIPS.HDL IS NULL	"A1g. High density lipoprotein-c (HDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0

System Queries														
sysq-619376	SYSQ_5193	LIPS.TRIGLYCERIDES	Field Null		LIPS.TRIGLYCERIDES IS NULL	"A1h. Triglycerides Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619379	SYSQ_5194	LIPS.PRIOR_LIPID	Field Null		LIPS.PRIOR_LIPID IS NULL	"A2. Was a fasting lipid profile obtained prior to the screening lipid profile?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:25	0	0	0	0	0	0
sysq-619381	SYSQ_5195	LIPS.PRIOR_LIPID_DT	Field Null		LIPS.PRIOR_LIPID_DT IS NULL	"A2a. Date of prior fasting lipid profile" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619382	SYSQ_5196	LIPS.PRIOR_LIPID_DT	Future Date		LIPS.PRIOR_LIPID_DT > Today	"A2a. Date of prior fasting lipid profile" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619385	SYSQ_5197	LIPS.PRIOR_CHOL	Field Null		LIPS.PRIOR_CHOL IS NULL	"A2b. Total Cholesterol Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619387	SYSQ_5198	LIPS.PRIOR_LDL	Field Null		LIPS.PRIOR_LDL IS NULL	"A2c. Low density lipoprotein-c (LDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619389	SYSQ_5199	LIPS.PRIOR_HDL	Field Null		LIPS.PRIOR_HDL IS NULL	"A2d. High density lipoprotein-c (HDL-C) Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619390	SYSQ_5200	LIPS.PRIOR_TRIGLY	Field Null		LIPS.PRIOR_TRIGLY IS NULL	"A2e. Triglycerides Result (mg/dL)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619393	SYSQ_5201	LIPS.PRIOR_PHYMEAS	Field Null		LIPS.PRIOR_PHYMEAS IS NULL	"A3. Were physical measurements (Height, Weight, BMI, and BMI Percentile) obtained within the previous 6 months before being considered for screening?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619395	SYSQ_5202	LIPS.PRIOR_HT	Field Null		LIPS.PRIOR_HT IS NULL	"A3a. Height (cm)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0

System Queries														
sysq-619397	SYSQ_5203	LIPS.PRIOR_WT	Field Null		LIPS.PRIOR_WT IS NULL	"A3b. Weight (kg)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619399	SYSQ_5204	LIPS.PRIOR_BMIP	Field Null		LIPS.PRIOR_BMIP IS NULL	"A3d. BMI Percentile" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619401	SYSQ_5205	LIPS.PRIOR_HT	Range		LIPS.PRIOR_HT < 120 OR LIPS.PRIOR_HT > 200	"A3a. Height (cm)" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619403	SYSQ_5206	LIPS.PRIOR_WT	Range		LIPS.PRIOR_WT < 20 OR LIPS.PRIOR_WT > 135	"A3b. Weight (kg)" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619405	SYSQ_5207	LIPS.LIPIDDAT	Other / Cross Page		FUNCTION--DATE_COMPARE(LIPS.LIPIDDAT, 10-20-ICF.ICF_DT) > 0	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619406	SYSQ_5208	LIPS.MEALDAT	Field Compare		LIPS.MEALDAT > LIPS.LIPIDDAT	"A1b. Date subject last ate" is after the "A1a. Blood draw date". Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619408	SYSQ_5209	LIPS.PRIOR_LIPID_DT	Field Compare		LIPS.PRIOR_LIPID_DT >= LIPS.LIPIDDAT	"A2a. Date of prior fasting lipid profile" is after or on the same date as screening lipid profile. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619410	SYSQ_5210	LIPS.LDL	Other / Cross Page		LIPS.LDL < 100 OR LIPS.LDL >= 160	The following Fasting Lipid Inclusion Criteria: LDL-C < 160 mg/dL and ≥ 100 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.		Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619413	SYSQ_5211	LIPS.TRIGLYCERIDES	Other / Cross Page		LIPS.TRIGLYCERIDES >= 500	The following Fasting Lipid Inclusion Criteria: TG < 500 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0

System Queries														
sysq-619415	SYSQ_5212	LIPS.NONHDLC	Other / Cross Page		LIPS.NONHDLC < 145	The following Fasting Lipid Inclusion Criteria: non-HDL-C ≥145 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.		Horng, Dunstan [DES] 14-SEP-20 14:38:26	0	0	0	0	0	0
sysq-619418	SYSQ_5213	LIPS.HDL	Other / Cross Page		(LIPS.TGHDLC < 3 AND LIPS.HDL >= 45 AND 10-40-DM.SEX = 1) OR (LIPS.TGHDLC < 3 AND LIPS.HDL >= 50 AND 10-40-DM.SEX = 2)	The following Fasting Lipid Inclusion Criteria: "TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls" was not met. Please confirm. If confirmed, the subject is not eligible.		Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619419	SYSQ_5214	LIPS.PRIOR_LDL	Other / Cross Page		LIPS.PRIOR_LDL < 100 OR LIPS.PRIOR_LDL >= 160	The following Fasting Lipid Inclusion Criteria: LDL-C < 160 mg/dL and ≥ 100 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.		Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619421	SYSQ_5215	LIPS.PRIOR_TRIGLY	Other / Cross Page		LIPS.PRIOR_TRIGLY >= 500	The following Fasting Lipid Inclusion Criteria: TG < 500 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619424	SYSQ_5216	LIPS.PNONHDLC	Other / Cross Page		LIPS.PNONHDLC < 145	The following Fasting Lipid Inclusion Criteria: non-HDL-C ≥145 mg/dL was not met. Please confirm. If confirmed, the subject is not eligible.		Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619425	SYSQ_5217	LIPS.PRIOR_HDL	Other / Cross Page		(LIPS.PTGHDLC < 3 AND LIPS.PRIOR_HDL >= 45 AND 10-40-DM.SEX = 1) OR (LIPS.PTGHDLC < 3 AND LIPS.PRIOR_HDL >= 50 AND 10-40-DM.SEX = 2)	The following Fasting Lipid Inclusion Criteria: "TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls" was not met. Please confirm. If confirmed, the subject is not eligible.		Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0

System Queries														
sysq-620399	SYSQ_5817	LIPS.LDLMETH	Field Null		LIPS.LDLMETH IS NULL	"A1f1. Method for LDL-C Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620401	SYSQ_5818	LIPS.PRIOR_LDLMETH	Field Null		LIPS.PRIOR_LDLMETH IS NULL	"A2c1. Method for LDL-C Result" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620403	SYSQ_5819	LIPS.PRIOR_SCRDAT	Field Null		LIPS.PRIOR_SCRDAT IS NULL	"A3a. Date measurements performed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620404	SYSQ_5820	LIPS.PRIOR_SCRDAT	Future Date		LIPS.PRIOR_SCRDAT > Today	"A3a. Date measurements performed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620406	SYSQ_5821	LIPS.PRIOR_SCRDAT	Other / Cross Page		(FUNCTION-DATE_COMPARE(LIPS.PRIOR_SCRDAT, 10-10-VIS.VISDAT) > 180 AND VISITID = 10) OR (FUNCTION-DATE_COMPARE(LIPS.PRIOR_SCRDAT, 10-10-VIS.VISDAT) < 0 AND VISITID = 10)	This date is not within 6 months of the screening visit. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0

System Queries													
sysq-620408	SYSQ_5822	LIPS.PRIOR_LIPID_DT	Other / Cross Page		(FUNCTION-DATE_COMPARE(LIPS.PRIOR_LIPID_DT, 10-10-VIS.VISDAT) > 90 AND VISITID = 10) OR (FUNCTION-DATE_COMPARE(LIPS.PRIOR_LIPID_DT, 10-10-VIS.VISDAT) < 0 AND VISITID = 10)	The date of the prior Fasting lipid profile (FLP) is not within 3 months of the screening visit. Please review and confirm.		Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620486	SYSQ_5887	LIPS.NONHDLC	Other / Cross Page	Protocol v5.0 updates	(10-20-ICF.ICFPROTV < 5 AND LIPS.NONHDLC < 145) OR (10-20-ICF.ICFPROTV = 5 AND LIPS.NONHDLC < 125)	Fasting Lipid Inclusion Criteria for non-HDL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620487	SYSQ_5888	LIPS.PNONHDLC	Other / Cross Page	Protocol v5 updates	(10-20-ICF.ICFPROTV < 5 AND LIPS.PNONHDLC < 145) OR (10-20-ICF.ICFPROTV = 5 AND LIPS.PNONHDLC < 125)	Fasting Lipid Inclusion Criteria for non-HDL was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620488	SYSQ_5889	LIPS.LDL	Other / Cross Page	Protocol v5 updates	(10-20-ICF.ICFPROTV < 5 AND (LIPS.LDL < 100 OR LIPS.LDL >= 160)) OR (10-20-ICF.ICFPROTV = 5 AND (LIPS.LDL < 90 OR LIPS.LDL >= 160))	Fasting Lipid Inclusion Criteria for LDL-C was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
sysq-620489	SYSQ_5890	LIPS.PRIOR_LDL	Other / Cross Page	Protocol v5 updates	(10-20-ICF.ICFPROTV < 5 AND (LIPS.PRIOR_LDL < 100 OR LIPS.PRIOR_LDL >= 160)) OR (10-20-ICF.ICFPROTV = 5 AND (LIPS.PRIOR_LDL < 90 OR LIPS.PRIOR_LDL >= 160))	Fasting Lipid Inclusion Criteria for LDL-C was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620490	SYSQ_5891	LIPS.HDL	Other / Cross Page	Protocol v5 updates	(10-20-ICF.ICFPROTV < 5 AND 10-40-DM.SEX = 1 AND (LIPS.TGHDLC < 3 AND LIPS.HDL >= 45)) OR (10-20-ICF.ICFPROTV < 5 AND 10-40-DM.SEX = 2 AND (LIPS.TGHDLC < 3 AND LIPS.HDL >= 50)) OR (10-20-ICF.ICFPROTV = 5 AND 10-40-DM.SEX = 1 AND (LIPS.TGHDLC < 2.5 AND LIPS.HDL >= 45)) OR (10-20-ICF.ICFPROTV = 5 AND 10-40-DM.SEX = 2 AND (LIPS.TGHDLC < 2.5 AND LIPS.HDL >= 50))	Fasting Lipid Inclusion Criteria for TG/HDL-C ratio and/or HDL-C was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
sysq-620491	SYSQ_5892	LIPS.PRIOR_HDL	Other / Cross Page	Protocol v5 updates	(10-20-ICF.ICFPROTV < 5 AND 10-40-DM.SEX = 1 AND (LIPS.PTGHDLC < 3 AND LIPS.PRIOR_HDL >= 45)) OR (10-20-ICF.ICFPROTV < 5 AND 10-40-DM.SEX = 2 AND (LIPS.PTGHDLC < 3 AND LIPS.PRIOR_HDL >= 50)) OR (10-20-ICF.ICFPROTV = 5 AND 10-40-DM.SEX = 1 AND (LIPS.PTGHDLC < 2.5 AND LIPS.PRIOR_HDL >= 45)) OR (10-20-ICF.ICFPROTV = 5 AND 10-40-DM.SEX = 2 AND (LIPS.PTGHDLC < 2.5 AND LIPS.PRIOR_HDL >= 50))	Fasting Lipid Inclusion Criteria for TG/HDL-C ratio and/or HDL-C was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
sysq-620492	SYSQ_5893	LIPS.PRIOR_LIPID_DT	Other / Cross Page	Protocol v4.1	((FUNCTION--DATE_COMPARE(LIPS.PRIOR_LIPID_DT, 10-10-VIS.VISDAT) > 90 AND VISITID = 10) OR (FUNCTION--DATE_COMPARE(LIPS.PRIOR_LIPID_DT, 10-10-VIS.VISDAT) < 0 AND VISITID = 10)) AND 10-20-ICF.ICFPROTV < 5	The date of the prior Fasting lipid profile (FLP) is not within 3 months of the screening visit. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620493	SYSQ_5894	LIPS.PRIOR_LIPID_DT	Other / Cross Page	Protocol v.5.0	((FUNCTION--DATE_COMPARE(LIPS.PRIOR_LIPID_DT, 10-10-VIS.VISDAT) > 180 AND VISITID = 10) OR (FUNCTION--DATE_COMPARE(LIPS.PRIOR_LIPID_DT, 10-10-VIS.VISDAT) < 0 AND VISITID = 10)) AND 10-20-ICF.ICFPROTV = 5	The date of the prior Fasting lipid profile (FLP) is not within 6 months of the screening visit. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620494	SYSQ_5895	LIPS.PRIOR_BMIP	Other / Cross Page	Protocol 4.1/5 - new	(10-20-ICF.ICFPROTV < 5 AND LIPS.PRIOR_BMIP < 95) OR (10-20-ICF.ICFPROTV = 5 AND LIPS.PRIOR_BMIP < 85)	Pre-screening Inclusion Criteria for BMI Percentile was not met. Please confirm. If confirmed, the subject is not eligible.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

pLifeStyle

Page

(Visit ID = 618799, Page ID =)

Unique Identifier page-618799-618799-618799-

	On average, over the past month how often did you eat or drink a serving of the following…		
SDV	* 1. Vegetables (not including potatoes, peas, corn)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS1Q
SDV	* 2. Fruit (not including juice)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS2Q
SDV	* 3. Beans and legumes (chickpeas, lentils)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS3Q
SDV	* 4. Nuts and seeds	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS4Q

SDV	* 5. Cold water fish (salmon, tuna, halibut)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS5Q
SDV	* 6. All other fish (including shellfish, shrimp, squid)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS6Q
SDV	* 7. Chicken or turkey with skin	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS7Q
SDV	* 8. Chicken or turkey without skin, eggs, tofu	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS8Q
SDV	* 9. Fresh red meats including beef, lamb, pork	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS9Q

SDV	* 10. Processed meats (deli meats, bacon, salami)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS10Q
SDV	* 11. Brown rice, whole grain bread, oatmeal, other grains, high fiber cereal, high fiber crackers	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS11Q
SDV	* 12. White bread, white rice, crackers, grits, regular cereal, pasta	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS12Q
SDV	* 13. Potatoes (baked, mashed, fried, chips)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS13Q
SDV	* 14. Candy, baked sweets (pastries, cakes, cookies, donuts, pie)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS14Q

On average, over the past month how often did you eat or drink a serving of the following…

SDV	* 15. Sweet drinks (energy or sports drinks, fruit punch, lemonade, sweetened tea or coffee)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS15Q
SDV	* 16. Regular soda	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS16Q
SDV	* 17. 100% juice	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS17Q
SDV	* 18. Unsweetened low fat dairy (milk, cheese, yoghurt)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS18Q
SDV	* 19. Unsweetened full fat dairy (butter, milk, cheese, yoghurt)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS19Q

SDV	* 20. Sweetened low or full fat dairy (yogurt, ice cream, frozen yogurt, flavored milk)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS20Q
SDV	* 21. Egg yolks, shrimp, squid, liver, pate	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS21Q
SDV	* 22. Canned foods, dried soups, frozen meals	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS22Q
SDV	* 23. Pizza	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS23Q
SDV	* 24. Fried foods (French fries, nuggets, chicken wings, fried fish)	○ Rarely or never ○ 1-2 times per WEEK ○ 3-4 times per WEEK ○ 5-7 times per WEEK ○ >=2 times per DAY	LSQ.LS24Q

Within the past 12 months…

SDV	* 25. My family worried about whether our food would run out before we got money to buy more.	○ Yes ○ No ○ Don't know ○ Prefer not to respond	LSQ.LS25Q
SDV	* 26. The food my family bought just didn't last and we didn't have money to get more.	○ Yes ○ No ○ Don't know ○ Prefer not to respond	LSQ.LS26Q
On average, over the past month how often did you…			
SDV	* 27. Eat breakfast at school or at home	○ Never ○ 1 day per WEEK ○ 2-3 days per WEEK ○ 4-5 days per WEEK ○ Almost daily	LSQ.LS27Q
SDV	* 28. Eat lunch at school or at home	○ Never ○ 1 day per WEEK ○ 2-3 days per WEEK ○ 4-5 days per WEEK ○ Almost daily	LSQ.LS28Q
SDV	* 29. Eat dinner together as a family	○ Never ○ 1 day per WEEK ○ 2-3 days per WEEK ○ 4-5 days per WEEK ○ Almost daily	LSQ.LS29Q
SDV	* 30. Eat fast food or at a restaurant (sit-down, take out)	○ Never ○ 1 day per WEEK ○ 2-3 days per WEEK ○ 4-5 days per WEEK ○ Almost daily	LSQ.LS30Q

SDV	* 31. Argue about healthy food choices	○ Never ○ 1 day per WEEK ○ 2-3 days per WEEK ○ 4-5 days per WEEK ○ Almost daily	LSQ.LS31Q
On average, over the past month how many hours per WEEK did you spend…			
SDV	* 32. Walking for exercise or transportation	○ < 1 hour per WEEK ○ 1-2 hours per WEEK ○ 3-4 hours per WEEK ○ 5-6 hours per WEEK ○ >=7 hours per WEEK	LSQ.LS32Q
SDV	* 33. In gym/PE class at school	○ < 1 hour per WEEK ○ 1-2 hours per WEEK ○ 3-4 hours per WEEK ○ 5-6 hours per WEEK ○ >=7 hours per WEEK	LSQ.LS33Q
SDV	* 34. Playing on a sports team	○ < 1 hour per WEEK ○ 1-2 hours per WEEK ○ 3-4 hours per WEEK ○ 5-6 hours per WEEK ○ >=7 hours per WEEK	LSQ.LS34Q

SDV	* 35. Doing other activities that make your heart beat fast and/or break a sweat	○ < 1 hour per WEEK ○ 1-2 hours per WEEK ○ 3-4 hours per WEEK ○ 5-6 hours per WEEK ○ >=7 hours per WEEK	LSQ.LS35Q
SDV	* 36. In TOTAL, how many hours did you exercise per week?	○ < 1 hour per WEEK ○ 1-2 hours per WEEK ○ 3-4 hours per WEEK ○ 5-6 hours per WEEK ○ >=7 hours per WEEK	LSQ.LS36Q
On average, over the past month how many hours per weekDAY did you spend…			
SDV	* 37. Watching TV or movies	○ None ○ >=2 hours per DAY ○ 3-4 hours per DAY ○ 5-6 hours per DAY ○ >= 7 hours per DAY	LSQ.LS37Q
SDV	* 38. Playing video games or on the computer (excluding homework)	○ None ○ >=2 hours per DAY ○ 3-4 hours per DAY ○ 5-6 hours per DAY ○ >= 7 hours per DAY	LSQ.LS38Q
SDV	* 39. Doing homework on a screen	○ None ○ >=2 hours per DAY ○ 3-4 hours per DAY ○ 5-6 hours per DAY ○ >= 7 hours per DAY	LSQ.LS39Q

SDV	* 40. During the WEEK, what was your daily TOTAL hours?	○ None ○ >=2 hours per DAY ○ 3-4 hours per DAY ○ 5-6 hours per DAY ○ >= 7 hours per DAY	LSQ.LS40Q
SDV	* 41. During the weekEND, what was your daily TOTAL hours?	○ None ○ >=2 hours per DAY ○ 3-4 hours per DAY ○ 5-6 hours per DAY ○ >= 7 hours per DAY	LSQ.LS41Q
Over the past month, on average…			
SDV	* 42. How many hours do you sleep per day (include naps and nighttime sleep)	○ <=5 ○ 6 ○ 7-8 ○ >=9	LSQ.LS42Q
SDV	* 43. Do you keep electronics in the room you sleep in? (phone, ipad etc, TV)	○ Never ○ Sometimes ○ Often ○ Always	LSQ.LS43Q
SDV	* 44. Do you snore?	○ Never ○ Sometimes ○ Often ○ Always	LSQ.LS44Q
SDV	* 45. Does anyone in your house smoke?	○ No ○ Yes, but not inside ○ Yes, inside the house/car ○ Don’t know ○ Prefer not to respond	LSQ.LS45Q

SDV	* 46. Do you smoke?	○ I've never smoked ○ I last smoked over a year ago ○ I smoke a few times a week ○ Yes, half a pack a day or more ○ Prefer not to respond	LSQ.LS46Q
SDV	* 47. Who completed this form?	○ Patient ○ Parent/guardian ○ Combined effort ○ Other	LSQ.LS47Q
SDV	* 48. Date completed		LSQ.LSDAT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618799	Section Header	0	On average, over the past month how often did you eat or drink a serving of the following…											
Page-2-618799	Radiolist Horizontal	0	1. Vegetables (not including potatoes, peas, corn)	LSQ.LS1Q	Yes				cLS_Eat_1M					
Page-3-618799	Radiolist Horizontal	0	2. Fruit (not including juice)	LSQ.LS2Q	Yes				cLS_Eat_1M					
Page-4-618799	Radiolist Horizontal	0	3. Beans and legumes (chickpeas, lentils)	LSQ.LS3Q	Yes				cLS_Eat_1M					
Page-5-618799	Radiolist Horizontal	0	4. Nuts and seeds	LSQ.LS4Q	Yes				cLS_Eat_1M					
Page-6-618799	Radiolist Horizontal	0	5. Cold water fish (salmon, tuna, halibut)	LSQ.LS5Q	Yes				cLS_Eat_1M					

Page Information														
Page-7-618799	Radiolist Horizontal	0	6. All other fish (including shellfish, shrimp, squid)	LSQ.LS6Q	Yes				cLS_Eat_1M					
Page-8-618799	Radiolist Horizontal	0	7. Chicken or turkey with skin	LSQ.LS7Q	Yes				cLS_Eat_1M					
Page-9-618799	Radiolist Horizontal	0	8. Chicken or turkey without skin, eggs, tofu	LSQ.LS8Q	Yes				cLS_Eat_1M					
Page-10-618799	Radiolist Horizontal	0	9. Fresh red meats including beef, lamb, pork	LSQ.LS9Q	Yes				cLS_Eat_1M					
Page-11-618799	Radiolist Horizontal	0	10. Processed meats (deli meats, bacon, salami)	LSQ.LS10Q	Yes				cLS_Eat_1M					
Page-12-618799	Radiolist Horizontal	0	11. Brown rice, whole grain bread, oatmeal, other grains, high fiber cereal, high fiber crackers	LSQ.LS11Q	Yes				cLS_Eat_1M					
Page-13-618799	Radiolist Horizontal	0	12. White bread, white rice, crackers, grits, regular cereal, pasta	LSQ.LS12Q	Yes				cLS_Eat_1M					
Page-14-618799	Radiolist Horizontal	0	13. Potatoes (baked, mashed, fried, chips)	LSQ.LS13Q	Yes				cLS_Eat_1M					
Page-15-618799	Radiolist Horizontal	0	14. Candy, baked sweets (pastries, cakes, cookies, donuts, pie)	LSQ.LS14Q	Yes				cLS_Eat_1M					
Page-16-618799	Section Header	0	On average, over the past month how often did you eat or drink a serving of the following…											
Page-17-618799	Radiolist Horizontal	0	15. Sweet drinks (energy or sports drinks, fruit punch, lemonade, sweetened tea or coffee)	LSQ.LS15Q	Yes				cLS_Eat_1M					
Page-18-618799	Radiolist Horizontal	0	16. Regular soda	LSQ.LS16Q	Yes				cLS_Eat_1M					
Page-19-618799	Radiolist Horizontal	0	17. 100% juice	LSQ.LS17Q	Yes				cLS_Eat_1M					
Page-20-618799	Radiolist Horizontal	0	18. Unsweetened low fat dairy (milk, cheese, yoghurt)	LSQ.LS18Q	Yes				cLS_Eat_1M					

Page Information														
Page-21-618799	Radiolist Horizontal	0	19. Unsweetened full fat dairy (butter, milk, cheese, yoghurt)	LSQ.LS19Q	Yes				cLS_Eat_1M					
Page-22-618799	Radiolist Horizontal	0	20. Sweetened low or full fat dairy (yogurt, ice cream, frozen yogurt, flavored milk)	LSQ.LS20Q	Yes				cLS_Eat_1M					
Page-23-618799	Radiolist Horizontal	0	21. Egg yolks, shrimp, squid, liver, pate	LSQ.LS21Q	Yes				cLS_Eat_1M					
Page-24-618799	Radiolist Horizontal	0	22. Canned foods, dried soups, frozen meals	LSQ.LS22Q	Yes				cLS_Eat_1M					
Page-25-618799	Radiolist Horizontal	0	23. Pizza	LSQ.LS23Q	Yes				cLS_Eat_1M					
Page-26-618799	Radiolist Horizontal	0	24. Fried foods (French fries, nuggets, chicken wings, fried fish)	LSQ.LS24Q	Yes				cLS_Eat_1M					
Page-27-618799	Section Header	0	Within the past 12 months…											
Page-28-618799	Radiolist Horizontal	0	25. My family worried about whether our food would run out before we got money to buy more.	LSQ.LS25Q	Yes				cLS_Eat_12M					
Page-29-618799	Radiolist Horizontal	0	26. The food my family bought just didn't last and we didn't have money to get more.	LSQ.LS26Q	Yes				cLS_Eat_12M					
Page-30-618799	Section Header	0	On average, over the past month how often did you…											
Page-31-618799	Radiolist Horizontal	0	27. Eat breakfast at school or at home	LSQ.LS27Q	Yes				cLS_Eat_Average					
Page-32-618799	Radiolist Horizontal	0	28. Eat lunch at school or at home	LSQ.LS28Q	Yes				cLS_Eat_Average					
Page-33-618799	Radiolist Horizontal	0	29. Eat dinner together as a family	LSQ.LS29Q	Yes				cLS_Eat_Average					
Page-34-618799	Radiolist Horizontal	0	30. Eat fast food or at a restaurant (sit-down, take out)	LSQ.LS30Q	Yes				cLS_Eat_Average					
Page-35-618799	Radiolist Horizontal	0	31. Argue about healthy food choices	LSQ.LS31Q	Yes				cLS_Eat_Average					

Page Information														
Page-36-618799	Section Header	0	On average, over the past month how many hours per WEEK did you spend…											
Page-37-618799	Radiolist Horizontal	0	32. Walking for exercise or transportation	LSQ.LS32Q	Yes				cLS_Exercise_Wk					
Page-38-618799	Radiolist Horizontal	0	33. In gym/PE class at school	LSQ.LS33Q	Yes				cLS_Exercise_Wk					
Page-39-618799	Radiolist Horizontal	0	34. Playing on a sports team	LSQ.LS34Q	Yes				cLS_Exercise_Wk					
Page-40-618799	Radiolist Horizontal	0	35. Doing other activities that make your heart beat fast and/or break a sweat	LSQ.LS35Q	Yes				cLS_Exercise_Wk					
Page-41-618799	Radiolist Horizontal	0	36. In TOTAL, how many hours did you exercise per week?	LSQ.LS36Q	Yes				cLS_Exercise_Wk					
Page-42-618799	Section Header	0	On average, over the past month how many hours per weekDAY did you spend…											
Page-43-618799	Radiolist Horizontal	0	37. Watching TV or movies	LSQ.LS37Q	Yes				cLS_Activities_WkDay					
Page-44-618799	Radiolist Horizontal	0	38. Playing video games or on the computer (excluding homework)	LSQ.LS38Q	Yes				cLS_Activities_WkDay					
Page-45-618799	Radiolist Horizontal	0	39. Doing homework on a screen	LSQ.LS39Q	Yes				cLS_Activities_WkDay					
Page-46-618799	Radiolist Horizontal	0	40. During the WEEK, what was your daily TOTAL hours?	LSQ.LS40Q	Yes				cLS_Activities_WkDay					Total hours of screen time
Page-47-618799	Radiolist Horizontal	0	41. During the weekEND, what was your daily TOTAL hours?	LSQ.LS41Q	Yes				cLS_Activities_WkDay					Total hours of screen time
Page-48-618799	Section Header	0	Over the past month, on average…											
Page-49-618799	Radiolist Horizontal	0	42. How many hours do you sleep per day (include naps and nighttime sleep)	LSQ.LS42Q	Yes				cLS_Sleep_hrs					
Page-50-618799	Section Header	0												

Page Information														
Page-51-618799	Radiolist Horizontal	0	43. Do you keep electronics in the room you sleep in? (phone, ipad etc, TV)	LSQ.LS43Q	Yes				cLS_Sleep_Desc					
Page-52-618799	Radiolist Horizontal	0	44. Do you snore?	LSQ.LS44Q	Yes				cLS_Sleep_Desc					
Page-53-618799	Section Header	0												
Page-54-618799	Radiolist Horizontal	0	45. Does anyone in your house smoke?	LSQ.LS45Q	Yes				cLS_Smoke_Others					
Page-55-618799	Radiolist Horizontal	0	46. Do you smoke?	LSQ.LS46Q	Yes				cLS_Smoke_You					
Page-56-618799	Section Header	0												
Page-57-618799	Radiolist Horizontal	0	47. Who completed this form?	LSQ.LS47Q	Yes				cLS_Compl_Form					
Page-58-618799	Date Partial	0	48. Date completed	LSQ.LSDAT	Yes									

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619427	SYSQ_5218	LSQ.LS1Q	Field Null		LSQ.LS1Q IS NULL	"1. Vegetables (not including potatoes, peas, corn)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619428	SYSQ_5219	LSQ.LS2Q	Field Null		LSQ.LS2Q IS NULL	"2. Fruit (not including juice)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619429	SYSQ_5220	LSQ.LS3Q	Field Null		LSQ.LS3Q IS NULL	"3. Beans and legumes (chickpeas, lentils)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0

System Queries														
sysq-619430	SYSQ_5221	LSQ.LS4Q	Field Null		LSQ.LS4Q IS NULL	"4. Nuts and seeds" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619431	SYSQ_5222	LSQ.LS5Q	Field Null		LSQ.LS5Q IS NULL	"5. Cold water fish (salmon, tuna, halibut)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619432	SYSQ_5223	LSQ.LS6Q	Field Null		LSQ.LS6Q IS NULL	"6. All other fish (including shellfish, shrimp, squid)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619433	SYSQ_5224	LSQ.LS7Q	Field Null		LSQ.LS7Q IS NULL	"7. Chicken or turkey with skin" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619434	SYSQ_5225	LSQ.LS8Q	Field Null		LSQ.LS8Q IS NULL	"8. Chicken or turkey without skin, eggs, tofu" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619435	SYSQ_5226	LSQ.LS9Q	Field Null		LSQ.LS9Q IS NULL	"9. Fresh red meats including beef, lamb, pork" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619436	SYSQ_5227	LSQ.LS10Q	Field Null		LSQ.LS10Q IS NULL	"10. Processed meats (deli meats, bacon, salami)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619437	SYSQ_5228	LSQ.LS11Q	Field Null		LSQ.LS11Q IS NULL	"11. Brown rice, whole grain bread, oatmeal, other grains, high fiber cereal, high fiber crackers" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619438	SYSQ_5229	LSQ.LS12Q	Field Null		LSQ.LS12Q IS NULL	"12. White bread, white rice, crackers, grits, regular cereal, pasta" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619439	SYSQ_5230	LSQ.LS13Q	Field Null		LSQ.LS13Q IS NULL	"13. Potatoes (baked, mashed, fried, chips)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0

System Queries														
sysq-619440	SYSQ_5231	LSQ.LS14Q	Field Null		LSQ.LS14Q IS NULL	"14. Candy, baked sweets (pastries, cakes, cookies, donuts, pie)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619441	SYSQ_5232	LSQ.LS15Q	Field Null		LSQ.LS15Q IS NULL	"15. Sweet drinks (energy or sports drinks, fruit punch, lemonade, sweetened tea or coffee)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619442	SYSQ_5233	LSQ.LS16Q	Field Null		LSQ.LS16Q IS NULL	"16. Regular soda" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619443	SYSQ_5234	LSQ.LS17Q	Field Null		LSQ.LS17Q IS NULL	"17. 100% juice" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619444	SYSQ_5235	LSQ.LS18Q	Field Null		LSQ.LS18Q IS NULL	"18. Unsweetened low fat dairy (milk, cheese, yoghurt)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619445	SYSQ_5236	LSQ.LS19Q	Field Null		LSQ.LS19Q IS NULL	"19. Unsweetened full fat dairy (butter, milk, cheese, yoghurt)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619446	SYSQ_5237	LSQ.LS20Q	Field Null		LSQ.LS20Q IS NULL	"20. Sweetened low or full fat dairy (yogurt, ice cream, frozen yogurt, flavored milk)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619447	SYSQ_5238	LSQ.LS21Q	Field Null		LSQ.LS21Q IS NULL	"21. Egg yolks, shrimp, squid, liver, pate" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619448	SYSQ_5239	LSQ.LS22Q	Field Null		LSQ.LS22Q IS NULL	"22. Canned foods, dried soups, frozen meals" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619449	SYSQ_5240	LSQ.LS23Q	Field Null		LSQ.LS23Q IS NULL	"23. Pizza" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0

System Queries														
sysq-619450	SYSQ_5241	LSQ.LS24Q	Field Null		LSQ.LS24Q IS NULL	"24. Fried foods (French fries, nuggets, chicken wings, fried fish)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619451	SYSQ_5242	LSQ.LS25Q	Field Null		LSQ.LS25Q IS NULL	"25. My family worried about whether our food would run out before we got money to buy more." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:27	0	0	0	0	0	0
sysq-619452	SYSQ_5243	LSQ.LS26Q	Field Null		LSQ.LS26Q IS NULL	"26. The food my family bought just didn't last and we didn't have money to get more." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619453	SYSQ_5244	LSQ.LS27Q	Field Null		LSQ.LS27Q IS NULL	"27. Eat breakfast at school or at home" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619454	SYSQ_5245	LSQ.LS28Q	Field Null		LSQ.LS28Q IS NULL	"28. Eat lunch at school or at home" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619455	SYSQ_5246	LSQ.LS29Q	Field Null		LSQ.LS29Q IS NULL	"29. Eat dinner together as a family" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619456	SYSQ_5247	LSQ.LS30Q	Field Null		LSQ.LS30Q IS NULL	"30. Eat fast food or at a restaurant (sit-down, take out)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619457	SYSQ_5248	LSQ.LS31Q	Field Null		LSQ.LS31Q IS NULL	"31. Argue about healthy food choices" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619458	SYSQ_5249	LSQ.LS32Q	Field Null		LSQ.LS32Q IS NULL	"32. Walking for exercise or transportation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619459	SYSQ_5250	LSQ.LS33Q	Field Null		LSQ.LS33Q IS NULL	"33. In gym/PE class at school" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0

System Queries														
sysq-619460	SYSQ_5251	LSQ.LS34Q	Field Null		LSQ.LS34Q IS NULL	"34. Playing on a sports team" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619461	SYSQ_5252	LSQ.LS35Q	Field Null		LSQ.LS35Q IS NULL	"35. Doing other activities that make your heart beat fast and/or break a sweat" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619462	SYSQ_5253	LSQ.LS36Q	Field Null		LSQ.LS36Q IS NULL	"36. In TOTAL, how many hours did you exercise per week?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619463	SYSQ_5254	LSQ.LS37Q	Field Null		LSQ.LS37Q IS NULL	"37. Watching TV or movies" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619464	SYSQ_5255	LSQ.LS38Q	Field Null		LSQ.LS38Q IS NULL	"38. Playing video games or on the computer (excluding homework)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619465	SYSQ_5256	LSQ.LS39Q	Field Null		LSQ.LS39Q IS NULL	"39. Doing homework on a screen" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619466	SYSQ_5257	LSQ.LS40Q	Field Null		LSQ.LS40Q IS NULL	"40. During the WEEK, what was your daily TOTAL hours?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619467	SYSQ_5258	LSQ.LS41Q	Field Null		LSQ.LS41Q IS NULL	"41. During the weekEND, what was your daily TOTAL hours?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619468	SYSQ_5259	LSQ.LS42Q	Field Null		LSQ.LS42Q IS NULL	"42. How many hours do you sleep per day (include naps and nighttime sleep)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619469	SYSQ_5260	LSQ.LS43Q	Field Null		LSQ.LS43Q IS NULL	"43. Do you keep electronics in the room you sleep in? (phone, ipad etc, TV)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0

System Queries														
sysq-619470	SYSQ_5261	LSQ.LS44Q	Field Null		LSQ.LS44Q IS NULL	"44. Do you snore?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619471	SYSQ_5262	LSQ.LS45Q	Field Null		LSQ.LS45Q IS NULL	"45. Does anyone in your house smoke?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619472	SYSQ_5263	LSQ.LS46Q	Field Null		LSQ.LS46Q IS NULL	"46. Do you smoke?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619473	SYSQ_5264	LSQ.LS47Q	Field Null		LSQ.LS47Q IS NULL	"47. Who completed this form?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:28	0	0	0	0	0	0
sysq-619474	SYSQ_5265	LSQ.LSDAT	Field Null		LSQ.LSDAT IS NULL	"48. Date completed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619475	SYSQ_5266	LSQ.LSDAT	Future Date		LSQ.LSDAT > Today	"48. Date completed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0

pPDIS

Page

(Visit ID = 618800, Page ID =)

Unique Identifier page-618800-618800-618800-

SECTION A: Permanent Discontinuation of Study Drug			
SDV	* A1. Date of permanent discontinuation of study drug		PDIS.DISCDAT
SDV	* A2. Reason for permanent discontinuation of study drug (select all that apply)	ADD DELETE SELECTED	PDIS.REASON
SDV	A2a. If Other reason, please specify		PDIS.SPECIFY
SDV	* A3. AE ID Number (if applicable):		PDIS.AESPID (format xxx)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618800	Section Header	0	SECTION A: Permanent Discontinuation of Study Drug											
Page-2-618800	Date	0	A1. Date of permanent discontinuation of study drug	PDIS.DISCDAT	Yes									
Page-3-618800	Many Select	0	A2. Reason for permanent discontinuation of study drug (select all that apply)	PDIS.REASON	Yes				cPDIS					
Page-4-618800	Text Field	1	A2a. If Other reason, please specify	PDIS.SPECIFY	Yes					200	99			
Page-5-618800	Numeric	0	A3. AE ID Number (if applicable):	PDIS.AESPID	Yes							3	0	Enter the AE ID number of the Adverse Event associated with the permanent discontinuation of the study drug.

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-620097	SYSQ_5660	PDIS.DISCDAT	Field Null		PDIS.DISCDAT IS NULL	"A1. Date of permanent discontinuation of study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620098	SYSQ_5661	PDIS.DISCDAT	Future Date		PDIS.DISCDAT > Today	"A1. Date of permanent discontinuation of study drug" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620101	SYSQ_5662	PDIS.REASON	Field Null		PDIS.REASON IS NULL	"A2. Reason for permanent discontinuation of study drug (select all that apply)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620103	SYSQ_5664	PDIS.SPECIFY	Other / Cross Page		PDIS.REASON NOT INTERSECTS 99 AND PDIS.SPECIFY IS NOT NULL	An 'Other reason' was not selected as a reason for permanent discontinuation of study drug, however, a response for other, specify was provided. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620105	SYSQ_5665	PDIS.AESPID	Field Null		PDIS.AESPID IS NULL	"A3. AE ID Number (if applicable):" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620107	SYSQ_5665b	PDIS.SPECIFY	Other / Cross Page		PDIS.REASON INTERSECTS 99 AND PDIS.SPECIFY IS NULL	An 'Other reason' was selected as one of the reasons for reason for permanent discontinuation of study drug, however, a response for other, specify was not provided. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0

pPDIS_4

Page

(Visit ID = 618801, Page ID =)

Unique Identifier page-618801-618801-618801-

SECTION A: Permanent Discontinuation of Study Drug			
SDV	* A1. Date of permanent discontinuation of study drug		PDIS.DISCDAT
SDV	* A2. Reason for permanent discontinuation of study drug (select all that apply)	ADD DELETE SELECTED	PDIS.REASON
SDV	A2a. If Other reason, please specify		PDIS.SPECIFY
SDV	* A3. AE ID Number (if applicable):		PDIS.AESPID (format xxx)

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618801	Section Header	0	SECTION A: Permanent Discontinuation of Study Drug											
Page-2-618801	Date	0	A1. Date of permanent discontinuation of study drug	PDIS.DISCDAT	Yes									
Page-3-618801	Many Select	0	A2. Reason for permanent discontinuation of study drug (select all that apply)	PDIS.REASON	Yes				cPDIS_4_					
Page-4-618801	Text Field	1	A2a. If Other reason, please specify	PDIS.SPECIFY	Yes					200	99			
Page-5-618801	Numeric	0	A3. AE ID Number (if applicable):	PDIS.AESPID	Yes							3	0	Enter the AE ID number of the Adverse Event associated with the permanent discontinuation of the study drug.

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-620096	SYSQ_5660	PDIS.DISCDAT	Field Null		PDIS.DISCDAT IS NULL	"A1. Date of permanent discontinuation of study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620099	SYSQ_5661	PDIS.DISCDAT	Future Date		PDIS.DISCDAT > Today	"A1. Date of permanent discontinuation of study drug" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620100	SYSQ_5662	PDIS.REASON	Field Null		PDIS.REASON IS NULL	"A2. Reason for permanent discontinuation of study drug (select all that apply)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620102	SYSQ_5664	PDIS.SPECIFY	Other / Cross Page		PDIS.REASON NOT INTERSECTS 99 AND PDIS.SPECIFY IS NOT NULL	An 'Other reason' was not selected as a reason for permanent discontinuation of study drug, however, a response for other, specify was provided. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620104	SYSQ_5665	PDIS.AESPID	Field Null		PDIS.AESPID IS NULL	"A3. AE ID Number (if applicable):" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620106	SYSQ_5665b	PDIS.SPECIFY	Other / Cross Page		PDIS.REASON INTERSECTS 99 AND PDIS.SPECIFY IS NULL	An 'Other reason' was selected as one of the reasons for reason for permanent discontinuation of study drug, however, a response for other, specify was not provided. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0

pPSCR_4

Page

(Visit ID = 618802, Page ID =)

Unique Identifier page-618802-618802-618802-

* Date pre-screened		PSCR.PSCRDAT
* Gender	○ Male ○ Female	PSCR.PSCGEN
* Did you approach or contact the participant/parent/legal guardian for potential enrollment in the DO-IT study?	○ Yes ○ No	PSCR.PSENRYN
* Did the participant/parent/legal guardian sign the informed consent form (ICF) for screening and potential enrollment in DO-IT study?	○ Yes ○ No	PSCR.PSICFYN
* Reason(s) the participant/parent/legal guardian was not approached and/or did not consent for screening and potential enrollment in the DO-IT study. Please select all applicable reasons	ADD DELETE SELECTED	PSCR.PSNOREAS
If reason included "Other", please specify:		PSCR.PSNOROTH

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618802	Date	0	Date pre-screened	PSCR.PSCRDAT										
Page-2-618802	Radiolist Horizontal	0	Gender	PSCR.PSCGEN					cSEX					

Page Information															
Page-3-618802	Radiolist Horizontal	0	Did you approach or contact the participant/parent/legal guardian for potential enrollment in the DO-IT study?	PSCR.PSENRYN					cYN					
Page-4-618802	Radiolist Horizontal	0	Did the participant/parent/legal guardian sign the informed consent form (ICF) for screening and potential enrollment in DO-IT study?	PSCR.PSCICFYN					cYN					
Page-5-618802	Many Select	1	Reason(s) the participant/parent/legal guardian was not approached and/or did not consent for screening and potential enrollment in the DO-IT study. Please select all applicable reasons	PSCR.PSNOREAS					cPSCNOREAS					
-- Page Dynamics (PSCR. PSNOREAS): Show When: PSCR.PSENRYN = 0 OR PSCR.PSCICFYN = 0														
Page-6-618802	Text Field	2	If reason included "Other", please specify:	PSCR.PSNOROTH						200	99			
-- Page Dynamics (PSCR. PSNOROTH): Show When: PSCR.PSENRYN = 0 OR PSCR.PSCICFYN = 0														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-620514	SYSQ_5915	PSCR.PSCRDAT	Field Null		PSCR.PSCRDAT IS NULL	"Date pre-screened" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620515	SYSQ_5916	PSCR.PSCRDAT	Future Date		PSCR.PSCRDAT > Today	"Date pre-screened" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620516	SYSQ_5917	PSCR.PSCGEN	Field Null		PSCR.PSCGEN IS NULL	"Gender" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620517	SYSQ_5918	PSCR.PSENRYN	Field Null		PSCR.PSENRYN IS NULL	"Did you approach or contact the participant/parent/legal guardian for potential enrollment in the DO-IT study?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0

System Queries														
sysq-620518	SYSQ_5919	PSCR.PSCICFYN	Field Null		PSCR.PSCICFYN IS NULL	"Did the participant/parent/legal guardian sign the informed consent form (ICF) for screening and potential enrollment in DO-IT study?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620519	SYSQ_5920	PSCR.PSNOREAS	Field Null		PSCR.PSNOREAS IS NULL	"Reason(s) the participant/parent/legal guardian was not approached and/or did not consent for screening and potential enrollment in the DO-IT study. Please select all applicable reasons" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0
sysq-620520	SYSQ_5921	PSCR.PSNOROTH	Other / Cross Page		PSCR.PSNOREAS INTERSECTS 99 AND PSCR.PSNOROTH IS NULL	Reason(s) the participant/parent/legal guardian was not approached and/or did not consent includes "99 - Other", however, a specification was not provided. Please provide.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:04	0	0	0	0	0	0

pPSQI

Page

(Visit ID = 618803, Page ID =)

Unique Identifier page-618803-618803-618803-

Pittsburgh Sleep Quality Index (PSQI)

SDV * Date questionnaire completed (by participant) — PSQI.PSQIDAT

SDV * Time questionnaire completed (by participant) — PSQI.PSQITIM (HH24:MI)

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night on weekdays and weekends?

Bed time (weekday)	SD	(HH24:MI)	**Bed time (weekend)**	SD	(HH24:MI)
	PSQI.PSWDBTIM			PSQI.PSWEBTIM	

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night on weekdays and weekends?

Minutes (weekday)	SD	(xxx)	**Minutes (weekend)**	SD	(xxx)
	PSQI.PSWDMINS			PSQI.PSWEMINS	

3. During the past month, what time have you usually gotten up in the morning on weekdays and weekends?

Wake up time (weekday)	SD	(HH24:MI)	**Wake up time (weekend)**	SD	(HH24:MI)
	PSQI.PSWDWTIM			PSQI.PSWEWTIM	

4. During the past month, how many hours of actual sleep did you get at night on weekdays and weekends?

(This may be different than the number of hours you spent in bed.)

Hours of sleep per night (weekday)	SD	(HH24:MI)	**Hours of sleep per night (weekend)**	SD	(HH24:MI)
	PSQI.PSWDHRS			PSQI.PSWEHRS	

5. During the past month, how would you rate your sleep quality overall for weekdays and weekends?

SDV	* Weekday	○ Very good ○ Fairly good ○ Fairly bad ○ Very bad	PSQI.PSWD QUAL
SDV	* Weekend	○ Very good ○ Fairly good ○ Fairly bad ○ Very bad	PSQI.PSWE QUAL

6. During the past month, how often have you taken medicine prescribed by your doctor or “over the counter” to help you sleep?	SDV	○ Not during the past month ○ Less than once a week ○ Once or twice a week ○ Three or more times a week ○ Never PSQI.PSMEDS

For each of the remaining questions, check the one best response. Please answerall questions.

7. During the past month, how often have you had trouble sleeping because you:

a. Could not get to sleep within 30 minutes	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7A	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7AW
b. Woke up in the middle of the night or early morning	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7B	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7BW
c. Had to get up to use the bathroom	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7C	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7CW

d. Could not breathe comfortably	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7D	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7DW
e. Coughed or snored loudly	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7E	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7EW
f. Felt too cold	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7F	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7FW

g. Felt too hot	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7G	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7GW
h. Had bad dreams	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7H	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7HW
i. Had pain	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7I	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7IW

j. Other reason(s)	SD ○ Not during the past month ○ Less than once a week ○ Once or twice a week ○ Three or more times a week PSQI.PSQI7J	Do these days include weekends	SD ○ Yes ○ No PSQI.PSQI7JW

SDV * j1. Please describe the other reasons _____ PSQI.PS7JDESC

8. During the past month, how often have you had trouble staying awake while in school, while eating meals, or while engaging in social activity?

SDV
- ○ Not during the past month
- ○ Less than once a week
- ○ Once or twice a week
- ○ Three or more times a week

PSQI.PSQI8Q

9. During the past month, how much of a problem has it been for you to keep up enough energy to get things done on weekdays and weekends?

SDV * Weekday
- ○ No problem at all
- ○ Slight problem
- ○ A noticeable problem
- ○ A very big problem

PSQI.PSQI9WDQ

SDV * Weekend
- ○ No problem at all
- ○ Slight problem
- ○ A noticeable problem
- ○ A very big problem

PSQI.PSQI9WEQ

10. Ask someone you live with how often, in the past month, you have had:

a. Loud snoring	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10A	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10AW
b. Long pauses between breaths while asleep	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10B	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10BW
c. Legs twitching or jerking while you sleep	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10C	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10CW

d. Episodes of disorientation or confusion while asleep	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10D	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10DW
e. Other restlessness while asleep, please describe	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10E	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10EW
SDV * e1. Please describe the other Other restlessness while asleep.		PSQI.PS10JDESC	

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618803	Section Header	0	Pittsburgh Sleep Quality Index (PSQI)											

Page Information														
Page-2-618803	Date	0	Date questionnaire completed (by participant)	PSQI.PSQIDAT	Yes									
Page-3-618803	Time	0	Time questionnaire completed (by participant)	PSQI.PSQITIM	Yes									
Page-4-618803	Section Header	0	INSTRUCTIONS: The following questions relate to your usual sleep habits during the past month <u>only</u>. Your answers should indicate the most accurate reply for the <u>majority</u> of days and nights in the past month. Please answer all questions.											
Page-5-618803	Help Text Line	0	1. During the past month, what time have you usually gone to bed at night on weekdays and weekends?											
Page-6-618803	Row Start/End	0												
Page-7-618803	Help Text Line	0	Bed time (weekday)											
Page-8-618803	Time	0	Bed time (weekday)	PSQI.PSWDBTIM	Yes									If a range was reported (i.e. between 9pm - 10pm), use the average (9:30pm) to enter this time.
Page-9-618803	Help Text Line	0	Bed time (weekend)											
Page-10-618803	Time	0	Bed time (weekend)	PSQI.PSWEBTIM	Yes									If a range was reported (i.e. between 9pm - 10pm), use the average (9:30pm) to enter this time.
Page-11-618803	Row Start/End	0												
Page-12-618803	Help Text Line	0	2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night on weekdays and weekends?											

Page Information														
Page-13-618803	Row Start/End	0												
Page-14-618803	Help Text Line	0	Minutes (weekday)											
Page-15-618803	Numeric	0	Minutes (weekday)	PSQI.PSWDMINS	Yes							3	0	If a range was reported, use the average to enter the minutes.
Page-16-618803	Help Text Line	0	Minutes (weekend)											
Page-17-618803	Numeric	0	Minutes (weekend)	PSQI.PSWEMINS	Yes							3	0	If a range was reported, use the average to enter the minutes.
Page-18-618803	Row Start/End	0												
Page-19-618803	Help Text Line	0	3. During the past month, what time have you usually gotten up in the morning on weekdays and weekends?											
Page-20-618803	Row Start/End	0												
Page-21-618803	Help Text Line	0	Wake up time (weekday)											
Page-22-618803	Time	0	Wake up time (weekday)	PSQI.PSWDWTIM	Yes									If a range was reported (i.e. between 8am - 9am), use the average (8:30am) to enter this time.
Page-23-618803	Help Text Line	0	Wake up time (weekend)											
Page-24-618803	Time	0	Wake up time (weekend)	PSQI.PSWEWTIM	Yes									If a range was reported (i.e. between 8am - 9am), use the average (8:30am) to enter this time.
Page-25-618803	Row Start/End	0												

Page Information														
Page-26-618803	Help Text Line	0	4. During the past month, how many hours of actual sleep did you get at night on weekdays and weekends?											
Page-27-618803	Help Text Line	0	(This may be different than the number of hours you spent in bed.)											
Page-28-618803	Row Start/End	0												
Page-29-618803	Help Text Line	0	Hours of sleep per night (weekday)											
Page-30-618803	Time	0	Hours of sleep per night (weekday)	PSQI.PSWDHRS	Yes									If a range was reported, use the average to enter the hours.
Page-31-618803	Help Text Line	0	Hours of sleep per night (weekend)											
Page-32-618803	Time	0	Hours of sleep per night (weekend)	PSQI.PSWEHRS	Yes									If a range was reported, use the average to enter the hours.
Page-33-618803	Row Start/End	0												
Page-34-618803	Help Text Line	0	5. During the past month, how would you rate your sleep quality overall for weekdays and weekends?											
Page-35-618803	Radiolist Horizontal	0	Weekday	PSQI.PSWDQUAL	Yes				cPSQI_Quality					
Page-36-618803	Radiolist Horizontal	0	Weekend	PSQI.PSWEQUAL	Yes				cPSQI_Quality					
Page-37-618803	Row Start/End	0												
Page-38-618803	Help Text Line	0	6. During the past month, how often have you taken medicine prescribed by your doctor or “over the counter” to help you sleep?											

Page Information														
Page-39-618803	Radiolist Horizontal	0	6. During the past month, how often have you taken medicine prescribed by your doctor or “over the counter” to help you sleep?	PSQI.PSMEDS	Yes				cPSQI_Occurance_NV					
Page-40-618803	Row Start/End	0												
Page-41-618803	Section Header	0	For each of the remaining questions, check the one best response. Please answer<u>all</u> questions.											
Page-42-618803	Help Text Line	0	7. During the past month, how often have you had trouble sleeping because you:											
Page-43-618803	Row Start/End	0												
Page-44-618803	Help Text Line	0	a. Could not get to sleep within 30 minutes											
Page-45-618803	Radiolist Horizontal	1	a. Could not get to sleep within 30 minutes	PSQI.PSQI7A	Yes				cPSQI_Occurance					
Page-46-618803	Help Text Line	0	Do these days include weekends											
Page-47-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7AW	Yes				cYN					
Page-48-618803	Row Start/End	0												
Page-49-618803	Row Start/End	0												
Page-50-618803	Help Text Line	0	b. Woke up in the middle of the night or early morning											
Page-51-618803	Radiolist Horizontal	1	b. Woke up in the middle of the night or early morning	PSQI.PSQI7B	Yes				cPSQI_Occurance					
Page-52-618803	Help Text Line	0	Do these days include weekends											

Page Information														
Page-53-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7BW	Yes				cYN					
Page-54-618803	Row Start/End	0												
Page-55-618803	Row Start/End	0												
Page-56-618803	Help Text Line	0	c. Had to get up to use the bathroom											
Page-57-618803	Radiolist Horizontal	1	c. Had to get up to use the bathroom	PSQI.PSQI7C	Yes				cPSQI_Occurance					
Page-58-618803	Help Text Line	0	Do these days include weekends											
Page-59-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7CW	Yes				cYN					
Page-60-618803	Row Start/End	0												
Page-61-618803	Row Start/End	0												
Page-62-618803	Help Text Line	0	d. Could not breathe comfortably											
Page-63-618803	Radiolist Horizontal	1	d. Could not breathe comfortably	PSQI.PSQI7D	Yes				cPSQI_Occurance					
Page-64-618803	Help Text Line	0	Do these days include weekends											
Page-65-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7DW	Yes				cYN					
Page-66-618803	Row Start/End	0												
Page-67-618803	Row Start/End	0												

Page Information														
Page-68-618803	Help Text Line	0	e. Coughed or snored loudly											
Page-69-618803	Radiolist Horizontal	1	e. Coughed or snored loudly	PSQI.PSQI7E	Yes				cPSQI_Occurance					
Page-70-618803	Help Text Line	0	Do these days include weekends											
Page-71-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7EW	Yes				cYN					
Page-72-618803	Row Start/End	0												
Page-73-618803	Row Start/End	0												
Page-74-618803	Help Text Line	0	f. Felt too cold											
Page-75-618803	Radiolist Horizontal	1	f. Felt too cold	PSQI.PSQI7F	Yes				cPSQI_Occurance					
Page-76-618803	Help Text Line	0	Do these days include weekends											
Page-77-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7FW	Yes				cYN					
Page-78-618803	Row Start/End	0												
Page-79-618803	Row Start/End	0												
Page-80-618803	Help Text Line	0	g. Felt too hot											
Page-81-618803	Radiolist Horizontal	1	g. Felt too hot	PSQI.PSQI7G	Yes				cPSQI_Occurance					
Page-82-618803	Help Text Line	0	Do these days include weekends											

Page Information														
Page-83-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7GW	Yes				cYN					
Page-84-618803	Row Start/End	0												
Page-85-618803	Row Start/End	0												
Page-86-618803	Help Text Line	0	h. Had bad dreams											
Page-87-618803	Radiolist Horizontal	1	h. Had bad dreams	PSQI.PSQI7H	Yes				cPSQI_Occurance					
Page-88-618803	Help Text Line	0	Do these days include weekends											
Page-89-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7HW	Yes				cYN					
Page-90-618803	Row Start/End	0												
Page-91-618803	Row Start/End	0												
Page-92-618803	Help Text Line	0	i. Had pain											
Page-93-618803	Radiolist Horizontal	1	i. Had pain	PSQI.PSQI7I	Yes				cPSQI_Occurance					
Page-94-618803	Help Text Line	0	Do these days include weekends											
Page-95-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7IW	Yes				cYN					
Page-96-618803	Row Start/End	0												
Page-97-618803	Row Start/End	0												

Page Information														
Page-98-618803	Help Text Line	0	j. Other reason(s)											
Page-99-618803	Radiolist Horizontal	1	j. Other reason(s)	PSQI.PSQI7J	Yes				cPSQI_Occurance					
Page-100-618803	Help Text Line	0	Do these days include weekends											
Page-101-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7JW	Yes				cYN					
Page-102-618803	Row Start/End	0												
Page-103-618803	Text Field	1	j1. Please describe the other reasons	PSQI.PS7JDESC	Yes					200	50			
Page-104-618803	Row Start/End	0												
Page-105-618803	Help Text Line	0	8. During the past month, how often have you had trouble staying awake while in school, while eating meals, or while engaging in social activity?											
Page-106-618803	Radiolist Horizontal	0	8. During the past month, how often have you had trouble staying awake while in school, while eating meals, or while engaging in social activity?	PSQI.PSQI8Q	Yes				cPSQI_Occurance					
Page-107-618803	Row Start/End	0												
Page-108-618803	Help Text Line	0	9. During the past month, how much of a problem has it been for you to keep up enough energy to get things done on weekdays and weekends?											
Page-109-618803	Radiolist Horizontal	0	Weekday	PSQI.PSQI9WDQ	Yes				cPSQI_Problem					
Page-110-618803	Radiolist Horizontal	0	Weekend	PSQI.PSQI9WEQ	Yes				cPSQI_Problem					

Page Information														
Page-111-618803	Help Text Line	0	10. Ask someone you live with how often, in the past month, you have had:											
Page-112-618803	Row Start/End	0												
Page-113-618803	Help Text Line	0	a. Loud snoring											
Page-114-618803	Radiolist Horizontal	1	a. Loud snoring	PSQI.PSQI10A	Yes				cPSQI_Occurance					
Page-115-618803	Help Text Line	0	Do these days include weekends											
Page-116-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10AW	Yes				cYN					
Page-117-618803	Row Start/End	0												
Page-118-618803	Row Start/End	0												
Page-119-618803	Help Text Line	0	b. Long pauses between breaths while asleep											
Page-120-618803	Radiolist Horizontal	1	b. Long pauses between breaths while asleep	PSQI.PSQI10B	Yes				cPSQI_Occurance					
Page-121-618803	Help Text Line	0	Do these days include weekends											
Page-122-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10BW	Yes				cYN					
Page-123-618803	Row Start/End	0												
Page-124-618803	Row Start/End	0												
Page-125-618803	Help Text Line	0	c. Legs twitching or jerking while you sleep											

Page Information														
Page-126-618803	Radiolist Horizontal	1	c. Legs twitching or jerking while you sleep	PSQI.PSQI10C	Yes				cPSQI_Occurance					
Page-127-618803	Help Text Line	0	Do these days include weekends											
Page-128-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10CW	Yes				cYN					
Page-129-618803	Row Start/End	0												
Page-130-618803	Row Start/End	0												
Page-131-618803	Help Text Line	0	d. Episodes of disorientation or confusion while asleep											
Page-132-618803	Radiolist Horizontal	1	d. Episodes of disorientation or confusion while asleep	PSQI.PSQI10D	Yes				cPSQI_Occurance					
Page-133-618803	Help Text Line	0	Do these days include weekends											
Page-134-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10DW	Yes				cYN					
Page-135-618803	Row Start/End	0												
Page-136-618803	Row Start/End	0												
Page-137-618803	Help Text Line	0	e. Other restlessness while asleep, please describe											
Page-138-618803	Radiolist Horizontal	1	e. Other restlessness while asleep, please describe	PSQI.PSQI10E	Yes				cPSQI_Occurance					
Page-139-618803	Help Text Line	0	Do these days include weekends											
Page-140-618803	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10EW	Yes				cYN					

Page Information														
Page-141-618803	Row Start/End	0												
Page-142-618803	Text Field	1	e1. Please describe the other Other restlessness while asleep.	PSQI.PS10JDESC	Yes					200	50			

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619476	SYSQ_5267	PSQI.PSQIDAT	Field Null		PSQI.PSQIDAT IS NULL	"Date questionnaire completed (by participant)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619478	SYSQ_5268	PSQI.PSQIDAT	Future Date		PSQI.PSQIDAT > Today	"Date questionnaire completed (by participant)" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619480	SYSQ_5269	PSQI.PSQITIM	Field Null		PSQI.PSQITIM IS NULL	"Time questionnaire completed (by participant)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619482	SYSQ_5270	PSQI.PSWDBTIM	Field Null		PSQI.PSWDBTIM IS NULL	"Bed time (weekday)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619484	SYSQ_5271	PSQI.PSWEBTIM	Field Null		PSQI.PSWEBTIM IS NULL	"Bed time (weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619487	SYSQ_5272	PSQI.PSWDMINS	Field Null		PSQI.PSWDMINS IS NULL	"Minutes (weekday)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619488	SYSQ_5273	PSQI.PSWEMINS	Field Null		PSQI.PSWEMINS IS NULL	"Minutes (weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619490	SYSQ_5274	PSQI.PSWDWTIM	Field Null		PSQI.PSWDWTIM IS NULL	"Wake up time (weekday)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0

System Queries														
sysq-619492	SYSQ_5275	PSQI.PSWEWTIM	Field Null		PSQI.PSWEWTIM IS NULL	"Wake up time (weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619494	SYSQ_5276	PSQI.PSWDHRS	Field Null		PSQI.PSWDHRS IS NULL	"Hours of sleep per night (weekday)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619496	SYSQ_5277	PSQI.PSWEHRS	Field Null		PSQI.PSWEHRS IS NULL	"Hours of sleep per night (weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619498	SYSQ_5278	PSQI.PSWDQUAL	Field Null		PSQI.PSWDQUAL IS NULL	"Weekday" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619501	SYSQ_5279	PSQI.PSWEQUAL	Field Null		PSQI.PSWEQUAL IS NULL	"Weekend" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619502	SYSQ_5280	PSQI.PSMEDS	Field Null		PSQI.PSMEDS IS NULL	"6. During the past month, how often have you taken medicine prescribed by your doctor or “over the counter” to help you sleep?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619505	SYSQ_5281	PSQI.PSQI7A	Field Null		PSQI.PSQI7A IS NULL	"a. Could not get to sleep within 30 minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619506	SYSQ_5282	PSQI.PSQI7AW	Field Null		PSQI.PSQI7AW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619509	SYSQ_5283	PSQI.PSQI7B	Field Null		PSQI.PSQI7B IS NULL	"b. Woke up in the middle of the night or early morning" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619510	SYSQ_5284	PSQI.PSQI7BW	Field Null		PSQI.PSQI7BW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0

System Queries														
sysq-619512	SYSQ_5285	PSQI.PSQI7C	Field Null		PSQI.PSQI7C IS NULL	"c. Had to get up to use the bathroom" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619515	SYSQ_5286	PSQI.PSQI7CW	Field Null		PSQI.PSQI7CW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619516	SYSQ_5287	PSQI.PSQI7D	Field Null		PSQI.PSQI7D IS NULL	"d. Could not breathe comfortably" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619519	SYSQ_5288	PSQI.PSQI7DW	Field Null		PSQI.PSQI7DW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619520	SYSQ_5289	PSQI.PSQI7E	Field Null		PSQI.PSQI7E IS NULL	"e. Coughed or snored loudly" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619523	SYSQ_5290	PSQI.PSQI7EW	Field Null		PSQI.PSQI7EW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619524	SYSQ_5291	PSQI.PSQI7F	Field Null		PSQI.PSQI7F IS NULL	"f. Felt too cold" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619526	SYSQ_5292	PSQI.PSQI7FW	Field Null		PSQI.PSQI7FW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619528	SYSQ_5293	PSQI.PSQI7G	Field Null		PSQI.PSQI7G IS NULL	"g. Felt too hot" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619530	SYSQ_5294	PSQI.PSQI7GW	Field Null		PSQI.PSQI7GW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0

System Queries														
sysq-619533	SYSQ_5295	PSQI.PSQI7H	Field Null		PSQI.PSQI7H IS NULL	"h. Had bad dreams" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619534	SYSQ_5296	PSQI.PSQI7HW	Field Null		PSQI.PSQI7HW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619536	SYSQ_5297	PSQI.PSQI7I	Field Null		PSQI.PSQI7I IS NULL	"i. Had pain" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619538	SYSQ_5298	PSQI.PSQI7IW	Field Null		PSQI.PSQI7IW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619541	SYSQ_5299	PSQI.PSQI7J	Field Null		PSQI.PSQI7J IS NULL	"j. Other reason(s)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619542	SYSQ_5300	PSQI.PSQI7JW	Field Null		PSQI.PSQI7JW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619545	SYSQ_5301	PSQI.PS7JDESC	Field Null		PSQI.PS7JDESC IS NULL	"j1. Please describe the other reasons" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619546	SYSQ_5302	PSQI.PSQI8Q	Field Null		PSQI.PSQI8Q IS NULL	"8. During the past month, how often have you had trouble staying awake while in school, while eating meals, or while engaging in social activity?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619549	SYSQ_5303	PSQI.PSQI9WDQ	Field Null		PSQI.PSQI9WDQ IS NULL	"Weekday" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619551	SYSQ_5304	PSQI.PSQI9WEQ	Field Null		PSQI.PSQI9WEQ IS NULL	"Weekend" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0

System Queries														
sysq-619553	SYSQ_5305	PSQI.PSQI10A	Field Null		PSQI.PSQI10A IS NULL	"a. Loud snoring" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619555	SYSQ_5306	PSQI.PSQI10AW	Field Null		PSQI.PSQI10AW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619557	SYSQ_5307	PSQI.PSQI10B	Field Null		PSQI.PSQI10B IS NULL	"b. Long pauses between breaths while asleep" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619558	SYSQ_5308	PSQI.PSQI10BW	Field Null		PSQI.PSQI10BW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619560	SYSQ_5309	PSQI.PSQI10C	Field Null		PSQI.PSQI10C IS NULL	"c. Legs twitching or jerking while you sleep" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619562	SYSQ_5310	PSQI.PSQI10CW	Field Null		PSQI.PSQI10CW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619565	SYSQ_5311	PSQI.PSQI10D	Field Null		PSQI.PSQI10D IS NULL	"d. Episodes of disorientation or confusion while asleep" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619566	SYSQ_5312	PSQI.PSQI10DW	Field Null		PSQI.PSQI10DW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619569	SYSQ_5313	PSQI.PSQI10E	Field Null		PSQI.PSQI10E IS NULL	"e. Other restlessness while asleep, please describe" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-619571	SYSQ_5314	PSQI.PSQI10EW	Field Null		PSQI.PSQI10EW IS NULL	"Do these days include weekends" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0

System Queries														
sysq-619573	SYSQ_5315	PSQI.PS10JDESC	Field Null		PSQI.PS10JDESC IS NULL	"e1. Please describe the other Other restlessness while asleep." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0

pPSQI_2

Page

(Visit ID = 618804, Page ID =)

Unique Identifier page-618804-618804-618804-

Pittsburgh Sleep Quality Index (PSQI)

SDV * Date questionnaire completed (by participant) — PSQI.PSQIDAT

SDV * Time questionnaire completed (by participant) — PSQI.PSQITIM (HH24:MI)

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night on weekdays and weekends?

Bed time (weekday)	SD	(HH24:MI)	**Bed time (weekend)**	SD	(HH24:MI)
	PSQI.PSWDBTIM			PSQI.PSWEBTIM	

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night on weekdays and weekends?

Minutes (weekday)	SD	(xxx)	**Minutes (weekend)**	SD	(xxx)
	PSQI.PSWDMINS			PSQI.PSWEMINS	

3. During the past month, what time have you usually gotten up in the morning on weekdays and weekends?

Wake up time (weekday)	SD	(HH24:MI)	**Wake up time (weekend)**	SD	(HH24:MI)
	PSQI.PSWDWTIM			PSQI.PSWEWTIM	

4. During the past month, how many hours of actual sleep did you get at night on weekdays and weekends?

(This may be different than the number of hours you spent in bed.)

Hours of sleep per night (weekday)	SD	(HH24:MI)	**Hours of sleep per night (weekend)**	SD	(HH24:MI)
	PSQI.PSWDHRS			PSQI.PSWEHRS	

5. During the past month, how would you rate your sleep quality overall for weekdays and weekends?

SDV	* Weekday	○ Very good ○ Fairly good ○ Fairly bad ○ Very bad	PSQI.PSWD QUAL
SDV	* Weekend	○ Very good ○ Fairly good ○ Fairly bad ○ Very bad	PSQI.PSWE QUAL

6. During the past month, how often have you taken medicine prescribed by your doctor or “over the counter” to help you sleep?	SDV	○ Not during the past month ○ Less than once a week ○ Once or twice a week ○ Three or more times a week ○ Never PSQI.PSMEDS

For each of the remaining questions, check the one best response. Please answerall questions.

7. During the past month, how often have you had trouble sleeping because you:

a. Could not get to sleep within 30 minutes	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7A	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7AW
b. Woke up in the middle of the night or early morning	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7B	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7BW
c. Had to get up to use the bathroom	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7C	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7CW

d. Could not breathe comfortably	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7D	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7DW
e. Coughed or snored loudly	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7E	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7EW
f. Felt too cold	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7F	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7FW

g. Felt too hot	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7G	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7GW
h. Had bad dreams	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7H	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7HW
i. Had pain	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI7I	Do these days include weekends	SD ○Yes ○No PSQI.PSQI7IW

j. Other reason(s)	SD ○ Not during the past month ○ Less than once a week ○ Once or twice a week ○ Three or more times a week PSQI.PSQI7J	Do these days include weekends	SD ○ Yes ○ No PSQI.PSQI7JW

SDV j1. Please describe the other reasons [ ] PSQI.PS7JDESC

8. During the past month, how often have you had trouble staying awake while in school, while eating meals, or while engaging in social activity?

SDV
- ○ Not during the past month
- ○ Less than once a week
- ○ Once or twice a week
- ○ Three or more times a week

PSQI.PSQI8Q

9. During the past month, how much of a problem has it been for you to keep up enough energy to get things done on weekdays and weekends?

SDV * Weekday
- ○ No problem at all
- ○ Slight problem
- ○ A noticeable problem
- ○ A very big problem

PSQI.PSQI9WDQ

SDV * Weekend
- ○ No problem at all
- ○ Slight problem
- ○ A noticeable problem
- ○ A very big problem

PSQI.PSQI9WEQ

10. Ask someone you live with how often, in the past month, you have had:

a. Loud snoring	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10A	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10AW
b. Long pauses between breaths while asleep	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10B	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10BW
c. Legs twitching or jerking while you sleep	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10C	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10CW

d. Episodes of disorientation or confusion while asleep	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10D	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10DW
e. Other restlessness while asleep, please describe	SD ○Not during the past month ○Less than once a week ○Once or twice a week ○Three or more times a week PSQI.PSQI10E	Do these days include weekends	SD ○Yes ○No PSQI.PSQI10EW
SDV e1. Please describe the other Other restlessness while asleep.		PSQI.PS10JDESC	

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618804	Section Header	0	Pittsburgh Sleep Quality Index (PSQI)											

Page Information														
Page-2-618804	Date	0	Date questionnaire completed (by participant)	PSQI.PSQIDAT	Yes									
Page-3-618804	Time	0	Time questionnaire completed (by participant)	PSQI.PSQITIM	Yes									
Page-4-618804	Section Header	0	INSTRUCTIONS: The following questions relate to your usual sleep habits during the past month <u>only</u>. Your answers should indicate the most accurate reply for the <u>majority</u> of days and nights in the past month. Please answer all questions.											
Page-5-618804	Help Text Line	0	1. During the past month, what time have you usually gone to bed at night on weekdays and weekends?											
Page-6-618804	Row Start/End	0												
Page-7-618804	Help Text Line	0	Bed time (weekday)											
Page-8-618804	Time	0	Bed time (weekday)	PSQI.PSWDBTIM	Yes									If a range was reported (i.e. between 9pm - 10pm), use the average (9:30pm) to enter this time.
Page-9-618804	Help Text Line	0	Bed time (weekend)											
Page-10-618804	Time	0	Bed time (weekend)	PSQI.PSWEBTIM	Yes									If a range was reported (i.e. between 9pm - 10pm), use the average (9:30pm) to enter this time.
Page-11-618804	Row Start/End	0												
Page-12-618804	Help Text Line	0	2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night on weekdays and weekends?											

Page Information														
Page-13-618804	Row Start/End	0												
Page-14-618804	Help Text Line	0	Minutes (weekday)											
Page-15-618804	Numeric	0	Minutes (weekday)	PSQI.PSWDMINS	Yes							3	0	If a range was reported, use the average to enter the minutes.
Page-16-618804	Help Text Line	0	Minutes (weekend)											
Page-17-618804	Numeric	0	Minutes (weekend)	PSQI.PSWEMINS	Yes							3	0	If a range was reported, use the average to enter the minutes.
Page-18-618804	Row Start/End	0												
Page-19-618804	Help Text Line	0	3. During the past month, what time have you usually gotten up in the morning on weekdays and weekends?											
Page-20-618804	Row Start/End	0												
Page-21-618804	Help Text Line	0	Wake up time (weekday)											
Page-22-618804	Time	0	Wake up time (weekday)	PSQI.PSWDWTIM	Yes									If a range was reported (i.e. between 8am - 9am), use the average (8:30am) to enter this time.
Page-23-618804	Help Text Line	0	Wake up time (weekend)											
Page-24-618804	Time	0	Wake up time (weekend)	PSQI.PSWEWTIM	Yes									If a range was reported (i.e. between 8am - 9am), use the average (8:30am) to enter this time.
Page-25-618804	Row Start/End	0												

Page Information														
Page-26-618804	Help Text Line	0	4. During the past month, how many hours of actual sleep did you get at night on weekdays and weekends?											
Page-27-618804	Help Text Line	0	(This may be different than the number of hours you spent in bed.)											
Page-28-618804	Row Start/End	0												
Page-29-618804	Help Text Line	0	Hours of sleep per night (weekday)											
Page-30-618804	Time	0	Hours of sleep per night (weekday)	PSQI.PSWDHRS	Yes									If a range was reported, use the average to enter the hours.
Page-31-618804	Help Text Line	0	Hours of sleep per night (weekend)											
Page-32-618804	Time	0	Hours of sleep per night (weekend)	PSQI.PSWEHRS	Yes									If a range was reported, use the average to enter the hours.
Page-33-618804	Row Start/End	0												
Page-34-618804	Help Text Line	0	5. During the past month, how would you rate your sleep quality overall for weekdays and weekends?											
Page-35-618804	Radiolist Horizontal	0	Weekday	PSQI.PSWDQUAL	Yes				cPSQI_Quality					
Page-36-618804	Radiolist Horizontal	0	Weekend	PSQI.PSWEQUAL	Yes				cPSQI_Quality					
Page-37-618804	Row Start/End	0												
Page-38-618804	Help Text Line	0	6. During the past month, how often have you taken medicine prescribed by your doctor or “over the counter” to help you sleep?											

Page Information														
Page-39-618804	Radiolist Horizontal	0	6. During the past month, how often have you taken medicine prescribed by your doctor or “over the counter” to help you sleep?	PSQI.PSMEDS	Yes				cPSQI_Occurance_NV					
Page-40-618804	Row Start/End	0												
Page-41-618804	Section Header	0	For each of the remaining questions, check the one best response. Please answer<u>all</u> questions.											
Page-42-618804	Help Text Line	0	7. During the past month, how often have you had trouble sleeping because you:											
Page-43-618804	Row Start/End	0												
Page-44-618804	Help Text Line	0	a. Could not get to sleep within 30 minutes											
Page-45-618804	Radiolist Horizontal	1	a. Could not get to sleep within 30 minutes	PSQI.PSQI7A	Yes				cPSQI_Occurance					
Page-46-618804	Help Text Line	0	Do these days include weekends											
Page-47-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7AW	Yes				cYN					
Page-48-618804	Row Start/End	0												
Page-49-618804	Row Start/End	0												
Page-50-618804	Help Text Line	0	b. Woke up in the middle of the night or early morning											
Page-51-618804	Radiolist Horizontal	1	b. Woke up in the middle of the night or early morning	PSQI.PSQI7B	Yes				cPSQI_Occurance					
Page-52-618804	Help Text Line	0	Do these days include weekends											

Page Information														
Page-53-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7BW	Yes				cYN					
Page-54-618804	Row Start/End	0												
Page-55-618804	Row Start/End	0												
Page-56-618804	Help Text Line	0	c. Had to get up to use the bathroom											
Page-57-618804	Radiolist Horizontal	1	c. Had to get up to use the bathroom	PSQI.PSQI7C	Yes				cPSQI_Occurance					
Page-58-618804	Help Text Line	0	Do these days include weekends											
Page-59-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7CW	Yes				cYN					
Page-60-618804	Row Start/End	0												
Page-61-618804	Row Start/End	0												
Page-62-618804	Help Text Line	0	d. Could not breathe comfortably											
Page-63-618804	Radiolist Horizontal	1	d. Could not breathe comfortably	PSQI.PSQI7D	Yes				cPSQI_Occurance					
Page-64-618804	Help Text Line	0	Do these days include weekends											
Page-65-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7DW	Yes				cYN					
Page-66-618804	Row Start/End	0												
Page-67-618804	Row Start/End	0												

Page Information														
Page-68-618804	Help Text Line	0	e. Coughed or snored loudly											
Page-69-618804	Radiolist Horizontal	1	e. Coughed or snored loudly	PSQI.PSQI7E	Yes				cPSQI_Occurance					
Page-70-618804	Help Text Line	0	Do these days include weekends											
Page-71-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7EW	Yes				cYN					
Page-72-618804	Row Start/End	0												
Page-73-618804	Row Start/End	0												
Page-74-618804	Help Text Line	0	f. Felt too cold											
Page-75-618804	Radiolist Horizontal	1	f. Felt too cold	PSQI.PSQI7F	Yes				cPSQI_Occurance					
Page-76-618804	Help Text Line	0	Do these days include weekends											
Page-77-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7FW	Yes				cYN					
Page-78-618804	Row Start/End	0												
Page-79-618804	Row Start/End	0												
Page-80-618804	Help Text Line	0	g. Felt too hot											
Page-81-618804	Radiolist Horizontal	1	g. Felt too hot	PSQI.PSQI7G	Yes				cPSQI_Occurance					
Page-82-618804	Help Text Line	0	Do these days include weekends											

Page Information														
Page-83-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7GW	Yes				cYN					
Page-84-618804	Row Start/End	0												
Page-85-618804	Row Start/End	0												
Page-86-618804	Help Text Line	0	h. Had bad dreams											
Page-87-618804	Radiolist Horizontal	1	h. Had bad dreams	PSQI.PSQI7H	Yes				cPSQI_Occurance					
Page-88-618804	Help Text Line	0	Do these days include weekends											
Page-89-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7HW	Yes				cYN					
Page-90-618804	Row Start/End	0												
Page-91-618804	Row Start/End	0												
Page-92-618804	Help Text Line	0	i. Had pain											
Page-93-618804	Radiolist Horizontal	1	i. Had pain	PSQI.PSQI7I	Yes				cPSQI_Occurance					
Page-94-618804	Help Text Line	0	Do these days include weekends											
Page-95-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7IW	Yes				cYN					
Page-96-618804	Row Start/End	0												
Page-97-618804	Row Start/End	0												

Page Information														
Page-98-618804	Help Text Line	0	j. Other reason(s)											
Page-99-618804	Radiolist Horizontal	1	j. Other reason(s)	PSQI.PSQI7J	Yes				cPSQI_Occurance					
Page-100-618804	Help Text Line	0	Do these days include weekends											
Page-101-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI7JW	Yes				cYN					
Page-102-618804	Row Start/End	0												
Page-103-618804	Text Field	1	j1. Please describe the other reasons	PSQI.PS7JDESC	Yes					200	50			
Page-104-618804	Row Start/End	0												
Page-105-618804	Help Text Line	0	8. During the past month, how often have you had trouble staying awake while in school, while eating meals, or while engaging in social activity?											
Page-106-618804	Radiolist Horizontal	0	8. During the past month, how often have you had trouble staying awake while in school, while eating meals, or while engaging in social activity?	PSQI.PSQI8Q	Yes				cPSQI_Occurance					
Page-107-618804	Row Start/End	0												
Page-108-618804	Help Text Line	0	9. During the past month, how much of a problem has it been for you to keep up enough energy to get things done on weekdays and weekends?											
Page-109-618804	Radiolist Horizontal	0	Weekday	PSQI.PSQI9WDQ	Yes				cPSQI_Problem					
Page-110-618804	Radiolist Horizontal	0	Weekend	PSQI.PSQI9WEQ	Yes				cPSQI_Problem					

Page Information														
Page-111-618804	Help Text Line	0	10. Ask someone you live with how often, in the past month, you have had:											
Page-112-618804	Row Start/End	0												
Page-113-618804	Help Text Line	0	a. Loud snoring											
Page-114-618804	Radiolist Horizontal	1	a. Loud snoring	PSQI.PSQI10A	Yes				cPSQI_Occurance					
Page-115-618804	Help Text Line	0	Do these days include weekends											
Page-116-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10AW	Yes				cYN					
Page-117-618804	Row Start/End	0												
Page-118-618804	Row Start/End	0												
Page-119-618804	Help Text Line	0	b. Long pauses between breaths while asleep											
Page-120-618804	Radiolist Horizontal	1	b. Long pauses between breaths while asleep	PSQI.PSQI10B	Yes				cPSQI_Occurance					
Page-121-618804	Help Text Line	0	Do these days include weekends											
Page-122-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10BW	Yes				cYN					
Page-123-618804	Row Start/End	0												
Page-124-618804	Row Start/End	0												
Page-125-618804	Help Text Line	0	c. Legs twitching or jerking while you sleep											

Page Information														
Page-126-618804	Radiolist Horizontal	1	c. Legs twitching or jerking while you sleep	PSQI.PSQI10C	Yes				cPSQI_Occurance					
Page-127-618804	Help Text Line	0	Do these days include weekends											
Page-128-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10CW	Yes				cYN					
Page-129-618804	Row Start/End	0												
Page-130-618804	Row Start/End	0												
Page-131-618804	Help Text Line	0	d. Episodes of disorientation or confusion while asleep											
Page-132-618804	Radiolist Horizontal	1	d. Episodes of disorientation or confusion while asleep	PSQI.PSQI10D	Yes				cPSQI_Occurance					
Page-133-618804	Help Text Line	0	Do these days include weekends											
Page-134-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10DW	Yes				cYN					
Page-135-618804	Row Start/End	0												
Page-136-618804	Row Start/End	0												
Page-137-618804	Help Text Line	0	e. Other restlessness while asleep, please describe											
Page-138-618804	Radiolist Horizontal	1	e. Other restlessness while asleep, please describe	PSQI.PSQI10E	Yes				cPSQI_Occurance					
Page-139-618804	Help Text Line	0	Do these days include weekends											
Page-140-618804	Radiolist Horizontal	0	Do these days include weekends	PSQI.PSQI10EW	Yes				cYN					

Page Information														
Page-141-618804	Row Start/End	0												
Page-142-618804	Text Field	1	e1. Please describe the other Other restlessness while asleep.	PSQI.PS10JDESC	Yes					200	50			

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619477	SYSQ_5267	PSQI.PSQIDAT	Field Null		PSQI.PSQIDAT IS NULL	"Date questionnaire completed (by participant)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619479	SYSQ_5268	PSQI.PSQIDAT	Future Date		PSQI.PSQIDAT > Today	"Date questionnaire completed (by participant)" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619481	SYSQ_5269	PSQI.PSQITIM	Field Null		PSQI.PSQITIM IS NULL	"Time questionnaire completed (by participant)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619483	SYSQ_5270	PSQI.PSWDBTIM	Field Null		PSQI.PSWDBTIM IS NULL	"Bed time (weekday)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619485	SYSQ_5271	PSQI.PSWEBTIM	Field Null		PSQI.PSWEBTIM IS NULL	"Bed time (weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619486	SYSQ_5272	PSQI.PSWDMINS	Field Null		PSQI.PSWDMINS IS NULL	"Minutes (weekday)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619489	SYSQ_5273	PSQI.PSWEMINS	Field Null		PSQI.PSWEMINS IS NULL	"Minutes (weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619491	SYSQ_5274	PSQI.PSWDWTIM	Field Null		PSQI.PSWDWTIM IS NULL	"Wake up time (weekday)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0

System Queries														
sysq-619493	SYSQ_5275	PSQI.PSWEWTIM	Field Null		PSQI.PSWEWTIM IS NULL	"Wake up time (weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619495	SYSQ_5276	PSQI.PSWDHRS	Field Null		PSQI.PSWDHRS IS NULL	"Hours of sleep per night (weekday)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619497	SYSQ_5277	PSQI.PSWEHRS	Field Null		PSQI.PSWEHRS IS NULL	"Hours of sleep per night (weekend)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619499	SYSQ_5278	PSQI.PSWDQUAL	Field Null		PSQI.PSWDQUAL IS NULL	"Weekday" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619500	SYSQ_5279	PSQI.PSWEQUAL	Field Null		PSQI.PSWEQUAL IS NULL	"Weekend" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619503	SYSQ_5280	PSQI.PSMEDS	Field Null		PSQI.PSMEDS IS NULL	"6. During the past month, how often have you taken medicine prescribed by your doctor or “over the counter” to help you sleep?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619504	SYSQ_5281	PSQI.PSQI7A	Field Null		PSQI.PSQI7A IS NULL	"a. Could not get to sleep within 30 minutes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619507	SYSQ_5282	PSQI.PSQI7AW	Field Null		PSQI.PSQI7AW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:29	0	0	0	0	0	0
sysq-619508	SYSQ_5283	PSQI.PSQI7B	Field Null		PSQI.PSQI7B IS NULL	"b. Woke up in the middle of the night or early morning" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619511	SYSQ_5284	PSQI.PSQI7BW	Field Null		PSQI.PSQI7BW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0

System Queries														
sysq-619513	SYSQ_5285	PSQI.PSQI7C	Field Null		PSQI.PSQI7C IS NULL	"c. Had to get up to use the bathroom" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619514	SYSQ_5286	PSQI.PSQI7CW	Field Null		PSQI.PSQI7CW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619517	SYSQ_5287	PSQI.PSQI7D	Field Null		PSQI.PSQI7D IS NULL	"d. Could not breathe comfortably" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619518	SYSQ_5288	PSQI.PSQI7DW	Field Null		PSQI.PSQI7DW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619521	SYSQ_5289	PSQI.PSQI7E	Field Null		PSQI.PSQI7E IS NULL	"e. Coughed or snored loudly" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619522	SYSQ_5290	PSQI.PSQI7EW	Field Null		PSQI.PSQI7EW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619525	SYSQ_5291	PSQI.PSQI7F	Field Null		PSQI.PSQI7F IS NULL	"f. Felt too cold" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619527	SYSQ_5292	PSQI.PSQI7FW	Field Null		PSQI.PSQI7FW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619529	SYSQ_5293	PSQI.PSQI7G	Field Null		PSQI.PSQI7G IS NULL	"g. Felt too hot" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619531	SYSQ_5294	PSQI.PSQI7GW	Field Null		PSQI.PSQI7GW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0

System Queries														
sysq-619532	SYSQ_5295	PSQI.PSQI7H	Field Null		PSQI.PSQI7H IS NULL	"h. Had bad dreams" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619535	SYSQ_5296	PSQI.PSQI7HW	Field Null		PSQI.PSQI7HW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619537	SYSQ_5297	PSQI.PSQI7I	Field Null		PSQI.PSQI7I IS NULL	"i. Had pain" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619539	SYSQ_5298	PSQI.PSQI7IW	Field Null		PSQI.PSQI7IW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:30	0	0	0	0	0	0
sysq-619540	SYSQ_5299	PSQI.PSQI7J	Field Null		PSQI.PSQI7J IS NULL	"j. Other reason(s)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619543	SYSQ_5300	PSQI.PSQI7JW	Field Null		PSQI.PSQI7JW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619544	SYSQ_5301	PSQI.PS7JDESC	Field Null		PSQI.PS7JDESC IS NULL	"j1. Please describe the other reasons" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619547	SYSQ_5302	PSQI.PSQI8Q	Field Null		PSQI.PSQI8Q IS NULL	"8. During the past month, how often have you had trouble staying awake while in school, while eating meals, or while engaging in social activity?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619548	SYSQ_5303	PSQI.PSQI9WDQ	Field Null		PSQI.PSQI9WDQ IS NULL	"Weekday" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619550	SYSQ_5304	PSQI.PSQI9WEQ	Field Null		PSQI.PSQI9WEQ IS NULL	"Weekend" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0

System Queries														
sysq-619552	SYSQ_5305	PSQI.PSQI10A	Field Null		PSQI.PSQI10A IS NULL	"a. Loud snoring" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619554	SYSQ_5306	PSQI.PSQI10AW	Field Null		PSQI.PSQI10AW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619556	SYSQ_5307	PSQI.PSQI10B	Field Null		PSQI.PSQI10B IS NULL	"b. Long pauses between breaths while asleep" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619559	SYSQ_5308	PSQI.PSQI10BW	Field Null		PSQI.PSQI10BW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619561	SYSQ_5309	PSQI.PSQI10C	Field Null		PSQI.PSQI10C IS NULL	"c. Legs twitching or jerking while you sleep" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619563	SYSQ_5310	PSQI.PSQI10CW	Field Null		PSQI.PSQI10CW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619564	SYSQ_5311	PSQI.PSQI10D	Field Null		PSQI.PSQI10D IS NULL	"d. Episodes of disorientation or confusion while asleep" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619567	SYSQ_5312	PSQI.PSQI10DW	Field Null		PSQI.PSQI10DW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619568	SYSQ_5313	PSQI.PSQI10E	Field Null		PSQI.PSQI10E IS NULL	"e. Other restlessness while asleep, please describe" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:31	0	0	0	0	0	0
sysq-619570	SYSQ_5314	PSQI.PSQI10EW	Field Null		PSQI.PSQI10EW IS NULL	"Do these days include weekends" cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0

System Queries														
sysq-619572	SYSQ_5315	PSQI.PS10JDESC	Field Null		PSQI.PS10JDESC IS NULL	"e1. Please describe the other Other restlessness while asleep." cannot be empty.		Horng, Dunstan [DES] 14-SEP-20 14:38:32	0	0	0	0	0	0
sysq-620412	SYSQ_5825	PSQI.PSQI7AW	Other / Cross Page	IF PSQI.PSQI7A <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7AW must = NOT NULL.	PSQI.PSQI7A <> 0 AND PSQI.PSQI7A IS NOT NULL AND PSQI.PSQI7AW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620413	SYSQ_5826	PSQI.PSQI7BW	Other / Cross Page	IF PSQI.PSQI7B <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7BW must = NOT NULL.	PSQI.PSQI7B <> 0 AND PSQI.PSQI7B IS NOT NULL AND PSQI.PSQI7BW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620414	SYSQ_5827	PSQI.PSQI7CW	Other / Cross Page	IF PSQI.PSQI7C <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7CW must = NOT NULL.	PSQI.PSQI7C <> 0 AND PSQI.PSQI7C IS NOT NULL AND PSQI.PSQI7CW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0

System Queries														
sysq-620415	SYSQ_5828	PSQI.PSQI7DW	Other / Cross Page	IF PSQI.PSQI7D <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7DW must = NOT NULL.	PSQI.PSQI7D <> 0 AND PSQI.PSQI7D IS NOT NULL AND PSQI.PSQI7DW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620416	SYSQ_5829	PSQI.PSQI7EW	Other / Cross Page	IF PSQI.PSQI7E <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7EW must = NOT NULL.	PSQI.PSQI7E <> 0 AND PSQI.PSQI7E IS NOT NULL AND PSQI.PSQI7EW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620417	SYSQ_5830	PSQI.PSQI7FW	Other / Cross Page	IF PSQI.PSQI7F <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7FW must = NOT NULL.	PSQI.PSQI7F <> 0 AND PSQI.PSQI7F IS NOT NULL AND PSQI.PSQI7FW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620418	SYSQ_5831	PSQI.PSQI7GW	Other / Cross Page	IF PSQI.PSQI7G <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7GW must = NOT NULL.	PSQI.PSQI7G <> 0 AND PSQI.PSQI7G IS NOT NULL AND PSQI.PSQI7GW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0

System Queries														
sysq-620419	SYSQ_5832	PSQI.PSQI7HW	Other / Cross Page	IF PSQI.PSQI7H <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7HW must = NOT NULL.	PSQI.PSQI7H <> 0 AND PSQI.PSQI7H IS NOT NULL AND PSQI.PSQI7HW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620420	SYSQ_5833	PSQI.PSQI7IW	Other / Cross Page	IF PSQI.PSQI7I <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7IW must = NOT NULL.	PSQI.PSQI7I <> 0 AND PSQI.PSQI7I IS NOT NULL AND PSQI.PSQI7IW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620421	SYSQ_5834	PSQI.PSQI7JW	Other / Cross Page	IF PSQI.PSQI7J <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI7JW must = NOT NULL.	PSQI.PSQI7J <> 0 AND PSQI.PSQI7J IS NOT NULL AND PSQI.PSQI7JW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620422	SYSQ_5835	PSQI.PS7JDESC	Other / Cross Page	IF PSQI.PSQI7J <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PS7JDESC must = NOT NULL.	PSQI.PSQI7J <> 0 AND PSQI.PSQI7J IS NOT NULL AND PSQI.PS7JDESC IS NULL	Other reason(s) are reported in the past month, however, a descripton of the Other reason(s) was not provided. Please provide.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0

System Queries														
sysq-620423	SYSQ_5836	PSQI.PS7JDESC	Other / Cross Page	IF PSQI.PSQI7J = 0 (Not during the past month), then PSQI.PS7JDESC must be = NULL	PSQI.PSQI7J = 0 AND PSQI.PS7JDESC IS NOT NULL	Other reason(s) was “Not during the past month”, however, a description was provided. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620424	SYSQ_5837	PSQI.PSQI10AW	Other / Cross Page	IF PSQI.PSQI10A <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI10AW must = NOT NULL.	PSQI.PSQI10A <> 0 AND PSQI.PSQI10A IS NOT NULL AND PSQI.PSQI10AW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week”, however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620425	SYSQ_5838	PSQI.PSQI10BW	Other / Cross Page	IF PSQI.PSQI10B <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI10BW must = NOT NULL.	PSQI.PSQI10B <> 0 AND PSQI.PSQI10B IS NOT NULL AND PSQI.PSQI10BW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week”, however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620426	SYSQ_5839	PSQI.PSQI10CW	Other / Cross Page	IF PSQI.PSQI10C <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI10CW must = NOT NULL.	PSQI.PSQI10C <> 0 AND PSQI.PSQI10C IS NOT NULL AND PSQI.PSQI10CW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week”, however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0

System Queries														
sysq-620427	SYSQ_5840	PSQI.PSQI10DW	Other / Cross Page	IF PSQI.PSQI10D <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI10DW must = NOT NULL.	PSQI.PSQI10D <> 0 AND PSQI.PSQI10D IS NOT NULL AND PSQI.PSQI10DW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620428	SYSQ_5841	PSQI.PSQI10EW	Other / Cross Page	IF PSQI.PSQI10E <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PSQI10EW must = NOT NULL.	PSQI.PSQI10E <> 0 AND PSQI.PSQI10E IS NOT NULL AND PSQI.PSQI10EW IS NULL	The reported frequency was "Less than once a week", "Once or twice a week" OR "Three or more times a week", however, a response to question “Do these include weekends” was not provided. Please provide or clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620429	SYSQ_5842	PSQI.PS10JDESC	Other / Cross Page	IF PSQI.PSQI10E <> 0 (Not during the past month) AND is NOT NULL, then PSQI.PS10JDESC must = NOT NULL.	PSQI.PSQI10E <> 0 AND PSQI.PSQI10E IS NOT NULL AND PSQI.PS10JDESC IS NULL	Other restlessness while asleep is reported in the past month, however, a descripton of the Other restlessness was not provided. Please provide.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0
sysq-620430	SYSQ_5843	PSQI.PS10JDESC	Other / Cross Page	IF PSQI.PSQI10E = 0 (Not during the past month), then PSQI.PS10JDESC must be = NULL	PSQI.PSQI10E = 0 AND PSQI.PS10JDESC IS NOT NULL	Other restlessness while asleep was “Not during the past month”, however, a description was provided. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0

pRANDOM

Page

(Visit ID = 618805, Page ID =)

Unique Identifier page-618805-618805-618805-

Section A. RANDOMIZATION CONFIRMATION			
SDV	* A1. Was the participant randomized?	○ Yes ○ No	RAND.RANDYN
SDV	* A1b. Randomization Date:		RAND.RANDDAT
SDV	* A1c. Please provide reason the participant was not randomized?	○ Not eligible ○ Other	RAND.RANDNREA
SDV	* A1c1. Please specify the other reason the participant was not randomized.		RAND.RANDNROTH

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618805	Section Header	0	Section A. RANDOMIZATION CONFIRMATION											
Page-2-618805	Radiolist Horizontal	0	A1. Was the participant randomized?	RAND.RANDYN	Yes				cYN					
Page-3-618805	Date	1	A1b. Randomization Date:	RAND.RANDDAT	Yes									
-- Page Dynamics (RAND. RANDDAT): Show When: RAND.RANDYN = 1														
Page-4-618805	Radiolist Horizontal	1	A1c. Please provide reason the participant was not randomized?	RAND.RANDNREA	Yes				cNRANDREAS					
-- Page Dynamics (RAND. RANDNREA): Show When: RAND.RANDYN = 0														
Page-5-618805	Text Field	2	A1c1. Please specify the other reason the participant was not randomized.	RAND.RANDNROTH	Yes					200	99			
-- Page Dynamics (RAND. RANDNROTH): Show When: RAND.RANDYN = 0 AND RAND.RANDNREA = 99														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619039	SYSQ_4995	RAND.RANDYN	Other / Cross Page		(Field[RAND.RANDYN] = '1') And HasSubject Status[Eligible]	Subject status indicates subject was not randomized. If eligible, please randomize or clarify your response.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619041	SYSQ_4996	RAND.RANDYN	Other / Cross Page		(Field[RAND.RANDYN] = '0') And HasSubject Status[Randomized]	Subject status indicates subject was randomized. Please update or clarify your response.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619796	SYSQ_5445	RAND.RANDYN	Field Null		RAND.RANDYN IS NULL	"A1. Was the participant randomized?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619798	SYSQ_5446	RAND.RANDDAT	Field Null		RAND.RANDDAT IS NULL	"A1b. Randomization Date:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619800	SYSQ_5447	RAND.RANDDAT	Future Date		RAND.RANDDAT > Today	"A1b. Randomization Date:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619802	SYSQ_5448	RAND.RANDNREA	Field Null		RAND.RANDNREA IS NULL	"A1c. Please provide reason the participant was not randomized?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619804	SYSQ_5449	RAND.RANDNROTH	Field Null		RAND.RANDNROTH IS NULL	"A1c1. Please specify the other reason the participant was not randomized." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0

pRANDOM_4

Page

(Visit ID = 618806, Page ID =)

Unique Identifier page-618806-618806-618806-

Section A. RANDOMIZATION CONFIRMATION			
SDV	* A1. Was the participant randomized?	○ Yes ○ No	RAND.RANDYN
SDV	* A1b. Randomization Date:		RAND.RANDDAT
SDV	* A1c. Please provide reason the participant was not randomized?	○ Not eligible ○ Other	RAND.RANDNREA
SDV	* A1c1. Please specify the other reason the participant was not randomized.		RAND.RANDNROTH

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618806	Section Header	0	Section A. RANDOMIZATION CONFIRMATION											
Page-2-618806	Radiolist Horizontal	0	A1. Was the participant randomized?	RAND.RANDYN	Yes				cYN					
Page-3-618806	Date	1	A1b. Randomization Date:	RAND.RANDDAT	Yes									
-- Page Dynamics (RAND. RANDDAT): Show When: RAND.RANDYN = 1														
Page-4-618806	Radiolist Horizontal	1	A1c. Please provide reason the participant was not randomized?	RAND.RANDNREA	Yes				cNRANDREAS					
-- Page Dynamics (RAND. RANDNREA): Show When: RAND.RANDYN = 0														
Page-5-618806	Text Field	2	A1c1. Please specify the other reason the participant was not randomized.	RAND.RANDNROTH	Yes					200	99			
-- Page Dynamics (RAND. RANDNROTH): Show When: RAND.RANDYN = 0 AND RAND.RANDNREA = 99														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619040	SYSQ_4995	RAND.RANDYN	Other / Cross Page		(Field[RAND.RANDYN] = '1') And HasSubjectStatus[Eligible]	Subject status indicates subject was not randomized. If eligible, please randomize or clarify your response.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619042	SYSQ_4996	RAND.RANDYN	Other / Cross Page		(Field[RAND.RANDYN] = '0') And HasSubjectStatus[Randomized]	Subject status indicates subject was randomized. Please update or clarify your response.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:14	0	0	0	0	0	0
sysq-619795	SYSQ_5445	RAND.RANDYN	Field Null		RAND.RANDYN IS NULL	"A1. Was the participant randomized?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619797	SYSQ_5446	RAND.RANDDAT	Field Null		RAND.RANDDAT IS NULL	"A1b. Randomization Date:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619799	SYSQ_5447	RAND.RANDDAT	Future Date		RAND.RANDDAT > Today	"A1b. Randomization Date:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619801	SYSQ_5448	RAND.RANDNREA	Field Null		RAND.RANDNREA IS NULL	"A1c. Please provide reason the participant was not randomized?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619803	SYSQ_5449	RAND.RANDNROTH	Field Null		RAND.RANDNROTH IS NULL	"A1c1. Please specify the other reason the participant was not randomized." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0

System Queries														
sysq-620496	SYSQ_5897	RAND.RANDDAT	Other / Cross Page	Protocol 4.1/5.0 - new query	VISITID = 20 AND (FUNCTION-DATE_COMPARE(10-10-VIS.VISDAT, RAND.RANDDAT) < 14 OR FUNCTION-DATE_COMPARE(10-10-VIS.VISDAT, RAND.RANDDAT) > 42)	Randomization date is either less than 2 weeks or more than 6 weeks from the screening visit. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

pREVIEW

Page

(Visit ID = 618807, Page ID =)

Unique Identifier page-618807-618807-618807-

A1. Date of review:		REVIEW.REVDAT
SECTION B: ADVERSE EVENT INFORMATION:		
Please enter the information below from the corresponding Adverse Event - Initial Report page. This information will be used to reconcile the Adverse Event report with the Medical Monitor report.		
B1. AE Number (from corresponding Adverse Event - Initial Report page)		REVIEW.AENUM (format xxx)
B2. Date of onset		REVIEW.STDAT
B3. Adverse Event term as reported by site		REVIEW.AETERM
SECTION C: MEDICAL MONITORING INFORMATION		
C1. Do you agree with the event name assigned by the site?	○ Yes ○ No	REVIEW.AETERMAGR
C1a. If No, specify event name:		REVIEW.AETERMREV
C2. In your opinion, is this event expected (nature or severity is consistent with information in the protocol, consent form, or Investigator brochure)?	○ Yes ○ No	REVIEW.EXPECTED
C3. In your opinion, what was the intensity/grade of this event? (select one):	○ Grade 1 - Mild ○ Grade 2 – Moderate ○ Grade 3 – Severe ○ Grade 4 – Life-threatening Or disabling ○ Grade 5 – Death	REVIEW.SEVERITY
C4. In your opinion, is this an SAE?	○ Yes ○ No	REVIEW.SAE
In your opinion, what, if any, of the following criteria were met with this event?: (answer all questions)		
C4a. Resulted in death	○ Yes ○ No	REVIEW.DEATH

	C4b. Immediate life-threatening event (immediate danger of death from event)	○ Yes ○ No	REVIEW.LIFE_THREAT
	C4c. Requires inpatient hospitalization or prolongation of existing hospitalization	○ Yes ○ No	REVIEW.HOSP
	C4d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	○ Yes ○ No	REVIEW.LIFE_FUNC
	C4e. Results in a congenital anomaly in the offspring of a participant	○ Yes ○ No	REVIEW.CONG_ANOM
	C4f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	○ Yes ○ No	REVIEW.IMPORT_EVENT
	C5. In your opinion, what was the relationship of the event to study drug? (select one):	○ Not related ○ Possibly Related ○ Probably Related ○ Definitely Related	REVIEW.CAUSALITY
	C6. Provide a brief summary of your review of this event:		REVIEW.COMMENTS

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618807	Date	0	A1. Date of review:	REVIEW.REVDAT										Initial report review date
Page-2-618807	Section Header	0	SECTION B: ADVERSE EVENT INFORMATION:											

Page Information														
Page-3-618807	Help Text Line	0	Please enter the information below from the corresponding Adverse Event - Initial Report page. This information will be used to reconcile the Adverse Event report with the Medical Monitor report.											
Page-4-618807	Numeric	0	B1. AE Number (from corresponding Adverse Event - Initial Report page)	REVIEW.AENUM								3	0	
Page-5-618807	Date	0	B2. Date of onset	REVIEW.STDAT										
Page-6-618807	Text Field	0	B3. Adverse Event term as reported by site	REVIEW.AETERM						150	50			
Page-7-618807	Section Header	0	SECTION C: MEDICAL MONITORING INFORMATION											
Page-8-618807	Radiolist Horizontal	0	C1. Do you agree with the event name assigned by the site?	REVIEW.AETERMAGR					cYN					
Page-9-618807	Text Field	1	C1a. If No, specify event name:	REVIEW.AETERMREV				Yes: MedDRA v20.1-5 Level		200	75			
-- Page Dynamics (REVIEW. AETERMREV): Show When: REVIEW.AETERMAGR = 0														
Page-10-618807	Radiolist Horizontal	0	C2. In your opinion, is this event expected (nature or severity is consistent with information in the protocol, consent form, or Investigator brochure)?	REVIEW.EXPECTED					cYN					
Page-11-618807	Radiolist Horizontal	0	C3. In your opinion, what was the intensity/grade of this event? (select one):	REVIEW.SEVERITY					cSEVERITY					
Page-12-618807	Radiolist Horizontal	0	C4. In your opinion, is this an SAE?	REVIEW.SAE					cYN					

Page Information														
Page-13-618807	Help Text Line	0	In your opinion, what, if any, of the following criteria were met with this event?: (answer all questions)											
-- Page Dynamics (.): Show When: REVIEW.SAE = 1														
Page-14-618807	Radiolist Horizontal	1	C4a. Resulted in death	REVIEW. DEATH					cYN					
-- Page Dynamics (REVIEW. DEATH): Show When: REVIEW.SAE = 1														
Page-15-618807	Radiolist Horizontal	1	C4b. Immediate life-threatening event (immediate danger of death from event)	REVIEW. LIFE_THREAT					cYN					
-- Page Dynamics (REVIEW. LIFE_THREAT): Show When: REVIEW.SAE = 1														
Page-16-618807	Radiolist Horizontal	1	C4c. Requires inpatient hospitalization or prolongation of existing hospitalization	REVIEW. HOSP					cYN					
-- Page Dynamics (REVIEW. HOSP): Show When: REVIEW.SAE = 1														
Page-17-618807	Radiolist Horizontal	1	C4d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	REVIEW. LIFE_FUNC					cYN					
-- Page Dynamics (REVIEW. LIFE_FUNC): Show When: REVIEW.SAE = 1														
Page-18-618807	Radiolist Horizontal	1	C4e. Results in a congenital anomaly in the offspring of a participant	REVIEW. CONG_ANOM					cYN					
-- Page Dynamics (REVIEW. CONG_ANOM): Show When: REVIEW.SAE = 1														
Page-19-618807	Radiolist Horizontal	1	C4f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	REVIEW. IMPORT_EVENT					cYN					
-- Page Dynamics (REVIEW. IMPORT_EVENT): Show When: REVIEW.SAE = 1														
Page-20-618807	Radiolist	0	C5. In your opinion, what was the relationship of the event to study drug? (select one):	REVIEW. CAUSALITY					cRELATED					
Page-21-618807	Comments	0	C6. Provide a brief summary of your review of this event:	REVIEW. COMMENTS										

pREVIEW_3

Page

(Visit ID = 618808, Page ID =)

Unique Identifier page-618808-618808-618808-

A1. Date of review:		REVIEW.REVDAT
SECTION B: ADVERSE EVENT INFORMATION:		
Please enter the information below from the corresponding Adverse Event - Initial Report page. This information will be used to reconcile the Adverse Event report with the Medical Monitor report.		
B1. AE Number (from corresponding Adverse Event - Initial Report page)		REVIEW.AENUM (format xxx)
B2. Date of onset		REVIEW.STDAT
B2a. Check if the Onset Date is partial – only Month and/or Year are reported.	☐	REVIEW.AESTDCHX
B2a1. Onset Date - Month	**B2a2. Onset Date - Year**	
(xx) REVIEW.STDATM	(xxxx) REVIEW.STDATY	
B3. Adverse Event term as reported by site		REVIEW.AETERM
SECTION C: MEDICAL MONITORING INFORMATION		
C1. Do you agree with the event name assigned by the site?	○ Yes ○ No	REVIEW.AETERMAGR
C1a. If No, specify event name:		REVIEW.AETERMREV
C2. In your opinion, is this event expected (nature or severity is consistent with information in the protocol, consent form, or Investigator brochure)?	○ Yes ○ No	REVIEW.EXPECTED
C3. In your opinion, what was the intensity/grade of this event? (select one):	○ Grade 1 - Mild ○ Grade 2 – Moderate ○ Grade 3 – Severe ○ Grade 4 – Life-threatening Or disabling ○ Grade 5 – Death	REVIEW.SEVERITY

C4. In your opinion, is this an SAE?	○ Yes ○ No	REVIEW.SAE
In your opinion, what, if any, of the following criteria were met with this event?: (answer all questions)		
C4a. Resulted in death	○ Yes ○ No	REVIEW.DEATH
C4b. Immediate life-threatening event (immediate danger of death from event)	○ Yes ○ No	REVIEW.LIFE_THREAT
C4c. Requires inpatient hospitalization or prolongation of existing hospitalization	○ Yes ○ No	REVIEW.HOSP
C4d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	○ Yes ○ No	REVIEW.LIFE_FUNC
C4e. Results in a congenital anomaly in the offspring of a participant	○ Yes ○ No	REVIEW.CONG_ANOM
C4f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	○ Yes ○ No	REVIEW.IMPORT_EVENT
C5. In your opinion, what was the relationship of the event to study drug? (select one):	○ Not related ○ Possibly Related ○ Probably Related ○ Definitely Related	REVIEW.CAUSALITY
C6. Provide a brief summary of your review of this event:		REVIEW.COMMENTS

Page Information															
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618808	Date	0	A1. Date of review:	REVIEW.REVDAT										Initial report review date
Page-2-618808	Section Header	0	SECTION B: ADVERSE EVENT INFORMATION:											
Page-3-618808	Help Text Line	0	Please enter the information below from the corresponding Adverse Event - Initial Report page. This information will be used to reconcile the Adverse Event report with the Medical Monitor report.											
Page-4-618808	Numeric	0	B1. AE Number (from corresponding Adverse Event - Initial Report page)	REVIEW.AENUM								3	0	
Page-5-618808	Date	0	B2. Date of onset	REVIEW.STDAT										
Page-6-618808	Check Box	1	B2a. Check if the Onset Date is partial – only Month and/or Year are reported.	REVIEW.AESTDCHX										Check if site provided only a Month and Year or only Year for the Onset Date.
-- Page Dynamics (REVIEW.AESTDCHX): Show When: REVIEW.STDAT IS NULL														
Page-7-618808	Row Start/End	0												
Page-8-618808	Help Text Line	0												
-- Page Dynamics (.): Show When: REVIEW.STDAT IS NULL AND REVIEW.AESTDCHX IS NOT NULL														
Page-9-618808	Help Text Line	0	B2a1. Onset Date - Month											
-- Page Dynamics (.): Show When: REVIEW.STDAT IS NULL AND REVIEW.AESTDCHX IS NOT NULL														
Page-10-618808	Help Text Line	0	B2a2. Onset Date - Year											
-- Page Dynamics (.): Show When: REVIEW.STDAT IS NULL AND REVIEW.AESTDCHX IS NOT NULL														

Page Information														
Page-11-618808	Row Start/End	0												
Page-12-618808	Row Start/End	0												
Page-13-618808	Help Text Line	0												
-- Page Dynamics (.): Show When: REVIEW.STDAT IS NULL AND REVIEW.AESTDCHX IS NOT NULL														
Page-14-618808	Numeric	0	B2a1. Onset Date - Month	REVIEW.STDATM								2	0	Enter up to 2 digits for the Month (i.e. "10" for October)
-- Page Dynamics (REVIEW. STDATM): Show When: REVIEW.STDAT IS NULL AND REVIEW.AESTDCHX IS NOT NULL														
Page-15-618808	Numeric	0	B2a2. Onset Date - Year	REVIEW.STDATY								4	0	Enter 4 digits for the Year (i.e. "2018")
-- Page Dynamics (REVIEW. STDATY): Show When: REVIEW.STDAT IS NULL AND REVIEW.AESTDCHX IS NOT NULL														
Page-16-618808	Row Start/End	0												
Page-17-618808	Text Field	0	B3. Adverse Event term as reported by site	REVIEW.AETERM						150	50			
Page-18-618808	Section Header	0	SECTION C: MEDICAL MONITORING INFORMATION											
Page-19-618808	Radiolist Horizontal	0	C1. Do you agree with the event name assigned by the site?	REVIEW.AETERMAGR					cYN					
Page-20-618808	Text Field	1	C1a. If No, specify event name:	REVIEW.AETERMREV				Yes : MedDRA v20.1 - 5 Level		200	75			
-- Page Dynamics (REVIEW. AETERMREV): Show When: REVIEW.AETERMAGR = 0														

Page Information														
Page-21-618808	Radiolist Horizontal	0	C2. In your opinion, is this event expected (nature or severity is consistent with information in the protocol, consent form, or Investigator brochure)?	REVIEW.EXPECTED					cYN					
Page-22-618808	Radiolist Horizontal	0	C3. In your opinion, what was the intensity/grade of this event? (select one):	REVIEW.SEVERITY					cSEVERITY					
Page-23-618808	Radiolist Horizontal	0	C4. In your opinion, is this an SAE?	REVIEW. SAE					cYN					
Page-24-618808	Help Text Line	0	In your opinion, what, if any, of the following criteria were met with this event?: (answer all questions)											
-- Page Dynamics (.): Show When: REVIEW.SAE = 1														
Page-25-618808	Radiolist Horizontal	1	C4a. Resulted in death	REVIEW. DEATH					cYN					
-- Page Dynamics (REVIEW. DEATH): Show When: REVIEW.SAE = 1														
Page-26-618808	Radiolist Horizontal	1	C4b. Immediate life-threatening event (immediate danger of death from event)	REVIEW.LIFE_THREAT					cYN					
-- Page Dynamics (REVIEW. LIFE_THREAT): Show When: REVIEW.SAE = 1														
Page-27-618808	Radiolist Horizontal	1	C4c. Requires inpatient hospitalization or prolongation of existing hospitalization	REVIEW. HOSP					cYN					
-- Page Dynamics (REVIEW. HOSP): Show When: REVIEW.SAE = 1														
Page-28-618808	Radiolist Horizontal	1	C4d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	REVIEW.LIFE_FUNC					cYN					
-- Page Dynamics (REVIEW. LIFE_FUNC): Show When: REVIEW.SAE = 1														
Page-29-618808	Radiolist Horizontal	1	C4e. Results in a congenital anomaly in the offspring of a participant	REVIEW.CONG_ANOM					cYN					
-- Page Dynamics (REVIEW. CONG_ANOM): Show When: REVIEW.SAE = 1														
Page-30-618808	Radiolist Horizontal	1	C4f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	REVIEW.IMPORT_EVENT					cYN					

Page Information														
-- Page Dynamics (REVIEW. IMPORT_EVENT): Show When: REVIEW.SAE = 1														
Page-31-618808	Radiolist	0	C5. In your opinion, what was the relationship of the event to study drug? (select one):	REVIEW.CAUSALITY					cRELATED					
Page-32-618808	Comments	0	C6. Provide a brief summary of your review of this event:	REVIEW.COMMENTS										

pSES

Page

(Visit ID = 618809, Page ID =)

Unique Identifier page-618809-618809-618809-

	General guidelines/criteria: The Site Coordinator will enter the socioeconomic status and census data based on the participant's home address at the baseline visit.		
SDV	* A1. Date of Information		SES.SES_DT
SDV	* A2. Country of Residence	○ United States ○ Canada ○ Other	SES.COUNTRY
	OTHER: If participant does not live in the United States or Canada, no census details will be collected. UNITED STATES: Go to the Census.Gov website and click on“American Fact Finder” on the menu bar on the bottom of the screen. On the next page you will see a section named “Address Search”. Click on the link to enter an address to find census data. Enter the street address, city, state and zip code and click “Go”. You will be directed to a table that lists the country, census track, block group and block for that address. Data enter the information from the "Geography Name" column, not the "Geography Code". If for any reason, a message pops up that the address does not exist, try another house number or an adjacent street address. The US Census is only updated every 10 years, and therefore it is possible to have new addresses not available in the data base. CANADA: Go to the Statistics Canada website and click on “Data Products” under the Census 2011 heading on the menu bar on the left site of the screen. Under “Standard Census Data Products” click on “Census Profiles”. Enter the person's postal code and click “submit”. You will be directed to a table that lists the CMA (Census Metropolitan Area) and the census tract.		
SDV	* A2a. State or Province of Residence		SES.STATE
SDV	* A2b. County or CMA (Census Metropolitan Area)		SES.COUNTY
SDV	* A2c. ZIP Code (US Only)		SES.ZIPCODE
SDV	* A2d. Census Tract		SES.TRACT (format xxxxxxx.xx)
SDV	* A2e. Census Block Group (US Only)		SES.BLOCK (format x)
SDV	* A3. Does the participant have medical insurance?	○ Yes ○ No ○ Declined to Answer	SES.INSUR_YN

SDV	* A3a. Type of insurance	○ Private ○ Public ○ Public and Private ○ Unknown	SES.INSUR_TYPE
SDV	* A4. What is the highest level of education that the participant's mother completed?	○ Kindergarten-6th Grade ○ 7th-9th Grade ○ 10th-11th Grade ○ High School Graduate/GED ○ Partial College, 2-Year College Diploma, or Trade School ○ 3- or 4-Year College/ University Graduate ○ Post Graduate Degree ○ Declined to Answer	SES.M_EDU

State and Province Abbreviations

United States

Alabama - AL
Alaska - AK
Arizona - AZ
Arkansas - AR
California - CA
Colorado - CO
Connecticut - CT
Delaware - DE
District of Columbia - DC
Florida - FL
Georgia - GA
Hawaii - HI
Idaho - ID
Illinois - IL
Indiana - IN
Iowa - IA
Kansas - KS
Kentucky - KY
Louisiana - LA
Maine - ME
Maryland - MD
Massachusetts - MA
Michigan - MI
Minnesota - MN
Mississippi - MS
Missouri - MO
Montana - MT
Nebraska - NE
Nevada - NV
New Hampshire - NH
New Jersey - NJ
New Mexico - NM
New York - NY
North Caroline - NC
North Dakota - ND
Ohio - OH
Oklahoma - OK
Oregon - OR
Pennsylvania - PA
Rhode Island - RI
South Carolina - SC
South Dakota - SD
Tennessee - TN
Texas - TX
Utah - UT
Vermont - VT
Virginia - VA
Washington - WA
West Virginia - WV
Wisconsin - WI
Wyoming - WY
Other - 99

Canada

Alberta - AB
British Columbia - BC
Manitoba - MB
New Brunswick - NB
Newfoundland and Labrador - NL
Northwest Territories - NT
Nova Scotia - NS
Nunavut - NU
Ontario - ON
Prince Edward Island - PE
Quebec - QC
Saskatchewan - SK
Yukon - YT
Other - 99

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618809	Help Text Line	0	General guidelines/criteria: The Site Coordinator will enter the socioeconomic status and census data based on the participant's home address at the baseline visit.											
Page-2-618809	Date	0	A1. Date of Information	SES. SES_DT	Yes									
Page-3-618809	Radiolist Horizontal	0	A2. Country of Residence	SES. COUNTRY	Yes				cCOUNTRY					
Page-4-618809	Help Text Line	0	OTHER: If participant does not live in the United States or Canada, no census details will be collected.											
-- Page Dynamics (.): Show When: SES.COUNTRY = 99														

Page Information														
Page -5- 618809	Help Text Line	0	UNITED STATES: Go to the Census.Gov website and click on“American Fact Finder” on the menu bar on the bottom of the screen. On the next page you will see a section named “Address Search”. Click on the link to enter an address to find census data. Enter the street address, city, state and zip code and click “Go”. You will be directed to a table that lists the country, census track, block group and block for that address. Data enter the information from the "Geography Name" column, <u>not</u> the "Geography Code". If for any reason, a message pops up that the address does not exist, try another house number or an adjacent street address. The US Census is only updated every 10 years, and therefore it is possible to have new addresses not available in the data base.											
-- Page Dynamics (.): Show When: SES.COUNTRY = 01														

Page Information														
Page-6-618809	Help Text Line	0	CANADA: Go to the Statistics Canada website and click on “Data Products” under the Census 2011 heading on the menu bar on the left site of the screen. Under “Standard Census Data Products” click on “Census Profiles”. Enter the person's postal code and click “submit”. You will be directed to a table that lists the CMA (Census Metropolitan Area) and the census tract.											
-- Page Dynamics (.): Show When: SES.COUNTRY = 02														
Page-7-618809	Text Field	1	A2a. State or Province of Residence	SES.STATE	Yes					2	2			
-- Page Dynamics (SES. STATE): Show When: SES.COUNTRY = 01 OR SES.COUNTRY = 02														
Page-8-618809	Text Field	1	A2b. County or CMA (Census Metropolitan Area)	SES.COUNTY	Yes					20	20			
-- Page Dynamics (SES. COUNTY): Show When: SES.COUNTRY = 01 OR SES.COUNTRY = 02														
Page-9-618809	Text Field	1	A2c. ZIP Code (US Only)	SES.ZIPCODE	Yes					6	10			
-- Page Dynamics (SES. ZIPCODE): Show When: SES.COUNTRY = 01														
Page-10-618809	Numeric	1	A2d. Census Tract	SES.TRACT	Yes							7	2	
-- Page Dynamics (SES. TRACT): Show When: SES.COUNTRY = 01 OR SES.COUNTRY = 02														
Page-11-618809	Numeric	1	A2e. Census Block Group (US Only)	SES.BLOCK	Yes							1	0	
-- Page Dynamics (SES. BLOCK): Show When: SES.COUNTRY = 01														
Page-12-618809	Radiolist	0	A3. Does the participant have medical insurance?	SES.INSUR_YN	Yes				cYNDECL					
Page-13-618809	Radiolist	1	A3a. Type of insurance	SES.INSUR_TYPE	Yes				cINSURANCE					
-- Page Dynamics (SES. INSUR_TYPE): Show When: SES.INSUR_YN = 1														

Page Information														
Page-14-618809	Radiolist	0	A4. What is the highest level of education that the participant's mother completed?	SES.M_EDU	Yes				cEDUCATION					
Page-15-618809	Section Header	0	State and Province Abbreviations											
-- Page Dynamics (.): Show When: SES.COUNTRY <> 99 AND (SES.COUNTRY = 01 OR SES.COUNTRY = 02)														
Page-16-618809	Help Text Line	0	<u>United States</u>											
-- Page Dynamics (.): Show When: SES.COUNTRY = 01														

Page Information														
Page -17- 618809	Help Text Line	0	Alabama - AL Alaska - AK Arizona - AZ Arkansas - AR California - CA Colorado - CO Connecticut - CT Delaware - DE District of Columbia - DC Florida - FL Georgia - GA Hawaii - HI Idaho - ID Illinois - IL Indiana - IN Iowa - IA Kansas - KS Kentucky - KY Louisiana - LA Maine - ME Maryland - MD Massachusetts - MA Michigan - MI Minnesota - MN Mississippi - MS Missouri - MO Montana - MT Nebraska - NE Nevada - NV New Hampshire - NH New Jersey - NJ New Mexico - NM New York - NY North Caroline - NC North Dakota - ND Ohio - OH Oklahoma - OK Oregon - OR Pennsylvania - PA Rhode Island - RI South Carolina - SC South Dakota - SD Tennessee - TN Texas - TX Utah - UT Vermont - VT Virginia - VA Washington - WA West Virginia - WV Wisconsin - WI Wyoming - WY Other - 99											
-- Page Dynamics (.): Show When: SES.COUNTRY = 01														
Page -18- 618809	Help Text Line	0	<u>Canada</u>											
-- Page Dynamics (.): Show When: SES.COUNTRY = 02														

Page Information														
Page-19-618809	Help Text Line	0	Alberta - AB British Columbia - BC Manitoba - MB New Brunswick - NB Newfoundland and Labrador - NL Northwest Territories - NT Nova Scotia - NS Nunavut - NU Ontario - ON Prince Edward Island - PE Quebec - QC Saskatchewan - SK Yukon - YT Other - 99											
-- Page Dynamics (.): Show When: SES.COUNTRY = 02														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618863	SYSQ_07767	SES.COUNTRY	Field Null		SES.COUNTRY IS NULL	"Country of Residence" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618864	SYSQ_07769	SES.STATE	Field Null		SES.STATE IS NULL	"State or Province of Residence" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618865	SYSQ_07771	SES.COUNTY	Field Null		SES.COUNTY IS NULL	"County or CMA (Census Metropolitan Area)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618866	SYSQ_07772	SES.ZIPCODE	Field Null		SES.ZIPCODE IS NULL	"ZIP Code (US Only)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618867	SYSQ_07773	SES.TRACT	Field Null		SES.TRACT IS NULL	"Census Tract" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618868	SYSQ_07774	SES.BLOCK	Field Null		SES.BLOCK IS NULL	"Census Block Group" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0

System Queries														
sysq-618875	SYSQ_2944	SES.SES_DT	Field Null		SES.SES_DT IS NULL	"Date of Information" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618876	SYSQ_2945	SES.SES_DT	Future Date		SES.SES_DT > Today	"Date of Information" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618877	SYSQ_2946	SES.INSUR_YN	Field Null		SES.INSUR_YN IS NULL	"Does the subject have medical insurance?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618878	SYSQ_2947	SES.INSUR_TYPE	Field Null		SES.INSUR_TYPE IS NULL	"Type of insurance" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618879	SYSQ_2948	SES.M_EDU	Field Null		SES.M_EDU IS NULL	"What is the highest level of education that the subject's mother completed?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0

pSRC

Page

(Visit ID = 618810, Page ID =)

Unique Identifier page-618810-618810-618810-

SECTION A: RECONSENT				
SDV	* A1. Was the patient reconsented for participation in the study?	○ Yes ○ No	SRC.SRCYN	
SDV	* A1a. Reconsent Date:		SRC.SRCDAT	
SDV	* A1b. Did the patient sign the adult informed consent form?	○ Yes ○ No	SRC.SRCPSIGN	
SDV	* A1b1. Did the patient sign the informed assent?	○ Yes ○ No	SRC.SRCIAFYN	
SDV	* A1b1a. Date assent signed		SRC.SCRIAFDAT	
SDV	* A1c. Was reconsent obtained for repository sample collection (DNA, plasma/serum and urine banking)?	○ Yes ○ No	SRC.SRCBANK	
SDV	* A1d. Specify reason patient was not reconsented for participation in the study?		SRC.SRCNREAS	
SDV	* A1e. Reason for reconsent	○ Subject reached age for signing adult consent form ○ Study protocol amendment ○ Other	SRC.SCRYREAS	
SDV	* A1e1. New protocol version		SRC.SCRPROTV	(format xx.x)
SDV	* A1e2. Specify other reason for reconsent		SRC.SCROREAS	

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text

Page Information														
Page-1-618810	Section Header	0	SECTION A: RECONSENT											
Page-2-618810	Radiolist Horizontal	0	A1. Was the patient reconsented for participation in the study?	SRC.SRCYN	Yes				cYN					
Page-3-618810	Date	1	A1a. Reconsent Date:	SRC.SRCDAT	Yes									
-- Page Dynamics (SRC. SRCDAT): Show When: SRC.SRCYN = 1														
Page-4-618810	Radiolist Horizontal	1	A1b. Did the patient sign the adult informed consent form?	SRC.SRCPSIGN	Yes				cYN					
-- Page Dynamics (SRC. SRCPSIGN): Show When: SRC.SRCYN = 1														
Page-5-618810	Radiolist Horizontal	2	A1b1. Did the patient sign the informed assent?	SRC.SRCIAFYN	Yes				cYN					
-- Page Dynamics (SRC. SRCIAFYN): Show When: SRC.SRCYN = 1 AND SRC.SRCPSIGN = 0														
Page-6-618810	Date	3	A1b1a. Date assent signed	SRC.SCRIAFDAT	Yes									
-- Page Dynamics (SRC. SCRIAFDAT): Show When: SRC.SRCPSIGN = 0 AND SRC.SRCIAFYN = 1														
Page-7-618810	Radiolist Horizontal	1	A1c. Was reconsent obtained for repository sample collection (DNA, plasma/serum and urine banking)?	SRC.SRCBANK	Yes				cYN					
-- Page Dynamics (SRC. SRCBANK): Show When: SRC.SRCYN = 1														
Page-8-618810	Text Field	1	A1d. Specify reason patient was not reconsented for participation in the study?	SRC.SRCNREAS	Yes					200	99			
-- Page Dynamics (SRC. SRCNREAS): Show When: SRC.SRCYN = 0														
Page-9-618810	Radiolist	1	A1e. Reason for reconsent	SRC.SCRYREAS	Yes				cSRCREAS					
-- Page Dynamics (SRC. SCRYREAS): Show When: SRC.SRCYN = 1														
Page-10-618810	Numeric	2	A1e1. New protocol version	SRC.SCRPROTV	Yes							2	1	
-- Page Dynamics (SRC. SCRPROTV): Show When: SRC.SRCYN = 1 AND SRC.SCRYREAS = 2														
Page-11-618810	Text Field	2	A1e2. Specify other reason for reconsent	SRC.SCROREAS	Yes					200	99			
-- Page Dynamics (SRC. SCROREAS): Show When: SRC.SRCYN = 1 AND SRC.SCRYREAS = 99														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619027	SYSQ_4986	SRC.SRCDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(SRC.SRCDAT, 10-20-ICF.ICF_DT) >= 0 OR FUNCTION-DATE_COMPARE(120-20-EOS.DATE, SRC.SRCDAT) > 0	Reconsent Date is prior/same as study entry ICF date (at screening) or after Date of study exit. Please clarify or update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619028	SYSQ_4987	SRC.SCRIAFDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(SRC.SCRIAFDAT, 10-20-ICF.ASSENT_DT) >= 0 OR FUNCTION-DATE_COMPARE(120-20-EOS.DATE, SRC.SCRIAFDAT) > 0	Reconsent of 'Assent' Date is prior/same as study entry assent date (at screening) or after Date of study exit. Please clarify or update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619030	SYSQ_4988	SRC.SCRYREAS	Other / Cross Page		SRC.SRCPSIGN = 0 AND SRC.SCRYREAS = 1	Subject reached age for signing adult consent form reason is reported, however, Did the patient sign the adult informed consent form question is No. Please review and reconcile.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619032	SYSQ_4989	SRC.SRCYN	Other / Cross Page		SRC.SRCYN = 1 AND SRC.SRCPSIGN = 0 AND SRC.SRCIAFYN = 0	Patient was reconsented however, both Did the patient sign the adult informed consent and informed assent are No. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619806	SYSQ_5450	SRC.SRCYN	Field Null		SRC.SRCYN IS NULL	"A1. Was the patient reconsented for participation in the study?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619807	SYSQ_5451	SRC.SRCDAT	Field Null		SRC.SRCDAT IS NULL	"A1a. Reconsent Date:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0

System Queries														
sysq-619809	SYSQ_5452	SRC.SRCDAT	Future Date		SRC.SRCDAT > Today	"A1a. Reconsent Date:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619812	SYSQ_5453	SRC.SRCPSIGN	Field Null		SRC.SRCPSIGN IS NULL	"A1b. Did the patient sign the adult informed consent form?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619813	SYSQ_5454	SRC.SRCIAFYN	Field Null		SRC.SRCIAFYN IS NULL	"A1b1. Did the patient sign the informed assent?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619816	SYSQ_5455	SRC.SCRIAFDAT	Field Null		SRC.SCRIAFDAT IS NULL	"A1b1a. Date assent signed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619817	SYSQ_5456	SRC.SCRIAFDAT	Future Date		SRC.SCRIAFDAT > Today	"A1b1a. Date assent signed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619819	SYSQ_5457	SRC.SRCBANK	Field Null		SRC.SRCBANK IS NULL	"A1c. Was reconsent obtained for repository sample collection (DNA, plasma/serum and urine banking)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619822	SYSQ_5458	SRC.SRCNREAS	Field Null		SRC.SRCNREAS IS NULL	"A1d. Specify reason patient was not reconsented for participation in the study?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619824	SYSQ_5459	SRC.SCRYREAS	Field Null		SRC.SCRYREAS IS NULL	"A1e. Reason for reconsent" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619825	SYSQ_5460	SRC.SCRPROTV	Field Null		SRC.SCRPROTV IS NULL	"A1e1. New protocol version" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-620293	SYSQ_5764	SRC.SCROREAS	Field Null		SRC.SCROREAS IS NULL	"A1e2. Specify other reason for reconsent" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0

pSRC_3

Page

(Visit ID = 618811, Page ID =)

Unique Identifier page-618811-618811-618811-

SECTION A: RECONSENT				
SDV	* A1. Was the patient reconsented for participation in the study?	○ Yes ○ No	SRC.SRCYN	
SDV	* A1a. Reconsent Date:		SRC.SRCDAT	
SDV	* A1a1. Internal identifier used by your site for this Informed Consent (i.e. version number or a date)		SRC.SRCVER	
SDV	* A1b. Did the patient sign the adult informed consent form?	○ Yes ○ No	SRC.SRCPSIGN	
SDV	* A1b1. Did the patient sign the informed assent?	○ Yes ○ No	SRC.SRCIAFYN	
SDV	* A1b1a. Date assent signed		SRC.SCRIAFDAT	
SDV	* A1c. Was reconsent obtained for repository sample collection (DNA, plasma/serum and urine banking)?	○ Yes ○ No	SRC.SRCBANK	
SDV	* A1d. Specify reason patient was not reconsented for participation in the study?		SRC.SRCNREAS	
SDV	* A1e. Reason for reconsent	○ Subject reached age for signing adult consent form ○ Study protocol amendment ○ Other	SRC.SCRYREAS	
SDV	* A1e1. New protocol version		SRC.SCRPROTV	(format xx.x)
SDV	* A1e2. Specify other reason for reconsent		SRC.SCROREAS	

Page Information														
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618811	Section Header	0	SECTION A: RECONSENT											
Page-2-618811	Radiolist Horizontal	0	A1. Was the patient reconsented for participation in the study?	SRC.SRCYN	Yes				cYN					
Page-3-618811	Date	1	A1a. Reconsent Date:	SRC.SRCDAT	Yes									
-- Page Dynamics (SRC.SRCDAT): Show When: SRC.SRCYN = 1														
Page-4-618811	Text Field	2	A1a1. Internal identifier used by your site for this Informed Consent (i.e. version number or a date)	SRC.SRCVER	Yes					50	50			
-- Page Dynamics (SRC.SRCVER): Show When: SRC.SRCYN = 1														
Page-5-618811	Radiolist Horizontal	1	A1b. Did the patient sign the adult informed consent form?	SRC.SRCPSIGN	Yes				cYN					
-- Page Dynamics (SRC.SRCPSIGN): Show When: SRC.SRCYN = 1														
Page-6-618811	Radiolist Horizontal	2	A1b1. Did the patient sign the informed assent?	SRC.SRCIAFYN	Yes				cYN					
-- Page Dynamics (SRC.SRCIAFYN): Show When: SRC.SRCYN = 1 AND SRC.SRCPSIGN = 0														
Page-7-618811	Date	3	A1b1a. Date assent signed	SRC.SCRIAFDAT	Yes									
-- Page Dynamics (SRC.SCRIAFDAT): Show When: SRC.SRCPSIGN = 0 AND SRC.SRCIAFYN = 1														
Page-8-618811	Radiolist Horizontal	1	A1c. Was reconsent obtained for repository sample collection (DNA, plasma/serum and urine banking)?	SRC.SRCBANK	Yes				cYN					
-- Page Dynamics (SRC.SRCBANK): Show When: SRC.SRCYN = 1														
Page-9-618811	Text Field	1	A1d. Specify reason patient was not reconsented for participation in the study?	SRC.SRCNREAS	Yes					200	99			
-- Page Dynamics (SRC.SRCNREAS): Show When: SRC.SRCYN = 0														
Page-10-618811	Radiolist	1	A1e. Reason for reconsent	SRC.SCRYREAS	Yes				cSRCREAS					
-- Page Dynamics (SRC.SCRYREAS): Show When: SRC.SRCYN = 1														

Page Information														
Page-11-618811	Numeric	2	A1e1. New protocol version	SRC.SCRPROTV	Yes							2	1	
-- Page Dynamics (SRC. SCRPROTV): Show When: SRC.SRCYN = 1 AND SRC.SCRYREAS = 2														
Page-12-618811	Text Field	2	A1e2. Specify other reason for reconsent	SRC.SCROREAS	Yes					200	99			
-- Page Dynamics (SRC. SCROREAS): Show When: SRC.SRCYN = 1 AND SRC.SCRYREAS = 99														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619026	SYSQ_4986	SRC.SRCDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(SRC.SRCDAT, 10-20-ICF.ICF_DT) >= 0 OR FUNCTION-DATE_COMPARE(120-20-EOS.DATE, SRC.SRCDAT) > 0	Reconsent Date is prior/same as study entry ICF date (at screening) or after Date of study exit. Please clarify or update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619029	SYSQ_4987	SRC.SCRIAFDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(SRC.SCRIAFDAT, 10-20-ICF.ASSENT_DT) >= 0 OR FUNCTION-DATE_COMPARE(120-20-EOS.DATE, SRC.SCRIAFDAT) > 0	Reconsent of 'Assent' Date is prior/same as study entry assent date (at screening) or after Date of study exit. Please clarify or update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619031	SYSQ_4988	SRC.SCRYREAS	Other / Cross Page		SRC.SRCPSIGN = 0 AND SRC.SCRYREAS = 1	Subject reached age for signing adult consent form reason is reported, however, Did the patient sign the adult informed consent form question is No. Please review and reconcile.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0

System Queries														
sysq-619033	SYSQ_4989	SRC.SRCYN	Other / Cross Page		SRC.SRCYN = 1 AND SRC.SRCPSIGN = 0 AND SRC.SRCIAFYN = 0	Patient was reconsented however, both Did the patient sign the adult informed consent and informed assent are No. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619805	SYSQ_5450	SRC.SRCYN	Field Null		SRC.SRCYN IS NULL	"A1. Was the patient reconsented for participation in the study?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619808	SYSQ_5451	SRC.SRCDAT	Field Null		SRC.SRCDAT IS NULL	"A1a. Reconsent Date:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619810	SYSQ_5452	SRC.SRCDAT	Future Date		SRC.SRCDAT > Today	"A1a. Reconsent Date:" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619811	SYSQ_5453	SRC.SRCPSIGN	Field Null		SRC.SRCPSIGN IS NULL	"A1b. Did the patient sign the adult informed consent form?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619814	SYSQ_5454	SRC.SRCIAFYN	Field Null		SRC.SRCIAFYN IS NULL	"A1b1. Did the patient sign the informed assent?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619815	SYSQ_5455	SRC.SCRIAFDAT	Field Null		SRC.SCRIAFDAT IS NULL	"A1b1a. Date assent signed" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619818	SYSQ_5456	SRC.SCRIAFDAT	Future Date		SRC.SCRIAFDAT > Today	"A1b1a. Date assent signed" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:39	0	0	0	0	0	0
sysq-619820	SYSQ_5457	SRC.SRCBANK	Field Null		SRC.SRCBANK IS NULL	"A1c. Was reconsent obtained for repository sample collection (DNA, plasma/serum and urine banking)?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619821	SYSQ_5458	SRC.SRCNREAS	Field Null		SRC.SRCNREAS IS NULL	"A1d. Specify reason patient was not reconsented for participation in the study?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0

System Queries														
sysq-619823	SYSQ_5459	SRC.SCRYREAS	Field Null		SRC.SCRYREAS IS NULL	"A1e. Reason for reconsent" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619826	SYSQ_5460	SRC.SCRPROTV	Field Null		SRC.SCRPROTV IS NULL	"A1e1. New protocol version" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-620292	SYSQ_5764	SRC.SCROREAS	Field Null		SRC.SCROREAS IS NULL	"A1e2. Specify other reason for reconsent" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620433	SYSQ_5846	SRC.SRCVER	Field Null		SRC.SRCVER IS NULL	"A1a1. Internal identifier used by your site for this Informed Consent (i.e. version number or a date)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:01	0	0	0	0	0	0

pSpecColl

Page

(Visit ID = 618812, Page ID =)

Unique Identifier page-618812-618812-618812-

SECTION A: BLOOD SAMPLE COLLECTION:		
* A1. Were blood samples collected for shipment to Central Laboratory for testing?	○ Yes ○ No	SCF.BLTESTYN
Enter the DOIT ID#s for blood samples that are collected for Central Laboratory or LabCorp. *In section A, enter the digits after "DOIT" on the sample label including dashes for samples ending in –A, -B, or –C only.* *For Example: Gold-top serum tube DOIT00-NNN-A1 collected at Baseline (Month 0), should be entered into the field below as 00-NNN-A1 (where "NNN" represents the 3-digit numeric ID assigned by the Central Lab) .*		
* A1a. If no, reason		SCF.BLTNREAS
* A1b. Date collected		SCF.BLTDAT
* A1c. Time collected	:	SCF.BLTTIM (HH24:MI)
* A1d. Number of tubes? Enter only the number of tubes collected for shipment to Central Laboratory for testing.		SCF.BLTTUBES (format xx)
* A1d1. Blood testing - Sample ID#		SCF.BLT1ID
* A1d2. Blood testing - Sample ID#		SCF.BLT2ID
* A1d3. Blood testing - Sample ID#		SCF.BLT3ID
* A1d4. Blood testing - Sample ID#		SCF.BLT4ID
* A1d5. Blood testing - Sample ID#		SCF.BLT5ID
* A1d6. Blood testing - Sample ID#		SCF.BLT6ID
* A1d7. Blood testing - Sample ID#		SCF.BLT7ID
* A1d8. Blood testing - Sample ID#		SCF.BLT8ID

* A1d9. Blood testing - Sample ID#		SCF.BLT9ID
* A1d10. Blood testing - Sample ID#		SCF.BLT10ID
* A1d11. Blood testing - Sample ID#		SCF.BLT11ID
* A1d12. Blood testing - Sample ID#		SCF.BLT12ID
* A1e. Was the blood sample collection shipped to the Central Laboratory?	○ Yes ○ No	SCF.BLTSHP
* A1e1. FedEx Tracking Number		SCF.BLTFEDEX
SECTION B. PLASMA/SERUM BANKING:		
PLASMA/SERUM BANKING is collected at Baseline, 6, 12, 18 and 24 Months.		
* B1. Were plasma/serum samples collected for banking?	○ Yes ○ No	SCF.BLBANKYN
* B1a. If no, reason not collected		SCF.BLBNREAS
* B1b. Date collected		SCF.BLBDAT
* B1c. Time collected	:	SCF.BLBTIM (HH24:MI)
* B1d. Plasma banking tube - Sample ID		SCF.BLB1ID
* B1e. Serum banking tube - Sample ID		SCF.BLB2ID
* B1f. Were the plasma/serum samples shipped to the repository?	○ Yes ○ No	SCF.BLBSHP
* B1f1. FedEx Tracking Number		SCF.BLBFEDEX
SECTION C. DNA BANKING:		
DNA BANKING is collected at Baseline and 24 Month ONLY		
* C1. Was DNA collected?	○ Yes ○ No	SCF.DNAYN
* C1a. If no, reason not collected		SCF.DNAREAS
* C1b. Sample collection type	○ Blood ○ Saliva	SCF.DNATYP
* C1c. Date collected		SCF.DNADAT
* C1d. Time collected	:	SCF.DNATIM (HH24:MI)

* C1e. DNA - Sample ID		SCF.DNAID
* C1f. Was the DNA specimen shipped to the repository?	○ Yes ○ No	SCF.DNASHP
* C1f1. FedEx Tracking Number		SCF.DNAFEDEX
SECTION D. URINE BANKING:		
URINE BANKING is collected at Baseline, 6 and 24 Months ONLY.		
* D1. Were urine samples collected for banking?	○ Yes ○ No	SCF.URINYN
* D1a. If no, reason not collected		SCF.URINREAS
* D1b. Date collected		SCF.URINDAT
* D1c. Time collected	:	SCF.URINTIM (HH24:MI)
* D1d. Number of tubes		SCF.URINTUBES (format xx)
* D1d1. Urine banking - Sample ID #1		SCF.URIN1ID
* D1d2. Urine banking - Sample ID #2		SCF.URIN2ID
* D1d3. Urine banking - Sample ID #3		SCF.URIN3ID
* D1e. Were the samples shipped to the Biorepository?	○ Yes ○ No	SCF.URINSHP
* D1e1. FedEx Tracking Number		SCF.URINFEDEX

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618812	Section Header	0	SECTION A: BLOOD SAMPLE COLLECTION:											
Page-2-618812	Radiolist Horizontal	0	A1. Were blood samples collected for shipment to Central Laboratory for testing?	SCF.BLTESTYN					cYN					

Page Information														
Page-3-618812	Help Text Line	0	Enter the DOIT ID#s for blood samples that are collected for Central Laboratory or LabCorp. In section A, enter the digits after “DOIT” on the sample label including dashes for samples ending in –A, -B, or –C only. For Example: Gold-top serum tube DOIT00-NNN-A1 collected at Baseline (Month 0), should be entered into the field below as 00-NNN-A1 (where “NNN” represents the 3-digit numeric ID assigned by the Central Lab) .											
Page-4-618812	Comments	1	A1a. If no, reason	SCF.BLTNREAS										
-- Page Dynamics (SCF. BLTNREAS): Show When: SCF.BLTESTYN = 0														
Page-5-618812	Date	1	A1b. Date collected	SCF.BLTDAT										
-- Page Dynamics (SCF. BLTDAT): Show When: SCF.BLTESTYN = 1														
Page-6-618812	Time	1	A1c. Time collected	SCF.BLTTIM										
-- Page Dynamics (SCF. BLTTIM): Show When: SCF.BLTESTYN = 1														
Page-7-618812	Numeric	1	A1d. Number of tubes? Enter only the number of tubes collected for shipment to Central Laboratory for testing.	SCF.BLTTUBES								2	0	Total number of tubes with labels DOITNN-NNN-A1 through –A4, -B1 through –B3, and –C
-- Page Dynamics (SCF. BLTTUBES): Show When: SCF.BLTESTYN = 1														
Page-8-618812	Text Field	2	A1d1. Blood testing - Sample ID#	SCF.BLT1ID						13	13			
-- Page Dynamics (SCF. BLT1ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 1														
Page-9-618812	Text Field	2	A1d2. Blood testing - Sample ID#	SCF.BLT2ID						13	13			
-- Page Dynamics (SCF. BLT2ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 2														
Page-10-618812	Text Field	2	A1d3. Blood testing - Sample ID#	SCF.BLT3ID						13	13			
-- Page Dynamics (SCF. BLT3ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 3														

Page Information															
Page-11-618812	Text Field	2	A1d4. Blood testing - Sample ID#	SCF.BLT4ID						13	13				
-- Page Dynamics (SCF. BLT4ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 4															
Page-12-618812	Text Field	2	A1d5. Blood testing - Sample ID#	SCF.BLT5ID						13	13				
-- Page Dynamics (SCF. BLT5ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 5															
Page-13-618812	Text Field	2	A1d6. Blood testing - Sample ID#	SCF.BLT6ID						13	13				
-- Page Dynamics (SCF. BLT6ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 6															
Page-14-618812	Text Field	2	A1d7. Blood testing - Sample ID#	SCF.BLT7ID						13	13				
-- Page Dynamics (SCF. BLT7ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 7															
Page-15-618812	Text Field	2	A1d8. Blood testing - Sample ID#	SCF.BLT8ID						13	13				
-- Page Dynamics (SCF. BLT8ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 8															
Page-16-618812	Text Field	2	A1d9. Blood testing - Sample ID#	SCF.BLT9ID						13	13				
-- Page Dynamics (SCF. BLT9ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 9															
Page-17-618812	Text Field	2	A1d10. Blood testing - Sample ID#	SCF.BLT10ID						13	13				
-- Page Dynamics (SCF. BLT10ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 10															
Page-18-618812	Text Field	2	A1d11. Blood testing - Sample ID#	SCF.BLT11ID						13	13				
-- Page Dynamics (SCF. BLT11ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 11															
Page-19-618812	Text Field	2	A1d12. Blood testing - Sample ID#	SCF.BLT12ID						13	13				
-- Page Dynamics (SCF. BLT12ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 12															
Page-20-618812	Radiolist Horizontal	1	A1e. Was the blood sample collection shipped to the Central Laboratory?	SCF.BLTSHP					cYN						
-- Page Dynamics (SCF. BLTSHP): Show When: SCF.BLTESTYN = 1															
Page-21-618812	Text Field	2	A1e1. FedEx Tracking Number	SCF.BLTFEDEX						30	30				
-- Page Dynamics (SCF. BLTFEDEX): Show When: SCF.BLTESTYN = 1 AND SCF.BLTSHP = 1															

Page Information														
Page-22-618812	Section Header	0	SECTION B. PLASMA/SERUM BANKING:											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90 OR VISITID = 140)														
Page-23-618812	Help Text Line	0	PLASMA/SERUM BANKING is collected at Baseline, 6, 12, 18 and 24 Months.											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90 OR VISITID = 140)														
Page-24-618812	Radiolist Horizontal	0	B1. Were plasma/serum samples collected for banking?	SCF. BLBANKYN					cYN					
-- Page Dynamics (SCF. BLBANKYN): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90 OR VISITID = 140)														
Page-25-618812	Comments	1	B1a. If no, reason not collected	SCF. BLBNREAS										
-- Page Dynamics (SCF. BLBNREAS): Show When: SCF.BLBANKYN = 0														
Page-26-618812	Date	1	B1b. Date collected	SCF. BLBDAT										
-- Page Dynamics (SCF. BLBDAT): Show When: SCF.BLBANKYN = 1														
Page-27-618812	Time	1	B1c. Time collected	SCF. BLBTIM										
-- Page Dynamics (SCF. BLBTIM): Show When: SCF.BLBANKYN = 1														
Page-28-618812	Text Field	1	B1d. Plasma banking tube - Sample ID	SCF. BLB1ID						13	13			For Plasma Banking, enter tubes with labels DOITNN-NNN-P1 and DOITNN-NNN-P2. Enter the digits after “DOIT” on the sample label including dashes (Example: if the sample label was DOIT00-001-P1, you would enter "00-001-P1" into the data entry field).
-- Page Dynamics (SCF. BLB1ID): Show When: SCF.BLBANKYN = 1														

Page Information														
Page-29-618812	Text Field	1	B1e. Serum banking tube - Sample ID	SCF.BLB2ID						13	13			For Serum Banking, enter tubes with labels DOITNN-NNN-S1 and DOITNN-NNN-S2. Enter the digits after “DOIT” on the sample label including dashes (Example: if the sample label was DOIT00-001-S1, you would enter "00-001-S1" into the data entry field).
-- Page Dynamics (SCF.BLB2ID): Show When: SCF.BLBANKYN = 1														
Page-30-618812	Radiolist Horizontal	1	B1f. Were the plasma/serum samples shipped to the repository?	SCF.BLBSHP					cYN					
-- Page Dynamics (SCF.BLBSHP): Show When: SCF.BLBANKYN = 1														
Page-31-618812	Text Field	2	B1f1. FedEx Tracking Number	SCF.BLBFEDEX						30	30			
-- Page Dynamics (SCF.BLBFEDEX): Show When: SCF.BLBANKYN = 1 AND SCF.BLBSHP = 1														
Page-32-618812	Section Header	0	SECTION C. DNA BANKING:											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 90 OR VISITID = 140)														
Page-33-618812	Help Text Line	0	DNA BANKING is collected at Baseline and 24 Month ONLY											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 90 OR VISITID = 140)														
Page-34-618812	Radiolist Horizontal	0	C1. Was DNA collected?	SCF.DNAYN					cYN					
-- Page Dynamics (SCF.DNAYN): Show When: (VISITID = 20 OR VISITID = 90 OR VISITID = 140)														
Page-35-618812	Comments	1	C1a. If no, reason not collected	SCF.DNAREAS										
-- Page Dynamics (SCF.DNAREAS): Show When: SCF.DNAYN = 0														
Page-36-618812	Radiolist Horizontal	1	C1b. Sample collection type	SCF.DNATYP					cDNATYPE					
-- Page Dynamics (SCF.DNATYP): Show When: SCF.DNAYN = 1														

Page Information														
Page-37-618812	Date	1	C1c. Date collected	SCF.DNADAT										
-- Page Dynamics (SCF. DNADAT): Show When: SCF.DNAYN = 1														
Page-38-618812	Time	1	C1d. Time collected	SCF.DNATIM										
-- Page Dynamics (SCF. DNATIM): Show When: SCF.DNAYN = 1														
Page-39-618812	Text Field	1	C1e. DNA - Sample ID	SCF.DNAID						13	13			Enter the digits after “DOIT” on the sample label including dashes for samples ending in –D (Example: if the sample label was DOIT00-001-D, you would enter "00-001-D" into the data entry field).</i>
-- Page Dynamics (SCF. DNAID): Show When: SCF.DNAYN = 1														
Page-40-618812	Radiolist Horizontal	1	C1f. Was the DNA specimen shipped to the repository?	SCF.DNASHP					cYN					
-- Page Dynamics (SCF. DNASHP): Show When: SCF.DNAYN = 1														
Page-41-618812	Text Field	2	C1f1. FedEx Tracking Number	SCF.DNAFEDEX						30	30			
-- Page Dynamics (SCF. DNAFEDEX): Show When: SCF.DNAYN = 1 AND SCF.DNASHP = 1														
Page-42-618812	Section Header	0	SECTION D. URINE BANKING:											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 90 OR VISITID = 140)														
Page-43-618812	Help Text Line	0	URINE BANKING is collected at Baseline, 6 and 24 Months ONLY.											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 90 OR VISITID = 140)														
Page-44-618812	Radiolist Horizontal	0	D1. Were urine samples collected for banking?	SCF.URINYN					cYN					
-- Page Dynamics (SCF. URINYN): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 90 OR VISITID = 140)														
Page-45-618812	Comments	1	D1a. If no, reason not collected	SCF.URINREAS										
-- Page Dynamics (SCF. URINREAS): Show When: SCF.URINYN = 0														

Page Information														
Page-46-618812	Date	1	D1b. Date collected	SCF.URINDAT										
-- Page Dynamics (SCF. URINDAT): Show When: SCF.URINYN = 1														
Page-47-618812	Time	1	D1c. Time collected	SCF.URINTIM										
-- Page Dynamics (SCF. URINTIM): Show When: SCF.URINYN = 1														
Page-48-618812	Numeric	1	D1d. Number of tubes	SCF.URINTUBES								2	0	D1d. Enter total number of tubes with labels DOITNN-NNN-U1 through –U2.
-- Page Dynamics (SCF. URINTUBES): Show When: SCF.URINYN = 1														
Page-49-618812	Text Field	2	D1d1. Urine banking - Sample ID #1	SCF.URIN1ID						13	13			Enter the digits after “DOIT” on the sample label including dashes for samples ending in –U (Example: if the sample labels were DOIT00-001-U1 and DOIT00-001-U2, you would enter "00-001-U1” and “00-001-U2" into the data entry fields).</i>
-- Page Dynamics (SCF. URIN1ID): Show When: SCF.URINYN = 1 AND SCF.URINTUBES >= 1														
Page-50-618812	Text Field	2	D1d2. Urine banking - Sample ID #2	SCF.URIN2ID						13	13			
-- Page Dynamics (SCF. URIN2ID): Show When: SCF.URINYN = 1 AND SCF.URINTUBES >= 2														
Page-51-618812	Text Field	2	D1d3. Urine banking - Sample ID #3	SCF.URIN3ID						13	13			
-- Page Dynamics (SCF. URIN3ID): Show When: SCF.URINYN = 1 AND SCF.URINTUBES >= 3														
Page-52-618812	Radiolist Horizontal	1	D1e. Were the samples shipped to the Biorepository?	SCF.URINSHP					cYN					
-- Page Dynamics (SCF. URINSHP): Show When: SCF.URINYN = 1														
Page-53-618812	Text Field	2	D1e1. FedEx Tracking Number	SCF.URINFEDEX						30	30			
-- Page Dynamics (SCF. URINFEDEX): Show When: SCF.URINYN = 1 AND SCF.URINSHP = 1														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618996	SYSQ_4969	SCF.DNAYN	Other / Cross Page		SCF.DNAYN <> 0 AND 10-20-ICF.DNA_CON = 0	Response to this question is not a "No" when subject did not consent to blood sample collection for DNA analysis at screening. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618997	SYSQ_4970	SCF.BLBANKYN	Other / Cross Page		SCF.BLBANKYN <> 0 AND 10-20-ICF.BLOOD_CON = 0	Response to this question is not a "No" when subject did not consent to plasma/serum banking samples for future analysis at screening. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618999	SYSQ_4971	SCF.URINYN	Other / Cross Page		SCF.URINYN <> 0 AND 10-20-ICF.URINE_CON = 0	Response to this question is not a "No" when subject did not consent to Urine banking samples for future analyses at screening. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-620181	SYSQ_5703	SCF.BLTESTYN	Field Null		SCF.BLTESTYN IS NULL	"A1. Were blood samples collected for shipment to Central Laboratory for testing?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620182	SYSQ_5704	SCF.BLTNREAS	Field Null		SCF.BLTNREAS IS NULL	"A1a. If no, reason" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620185	SYSQ_5705	SCF.BLTDAT	Field Null		SCF.BLTDAT IS NULL	"A1b. Date collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620186	SYSQ_5706	SCF.BLTDAT	Future Date		SCF.BLTDAT > Today	"A1b. Date collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620188	SYSQ_5707	SCF.BLTTIM	Field Null		SCF.BLTTIM IS NULL	"A1c. Time collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0

System Queries														
sysq-620191	SYSQ_5708	SCF.BLTTUBES	Field Null		SCF.BLTTUBES IS NULL	"A1d. Number of tubes? Enter only the number of tubes collected for shipment to Central Laboratory for testing." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620192	SYSQ_5709	SCF.BLT1ID	Field Null		SCF.BLT1ID IS NULL	"A1d1. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620195	SYSQ_5710	SCF.BLT2ID	Field Null		SCF.BLT2ID IS NULL	"A1d2. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620197	SYSQ_5711	SCF.BLT3ID	Field Null		SCF.BLT3ID IS NULL	"A1d3. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620198	SYSQ_5712	SCF.BLT4ID	Field Null		SCF.BLT4ID IS NULL	"A1d4. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620200	SYSQ_5713	SCF.BLT5ID	Field Null		SCF.BLT5ID IS NULL	"A1d5. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620203	SYSQ_5714	SCF.BLT6ID	Field Null		SCF.BLT6ID IS NULL	"A1d6. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620205	SYSQ_5715	SCF.BLT7ID	Field Null		SCF.BLT7ID IS NULL	"A1d7. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620206	SYSQ_5716	SCF.BLT8ID	Field Null		SCF.BLT8ID IS NULL	"A1d8. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0

System Queries														
sysq-620209	SYSQ_5717	SCF.BLT9ID	Field Null		SCF.BLT9ID IS NULL	"A1d9. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620210	SYSQ_5718	SCF.BLT10ID	Field Null		SCF.BLT10ID IS NULL	"A1d10. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620212	SYSQ_5719	SCF.BLT11ID	Field Null		SCF.BLT11ID IS NULL	"A1d11. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620214	SYSQ_5720	SCF.BLT12ID	Field Null		SCF.BLT12ID IS NULL	"A1d12. Blood testing - Sample ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620217	SYSQ_5721	SCF.BLTSHP	Field Null		SCF.BLTSHP IS NULL	"A1e. Was the blood sample collection shipped to the Central Laboratory?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620219	SYSQ_5722	SCF.BLTFEDEX	Field Null		SCF.BLTFEDEX IS NULL	"A1e1. FedEx Tracking Number" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620221	SYSQ_5723	SCF.BLBANKYN	Field Null		SCF.BLBANKYN IS NULL	"B1. Were plasma/serum samples collected for banking?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620222	SYSQ_5724	SCF.BLBNREAS	Field Null		SCF.BLBNREAS IS NULL	"B1a. If no, reason not collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620224	SYSQ_5725	SCF.BLBDAT	Field Null		SCF.BLBDAT IS NULL	"B1b. Date collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620226	SYSQ_5726	SCF.BLBDAT	Future Date		SCF.BLBDAT > Today	"B1b. Date collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0

System Queries														
sysq-620229	SYSQ_5727	SCF.BLBTIM	Field Null		SCF.BLBTIM IS NULL	"B1c. Time collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620231	SYSQ_5728	SCF.BLB1ID	Field Null		SCF.BLB1ID IS NULL	"B1d. Plasma banking tube - Sample ID" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620233	SYSQ_5729	SCF.BLB2ID	Field Null		SCF.BLB2ID IS NULL	"B1e. Serum banking tube - Sample ID" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620234	SYSQ_5730	SCF.BLBSHP	Field Null		SCF.BLBSHP IS NULL	"B1f. Were the plasma/serum samples shipped to the repository?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620236	SYSQ_5731	SCF.BLBFEDEX	Field Null		SCF.BLBFEDEX IS NULL	"B1f1. FedEx Tracking Number" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620239	SYSQ_5732	SCF.DNAYN	Field Null		SCF.DNAYN IS NULL	"C1. Was DNA collected?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620241	SYSQ_5733	SCF.DNAREAS	Field Null		SCF.DNAREAS IS NULL	"C1a. If no, reason not collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620242	SYSQ_5734	SCF.DNATYP	Field Null		SCF.DNATYP IS NULL	"C1b. Sample collection type" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620244	SYSQ_5735	SCF.DNADAT	Field Null		SCF.DNADAT IS NULL	"C1c. Date collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620246	SYSQ_5736	SCF.DNADAT	Future Date		SCF.DNADAT > Today	"C1c. Date collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0

System Queries														
sysq-620249	SYSQ_5737	SCF.DNATIM	Field Null		SCF.DNATIM IS NULL	"C1d. Time collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620251	SYSQ_5738	SCF.DNAID	Field Null		SCF.DNAID IS NULL	"C1e. DNA - Sample ID" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620253	SYSQ_5739	SCF.DNASHP	Field Null		SCF.DNASHP IS NULL	"C1f. Was the DNA specimen shipped to the repository?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620254	SYSQ_5740	SCF.DNAFEDEX	Field Null		SCF.DNAFEDEX IS NULL	"C1f1. FedEx Tracking Number" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620257	SYSQ_5741	SCF.URINYN	Field Null		SCF.URINYN IS NULL	"D1. Were urine samples collected for banking?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620259	SYSQ_5742	SCF.URINREAS	Field Null		SCF.URINREAS IS NULL	"D1a. If no, reason not collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620261	SYSQ_5743	SCF.URINDAT	Field Null		SCF.URINDAT IS NULL	"D1b. Date collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620263	SYSQ_5744	SCF.URINDAT	Future Date		SCF.URINDAT > Today	"D1b. Date collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620264	SYSQ_5745	SCF.URINTIM	Field Null		SCF.URINTIM IS NULL	"D1c. Time collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620267	SYSQ_5746	SCF.URINTUBES	Field Null		SCF.URINTUBES IS NULL	"D1d. Number of tubes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0

System Queries														
sysq-620268	SYSQ_5747	SCF.URIN1ID	Field Null		SCF.URIN1ID IS NULL	"D1d1. Urine banking - Sample ID #1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620270	SYSQ_5748	SCF.URIN2ID	Field Null		SCF.URIN2ID IS NULL	"D1d2. Urine banking - Sample ID #2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620272	SYSQ_5749	SCF.URIN3ID	Field Null		SCF.URIN3ID IS NULL	"D1d3. Urine banking - Sample ID #3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620275	SYSQ_5750	SCF.URINSHP	Field Null		SCF.URINSHP IS NULL	"D1e. Were the samples shipped to the Biorepository?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620277	SYSQ_5751	SCF.URINFEDEX	Field Null		SCF.URINFEDEX IS NULL	"D1e1. FedEx Tracking Number" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620278	SYSQ_5752	SCF.BLTTUBES	Range		SCF.BLTTUBES < 1 OR SCF.BLTTUBES > 12	"A1d. Number of tubes?" is not within expected range. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620281	SYSQ_5753	SCF.URINTUBES	Range		SCF.URINTUBES < 1 OR SCF.URINTUBES > 3	"D1d. Number of tubes" is not within expected range. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0

pSpecColl_2

Page

(Visit ID = 618813, Page ID =)

Unique Identifier page-618813-618813-618813-

SECTION A: BLOOD SAMPLE COLLECTION:

* A1. Were blood samples collected for shipment to Central Laboratory for testing?	○ Yes ○ No	SCF.BLTESTYN

Enter the DOIT ID#s for blood samples that are collected for Central Laboratory or LabCorp.
In section A, enter the digits after "DOIT" on the sample label including dashes for samples ending in –A, -B, or –C only.
For Example: Gold-top serum tube DOIT00-NNN-A1 collected at Baseline (Month 0), should be entered into the field below as 00-NNN-A1 (where "NNN" represents the 3-digit numeric ID assigned by the Central Lab) .

The Question below: "A1d. Number of tubes?" should be ONLY the Number of tubes that were actually SHIPPED to Central Laboratory for testing and NOT the overall number collected.

* A1a. If no, reason		SCF.BLTNREAS
* A1b. Date collected		SCF.BLTDAT
* A1c. Time collected	:	SCF.BLTTIM (HH24:MI)
* A1d. Number of tubes? Enter only the number of tubes collected for shipment to Central Laboratory for testing.		SCF.BLTTUBES (format xx)
* A1d1. Blood testing - DOIT ID#		SCF.BLT1ID
* A1d2. Blood testing - DOIT ID#		SCF.BLT2ID
* A1d3. Blood testing - DOIT ID#		SCF.BLT3ID
* A1d4. Blood testing - DOIT ID#		SCF.BLT4ID
* A1d5. Blood testing - DOIT ID#		SCF.BLT5ID
* A1d6. Blood testing - DOIT ID#		SCF.BLT6ID

* A1d7. Blood testing - DOIT ID#		SCF.BLT7ID
* A1d8. Blood testing - DOIT ID#		SCF.BLT8ID
* A1d9. Blood testing - DOIT ID#		SCF.BLT9ID
* A1d10. Blood testing - DOIT ID#		SCF.BLT10ID
* A1d11. Blood testing - DOIT ID#		SCF.BLT11ID
* A1d12. Blood testing - DOIT ID#		SCF.BLT12ID
* A1e. Was the blood sample collection shipped to the Central Laboratory?	○ Yes ○ No	SCF.BLTSHP
* A1e1. Shipment Tracking Number		SCF.BLTFEDEX
SECTION B. PLASMA/SERUM BANKING:		
PLASMA/SERUM BANKING is collected at Baseline, 6, 12, 18 and 24 Months.		
* B1. Were plasma/serum samples collected for banking?	○ Yes ○ No	SCF.BLBANKYN
* B1a. If no, reason not collected		SCF.BLBNREAS
* B1b. Date collected		SCF.BLBDAT
* B1c. Time collected	:	SCF.BLBTIM (HH24:MI)
* B1d1. Plasma banking tube - DOIT ID#1		SCF.BLB1ID
* B1d2. Plasma banking tube - DOIT ID#2		SCF.BLB1ID2D
* B1e1. Serum banking tube - DOIT ID#1		SCF.BLB2ID
* B1e2. Serum banking tube - DOIT ID#2		SCF.BLB2ID2E
* B1f. Were the plasma/serum samples shipped to the repository?	○ Yes ○ No	SCF.BLBSHP
* B1f1. Shipment Tracking Number		SCF.BLBFEDEX
SECTION C. DNA BANKING:		
DNA BANKING is collected at Baseline and 24 Month ONLY		
* C1. Was DNA collected?	○ Yes ○ No	SCF.DNAYN

	* C1a. If no, reason not collected		SCF.DNAREAS
	* C1b. Sample collection type	○ Blood ○ Saliva	SCF.DNATYP
	* C1c. Date collected		SCF.DNADAT
	* C1d. Time collected		SCF.DNATIM (HH24:MI)
	* C1e. DNA - DOIT ID #		SCF.DNAID
	* C1f. Was the DNA specimen shipped to the repository?	○ Yes ○ No	SCF.DNASHP
	* C1f1. Shipment Tracking Number		SCF.DNAFEDEX
SECTION D. URINE BANKING:			
	URINE BANKING is collected at Baseline, 6 and 24 Months ONLY.		
	* D1. Were urine samples collected for banking?	○ Yes ○ No	SCF.URINYN
	* D1a. If no, reason not collected		SCF.URINREAS
	* D1b. Date collected		SCF.URINDAT
	* D1c. Time collected		SCF.URINTIM (HH24:MI)
	* D1d. Number of tubes		SCF.URINTUBES (format xx)
	* D1d1. Urine banking - DOIT ID #1		SCF.URIN1ID
	* D1d2. Urine banking - DOIT ID #2		SCF.URIN2ID
	* D1d3. Urine banking - DOIT ID #3		SCF.URIN3ID
	* D1e. Were the samples shipped to the Biorepository?	○ Yes ○ No	SCF.URINSHP
	* D1e1. Shipment Tracking Number		SCF.URINFEDEX

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text

Page Information															
Page-1-618813	Section Header	0	SECTION A: BLOOD SAMPLE COLLECTION:												
Page-2-618813	Radiolist Horizontal	0	A1. Were blood samples collected for shipment to Central Laboratory for testing?	SCF.BLTESTYN					cYN						
Page-3-618813	Help Text Line	0	Enter the DOIT ID#s for blood samples that are collected for Central Laboratory or LabCorp. In section A, enter the digits after “DOIT” on the sample label including dashes for samples ending in –A, -B, or –C only. For Example: Gold-top serum tube DOIT00-NNN-A1 collected at Baseline (Month 0), should be entered into the field below as 00-NNN-A1 (where “NNN” represents the 3-digit numeric ID assigned by the Central Lab) . The Question below: "A1d. Number of tubes?" should be ONLY the Number of tubes that were actually <u>SHIPPED</u> to Central Laboratory for testing and NOT the overall number collected.												
Page-4-618813	Comments	1	A1a. If no, reason	SCF.BLTNREAS											
-- Page Dynamics (SCF.BLTNREAS): Show When: SCF.BLTESTYN = 0															
Page-5-618813	Date	1	A1b. Date collected	SCF.BLTDAT											
-- Page Dynamics (SCF.BLTDAT): Show When: SCF.BLTESTYN = 1															
Page-6-618813	Time	1	A1c. Time collected	SCF.BLTTIM											
-- Page Dynamics (SCF.BLTTIM): Show When: SCF.BLTESTYN = 1															

Page Information														
Page-7-618813	Numeric	1	A1d. Number of tubes? Enter only the number of tubes collected for shipment to Central Laboratory for testing.	SCF.BLTTUBES								2	0	Total number of tubes with labels DOITNN-NNN-A1 through –A4, -B1 through –B3, and –C <font color = '#FF0000'>"A1d. Number of tubes?" refers to ONLY the Number of tubes that were actually <u>SHIPPED</u> to Central Laboratory for testing and NOT the overall number collected.
-- Page Dynamics (SCF. BLTTUBES): Show When: SCF.BLTESTYN = 1														
Page-8-618813	Text Field	2	A1d1. Blood testing - DOIT ID#	SCF.BLT1ID						13	13			
-- Page Dynamics (SCF. BLT1ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 1														
Page-9-618813	Text Field	2	A1d2. Blood testing - DOIT ID#	SCF.BLT2ID						13	13			
-- Page Dynamics (SCF. BLT2ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 2														
Page-10-618813	Text Field	2	A1d3. Blood testing - DOIT ID#	SCF.BLT3ID						13	13			
-- Page Dynamics (SCF. BLT3ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 3														
Page-11-618813	Text Field	2	A1d4. Blood testing - DOIT ID#	SCF.BLT4ID						13	13			
-- Page Dynamics (SCF. BLT4ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 4														
Page-12-618813	Text Field	2	A1d5. Blood testing - DOIT ID#	SCF.BLT5ID						13	13			
-- Page Dynamics (SCF. BLT5ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 5														
Page-13-618813	Text Field	2	A1d6. Blood testing - DOIT ID#	SCF.BLT6ID						13	13			
-- Page Dynamics (SCF. BLT6ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 6														
Page-14-618813	Text Field	2	A1d7. Blood testing - DOIT ID#	SCF.BLT7ID						13	13			
-- Page Dynamics (SCF. BLT7ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 7														

Page Information														
Page-15-618813	Text Field	2	A1d8. Blood testing - DOIT ID#	SCF.BLT8ID						13	13			
-- Page Dynamics (SCF. BLT8ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 8														
Page-16-618813	Text Field	2	A1d9. Blood testing - DOIT ID#	SCF.BLT9ID						13	13			
-- Page Dynamics (SCF. BLT9ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 9														
Page-17-618813	Text Field	2	A1d10. Blood testing - DOIT ID#	SCF.BLT10ID						13	13			
-- Page Dynamics (SCF. BLT10ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 10														
Page-18-618813	Text Field	2	A1d11. Blood testing - DOIT ID#	SCF.BLT11ID						13	13			
-- Page Dynamics (SCF. BLT11ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 11														
Page-19-618813	Text Field	2	A1d12. Blood testing - DOIT ID#	SCF.BLT12ID						13	13			
-- Page Dynamics (SCF. BLT12ID): Show When: SCF.BLTESTYN = 1 AND SCF.BLTTUBES >= 12														
Page-20-618813	Radiolist Horizontal	1	A1e. Was the blood sample collection shipped to the Central Laboratory?	SCF.BLTSHP					cYN					
-- Page Dynamics (SCF. BLTSHP): Show When: SCF.BLTESTYN = 1														
Page-21-618813	Text Field	2	A1e1. Shipment Tracking Number	SCF.BLTFEDEX						30	30			Enter the UPS (or FedEX) tracking number of the shipment.
-- Page Dynamics (SCF. BLTFEDEX): Show When: SCF.BLTESTYN = 1 AND SCF.BLTSHP = 1														
Page-22-618813	Section Header	0	SECTION B. PLASMA/SERUM BANKING:											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90 OR VISITID = 140)														
Page-23-618813	Help Text Line	0	PLASMA/SERUM BANKING is collected at Baseline, 6, 12, 18 and 24 Months.											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90 OR VISITID = 140)														
Page-24-618813	Radiolist Horizontal	0	B1. Were plasma/serum samples collected for banking?	SCF.BLBANKYN					cYN					
-- Page Dynamics (SCF. BLBANKYN): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90 OR VISITID = 140)														
Page-25-618813	Comments	1	B1a. If no, reason not collected	SCF.BLBNREAS										

Page Information														
-- Page Dynamics (SCF. BLBNREAS): Show When: SCF.BLBANKYN = 0														
Page-26-618813	Date	1	B1b. Date collected	SCF. BLBDAT										
-- Page Dynamics (SCF. BLBDAT): Show When: SCF.BLBANKYN = 1														
Page-27-618813	Time	1	B1c. Time collected	SCF. BLBTIM										
-- Page Dynamics (SCF. BLBTIM): Show When: SCF.BLBANKYN = 1														
Page-28-618813	Text Field	1	B1d1. Plasma banking tube - DOIT ID#1	SCF. BLB1ID						13	13			For Plasma Banking, enter tubes with labels DOITNN-NNN-P1 and DOITNN-NNN-P2. Enter the digits after “DOIT” on the sample label including dashes (Example: if the sample label was DOIT00-001-P1, you would enter "00-001-P1" into the data entry field).
-- Page Dynamics (SCF. BLB1ID): Show When: SCF.BLBANKYN = 1														
Page-29-618813	Text Field	1	B1d2. Plasma banking tube - DOIT ID#2	SCF. BLB1ID2D						13	13			For Plasma Banking, enter tubes with labels DOITNN-NNN-P1 and DOITNN-NNN-P2. Enter the digits after “DOIT” on the sample label including dashes (Example: if the sample label was DOIT00-001-P1, you would enter "00-001-P1" into the data entry field).
-- Page Dynamics (SCF. BLB1ID2D): Show When: SCF.BLBANKYN = 1														

Page Information														
Page-30-618813	Text Field	1	B1e1. Serum banking tube - DOIT ID#1	SCF.BLB2ID						13	13			For Serum Banking, enter tubes with labels DOITNN-NNN-S1 and DOITNN-NNN-S2. Enter the digits after “DOIT” on the sample label including dashes (Example: if the sample label was DOIT00-001-S1, you would enter "00-001-S1" into the data entry field).
-- Page Dynamics (SCF.BLB2ID): Show When: SCF.BLBANKYN = 1														
Page-31-618813	Text Field	1	B1e2. Serum banking tube - DOIT ID#2	SCF.BLB2ID2E						13	13			For Serum Banking, enter tubes with labels DOITNN-NNN-S1 and DOITNN-NNN-S2. Enter the digits after “DOIT” on the sample label including dashes (Example: if the sample label was DOIT00-001-S1, you would enter "00-001-S1" into the data entry field).
-- Page Dynamics (SCF.BLB2ID2E): Show When: SCF.BLBANKYN = 1														
Page-32-618813	Radiolist Horizontal	1	B1f. Were the plasma/serum samples shipped to the repository?	SCF.BLBSHP					cYN					
-- Page Dynamics (SCF.BLBSHP): Show When: SCF.BLBANKYN = 1														
Page-33-618813	Text Field	2	B1f1. Shipment Tracking Number	SCF.BLBFEDEX						30	30			Enter the UPS (or FedEX) tracking number of the shipment.
-- Page Dynamics (SCF.BLBFEDEX): Show When: SCF.BLBANKYN = 1 AND SCF.BLBSHP = 1														
Page-34-618813	Section Header	0	SECTION C. DNA BANKING:											

Page Information														
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 90 OR VISITID = 140)														
Page-35-618813	Help Text Line	0	DNA BANKING is collected at Baseline and 24 Month ONLY											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 90 OR VISITID = 140)														
Page-36-618813	Radiolist Horizontal	0	C1. Was DNA collected?	SCF.DNAYN					cYN					
-- Page Dynamics (SCF. DNAYN): Show When: (VISITID = 20 OR VISITID = 90 OR VISITID = 140)														
Page-37-618813	Comments	1	C1a. If no, reason not collected	SCF.DNAREAS										
-- Page Dynamics (SCF. DNAREAS): Show When: SCF.DNAYN = 0														
Page-38-618813	Radiolist Horizontal	1	C1b. Sample collection type	SCF.DNATYP					cDNATYPE					
-- Page Dynamics (SCF. DNATYP): Show When: SCF.DNAYN = 1														
Page-39-618813	Date	1	C1c. Date collected	SCF.DNADAT										
-- Page Dynamics (SCF. DNADAT): Show When: SCF.DNAYN = 1														
Page-40-618813	Time	1	C1d. Time collected	SCF.DNATIM										
-- Page Dynamics (SCF. DNATIM): Show When: SCF.DNAYN = 1														
Page-41-618813	Text Field	1	C1e. DNA - DOIT ID #	SCF.DNAID						13	13			Enter the digits after “DOIT” on the sample label including dashes for samples ending in –D (Example: if the sample label was DOIT00-001-D, you would enter "00-001-D" into the data entry field).</i>
-- Page Dynamics (SCF. DNAID): Show When: SCF.DNAYN = 1														
Page-42-618813	Radiolist Horizontal	1	C1f. Was the DNA specimen shipped to the repository?	SCF.DNASHP					cYN					
-- Page Dynamics (SCF. DNASHP): Show When: SCF.DNAYN = 1														
Page-43-618813	Text Field	2	C1f1. Shipment Tracking Number	SCF.DNAFEDEX						30	30			Enter the UPS (or FedEX) tracking number of the shipment.
-- Page Dynamics (SCF. DNAFEDEX): Show When: SCF.DNAYN = 1 AND SCF.DNASHP = 1														

Page Information														
Page-44-618813	Section Header	0	SECTION D. URINE BANKING:											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 90 OR VISITID = 140)														
Page-45-618813	Help Text Line	0	URINE BANKING is collected at Baseline, 6 and 24 Months ONLY.											
-- Page Dynamics (.): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 90 OR VISITID = 140)														
Page-46-618813	Radiolist Horizontal	0	D1. Were urine samples collected for banking?	SCF.URINYN					cYN					
-- Page Dynamics (SCF. URINYN): Show When: (VISITID = 20 OR VISITID = 50 OR VISITID = 90 OR VISITID = 140)														
Page-47-618813	Comments	1	D1a. If no, reason not collected	SCF.URINREAS										
-- Page Dynamics (SCF. URINREAS): Show When: SCF.URINYN = 0														
Page-48-618813	Date	1	D1b. Date collected	SCF.URINDAT										
-- Page Dynamics (SCF. URINDAT): Show When: SCF.URINYN = 1														
Page-49-618813	Time	1	D1c. Time collected	SCF.URINTIM										
-- Page Dynamics (SCF. URINTIM): Show When: SCF.URINYN = 1														
Page-50-618813	Numeric	1	D1d. Number of tubes	SCF.URINTUBES								2	0	D1d. Enter total number of tubes with labels DOITNN-NNN-U1 through –U2.
-- Page Dynamics (SCF. URINTUBES): Show When: SCF.URINYN = 1														
Page-51-618813	Text Field	2	D1d1. Urine banking - DOIT ID #1	SCF.URIN1ID						13	13			Enter the digits after “DOIT” on the sample label including dashes for samples ending in –U (Example: if the sample labels were DOIT00-001-U1 and DOIT00-001-U2, you would enter "00-001-U1” and “00-001-U2" into the data entry fields).</i>
-- Page Dynamics (SCF. URIN1ID): Show When: SCF.URINYN = 1 AND SCF.URINTUBES >= 1														

Page Information															
Page-52-618813	Text Field	2	D1d2. Urine banking - DOIT ID #2	SCF.URIN2ID						13	13				
-- Page Dynamics (SCF.URIN2ID): Show When: SCF.URINYN = 1 AND SCF.URINTUBES >= 2															
Page-53-618813	Text Field	2	D1d3. Urine banking - DOIT ID #3	SCF.URIN3ID						13	13				
-- Page Dynamics (SCF.URIN3ID): Show When: SCF.URINYN = 1 AND SCF.URINTUBES >= 3															
Page-54-618813	Radiolist Horizontal	1	D1e. Were the samples shipped to the Biorepository?	SCF.URINSHP					cYN						
-- Page Dynamics (SCF.URINSHP): Show When: SCF.URINYN = 1															
Page-55-618813	Text Field	2	D1e1. Shipment Tracking Number	SCF.URINFEDEX						30	30			Enter the UPS (or FedEX) tracking number of the shipment.	
-- Page Dynamics (SCF.URINFEDEX): Show When: SCF.URINYN = 1 AND SCF.URINSHP = 1															

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618995	SYSQ_4969	SCF.DNAYN	Other / Cross Page		SCF.DNAYN <> 0 AND 10-20-ICF.DNA_CON = 0	Response to this question is not a "No" when subject did not consent to blood sample collection for DNA analysis at screening. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-618998	SYSQ_4970	SCF.BLBANKYN	Other / Cross Page		SCF.BLBANKYN <> 0 AND 10-20-ICF.BLOOD_CON = 0	Response to this question is not a "No" when subject did not consent to plasma/serum banking samples for future analysis at screening. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619000	SYSQ_4971	SCF.URINYN	Other / Cross Page		SCF.URINYN <> 0 AND 10-20-ICF.URINE_CON = 0	Response to this question is not a "No" when subject did not consent to Urine banking samples for future analyses at screening. Please review and update.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-620180	SYSQ_5703	SCF.BLTESTYN	Field Null		SCF.BLTESTYN IS NULL	"A1. Were blood samples collected for shipment to Central Laboratory for testing?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0

System Queries														
sysq-620183	SYSQ_5704	SCF.BLTNREAS	Field Null		SCF.BLTNREAS IS NULL	"A1a. If no, reason" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620184	SYSQ_5705	SCF.BLTDAT	Field Null		SCF.BLTDAT IS NULL	"A1b. Date collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620187	SYSQ_5706	SCF.BLTDAT	Future Date		SCF.BLTDAT > Today	"A1b. Date collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620189	SYSQ_5707	SCF.BLTTIM	Field Null		SCF.BLTTIM IS NULL	"A1c. Time collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620190	SYSQ_5708	SCF.BLTTUBES	Field Null		SCF.BLTTUBES IS NULL	"A1d. Number of tubes? Enter only the number of tubes collected for shipment to Central Laboratory for testing." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620193	SYSQ_5709	SCF.BLT1ID	Field Null		SCF.BLT1ID IS NULL	"A1d1. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620194	SYSQ_5710	SCF.BLT2ID	Field Null		SCF.BLT2ID IS NULL	"A1d2. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620196	SYSQ_5711	SCF.BLT3ID	Field Null		SCF.BLT3ID IS NULL	"A1d3. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620199	SYSQ_5712	SCF.BLT4ID	Field Null		SCF.BLT4ID IS NULL	"A1d4. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0

System Queries														
sysq-620201	SYSQ_5713	SCF.BLT5ID	Field Null		SCF.BLT5ID IS NULL	"A1d5. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620202	SYSQ_5714	SCF.BLT6ID	Field Null		SCF.BLT6ID IS NULL	"A1d6. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:53	0	0	0	0	0	0
sysq-620204	SYSQ_5715	SCF.BLT7ID	Field Null		SCF.BLT7ID IS NULL	"A1d7. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620207	SYSQ_5716	SCF.BLT8ID	Field Null		SCF.BLT8ID IS NULL	"A1d8. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620208	SYSQ_5717	SCF.BLT9ID	Field Null		SCF.BLT9ID IS NULL	"A1d9. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620211	SYSQ_5718	SCF.BLT10ID	Field Null		SCF.BLT10ID IS NULL	"A1d10. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620213	SYSQ_5719	SCF.BLT11ID	Field Null		SCF.BLT11ID IS NULL	"A1d11. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620215	SYSQ_5720	SCF.BLT12ID	Field Null		SCF.BLT12ID IS NULL	"A1d12. Blood testing - DOIT ID#" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620216	SYSQ_5721	SCF.BLTSHP	Field Null		SCF.BLTSHP IS NULL	"A1e. Was the blood sample collection shipped to the Central Laboratory?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620218	SYSQ_5722	SCF.BLTFEDEX	Field Null		SCF.BLTFEDEX IS NULL	"A1e1. Shipment Tracking Number" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0

System Queries														
sysq-620220	SYSQ_57023	SCF.BLBANKYN	Field Null		SCF.BLBANKYN IS NULL	"B1. Were plasma/serum samples collected for banking?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620223	SYSQ_57024	SCF.BLBNREAS	Field Null		SCF.BLBNREAS IS NULL	"B1a. If no, reason not collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620225	SYSQ_57025	SCF.BLBDAT	Field Null		SCF.BLBDAT IS NULL	"B1b. Date collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620227	SYSQ_57026	SCF.BLBDAT	Future Date		SCF.BLBDAT > Today	"B1b. Date collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620228	SYSQ_57027	SCF.BLBTIM	Field Null		SCF.BLBTIM IS NULL	"B1c. Time collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620230	SYSQ_57028	SCF.BLB1ID	Field Null		SCF.BLB1ID IS NULL	"B1d. Plasma banking tube - DOIT ID #1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:54	0	0	0	0	0	0
sysq-620232	SYSQ_57029	SCF.BLB2ID	Field Null		SCF.BLB2ID IS NULL	"B1e. Serum banking tube - DOIT ID #1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620235	SYSQ_57030	SCF.BLBSHP	Field Null		SCF.BLBSHP IS NULL	"B1f. Were the plasma/serum samples shipped to the repository?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620237	SYSQ_57031	SCF.BLBFEDEX	Field Null		SCF.BLBFEDEX IS NULL	"B1f1. Shipment Tracking Number" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620238	SYSQ_57032	SCF.DNAYN	Field Null		SCF.DNAYN IS NULL	"C1. Was DNA collected?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0

System Queries														
sysq-620240	SYSQ_5733	SCF.DNAREAS	Field Null		SCF.DNAREAS IS NULL	"C1a. If no, reason not collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620243	SYSQ_5734	SCF.DNATYP	Field Null		SCF.DNATYP IS NULL	"C1b. Sample collection type" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620245	SYSQ_5735	SCF.DNADAT	Field Null		SCF.DNADAT IS NULL	"C1c. Date collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620247	SYSQ_5736	SCF.DNADAT	Future Date		SCF.DNADAT > Today	"C1c. Date collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620248	SYSQ_5737	SCF.DNATIM	Field Null		SCF.DNATIM IS NULL	"C1d. Time collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620250	SYSQ_5738	SCF.DNAID	Field Null		SCF.DNAID IS NULL	"C1e. DNA - DOIT ID" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620252	SYSQ_5739	SCF.DNASHP	Field Null		SCF.DNASHP IS NULL	"C1f. Was the DNA specimen shipped to the repository?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620255	SYSQ_5740	SCF.DNAFEDEX	Field Null		SCF.DNAFEDEX IS NULL	"C1f1. Shipment Tracking Number" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620256	SYSQ_5741	SCF.URINYN	Field Null		SCF.URINYN IS NULL	"D1. Were urine samples collected for banking?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:55	0	0	0	0	0	0
sysq-620258	SYSQ_5742	SCF.URINREAS	Field Null		SCF.URINREAS IS NULL	"D1a. If no, reason not collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0

System Queries														
sysq-620260	SYSQ_5743	SCF.URINDAT	Field Null		SCF.URINDAT IS NULL	"D1b. Date collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620262	SYSQ_5744	SCF.URINDAT	Future Date		SCF.URINDAT > Today	"D1b. Date collected" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620265	SYSQ_5745	SCF.URINTIM	Field Null		SCF.URINTIM IS NULL	"D1c. Time collected" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620266	SYSQ_5746	SCF.URINTUBES	Field Null		SCF.URINTUBES IS NULL	"D1d. Number of tubes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620269	SYSQ_5747	SCF.URIN1ID	Field Null		SCF.URIN1ID IS NULL	"D1d1. Urine banking - DOIT ID #1" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620271	SYSQ_5748	SCF.URIN2ID	Field Null		SCF.URIN2ID IS NULL	"D1d2. Urine banking - DOIT ID #2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620273	SYSQ_5749	SCF.URIN3ID	Field Null		SCF.URIN3ID IS NULL	"D1d3. Urine banking - DOIT ID #3" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620274	SYSQ_5750	SCF.URINSHP	Field Null		SCF.URINSHP IS NULL	"D1e. Were the samples shipped to the Biorepository?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620276	SYSQ_5751	SCF.URINFEDEX	Field Null		SCF.URINFEDEX IS NULL	"D1e1. Shipment Tracking Number" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620279	SYSQ_5752	SCF.BLTTUBES	Range		SCF.BLTTUBES < 1 OR SCF.BLTTUBES > 12	"A1d. Number of tubes?" is not within expected range. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0

System Queries														
sysq-620280	SYSQ_5753	SCF.URINTUBES	Range		SCF.URINTUBES < 1 OR SCF.URINTUBES > 3	"D1d. Number of tubes" is not within expected range. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:56	0	0	0	0	0	0
sysq-620410	SYSQ_5823	SCF.BLB1ID2D	Field Null		SCF.BLB1ID2D IS NULL	"B1d2. Plasma banking tube - DOIT ID#2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0
sysq-620411	SYSQ_5824	SCF.BLB2ID2E	Field Null		SCF.BLB2ID2E IS NULL	"B1e2. Serum banking tube - DOIT ID#2" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:00	0	0	0	0	0	0

pTDIS

Page

(Visit ID = 618814, Page ID =)

Unique Identifier page-618814-618814-618814-

SECTION A: Temporary Discontinuation of Study Drug			
SDV	* A1. Date of temporary discontinuation of study drug		TDIS.TDISDAT
SDV	* A2. Reason for temporary Discontinuation of Study Drug (select all that apply)	ADD DELETE SELECTED	TDIS.REASON
SDV	A2a. If Other reason, please Specify		TDIS.SPECIFY
SDV	* A3. AE ID Number (if applicable):		TDIS.AESPID (format xxx)
SDV	* A4. Was the study drug restarted?	Yes No	TDIS.TDSTYN
SDV	* A4a. Restart Date		TDIS.TDSTDAT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618814	Section Header	0	SECTION A: Temporary Discontinuation of Study Drug											
Page-2-618814	Date	0	A1. Date of temporary discontinuation of study drug	TDIS.TDISDAT	Yes									
Page-3-618814	Many Select	0	A2. Reason for temporary Discontinuation of Study Drug (select all that apply)	TDIS.REASON	Yes				cTDIS					Select an item from the list and click the Add button. Multiple items may be added individually.
Page-4-618814	Text Field	1	A2a. If Other reason, please Specify	TDIS.SPECIFY	Yes					200	99			Only complete this field if the "Other reason" option was selected.

Page Information														
Page-5-618814	Numeric	0	A3. AE ID Number (if applicable):	TDIS.AESPID	Yes							3	0	Enter the AE ID number of the Adverse Event associated with the temporary discontinuation of study drug.
Page-6-618814	Radiolist Horizontal	0	A4. Was the study drug restarted?	TDIS.TDSTYN	Yes				cYN					
Page-7-618814	Date	1	A4a. Restart Date	TDIS.TDSTDAT	Yes									
-- Page Dynamics (TDIS. TDSTDAT): Show When: TDIS.TDSTYN = 1														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-618880	SYSQ_4492	TDIS.REASON	Field Null		TDIS.REASON IS NULL	"B3. Reason for temporary Discontinuation of Study Drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-620087	SYSQ_5651	TDIS.TDISDAT	Field Null		TDIS.TDISDAT IS NULL	"A1. Date of temporary discontinuation of study drug" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620088	SYSQ_5652	TDIS.TDISDAT	Future Date		TDIS.TDISDAT > Today	"A1. Date of temporary discontinuation of study drug" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620089	SYSQ_5653	TDIS.AESPID	Field Null		TDIS.AESPID IS NULL	"A3. AE ID Number (if applicable):" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620090	SYSQ_5654	TDIS.TDSTYN	Field Null		TDIS.TDSTYN IS NULL	"A4. Was the study drug restarted?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0
sysq-620091	SYSQ_5655	TDIS.TDSTDAT	Field Null		TDIS.TDSTDAT IS NULL	"A4a. Restart Date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:49	0	0	0	0	0	0

System Queries														
sysq-620092	SYSQ_5656	TDIS.TDSTDAT	Future Date		TDIS.TDSTDAT > Today	"A4a. Restart Date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620093	SYSQ_5657	TDIS.TDSTDAT	Field Compare		TDIS.TDSTDAT < TDIS.TDISDAT	"A4a. Restart Date" is prior to Date of temporary discontinuation of study drug. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620094	SYSQ_5658	TDIS.SPECIFY	Other / Cross Page		TDIS.REASON NOT INTERSECTS 99 AND TDIS.SPECIFY IS NOT NULL	An 'Other reason' was not selected as a reason for temporary Discontinuation of Study Drug, however, a response for other was provided. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0
sysq-620095	SYSQ_5659	TDIS.SPECIFY	Other / Cross Page		TDIS.REASON INTERSECTS 99 AND TDIS.SPECIFY IS NULL	An 'Other reason' was selected as one of the reasons for temporary Discontinuation of Study Drug, however, a response for other, specify was not provided. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:50	0	0	0	0	0	0

pTSTAGE_F

Page

(Visit ID = 618815, Page ID =)

Unique Identifier page-618815-618815-618815-

SECTION A: GENERAL INFORMATION			
SDV	* A1. Visit Date		TSTAGE_F. VISIT_DT
SDV	* A2: Age		TSTAGE_F. AGE (format xx)
SDV	* A3: Had menarche (first menses) occurred?	○ Yes ○ No	TSTAGE_F. MENSES
SDV	* A3a. Age at menarche (first menses):		TSTAGE_F. AGEMENSES (format xx)

SECTION B: GIRLS TANNER STAGE - BREAST DEVELOPMENT AND PUBIC HAIR

Physical changes are important events. These changes start at different ages. It usually takes about four years from the first changes to the last. Please enter the stage that most closely matches your breast and public hair development.

Refer to the pictures shown below enter the most closely matches your breast development and pubic hair.

Description of Stages for Breast Development:
Stage 1: No breast development
Stage 2: Small bumps under the nipples. The darker skin around the nipples looks bigger.
Stage 3: Larger bumps that are smooth. Each breast is only one bump.
Stage 4: The darker skin and nipple are a bump on the top of the bump of the breast
Stage 5: The darker skin around the nipple is smooth with the rest of the breast. The nipple may poke out from the darker skin.

SDV	* B1. Please provide the most accurate response and only check one response.	○ Stage 1 ○ Stage 2 ○ Stage 3 ○ Stage 4 ○ Stage 5	TSTAGE_F. BREAST

Description of Stages for Pubic Hair Development:
(If you shave your hair, think about the places where you need to shave and that will help you decide which stage best describes you.)
Stage 1: No hair
Stage 2: A few long, darker hairs. The hairs may be straight or curled and are only along the “lips”, close to the middle of the genital (private) area.
Stage 3: More hair than stage 2. The hair is also darker, thicker and curlier and grows farther away from the middle.
Stage 4: Thick, curly hair, more than for stage 3, but doesn’t cover the inner thighs.
Stage 5: Thick, curly hair that extends onto inner thighs.

SDV	* B2. Please provide the most accurate response and only check one response.	○ Stage 1 ○ Stage 2 ○ Stage 3 ○ Stage 4 ○ Stage 5	TSTAGE_F. PUBIC

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618815	Section Header	0	SECTION A: GENERAL INFORMATION											
Page-2-618815	Date	0	A1. Visit Date	TSTAGE_F. VISIT_DT	Yes									
Page-3-618815	Numeric	0	A2: Age	TSTAGE_F. AGE	Yes							2	0	
Page-4-618815	Radiolist Horizontal	0	A3: Had menarche (first menses) occurred?	TSTAGE_F. MENSES	Yes				cYN					
Page-5-618815	Numeric	1	A3a. Age at menarche (first menses):	TSTAGE_F. AGEMENSES	Yes							2	0	
-- Page Dynamics (TSTAGE_F. AGEMENSES): Show When: TSTAGE_F.MENSES = 1														
Page-6-618815	Section Header	0	SECTION B: GIRLS TANNER STAGE - BREAST DEVELOPMENT AND PUBIC HAIR											
Page-7-618815	Help Text Line	0	Physical changes are important events. These changes start at different ages. It usually takes about four years from the first changes to the last. Please enter the stage that most closely matches your breast and public hair development.											
Page-8-618815	Help Text Line	0	Refer to the pictures shown below enter the most closely matches your breast development and pubic hair.											

Page Information														
Page-9-618815	Help Text Line	0	<img src="https://secure.eclinicalos.com/customStyles/9094/Tanner_stage_girl_50.jpg">											
Page-10-618815	Help Text Line	0	Description of Stages for Breast Development: Stage 1: No breast development Stage 2: Small bumps under the nipples. The darker skin around the nipples looks bigger. Stage 3: Larger bumps that are smooth. Each breast is only one bump. Stage 4: The darker skin and nipple are a bump on the top of the bump of the breast Stage 5: The darker skin around the nipple is smooth with the rest of the breast. The nipple may poke out from the darker skin.											
Page-11-618815	Radiolist	0	B1. Please provide the most accurate response and only check one response.	TSTAGE_F.BREAST	Yes				cSTAGES					
Page-12-618815	Help Text Line	0	Description of Stages for Pubic Hair Development: (If you shave your hair, think about the places where you need to shave and that will help you decide which stage best describes you.) Stage 1: No hair Stage 2: A few long, darker hairs. The hairs may be straight or curled and are only along the “lips”, close to the middle of the genital (private) area. Stage 3: More hair than stage 2. The hair is also darker, thicker and curlier and grows farther away from the middle. Stage 4: Thick, curly hair, more than for stage 3, but doesn’t cover the inner thighs. Stage 5: Thick, curly hair that extends onto inner thighs.											
Page-13-618815	Radiolist	0	B2. Please provide the most accurate response and only check one response.	TSTAGE_F.PUBIC	Yes				cSTAGES					

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619827	SYSQ_5462	TSTAGE_F.VISIT_DT	Field Null		TSTAGE_F.VISIT_DT IS NULL	"A1. Visit Date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619828	SYSQ_5463	TSTAGE_F.VISIT_DT	Future Date		TSTAGE_F.VISIT_DT > Today	"A1. Visit Date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619829	SYSQ_5464	TSTAGE_F.AGE	Field Null		TSTAGE_F.AGE IS NULL	"A2: Age" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619830	SYSQ_5465	TSTAGE_F.MENSES	Field Null		TSTAGE_F.MENSES IS NULL	"A3: Had menarche (first menses) occurred?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619831	SYSQ_5466	TSTAGE_F.AGEMENSES	Field Null		TSTAGE_F.AGEMENSES IS NULL	"A3a. Age at menarche (first menses):" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619832	SYSQ_5467	TSTAGE_F.BREAST	Field Null		TSTAGE_F.BREAST IS NULL	"B1. Please provide the most accurate response and only check one response." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619833	SYSQ_5468	TSTAGE_F.PUBIC	Field Null		TSTAGE_F.PUBIC IS NULL	"B2. Please provide the most accurate response and only check one response." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0

pTSTAGE_M

Page

(Visit ID = 618816, Page ID =)

Unique Identifier page-618816-618816-618816-

SECTION A: GENERAL INFORMATION

SDV	* A1. Visit Date		TSTAGE_M. VISIT_DT
SDV	* A2: Age		TSTAGE_M. AGE (format xx)

SECTION B: BOYS TANNER STAGE - GENITAL DEVELOPMENT OF PENIS AND PUBIC HAIR

Physical changes are important events. These changes start at different ages. It usually takes about four years from the first changes to the last. Please enter the stage that most closely matches your penis, testes and public hair development.

Refer to the pictures shown below enter the most closely matches your genital development and pubic hair.

Description of Stages for Penis Development:
Stage 1: Prepubertal – no growth of penis or testes (“balls”)
Stage 2: Testes (“balls”) have started growing. The scrotum skin (the “sack”) looks more red and has wrinkles.
Stage 3: The penis is longer, but not thicker. The testes (“balls”) are larger
Stage 4: The penis is longer and thicker, and the “head” of the penis is larger. The testes (“balls”) are even larger. The scrotum skin (the “sack”) looks darker.
Stage 5: The penis and testes (“balls”) have stopped growing

SDV	* B1. Please provide the most accurate response and only check one response.	○ Stage 1 ○ Stage 2 ○ Stage 3 ○ Stage 4 ○ Stage 5	TSTAGE_M. PENIS

Description of stages for Pubic Hair Development:
(If you shave your hair, think about the places where you need to shave and that will help you decide which stage best describes you.)
Stage 1: No hair
Stage 2: A few long, darker hairs. The hairs may be straight or curled and are only around the base of the penis.
Stage 3: More hair than Stage 2. The hair is also darker, thicker and curlier and grows father away from the base of the penis
Stage 4: Thick, curly hair, more than for stage 3, but doesn’t cover the inner thighs.
Stage 5: Thick, curly hair that extends onto inner thighs.

SDV	* B2. Please provide the most accurate response and only check one response.	○ Stage 1 ○ Stage 2 ○ Stage 3 ○ Stage 4 ○ Stage 5	TSTAGE_M. PUBIC

Page Information														
Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618816	Section Header	0	SECTION A: GENERAL INFORMATION											
Page-2-618816	Date	0	A1. Visit Date	TSTAGE_M.VISIT_DT	Yes									
Page-3-618816	Numeric	0	A2: Age	TSTAGE_M. AGE	Yes							2	0	
Page-4-618816	Section Header	0	SECTION B: BOYS TANNER STAGE - GENITAL DEVELOPMENT OF PENIS AND PUBIC HAIR											
Page-5-618816	Help Text Line	0	Physical changes are important events. These changes start at different ages. It usually takes about four years from the first changes to the last. Please enter the stage that most closely matches your penis, testes and public hair development.											
Page-6-618816	Help Text Line	0	Refer to the pictures shown below enter the most closely matches your genital development and pubic hair.											
Page-7-618816	Help Text Line	0	<img src="https://secure.eclinicalos.com/customStyles/9094/Tanner_stage_boy__50.jpg">											

Page Information														
Page-8-618816	Help Text Line	0	Description of Stages for Penis Development: Stage 1: Prepubertal – no growth of penis or testes (“balls”) Stage 2: Testes (“balls”) have started growing. The scrotum skin (the “sack”) looks more red and has wrinkles. Stage 3: The penis is longer, but not thicker. The testes (“balls”) are larger Stage 4: The penis is longer and thicker, and the “head” of the penis is larger. The testes (“balls”) are even larger. The scrotum skin (the “sack”) looks darker. Stage 5: The penis and testes (“balls”) have stopped growing											
Page-9-618816	Radiolist	0	B1. Please provide the most accurate response and only check one response.	TSTAGE_M.PENIS	Yes				cSTAGES					
Page-10-618816	Help Text Line	0	Description of stages for Pubic Hair Development: (If you shave your hair, think about the places where you need to shave and that will help you decide which stage best describes you.) Stage 1: No hair Stage 2: A few long, darker hairs. The hairs may be straight or curled and are only around the base of the penis. Stage 3: More hair than Stage 2. The hair is also darker, thicker and curlier and grows father away from the base of the penis Stage 4: Thick, curly hair, more than for stage 3, but doesn’t cover the inner thighs. Stage 5: Thick, curly hair that extends onto inner thighs.											
Page-11-618816	Radiolist	0	B2. Please provide the most accurate response and only check one response.	TSTAGE_M.PUBIC	Yes				cSTAGES					

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619834	SYSQ_5469	TSTAGE_M.VISIT_DT	Field Null		TSTAGE_M.VISIT_DT IS NULL	"A1. Visit Date" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619835	SYSQ_5470	TSTAGE_M.VISIT_DT	Future Date		TSTAGE_M.VISIT_DT > Today	"A1. Visit Date" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619836	SYSQ_5471	TSTAGE_M.AGE	Field Null		TSTAGE_M.AGE IS NULL	"A2: Age" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619837	SYSQ_5472	TSTAGE_M.PENIS	Field Null		TSTAGE_M.PENIS IS NULL	"B1. Please provide the most accurate response and only check one response." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619838	SYSQ_5473	TSTAGE_M.PUBIC	Field Null		TSTAGE_M.PUBIC IS NULL	"B2. Please provide the most accurate response and only check one response." cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0

pUNMASK

Page

(Visit ID = 618817, Page ID =)

Unique Identifier page-618817-618817-618817-

Section A: UNMASKING

Complete one form for each individual who was unmasked

* A1. Who was unmasked?	○ Participant ○ Study staff member ○ Non-study staff member	UNMASK.UNMWHO
* A1a. Initials of staff member		UNMASK.UNMWINT
* A2. Primary reason for unmasking	○ Clinical evidence of rhabdomyolysis ○ Severe hypretriglyceridemia (confirmed TG levels >1000 mg/dL) ○ Other emergency situation which requires knowledge of study treatment to assure safety of subject. ○ Other	UNMASK.UNMREAS
* A2a. Specify other reason		UNMASK.UNMROTH
* A3. Brief description of how and/or why the unmasking occurred		UNMASK.UNMDESC
* A4. Date of disclosure (unmasking)		UNMASK.UNMDAT

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text

Page Information														
Page-1-618817	Section Header	0	Section A: UNMASKING											
Page-2-618817	Help Text Line	0	Complete one form for each individual who was unmasked											
Page-3-618817	Radiolist	0	A1. Who was unmasked?	UNMASK.UNMWHO					cUNMASKWHO					
Page-4-618817	Text Field	1	A1a. Initials of staff member	UNMASK.UNMWINT						3	3			
-- Page Dynamics (UNMASK. UNMWINT): Show When: UNMASK.UNMWHO = 2 OR UNMASK.UNMWHO = 3														
Page-5-618817	Radiolist	0	A2. Primary reason for unmasking	UNMASK.UNMREAS					cUNMASKREAS					
Page-6-618817	Text Field	1	A2a. Specify other reason	UNMASK.UNMROTH						200	99			
-- Page Dynamics (UNMASK. UNMROTH): Show When: UNMASK.UNMREAS = 99														
Page-7-618817	Comments	0	A3. Brief description of how and/or why the unmasking occurred	UNMASK.UNMDESC										
Page-8-618817	Date	0	A4. Date of disclosure (unmasking)	UNMASK.UNMDAT										

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619024	SYSQ_4984	UNMASK.UNMREAS	Other / Cross Page		UNMASK.UNMREAS = 1 OR UNMASK.UNMREAS = 2	Please complete the corresponding AE (Adverse Events) Form(s).	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0

System Queries														
sysq-619025	SYSQ_4985	UNMASK.UNMDAT	Other / Cross Page		FUNCTION-DATE_COMPARE(UNMASK.UNMDAT, 20-140-RAND.RANDDAT) > 0 OR FUNCTION-DATE_COMPARE(120-20-EOS.DATE, UNMASK.UNMDAT) > 0	Date of disclosure (unmasking) is prior to randomization or after the study exit date. Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:13	0	0	0	0	0	0
sysq-619839	SYSQ_5474	UNMASK.UNMWHO	Field Null		UNMASK.UNMWHO IS NULL	"A1. Who was unmasked?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619840	SYSQ_5475	UNMASK.UNMWINT	Field Null		UNMASK.UNMWINT IS NULL	"A1a. Initials of staff member" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619841	SYSQ_5476	UNMASK.UNMREAS	Field Null		UNMASK.UNMREAS IS NULL	"A2. Primary reason for unmasking" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619842	SYSQ_5477	UNMASK.UNMROTH	Field Null		UNMASK.UNMROTH IS NULL	"A2a. Specify other reason" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619843	SYSQ_5478	UNMASK.UNMDESC	Field Null		UNMASK.UNMDESC IS NULL	"A3. Brief description of how and/or why the unmasking occurred" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619844	SYSQ_5479	UNMASK.UNMDAT	Field Null		UNMASK.UNMDAT IS NULL	"A4. Date of disclosure (unmasking)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619845	SYSQ_5480	UNMASK.UNMDAT	Future Date		UNMASK.UNMDAT > Today	"A4. Date of disclosure (unmasking)" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0

pVASCMEAS

Page

(Visit ID = 618818, Page ID =)

Unique Identifier page-618818-618818-618818-

SECTION A: VASCULAR MEASURES		
* A1. Was the Pulse wave velocity (PWV) measurement obtained?	○ Yes ○ No	VM.PWVPERF
* A1a. Date of PWV measure		VM.PWVDAT
* A1b. Sent to core lab?	○ Yes ○ No	VM.PWVCLAB
* A2. Was a Carotid Artery Intima-Media Thickness (CIMT) measurement obtained?	○ Yes ○ No	VM.CIMTPERF
* A2a. Date of CIMT measure		VM.CIMTDAT
* A2b. Sent to core lab?	○ Yes ○ No	VM.CIMTCLAB
* A3. Was a Carotid Artery Stiffness measurement obtained?	○ Yes ○ No	VM.CASPERF
* A3a. Date of Carotid artery stiffness measure		VM.CASDAT
* A3b. Sent to core lab?	○ Yes ○ No	VM.CASCLAB

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618818	Section Header	0	SECTION A: VASCULAR MEASURES											
Page-2-618818	Radiolist Horizontal	0	A1. Was the Pulse wave velocity (PWV) measurement obtained?	VM.PWVPERF					cYN					

Page Information															
Page-3-618818	Date	1	A1a. Date of PWV measure	VM.PWVDAT											
-- Page Dynamics (VM. PWVDAT): Show When: VM.PWVPERF = 1															
Page-4-618818	Radiolist Horizontal	1	A1b. Sent to core lab?	VM.PWVCLAB					cYN						
-- Page Dynamics (VM. PWVCLAB): Show When: VM.PWVPERF = 1															
Page-5-618818	Radiolist Horizontal	0	A2. Was a Carotid Artery Intima-Media Thickness (CIMT) measurement obtained?	VM.CIMTPERF					cYN						
Page-6-618818	Date	1	A2a. Date of CIMT measure	VM.CIMTDAT											
-- Page Dynamics (VM. CIMTDAT): Show When: VM.CIMTPERF = 1															
Page-7-618818	Radiolist Horizontal	1	A2b. Sent to core lab?	VM.CIMTCLAB					cYN						
-- Page Dynamics (VM. CIMTCLAB): Show When: VM.CIMTPERF = 1															
Page-8-618818	Radiolist Horizontal	0	A3. Was a Carotid Artery Stiffness measurement obtained?	VM.CASPERF					cYN						
Page-9-618818	Date	1	A3a. Date of Carotid artery stiffness measure	VM.CASDAT											
-- Page Dynamics (VM. CASDAT): Show When: VM.CASPERF = 1															
Page-10-618818	Radiolist Horizontal	1	A3b. Sent to core lab?	VM.CASCLAB					cYN						
-- Page Dynamics (VM. CASCLAB): Show When: VM.CASPERF = 1															

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph

System Queries														
sysq-618994	SYSQ_4968	VM.PWVPERF	Other / Cross Page		(VM.PWVPERF = 0 OR VM.CIMTPERF = 0 OR VM.CASPERF = 0) AND 20-140-RAND.RANDYN = 1 AND (VISITID = 20 OR VISITID = 50 OR VISITID = 70 OR VISITID = 90)	PWV, CIMT and/or Carotid Artery Stiffness are/is reported as not done. Please confirm and if confirmed, complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:12	0	0	0	0	0	0
sysq-619219	SYSQ_5064	VM.PWVPERF	Field Null		VM.PWVPERF IS NULL	"A1. Was the Pulse wave velocity (PWV) measurement obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619220	SYSQ_5065	VM.PWVDAT	Field Null		VM.PWVDAT IS NULL	"A1a. Date of PWV measure" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619221	SYSQ_5066	VM.PWVDAT	Future Date		VM.PWVDAT > Today	"A1a. Date of PWV measure" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619222	SYSQ_5067	VM.PWVCLAB	Field Null		VM.PWVCLAB IS NULL	"A1b. Sent to core lab?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619223	SYSQ_5068	VM.CIMTPERF	Field Null		VM.CIMTPERF IS NULL	"A2. Was a Carotid Artery Intima-Media Thickness (CIMT) measurement obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619224	SYSQ_5069	VM.CIMTDAT	Field Null		VM.CIMTDAT IS NULL	"A2a. Date of CIMT measure" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619225	SYSQ_5070	VM.CIMTDAT	Future Date		VM.CIMTDAT > Today	"A2a. Date of CIMT measure" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0

System Queries														
sysq-619226	SYSQ_5071	VM.CIMTCLAB	Field Null		VM.CIMTCLAB IS NULL	"A2b. Sent to core lab?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619227	SYSQ_5072	VM.CASPERF	Field Null		VM.CASPERF IS NULL	"A3. Was a Carotid Artery Stiffness measurement obtained?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619228	SYSQ_5073	VM.CASDAT	Field Null		VM.CASDAT IS NULL	"A3a. Date of Carotid artery stiffness measure" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619229	SYSQ_5074	VM.CASDAT	Future Date		VM.CASDAT > Today	"A3a. Date of Carotid artery stiffness measure" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619230	SYSQ_5075	VM.CASCLAB	Field Null		VM.CASCLAB IS NULL	"A3b. Sent to core lab?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0

pVIS

Page

(Visit ID = 618819, Page ID =)

Unique Identifier page-618819-618819-618819-

SECTION A: VISIT DETAILS			
SDV	* A1. Date of visit		VIS.VISDAT
SDV	* A2. Were there any adverse events experienced since last visit?	○ Yes ○ No	VIS.VISAEYN
	If Yes, please complete AE (Adverse Events) Form(s) in the LOG (Addable Log Pages) Visit.		
SDV	* A3. Is the subject taking any concomitant medications, non-prescription medication, vitamins or herbal supplements?	○ Yes ○ No	VIS.VISCMDYN
	If Yes, please complete CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.		
SECTION B: FAMILY HISTORY			
	Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).		
SDV	* B1. Does the participant have any biological relatives with a history of premature CVD?	○ Yes ○ No ○ Unknown	VIS.VISFHXYN
	If Yes, please complete CVDFHX (Family History of CVD) Form(s) in the LOG (Addable Log Pages) Visit for each of the participants biological relatives with history of premature CVD.		
SDV	* B1a. How many biological relatives does the participant have with premature CVD?		VIS.VISFHXNUM (format xx)
SDV	* B2. Have there been any updates to the participant's family history of premature CVD since last visit?	○ Yes ○ No	VIS.VISFHXCHG
	If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.		

SDV	* B2a. Did the total number of the participant's biological relatives with premature CVD change?	○ Yes ○ No	VIS.VISFHXCTOT
SDV	* B2b. Total number of biological relatives with premature CVD		VIS.VISFHXCNUM (format xx)
SECTION C: SYMPTOMS ASSESSMENT			
	Has the participant experienced any of the following symptoms during this reporting period...		
	For the Baseline Visit, please report any symptoms experienced since last visit.		
SDV	* C1. Unexplained and/or persistent muscle pain, tenderness or weakness	○ Yes ○ No ○ Unknown	VIS.SYMMUSCL
SDV	* C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	○ Yes ○ No ○ Unknown	VIS.SYMUSCINJ
SDV	* C1b. Date of first new muscle symptom		VIS.SYMUSDAT
SDV	* C2. Brown or red urine	○ Yes ○ No ○ Unknown	VIS.SYMURINE
SDV	* C3. Appearance of fatigue	○ Yes ○ No ○ Unknown	VIS.SYMFATIG
SDV	* C4. Nausea and/or Vomiting	○ Yes ○ No ○ Unknown	VIS.SYMNAUS
SDV	* C5. Right upper quadrant pain or tenderness	○ Yes ○ No ○ Unknown	VIS.SYMPAIN
SDV	* C6. Eosinophilia (> 5%)	○ Yes ○ No ○ Unknown	VIS.SYMEOSIN
SDV	* C7. Elevations in liver enzymes	○ Yes ○ No ○ Unknown	VIS.SYMLIVER
SDV	* C8. Yellow skin or eye discoloration (jaundice)	○ Yes ○ No ○ Unknown	VIS.SYMJAUND

SDV	* C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	○ Yes ○ No ○ Unknown	VIS.SYMTHRST
SDV	* C10. Rash and itching	○ Yes ○ No ○ Unknown	VIS.SYMRASH
SDV	* C11. Diarrhea	○ Yes ○ No ○ Unknown	VIS.SYMDIAR
SDV	* C12. Constipation	○ Yes ○ No ○ Unknown	VIS.SYMCONST
SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING			
SDV	* D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	○ Yes ○ No	VIS.PREG_CON
SDV	* D2. Did subject confirm abstinence or use of contraceptives measures?	○ Yes ○ No	VIS.ABS_CONTRA

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618819	Section Header	0	SECTION A: VISIT DETAILS											
Page-2-618819	Date	0	A1. Date of visit	VIS.VISDAT	Yes									
Page-3-618819	Radiolist Horizontal	0	A2. Were there any adverse events experienced since last visit?	VIS.VISAEYN	Yes				cYN					
-- Page Dynamics (VIS. VISAEYN): Show When: VISITID = 20														
Page-4-618819	Help Text Line	1	If Yes, please complete AE (Adverse Events) Form(s) in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: VISITID = 20 AND VIS.VISAEYN = 1														

Page Information															
Page-5-618819	Radiolist Horizontal	0	A3. Is the subject taking any concomitant medications, non-prescription medication, vitamins or herbal supplements?	VIS. VISCMDYN	Yes				cYN					
-- Page Dynamics (VIS. VISCMDYN): Show When: VISITID = 20															
Page-6-618819	Help Text Line	1	If Yes, please complete CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.												
-- Page Dynamics (.): Show When: VISITID = 20 AND VIS.VISCMDYN = 1															
Page-7-618819	Section Header	0	SECTION B: FAMILY HISTORY												
Page-8-618819	Help Text Line	0	Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).												
Page-9-618819	Radiolist	0	B1. Does the participant have any biological relatives with a history of premature CVD?	VIS. VISFHXYN	Yes				cYNUNK					Screening visit only
-- Page Dynamics (VIS. VISFHXYN): Show When: VISITID = 10															
Page-10-618819	Help Text Line	1	If Yes, please complete CVDFHX (Family History of CVD) Form(s) in the LOG (Addable Log Pages) Visit for each of the participants biological relatives with history of premature CVD.												
-- Page Dynamics (.): Show When: VIS.VISFHXYN = 1 AND VISITID = 10															
Page-11-618819	Numeric	1	B1a. How many biological relatives does the participant have with premature CVD?	VIS. VISFHXNUM	Yes							2	0		
-- Page Dynamics (VIS. VISFHXNUM): Show When: VIS.VISFHXYN = 1 AND VISITID = 10															
Page-12-618819	Radiolist Horizontal	0	B2. Have there been any updates to the participant's family history of premature CVD since last visit?	VIS. VISFHXCHG	Yes				cYN					Baseline visit only
-- Page Dynamics (VIS. VISFHXCHG): Show When: VISITID = 20															

Page Information														
Page-13-618819	Help Text Line	1	If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.											
-- Page Dynamics (.): Show When: VIS.VISFHXCHG = 1 AND VISITID = 20														
Page-14-618819	Radiolist Horizontal	1	B2a. Did the total number of the participant's biological relatives with premature CVD change?	VIS.VISFHXCTOT	Yes				cYN					
-- Page Dynamics (VIS. VISFHXCTOT): Show When: VIS.VISFHXCHG = 1 AND VISITID = 20														
Page-15-618819	Numeric	1	B2b. Total number of biological relatives with premature CVD	VIS.VISFHXCNUM	Yes							2	0	
-- Page Dynamics (VIS. VISFHXCNUM): Show When: VIS.VISFHXCHG = 1 AND VIS.VISFHXCTOT = 1 AND VISITID = 20														
Page-16-618819	Section Header	0	SECTION C: SYMPTOMS ASSESSMENT											
Page-17-618819	Help Text Line	0	Has the participant experienced <u>any of the following symptoms</u> during this reporting period...											
Page-18-618819	Help Text Line	0	For the <u>Baseline Visit</u>, please report any symptoms experienced since last visit.											
-- Page Dynamics (.): Show When: VISITID = 20														
Page-19-618819	Radiolist Horizontal	0	C1. Unexplained and/or persistent muscle pain, tenderness or weakness	VIS.SYMMUSCL	Yes				cYNUNK					
Page-20-618819	Radiolist Horizontal	1	C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	VIS.SYMUSCINJ	Yes				cYNUNK					
-- Page Dynamics (VIS. SYMUSCINJ): Show When: VIS.SYMMUSCL = 1														
Page-21-618819	Date	1	C1b. Date of first new muscle symptom	VIS.SYMUSDAT	Yes									Enter the date of the first new symptom
-- Page Dynamics (VIS. SYMUSDAT): Show When: VIS.SYMMUSCL = 1														
Page-22-618819	Radiolist Horizontal	0	C2. Brown or red urine	VIS.SYMURINE	Yes				cYNUNK					

Page Information															
Page-23-618819	Radiolist Horizontal	0	C3. Appearance of fatigue	VIS.SYMFATIG	Yes				cYNUNK						
Page-24-618819	Radiolist Horizontal	0	C4. Nausea and/or Vomiting	VIS.SYMNAUS	Yes				cYNUNK						
Page-25-618819	Radiolist Horizontal	0	C5. Right upper quadrant pain or tenderness	VIS.SYMPAIN	Yes				cYNUNK						
Page-26-618819	Radiolist Horizontal	0	C6. Eosinophilia (> 5%)	VIS.SYMEOSIN	Yes				cYNUNK						
Page-27-618819	Radiolist Horizontal	0	C7. Elevations in liver enzymes	VIS.SYMLIVER	Yes				cYNUNK						
Page-28-618819	Radiolist Horizontal	0	C8. Yellow skin or eye discoloration (jaundice)	VIS.SYMJAUND	Yes				cYNUNK						
Page-29-618819	Radiolist Horizontal	0	C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	VIS.SYMTHRST	Yes				cYNUNK						
Page-30-618819	Radiolist Horizontal	0	C10. Rash and itching	VIS.SYMRASH	Yes				cYNUNK						
Page-31-618819	Radiolist Horizontal	0	C11. Diarrhea	VIS.SYMDIAR	Yes				cYNUNK						
Page-32-618819	Radiolist Horizontal	0	C12. Constipation	VIS.SYMCONST	Yes				cYNUNK						
Page-33-618819	Section Header	0	SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING												
Page-34-618819	Radiolist Horizontal	0	D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	VIS.PREG_CON	Yes				cYN						
Page-35-618819	Radiolist Horizontal	0	D2. Did subject confirm abstinence or use of contraceptives measures?	VIS.ABS_CONTRA	Yes				cYN						

System Queries													
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph

System Queries														
sysq-618889	SYSQ_4898	VIS.VISDAT	Other / Cross Page		VISITID = 10 AND 10-20-ICF.ICF_DT > VIS.VISDAT	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618891	SYSQ_4899	VIS.VISDAT	Other / Cross Page		VISITID = 20 AND (FUNCTION-DATE_COMPARE(10-10-VIS.VISDAT,VIS.VISDAT) < 0 OR FUNCTION-DATE_COMPARE(10-10-VIS.VISDAT,VIS.VISDAT) > 42)	This date is not within 6 weeks of the screening visit. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618893	SYSQ_4900	VIS.VISAEYN	Other / Cross Page		VIS.VISAEYN = 1 AND VISITID = 20	Please complete a corresponding AE (Adverse Events) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618895	SYSQ_4901	VIS.VISFHXYN	Other / Cross Page		VIS.VISFHXYN = 1	Please complete the corresponding CVDFHX (Family History of CVD) Form(s) in the LOG (Addable Log Pages) Visit for each of the participants biological relatives with history of premature CVD.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618897	SYSQ_4902	VIS.VISCMDYN	Other / Cross Page		VIS.VISCMDYN = 1 AND VISITID = 20	Please complete the corresponding CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618900	SYSQ_4903	VIS.VISFHXCHG	Other / Cross Page		VIS.VISFHXCHG = 1 AND VISITID = 20	Please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0

System Queries														
sysq-618901	SYSQ_4904	VIS.SYMMUSCL	Other / Cross Page		(VIS.SYMMUSCL = 1 OR VIS.SYMURINE = 1 OR VIS.SYMFATIG = 1 OR VIS.SYMNAUS = 1 OR VIS.SYMPAIN = 1 OR VIS.SYMEOSIN = 1 OR VIS.SYMLIVER = 1 OR VIS.SYMJAUND = 1 OR VIS.SYMTHRST = 1 OR VIS.SYMRASH = 1 OR VIS.SYMDIAR = 1 OR VIS.SYMCONST = 1) AND VISITID = 20	Symptoms are reported during this reporting period/since last visit. If these are new or worsening symptoms since last visit, then please report on the corresponding AE (Adverse Events) Form(s).	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-619162	SYSQ_5035	VIS.SYMUSDAT	Other / Cross Page		VISITID = 20 AND FUNCTION-DATE_COMPARE(VIS.SYMUSDAT, 10-10-VIS.VISDAT) >= 0	Date of first new muscle symptom since previous reporting period is either the same as or prior to the last reporting period (screening visit). Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619163	SYSQ_5036	VIS.VISDAT	Field Null		VIS.VISDAT IS NULL	"A1. Date of visit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619166	SYSQ_5037	VIS.VISDAT	Future Date		VIS.VISDAT > Today	"A1. Date of visit" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619168	SYSQ_5038	VIS.VISAEYN	Field Null		VIS.VISAEYN IS NULL	"A2. Were there any adverse events experienced since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619169	SYSQ_5039	VIS.VISCMDYN	Field Null		VIS.VISCMDYN IS NULL	"A3. Is the subject taking any concomitant medications, non-prescription medication, vitamins or herbal supplements?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0

System Queries														
sysq-619171	SYSQ_5040	VIS.VISFHXYN	Field Null		VIS.VISFHXYN IS NULL	"B1. Does the participant have any biological relatives with a history of premature CVD?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619173	SYSQ_5041	VIS.VISFHXNUM	Field Null		VIS.VISFHXNUM IS NULL	"B1a. How many biological relatives does the participant have with premature CVD?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619175	SYSQ_5042	VIS.VISFHXNUM	Range		VIS.VISFHXNUM <= 0 OR VIS.VISFHXNUM > 20	"B1a. How many biological relatives does the participant have with premature CVD?" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619178	SYSQ_5043	VIS.VISFHXCHG	Field Null		VIS.VISFHXCHG IS NULL	"B2. Have there been any updates to the participant's family history of premature CVD since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619180	SYSQ_5044	VIS.VISFHXCTOT	Field Null		VIS.VISFHXCTOT IS NULL	"B2a. Did the total number of the participant's biological relatives with premature CVD change?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619181	SYSQ_5045	VIS.VISFHXCNUM	Field Null		VIS.VISFHXCNUM IS NULL	"B2b. Total number of biological relatives with premature CVD" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619184	SYSQ_5046	VIS.SYMMUSCL	Field Null		VIS.SYMMUSCL IS NULL	"C1. Unexplained and/or persistent muscle pain, tenderness or weakness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619185	SYSQ_5047	VIS.SYMUSCINJ	Field Null		VIS.SYMUSCINJ IS NULL	"C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent usual physical activity or any recent trauma or injury?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619187	SYSQ_5048	VIS.SYMUSDAT	Field Null		VIS.SYMUSDAT IS NULL	"C1b. Date of first new muscle symptom" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0

System Queries														
sysq-619190	SYSQ_5049	VIS.SYMUSDAT	Future Date		VIS.SYMUSDAT > Today	"C1b. Date of first new muscle symptom" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619192	SYSQ_5050	VIS.SYMURINE	Field Null		VIS.SYMURINE IS NULL	"C2. Brown or red urine" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619194	SYSQ_5051	VIS.SYMFATIG	Field Null		VIS.SYMFATIG IS NULL	"C3. Appearance of fatigue" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619195	SYSQ_5052	VIS.SYMNAUS	Field Null		VIS.SYMNAUS IS NULL	"C4. Nausea and/or Vomiting" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619198	SYSQ_5053	VIS.SYMPAIN	Field Null		VIS.SYMPAIN IS NULL	"C5. Right upper quadrant pain or tenderness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619200	SYSQ_5054	VIS.SYMEOSIN	Field Null		VIS.SYMEOSIN IS NULL	"C6. Eosinophilia (> 5%)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619202	SYSQ_5055	VIS.SYMLIVER	Field Null		VIS.SYMLIVER IS NULL	"C7. Elevations in liver enzymes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619203	SYSQ_5056	VIS.SYMJAUND	Field Null		VIS.SYMJAUND IS NULL	"C8. Yellow skin or eye discoloration (jaundice)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619205	SYSQ_5057	VIS.SYMTHRST	Field Null		VIS.SYMTHRST IS NULL	"C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619207	SYSQ_5058	VIS.SYMRASH	Field Null		VIS.SYMRASH IS NULL	"C10. Rash and itching" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0

System Queries														
sysq-619209	SYSQ_5059	VIS.SYMDIAR	Field Null		VIS.SYMDIAR IS NULL	"C11. Diarrhea" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619211	SYSQ_5060	VIS.SYMCONST	Field Null		VIS.SYMCONST IS NULL	"C12. Constipation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619214	SYSQ_5061	VIS.PREG_CON	Field Null		VIS.PREG_CON IS NULL	"D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619216	SYSQ_5062	VIS.ABS_CONTRA	Field Null		VIS.ABS_CONTRA IS NULL	"D2. Did subject confirm abstinence or use of contraceptives measures?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-619217	SYSQ_5063	VIS.VISFHXCNUM	Range		VIS.VISFHXCNUM <= 0 OR VIS.VISFHXCNUM > 20	"B2b. Total number of biological relatives with premature CVD" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0

pVISF

Page

(Visit ID = 618820, Page ID =)

Unique Identifier page-618820-618820-618820-

SECTION A: VISIT DETAILS			
SDV	* A1. Was the visit completed?	○ Yes ○ No	VISF.VISFYN
SDV	* A1a. Date of contact		VISF.VISFDAT
SDV	* A1b. Type of follow-up	○ Clinic/office visit ○ Telephone contact with subject ○ Parent/guardian contact ○ Other	VISF.VISFTYP
SDV	* A1b1. Specify the other follow-up type		VISF.VISFTYPO
SDV	* A1c. Was masking maintained since last visit through the completion of this visit and all associated assessments?	○ Yes ○ No	VISF.VISFMASK
	If No, please complete an UNMASK (Unmasking Form) in the LOG (Addable Log Pages) Visit. Complete 1 UNMASK form per individual (participant, study staff member or non-study staff member) who was unmasked.		
SDV	* A1d. If No, Reason	○ Missed Visit ○ Subject Withdrawn	VISF.VISFNREAS
SDV	* A2. Were there any changes to existing adverse events or new adverse events experienced since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFAEYN
	If Yes, please update and/or create a new AE (Adverse Events) Form in the LOG (Addable Log Pages) Visit.		
SDV	* A3. Did subject start study medication treatment since being randomized?	○ Yes ○ No	VISF.VISFSMTRT
SDV	* A3a. Date First Dose taken		VISF.VISFSMDAT
SDV	* A3b. Were there any changes to study medication since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFSMYN

SDV	* A3c. Type of change	○ Temporarily stopped ○ Permanently discontinued ○ Other	VISF.VISFSMCHG

If Temporarily Stopped, please complete the TDIS (Temporary Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.

If Permanently Discontinued, please complete the PDIS (Permanent Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.

SDV	* A4. Were there any changes to existing or the addition of new concomitant medications, non-prescription medication, vitamins or herbal supplements since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFCMYN

If Yes, please update and/or create a new CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit.

SECTION B: FAMILY HISTORY

Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).

SDV	* B1. Have there been any updates to the participant's family history of premature CVD since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFAMHX

If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.

SDV	* B1a. Did the total number of the participant's biological relatives with premature CVD change?	○ Yes ○ No	VISF.VISFHXCHG
SDV	* B1a1. Total number of biological relatives with premature CVD	[ ]	VISF.VISFHXNUM (format xx)

SECTION C: SYMPTOMS ASSESSMENT

Has the participant experienced any of the following symptoms since last visit...

SDV	* C1. Unexplained and/or persistent muscle pain, tenderness or weakness	○ Yes ○ No ○ Unknown	VISF.SYMMUSCL

SDV	* C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	○ Yes ○ No ○ Unknown	VISF.SYMUSCINJ
SDV	* C1b. Date of first new muscle symptom		VISF.SYMUSDAT
SDV	* C2. Brown or red urine	○ Yes ○ No ○ Unknown	VISF.SYMURINE
SDV	* C3. Appearance of fatigue	○ Yes ○ No ○ Unknown	VISF.SYMFATIG
SDV	* C4. Nausea and/or Vomiting	○ Yes ○ No ○ Unknown	VISF.SYMNAUS
SDV	* C5. Right upper quadrant pain or tenderness	○ Yes ○ No ○ Unknown	VISF.SYMPAIN
SDV	* C6. Eosinophilia (> 5%)	○ Yes ○ No ○ Unknown	VISF.SYMEOSIN
SDV	* C7. Elevations in liver enzymes	○ Yes ○ No ○ Unknown	VISF.SYMLIVER
SDV	* C8. Yellow skin or eye discoloration (jaundice)	○ Yes ○ No ○ Unknown	VISF.SYMJAUND
SDV	* C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	○ Yes ○ No ○ Unknown	VISF.SYMTHRST
SDV	* C10. Rash and itching	○ Yes ○ No ○ Unknown	VISF.SYMRASH
SDV	* C11. Diarrhea	○ Yes ○ No ○ Unknown	VISF.SYMDIAR
SDV	* C12. Constipation	○ Yes ○ No ○ Unknown	VISF.SYMCONST
SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING			

SDV	* D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	○ Yes ○ No	VISF.PREG_CON
SDV	* D2. Did subject confirm abstinence or use of contraceptives measures?	○ Yes ○ No	VISF.ABS_CONTRA
SECTION E: ASSESSMENTS			
	Select "Yes" or "No" to indicate whether the assessment was performed at this followup visit.		
SDV	* E1. Preventive Cardiology Lifestyle Screener Questionnaire	○ Yes ○ No	VISF.LIFESTYN
SDV	* E2. Pittsburgh Sleep Quality Index	○ Yes ○ No	VISF.PSQIYN
SDV	* E3. Was data obtained from the Fitbit physical activity tracker device?	○ Yes ○ No	VISF.FBITYN
SDV	* E4. Tanner staging (self report)	○ Yes ○ No	VISF.TANSYN
SDV	* E5. Labs	○ Yes ○ No	VISF.LABYN
SDV	* E6. Anthropometry, blood pressure measurements	○ Yes ○ No	VISF.ANTHROPYN
SDV	* E7. Vascular measures (PWV, CIMT, carotid stiffness)	○ Yes ○ No	VISF.VASCMYN

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618820	Section Header	0	SECTION A: VISIT DETAILS											
Page-2-618820	Radiolist Horizontal	0	A1. Was the visit completed?	VISF.VISFYN	Yes				cYN					
Page-3-618820	Date	1	A1a. Date of contact	VISF.VISFDAT	Yes									
-- Page Dynamics (VISF. VISFDAT): Show When: VISF.VISFYN = 1														

Page Information														
Page-4-618820	Radiolist	1	A1b. Type of follow-up	VISF.VISFTYP	Yes				cVISFTYPE					
-- Page Dynamics (VISF. VISFTYP): Show When: VISF.VISFYN = 1														
Page-5-618820	Text Field	2	A1b1. Specify the other follow-up type	VISF.VISFTYPO	Yes					100	50			
-- Page Dynamics (VISF. VISFTYPO): Show When: VISF.VISFYN = 1 AND VISF.VISFTYP = 99														
Page-6-618820	Radiolist Horizontal	1	A1c. Was masking maintained since last visit through the completion of this visit and all associated assessments?	VISF.VISFMASK	Yes				cYN					
-- Page Dynamics (VISF. VISFMASK): Show When: VISF.VISFYN = 1														
Page-7-618820	Help Text Line	1	If No, please complete an UNMASK (Unmasking Form) in the LOG (Addable Log Pages) Visit. Complete 1 UNMASK form per individual (participant, study staff member or non-study staff member) who was unmasked.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFMASK = 0														
Page-8-618820	Radiolist	2	A1d. If No, Reason	VISF.VISFNREAS	Yes				cVISFNREAS					
-- Page Dynamics (VISF. VISFNREAS): Show When: VISF.VISFYN = 0														
Page-9-618820	Radiolist Horizontal	0	A2. Were there any <u>changes to existing adverse events</u> or <u>new adverse events</u> experienced since last visit?	VISF.VISFAEYN	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFAEYN): Show When: VISF.VISFYN = 1														
Page-10-618820	Help Text Line	1	If Yes, please update and/or create a new AE (Adverse Events) Form in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFAEYN = 1														
Page-11-618820	Radiolist	0	A3. Did subject start study medication treatment since being randomized?	VISF.VISFSMTRT	Yes				cYN					
-- Page Dynamics (VISF. VISFSMTRT): Show When: VISF.VISFYN = 1 AND VISITID = 30														
Page-12-618820	Date	1	A3a. Date First Dose taken	VISF.VISFSMDAT	Yes									
-- Page Dynamics (VISF. VISFSMDAT): Show When: VISF.VISFYN = 1 AND VISF.VISFSMTRT = 1 AND VISITID = 30														

Page Information														
Page-13-618820	Radiolist Horizontal	0	A3b. Were there any changes to study medication since last visit?	VISF.VISFSMYN	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFSMYN): Show When: VISF.VISFYN = 1														
Page-14-618820	Radiolist Horizontal	1	A3c. Type of change	VISF.VISFSMCHG	Yes				cStudyMedChg					
-- Page Dynamics (VISF. VISFSMCHG): Show When: VISF.VISFYN = 1 AND VISF.VISFSMYN = 1														
Page-15-618820	Help Text Line	1	If Temporarily Stopped, please complete the TDIS (Temporary Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFSMCHG = 1														
Page-16-618820	Help Text Line	1	If Permanently Discontinued, please complete the PDIS (Permanent Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFSMCHG = 2														
Page-17-618820	Radiolist Horizontal	0	A4. Were there any <u>changes to existing or the addition of <u>new concomitant medications, non-prescription medication, vitamins or herbal supplements</u> since last visit?	VISF.VISFCMYN	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFCMYN): Show When: VISF.VISFYN = 1														
Page-18-618820	Help Text Line	1	If Yes, please update and/or create a new CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFCMYN = 1														
Page-19-618820	Section Header	0	SECTION B: FAMILY HISTORY											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														

Page Information														
Page-20-618820	Help Text Line	0	Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-21-618820	Radiolist Horizontal	0	B1. Have there been any updates to the participant's family history of premature CVD since last visit?	VISF. VISFAMHX	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFAMHX): Show When: VISF.VISFYN = 1														
Page-22-618820	Help Text Line	1	If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFAMHX = 1														
Page-23-618820	Radiolist Horizontal	1	B1a. Did the total number of the participant's biological relatives with premature CVD change?	VISF. VISFHXCHG	Yes				cYN					
-- Page Dynamics (VISF. VISFHXCHG): Show When: VISF.VISFYN = 1 AND VISF.VISFAMHX = 1														
Page-24-618820	Numeric	2	B1a1. Total number of biological relatives with premature CVD	VISF. VISFHXNUM	Yes							2	0	
-- Page Dynamics (VISF. VISFHXNUM): Show When: VISF.VISFAMHX = 1 AND VISF.VISFHXCHG = 1														
Page-25-618820	Section Header	0	SECTION C: SYMPTOMS ASSESSMENT											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-26-618820	Help Text Line	0	Has the participant experienced <u>any of the following symptoms</u> since last visit...											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														

Page Information														
Page-27-618820	Radiolist Horizontal	0	C1. Unexplained and/or persistent muscle pain, tenderness or weakness	VISF.SYMMUSCL	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMMUSCL): Show When: VISF.VISFYN = 1														
Page-28-618820	Radiolist Horizontal	1	C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	VISF.SYMUSCINJ	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMUSCINJ): Show When: VISF.VISFYN = 1 AND VISF.SYMMUSCL = 1														
Page-29-618820	Date	1	C1b. Date of first new muscle symptom	VISF.SYMUSDAT	Yes									Enter the date of the first new symptom
-- Page Dynamics (VISF. SYMUSDAT): Show When: VISF.VISFYN = 1 AND VISF.SYMMUSCL = 1														
Page-30-618820	Radiolist Horizontal	0	C2. Brown or red urine	VISF.SYMURINE	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMURINE): Show When: VISF.VISFYN = 1														
Page-31-618820	Radiolist Horizontal	0	C3. Appearance of fatigue	VISF.SYMFATIG	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMFATIG): Show When: VISF.VISFYN = 1														
Page-32-618820	Radiolist Horizontal	0	C4. Nausea and/or Vomiting	VISF.SYMNAUS	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMNAUS): Show When: VISF.VISFYN = 1														
Page-33-618820	Radiolist Horizontal	0	C5. Right upper quadrant pain or tenderness	VISF.SYMPAIN	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMPAIN): Show When: VISF.VISFYN = 1														
Page-34-618820	Radiolist Horizontal	0	C6. Eosinophilia (> 5%)	VISF.SYMEOSIN	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMEOSIN): Show When: VISF.VISFYN = 1														
Page-35-618820	Radiolist Horizontal	0	C7. Elevations in liver enzymes	VISF.SYMLIVER	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMLIVER): Show When: VISF.VISFYN = 1														
Page-36-618820	Radiolist Horizontal	0	C8. Yellow skin or eye discoloration (jaundice)	VISF.SYMJAUND	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMJAUND): Show When: VISF.VISFYN = 1														
Page-37-618820	Radiolist Horizontal	0	C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	VISF.SYMTHRST	Yes				cYNUNK					

Page Information														
-- Page Dynamics (VISF. SYMTHRST): Show When: VISF.VISFYN = 1														
Page-38-618820	Radiolist Horizontal	0	C10. Rash and itching	VISF.SYMRASH	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMRASH): Show When: VISF.VISFYN = 1														
Page-39-618820	Radiolist Horizontal	0	C11. Diarrhea	VISF.SYMDIAR	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMDIAR): Show When: VISF.VISFYN = 1														
Page-40-618820	Radiolist Horizontal	0	C12. Constipation	VISF.SYMCONST	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMCONST): Show When: VISF.VISFYN = 1														
Page-41-618820	Section Header	0	SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-42-618820	Radiolist Horizontal	0	D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	VISF.PREG_CON	Yes				cYN					
-- Page Dynamics (VISF. PREG_CON): Show When: VISF.VISFYN = 1														
Page-43-618820	Radiolist Horizontal	0	D2. Did subject confirm abstinence or use of contraceptives measures?	VISF.ABS_CONTRA	Yes				cYN					
-- Page Dynamics (VISF. ABS_CONTRA): Show When: VISF.VISFYN = 1														
Page-44-618820	Section Header	0	SECTION E: ASSESSMENTS											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-45-618820	Help Text Line	0	Select "Yes" or "No" to indicate whether the assessment was performed at this followup visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-46-618820	Radiolist Horizontal	0	E1. Preventive Cardiology Lifestyle Screener Questionnaire	VISF.LIFESTYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. LIFESTYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														
Page-47-618820	Radiolist Horizontal	0	E2. Pittsburgh Sleep Quality Index	VISF.PSQIYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. PSQIYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														

Page Information														
Page-48-618820	Radiolist Horizontal	0	E3. Was data obtained from the Fitbit physical activity tracker device?	VISF.FBITYN	Yes				cYN					At 1, 6, 12 and 24 Months. Must be worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit.
-- Page Dynamics (VISF. FBITYN): Show When: VISF.VISFYN = 1 AND (VISITID = 30 OR VISITID = 50 OR VISITID = 70 OR VISITID = 90)														
Page-49-618820	Radiolist Horizontal	0	E4. Tanner staging (self report)	VISF.TANSYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. TANSYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														
Page-50-618820	Radiolist Horizontal	0	E5. Labs	VISF.LABYN	Yes				cYN					This includes samples collected for local testing (and results) and core lab/biorepository. Please enter "Yes" if samples were collected for either local testing and/or core lab/biorepository testing.
-- Page Dynamics (VISF. LABYN): Show When: VISF.VISFYN = 1														
Page-51-618820	Radiolist Horizontal	0	E6. Anthropometry, blood pressure measurements	VISF.ANTHROPYN	Yes				cYN					At 3, 6, 12, 18 and 24 Months
-- Page Dynamics (VISF. ANTHROPYN): Show When: VISF.VISFYN = 1 AND (VISITID = 40 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90)														
Page-52-618820	Radiolist Horizontal	0	E7. Vascular measures (PWV, CIMT, carotid stiffness)	VISF.VASCMYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. VASCMYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														

System Queries													
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619846	SYSQ_5481	VISF.VISFYN	Other / Cross Page		VISF.VISFYN <> 1	If visit was not completed, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0

System Queries														
sysq-619848	SYSQ_5482a	VISF.VISFMASK	Other / Cross Page		VISF.VISFMASK <> 1	If masking was not maintained since last visit and including this visit, please complete a corresponding UNMASK (Unmasking Form).	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619852	SYSQ_5483a	VISF.VISFAEYN	Other / Cross Page		VISF.VISFAEYN = 1	Please complete a corresponding AE (Adverse Events) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619855	SYSQ_5484a	VISF.VISFCMYN	Other / Cross Page		VISF.VISFCMYN = 1	Please update and/or complete the corresponding CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619857	SYSQ_5485a	VISF.VISFAMHX	Other / Cross Page		VISF.VISFAMHX = 1	Please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619860	SYSQ_5486a	VISF.VISFSMCHG	Other / Cross Page		VISF.VISFSMCHG = 1	Please complete a TDIS (Temporary Discontinuation of Study Drug) Form in the SDV (Study Drug) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619864	SYSQ_5487a	VISF.VISFSMCHG	Other / Cross Page		VISF.VISFSMCHG = 2	Please complete a PDIS (Permanent Discontinuation of Study Drug) Form in the SDV (Study Drug) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0

System Queries														
sysq-619867	SYSQ_5488a	VISF.SYMMUSCL	Other / Cross Page		(Field[VISF.SYMMUSCL] = '1') Or ((Field[VISF.SYMURINE] = '1') Or ((Field[VISF.SYMFATIG] = '1') Or ((Field[VISF.SYMNAUS] = '1') Or ((Field[VISF.SYMPAIN] = '1') Or ((Field[VISF.SYMEOSIN] = '1') Or ((Field[VISF.SYMLIVER] = '1') Or ((Field[VISF.SYMJAUND] = '1') Or ((Field[VISF.SYMTHRST] = '1') Or ((Field[VISF.SYMRASH] = '1') Or ((Field[VISF.SYMDIAR] = '1') Or (Field[VISF.SYMCONST] = '1'))))))))))	Symptoms are reported during this reporting period/since last visit. If these are new or worsening symptoms since last visit, then please report on the corresponding AE (Adverse Events) Form(s).	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619870	SYSQ_5489	VISF.PREG_CON	Other / Cross Page		VISF.PREG_CON <> 1 AND 10-40-DM.SEX = 2	Pregnancy/contraception counseling is required at this visit. If not done, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619872	SYSQ_5490	VISF.ABS_CONTRA	Other / Cross Page		VISF.ABS_CONTRA <> 1 AND 10-40-DM.SEX = 2	Use of oral contraceptives or abstinence is required to be verified at this visit. If not verified, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619874	SYSQ_5491	VISF.LIFESTYN	Other / Cross Page		VISF.LIFESTYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619875	SYSQ_5492	VISF.PSQIYN	Other / Cross Page		VISF.PSQIYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0

System Queries														
sysq-619877	SYSQ_5493	VISF.FBITYN	Other / Cross Page		VISF.FBITYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619879	SYSQ_5494	VISF.TANSYN	Other / Cross Page		VISF.TANSYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619881	SYSQ_5495	VISF.LABYN	Other / Cross Page		VISF.LABYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619884	SYSQ_5496	VISF.ANTHROPYN	Other / Cross Page		VISF.ANTHROPYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619885	SYSQ_5497	VISF.VASCMYN	Other / Cross Page		VISF.VASCMYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619888	SYSQ_5498	VISF.VISFYN	Field Null		VISF.VISFYN IS NULL	"A1. Was the visit completed?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619890	SYSQ_5499	VISF.VISFDAT	Field Null		VISF.VISFDAT IS NULL	"A1a. Date of contact" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619891	SYSQ_5500	VISF.VISFDAT	Future Date		VISF.VISFDAT > Today	"A1a. Date of contact" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619893	SYSQ_5501	VISF.VISFTYP	Field Null		VISF.VISFTYP IS NULL	"A1b. Type of follow-up" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619896	SYSQ_5502	VISF.VISFTYPO	Field Null		VISF.VISFTYPO IS NULL	"A1b1. Specify the other follow-up type" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0

System Queries														
sysq-619897	SYSQ_55503	VISF.VISFMASK	Field Null		VISF.VISFMASK IS NULL	"A1c. Was masking maintained since last visit through the completion of this visit and all associated assessments?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619900	SYSQ_55504	VISF.VISFNREAS	Field Null		VISF.VISFNREAS IS NULL	"A1d. If No, Reason" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619902	SYSQ_55505	VISF.VISFAEYN	Field Null		VISF.VISFAEYN IS NULL	"A2. Were there any <u>changes to existing adverse events</u> or <u>new adverse events</u> experienced since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619903	SYSQ_55506	VISF.VISFSMYN	Field Null		VISF.VISFSMYN IS NULL	"A3. Were there any changes to study medication since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619906	SYSQ_55507	VISF.VISFSMCHG	Field Null		VISF.VISFSMCHG IS NULL	"A3a. Type of change" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619907	SYSQ_55508	VISF.VISFCMYN	Field Null		VISF.VISFCMYN IS NULL	"A4. Were there any <u>changes to existing or the addition of <u>new concomitant medications, non-prescription medication, vitamins or herbal supplements</u> since last visit?</u>" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619910	SYSQ_55509	VISF.VISFAMHX	Field Null		VISF.VISFAMHX IS NULL	"B1. Have there been any updates to the participant's family history of premature CVD since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619911	SYSQ_55510	VISF.VISFHXCHG	Field Null		VISF.VISFHXCHG IS NULL	"B1a. Did the total number of the participant's biological relatives with premature CVD change?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619913	SYSQ_55511	VISF.VISFHXNUM	Field Null		VISF.VISFHXNUM IS NULL	"B1a1. Total number of biological relatives with premature CVD" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0

System Queries														
sysq-619916	SYSQ_5512	VISF.SYMMUSCL	Field Null		VISF.SYMMUSCL IS NULL	"C1. Unexplained and/or persistent muscle pain, tenderness or weakness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619917	SYSQ_5513	VISF.SYMUSCINJ	Field Null		VISF.SYMUSCINJ IS NULL	"C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent usual physical activity or any recent trauma or injury?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619919	SYSQ_5514	VISF.SYMUSDAT	Field Null		VISF.SYMUSDAT IS NULL	"C1b. Date of first new muscle symptom" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619921	SYSQ_5515	VISF.SYMUSDAT	Future Date		VISF.SYMUSDAT > Today	"C1b. Date of first new muscle symptom" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619923	SYSQ_5516	VISF.SYMURINE	Field Null		VISF.SYMURINE IS NULL	"C2. Brown or red urine" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619926	SYSQ_5517	VISF.SYMFATIG	Field Null		VISF.SYMFATIG IS NULL	"C3. Appearance of fatigue" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619928	SYSQ_5518	VISF.SYMNAUS	Field Null		VISF.SYMNAUS IS NULL	"C4. Nausea and/or Vomiting" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619929	SYSQ_5519	VISF.SYMPAIN	Field Null		VISF.SYMPAIN IS NULL	"C5. Right upper quadrant pain or tenderness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619932	SYSQ_5520	VISF.SYMEOSIN	Field Null		VISF.SYMEOSIN IS NULL	"C6. Eosinophilia (> 5%)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0

System Queries														
sysq-619934	SYSQ_5521	VISF.SYMLIVER	Field Null		VISF.SYMLIVER IS NULL	"C7. Elevations in liver enzymes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619936	SYSQ_5522	VISF.SYMJAUND	Field Null		VISF.SYMJAUND IS NULL	"C8. Yellow skin or eye discoloration (jaundice)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619937	SYSQ_5523	VISF.SYMTHRST	Field Null		VISF.SYMTHRST IS NULL	"C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619939	SYSQ_5524	VISF.SYMRASH	Field Null		VISF.SYMRASH IS NULL	"C10. Rash and itching" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619941	SYSQ_5525	VISF.SYMDIAR	Field Null		VISF.SYMDIAR IS NULL	"C11. Diarrhea" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619943	SYSQ_5526	VISF.SYMCONST	Field Null		VISF.SYMCONST IS NULL	"C12. Constipation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619946	SYSQ_5527	VISF.PREG_CON	Field Null		VISF.PREG_CON IS NULL	"D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619947	SYSQ_5528	VISF.ABS_CONTRA	Field Null		VISF.ABS_CONTRA IS NULL	"D2. Did subject confirm abstinence or use of contraceptives measures?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619950	SYSQ_5529	VISF.LIFESTYN	Field Null		VISF.LIFESTYN IS NULL	"E1. Preventive Cardiology Lifestyle Screener Questionnaire" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619952	SYSQ_5530	VISF.PSQIYN	Field Null		VISF.PSQIYN IS NULL	"E2. Pittsburgh Sleep Quality Index" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0

System Queries														
sysq-619954	SYSQ_5531	VISF.FBITYN	Field Null		VISF.FBITYN IS NULL	"E3. Was data obtained from the Fitbit physical activity tracker device?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619956	SYSQ_5532	VISF.TANSYN	Field Null		VISF.TANSYN IS NULL	"E4. Tanner staging (self report)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619958	SYSQ_5533	VISF.LABYN	Field Null		VISF.LABYN IS NULL	"E5. Labs" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619960	SYSQ_5534	VISF.ANTHROPYN	Field Null		VISF.ANTHROPYN IS NULL	"E6. Anthropometry, blood pressure measurements" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619961	SYSQ_5535	VISF.VASCMYN	Field Null		VISF.VASCMYN IS NULL	"E7. Vascular measures (PWV, CIMT, carotid stiffness)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-620294	SYSQ_5765	VISF.VISFSMTRT	Field Null		VISF.VISFSMTRT IS NULL	"A3. Did subject start study medication treatment since being randomized?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620297	SYSQ_5766	VISF.VISFSMDAT	Field Null		VISF.VISFSMDAT IS NULL	"A3a. Date First Dose taken" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620298	SYSQ_5767	VISF.VISFSMDAT	Future Date		VISF.VISFSMDAT > Today	"A3a. Date First Dose taken" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0

pVISF_4

Page

(Visit ID = 618821, Page ID =)

Unique Identifier page-618821-618821-618821-

SECTION A: VISIT DETAILS			
SDV	* A1. Was the visit completed?	○ Yes ○ No	VISF.VISFYN
SDV	* A1a. Date of contact		VISF.VISFDAT
SDV	* A1b. Type of follow-up	○ Clinic/office visit ○ Telephone contact with subject ○ Parent/guardian contact ○ Other	VISF.VISFTYP
SDV	* A1b1. Specify the other follow-up type		VISF.VISFTYPO
SDV	* A1c. Was masking maintained since last visit through the completion of this visit and all associated assessments?	○ Yes ○ No	VISF.VISFMASK
	If No, please complete an UNMASK (Unmasking Form) in the LOG (Addable Log Pages) Visit. Complete 1 UNMASK form per individual (participant, study staff member or non-study staff member) who was unmasked.		
SDV	* A1d. If No, Reason	○ Missed Visit ○ Subject Withdrawn	VISF.VISFNREAS
SDV	* A2. Were there any changes to existing adverse events or new adverse events experienced since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFAEYN
	If Yes, please update and/or create a new AE (Adverse Events) Form in the LOG (Addable Log Pages) Visit.		
SDV	* A3. Did subject start study medication treatment since being randomized?	○ Yes ○ No	VISF.VISFSMTRT
SDV	* A3a. Date First Dose taken		VISF.VISFSMDAT
SDV	* A3b. Were there any changes to study medication since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFSMYN

SDV	* A3c. Type of change	○ Temporarily stopped ○ Permanently discontinued ○ Other	VISF.VISFSMCHG

If Temporarily Stopped, please complete the TDIS (Temporary Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.

If Permanently Discontinued, please complete the PDIS (Permanent Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.

SDV	* A4. Were there any changes to existing or the addition of new concomitant medications, non-prescription medication, vitamins or herbal supplements since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFCMYN

If Yes, please update and/or create a new CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit.

SECTION B: FAMILY HISTORY

Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).

SDV	* B1. Have there been any updates to the participant's family history of premature CVD since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFAMHX

If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.

SDV	* B1a. Did the total number of the participant's biological relatives with premature CVD change?	○ Yes ○ No	VISF.VISFHXCHG
SDV	* B1a1. Total number of biological relatives with premature CVD	[ ]	VISF.VISFHXNUM (format xx)

SECTION C: SYMPTOMS ASSESSMENT

Has the participant experienced any of the following symptoms since last visit...

SDV	* C1. Unexplained and/or persistent muscle pain, tenderness or weakness	○ Yes ○ No ○ Unknown	VISF.SYMMUSCL

SDV	* C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	○ Yes ○ No ○ Unknown	VISF.SYMUSCINJ
SDV	* C1b. Date of first new muscle symptom		VISF.SYMUSDAT
SDV	* C2. Brown or red urine	○ Yes ○ No ○ Unknown	VISF.SYMURINE
SDV	* C3. Appearance of fatigue	○ Yes ○ No ○ Unknown	VISF.SYMFATIG
SDV	* C4. Nausea and/or Vomiting	○ Yes ○ No ○ Unknown	VISF.SYMNAUS
SDV	* C5. Right upper quadrant pain or tenderness	○ Yes ○ No ○ Unknown	VISF.SYMPAIN
SDV	* C6. Eosinophilia (> 5%)	○ Yes ○ No ○ Unknown	VISF.SYMEOSIN
SDV	* C7. Elevations in liver enzymes	○ Yes ○ No ○ Unknown	VISF.SYMLIVER
SDV	* C8. Yellow skin or eye discoloration (jaundice)	○ Yes ○ No ○ Unknown	VISF.SYMJAUND
SDV	* C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	○ Yes ○ No ○ Unknown	VISF.SYMTHRST
SDV	* C10. Rash and itching	○ Yes ○ No ○ Unknown	VISF.SYMRASH
SDV	* C11. Diarrhea	○ Yes ○ No ○ Unknown	VISF.SYMDIAR
SDV	* C12. Constipation	○ Yes ○ No ○ Unknown	VISF.SYMCONST
SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING			

SDV	* D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	○ Yes ○ No	VISF.PREG_CON
SDV	* D2. Did subject confirm abstinence or use of contraceptives measures?	○ Yes ○ No	VISF.ABS_CONTRA
SECTION E: ASSESSMENTS			
	Select "Yes" or "No" to indicate whether the assessment was performed at this followup visit.		
SDV	* E1. Preventive Cardiology Lifestyle Screener Questionnaire	○ Yes ○ No	VISF.LIFESTYN
SDV	* E2. Pittsburgh Sleep Quality Index	○ Yes ○ No	VISF.PSQIYN
SDV	* E3. Was data obtained from the Fitbit physical activity tracker device?	○ Yes ○ No	VISF.FBITYN
SDV	* E4. Tanner staging (self report)	○ Yes ○ No	VISF.TANSYN
SDV	* E5. Labs	○ Yes ○ No	VISF.LABYN
SDV	* E6. Anthropometry, blood pressure measurements	○ Yes ○ No	VISF.ANTHROPYN
SDV	* E7. Vascular measures (PWV, CIMT, carotid stiffness)	○ Yes ○ No	VISF.VASCMYN

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618821	Section Header	0	SECTION A: VISIT DETAILS											
Page-2-618821	Radiolist Horizontal	0	A1. Was the visit completed?	VISF.VISFYN	Yes				cYN					
Page-3-618821	Date	1	A1a. Date of contact	VISF.VISFDAT	Yes									
-- Page Dynamics (VISF. VISFDAT): Show When: VISF.VISFYN = 1														

Page Information														
Page-4-618821	Radiolist	1	A1b. Type of follow-up	VISF.VISFTYP	Yes				cVISFTYPE					
-- Page Dynamics (VISF. VISFTYP): Show When: VISF.VISFYN = 1														
Page-5-618821	Text Field	2	A1b1. Specify the other follow-up type	VISF.VISFTYPO	Yes					100	50			
-- Page Dynamics (VISF. VISFTYPO): Show When: VISF.VISFYN = 1 AND VISF.VISFTYP = 99														
Page-6-618821	Radiolist Horizontal	1	A1c. Was masking maintained since last visit through the completion of this visit and all associated assessments?	VISF.VISFMASK	Yes				cYN					
-- Page Dynamics (VISF. VISFMASK): Show When: VISF.VISFYN = 1														
Page-7-618821	Help Text Line	1	If No, please complete an UNMASK (Unmasking Form) in the LOG (Addable Log Pages) Visit. Complete 1 UNMASK form per individual (participant, study staff member or non-study staff member) who was unmasked.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFMASK = 0														
Page-8-618821	Radiolist	2	A1d. If No, Reason	VISF.VISFNREAS	Yes				cVISFNREAS					
-- Page Dynamics (VISF. VISFNREAS): Show When: VISF.VISFYN = 0														
Page-9-618821	Radiolist Horizontal	0	A2. Were there any <u>changes to existing adverse events</u> or <u>new adverse events</u> experienced since last visit?	VISF.VISFAEYN	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFAEYN): Show When: VISF.VISFYN = 1														
Page-10-618821	Help Text Line	1	If Yes, please update and/or create a new AE (Adverse Events) Form in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFAEYN = 1														
Page-11-618821	Radiolist	0	A3. Did subject start study medication treatment since being randomized?	VISF.VISFSMTRT	Yes				cYN					
-- Page Dynamics (VISF. VISFSMTRT): Show When: VISF.VISFYN = 1 AND VISITID = 30														
Page-12-618821	Date	1	A3a. Date First Dose taken	VISF.VISFSMDAT	Yes									
-- Page Dynamics (VISF. VISFSMDAT): Show When: VISF.VISFYN = 1 AND VISF.VISFSMTRT = 1 AND VISITID = 30														

Page Information														
Page-13-618821	Radiolist Horizontal	0	A3b. Were there any changes to study medication since last visit?	VISF.VISFSMYN	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFSMYN): Show When: VISF.VISFYN = 1														
Page-14-618821	Radiolist Horizontal	1	A3c. Type of change	VISF.VISFSMCHG	Yes				cStudyMedChg					
-- Page Dynamics (VISF. VISFSMCHG): Show When: VISF.VISFYN = 1 AND VISF.VISFSMYN = 1														
Page-15-618821	Help Text Line	1	If Temporarily Stopped, please complete the TDIS (Temporary Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFSMCHG = 1														
Page-16-618821	Help Text Line	1	If Permanently Discontinued, please complete the PDIS (Permanent Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFSMCHG = 2														
Page-17-618821	Radiolist Horizontal	0	A4. Were there any <u>changes to existing or the addition of <u>new concomitant medications, non-prescription medication, vitamins or herbal supplements</u> since last visit?	VISF.VISFCMYN	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFCMYN): Show When: VISF.VISFYN = 1														
Page-18-618821	Help Text Line	1	If Yes, please update and/or create a new CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFCMYN = 1														
Page-19-618821	Section Header	0	SECTION B: FAMILY HISTORY											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														

Page Information														
Page-20-618821	Help Text Line	0	Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-21-618821	Radiolist Horizontal	0	B1. Have there been any updates to the participant's family history of premature CVD since last visit?	VISF. VISFAMHX	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFAMHX): Show When: VISF.VISFYN = 1														
Page-22-618821	Help Text Line	1	If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFAMHX = 1														
Page-23-618821	Radiolist Horizontal	1	B1a. Did the total number of the participant's biological relatives with premature CVD change?	VISF. VISFHXCHG	Yes				cYN					
-- Page Dynamics (VISF. VISFHXCHG): Show When: VISF.VISFYN = 1 AND VISF.VISFAMHX = 1														
Page-24-618821	Numeric	2	B1a1. Total number of biological relatives with premature CVD	VISF. VISFHXNUM	Yes							2	0	
-- Page Dynamics (VISF. VISFHXNUM): Show When: VISF.VISFAMHX = 1 AND VISF.VISFHXCHG = 1														
Page-25-618821	Section Header	0	SECTION C: SYMPTOMS ASSESSMENT											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-26-618821	Help Text Line	0	Has the participant experienced <u>any of the following symptoms</u> since last visit...											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														

Page Information														
Page-27-618821	Radiolist Horizontal	0	C1. Unexplained and/or persistent muscle pain, tenderness or weakness	VISF.SYMMUSCL	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMMUSCL): Show When: VISF.VISFYN = 1														
Page-28-618821	Radiolist Horizontal	1	C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	VISF.SYMUSCINJ	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMUSCINJ): Show When: VISF.VISFYN = 1 AND VISF.SYMMUSCL = 1														
Page-29-618821	Date	1	C1b. Date of first new muscle symptom	VISF.SYMUSDAT	Yes									Enter the date of the first new symptom
-- Page Dynamics (VISF. SYMUSDAT): Show When: VISF.VISFYN = 1 AND VISF.SYMMUSCL = 1														
Page-30-618821	Radiolist Horizontal	0	C2. Brown or red urine	VISF.SYMURINE	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMURINE): Show When: VISF.VISFYN = 1														
Page-31-618821	Radiolist Horizontal	0	C3. Appearance of fatigue	VISF.SYMFATIG	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMFATIG): Show When: VISF.VISFYN = 1														
Page-32-618821	Radiolist Horizontal	0	C4. Nausea and/or Vomiting	VISF.SYMNAUS	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMNAUS): Show When: VISF.VISFYN = 1														
Page-33-618821	Radiolist Horizontal	0	C5. Right upper quadrant pain or tenderness	VISF.SYMPAIN	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMPAIN): Show When: VISF.VISFYN = 1														
Page-34-618821	Radiolist Horizontal	0	C6. Eosinophilia (> 5%)	VISF.SYMEOSIN	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMEOSIN): Show When: VISF.VISFYN = 1														
Page-35-618821	Radiolist Horizontal	0	C7. Elevations in liver enzymes	VISF.SYMLIVER	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMLIVER): Show When: VISF.VISFYN = 1														
Page-36-618821	Radiolist Horizontal	0	C8. Yellow skin or eye discoloration (jaundice)	VISF.SYMJAUND	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMJAUND): Show When: VISF.VISFYN = 1														
Page-37-618821	Radiolist Horizontal	0	C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	VISF.SYMTHRST	Yes				cYNUNK					

Page Information														
-- Page Dynamics (VISF. SYMTHRST): Show When: VISF.VISFYN = 1														
Page-38-618821	Radiolist Horizontal	0	C10. Rash and itching	VISF.SYMRASH	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMRASH): Show When: VISF.VISFYN = 1														
Page-39-618821	Radiolist Horizontal	0	C11. Diarrhea	VISF.SYMDIAR	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMDIAR): Show When: VISF.VISFYN = 1														
Page-40-618821	Radiolist Horizontal	0	C12. Constipation	VISF.SYMCONST	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMCONST): Show When: VISF.VISFYN = 1														
Page-41-618821	Section Header	0	SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-42-618821	Radiolist Horizontal	0	D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	VISF.PREG_CON	Yes				cYN					
-- Page Dynamics (VISF. PREG_CON): Show When: VISF.VISFYN = 1														
Page-43-618821	Radiolist Horizontal	0	D2. Did subject confirm abstinence or use of contraceptives measures?	VISF.ABS_CONTRA	Yes				cYN					
-- Page Dynamics (VISF. ABS_CONTRA): Show When: VISF.VISFYN = 1														
Page-44-618821	Section Header	0	SECTION E: ASSESSMENTS											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-45-618821	Help Text Line	0	Select "Yes" or "No" to indicate whether the assessment was performed at this followup visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-46-618821	Radiolist Horizontal	0	E1. Preventive Cardiology Lifestyle Screener Questionnaire	VISF.LIFESTYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. LIFESTYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														
Page-47-618821	Radiolist Horizontal	0	E2. Pittsburgh Sleep Quality Index	VISF.PSQIYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. PSQIYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														

Page Information														
Page-48-618821	Radiolist Horizontal	0	E3. Was data obtained from the Fitbit physical activity tracker device?	VISF.FBITYN	Yes				cYN					At 1, 6, 12 and 24 Months. Must be worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit.
-- Page Dynamics (VISF. FBITYN): Show When: VISF.VISFYN = 1 AND (VISITID = 30 OR VISITID = 50 OR VISITID = 70 OR VISITID = 90)														
Page-49-618821	Radiolist Horizontal	0	E4. Tanner staging (self report)	VISF.TANSYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. TANSYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														
Page-50-618821	Radiolist Horizontal	0	E5. Labs	VISF.LABYN	Yes				cYN					This includes samples collected for local testing (and results) and core lab/biorepository. Please enter "Yes" if samples were collected for either local testing and/or core lab/biorepository testing.
-- Page Dynamics (VISF. LABYN): Show When: VISF.VISFYN = 1														
Page-51-618821	Radiolist Horizontal	0	E6. Anthropometry, blood pressure measurements	VISF.ANTHROPYN	Yes				cYN					At 3, 6, 12, 18 and 24 Months
-- Page Dynamics (VISF. ANTHROPYN): Show When: VISF.VISFYN = 1 AND (VISITID = 40 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90)														
Page-52-618821	Radiolist Horizontal	0	E7. Vascular measures (PWV, CIMT, carotid stiffness)	VISF.VASCMYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. VASCMYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619847	SYSQ_5481	VISF.VISFYN	Other / Cross Page		VISF.VISFYN <> 1	If visit was not completed, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0

System Queries														
sysq-619849	SYSQ_5482a	VISF.VISFMASK	Other / Cross Page		VISF.VISFMASK <> 1	If masking was not maintained since last visit and including this visit, please complete a corresponding UNMASK (Unmasking Form).	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619851	SYSQ_5483a	VISF.VISFAEYN	Other / Cross Page		VISF.VISFAEYN = 1	Please complete a corresponding AE (Adverse Events) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0
sysq-619854	SYSQ_5484a	VISF.VISFCMYN	Other / Cross Page		VISF.VISFCMYN = 1	Please update and/or complete the corresponding CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619858	SYSQ_5485a	VISF.VISFAMHX	Other / Cross Page		VISF.VISFAMHX = 1	Please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619861	SYSQ_5486a	VISF.VISFSMCHG	Other / Cross Page		VISF.VISFSMCHG = 1	Please complete a TDIS (Temporary Discontinuation of Study Drug) Form in the SDV (Study Drug) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619863	SYSQ_5487a	VISF.VISFSMCHG	Other / Cross Page		VISF.VISFSMCHG = 2	Please complete a PDIS (Permanent Discontinuation of Study Drug) Form in the SDV (Study Drug) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0

System Queries														
sysq-619866	SYSQ_5488a	VISF.SYMMUSCL	Other / Cross Page		(Field[VISF.SYMMUSCL] = '1') Or ((Field[VISF.SYMURINE] = '1') Or ((Field[VISF.SYMFATIG] = '1') Or ((Field[VISF.SYMNAUS] = '1') Or ((Field[VISF.SYMPAIN] = '1') Or ((Field[VISF.SYMEOSIN] = '1') Or ((Field[VISF.SYMLIVER] = '1') Or ((Field[VISF.SYMJAUND] = '1') Or ((Field[VISF.SYMTHRST] = '1') Or ((Field[VISF.SYMRASH] = '1') Or ((Field[VISF.SYMDIAR] = '1') Or (Field[VISF.SYMCONST] = '1'))))))))))	Symptoms are reported during this reporting period/since last visit. If these are new or worsening symptoms since last visit, then please report on the corresponding AE (Adverse Events) Form(s).	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619869	SYSQ_5489	VISF.PREG_CON	Other / Cross Page		VISF.PREG_CON <> 1 AND 10-40-DM.SEX = 2	Pregnancy/contraception counseling is required at this visit. If not done, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619871	SYSQ_5490	VISF.ABS_CONTRA	Other / Cross Page		VISF.ABS_CONTRA <> 1 AND 10-40-DM.SEX = 2	Use of oral contraceptives or abstinence is required to be verified at this visit. If not verified, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619873	SYSQ_5491	VISF.LIFESTYN	Other / Cross Page		VISF.LIFESTYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619876	SYSQ_5492	VISF.PSQIYN	Other / Cross Page		VISF.PSQIYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0

System Queries														
sysq-619878	SYSQ_5493	VISF.FBITYN	Other / Cross Page		VISF.FBITYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619880	SYSQ_5494	VISF.TANSYN	Other / Cross Page		VISF.TANSYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619882	SYSQ_5495	VISF.LABYN	Other / Cross Page		VISF.LABYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619883	SYSQ_5496	VISF.ANTHROPYN	Other / Cross Page		VISF.ANTHROPYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619886	SYSQ_5497	VISF.VASCMYN	Other / Cross Page		VISF.VASCMYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619887	SYSQ_5498	VISF.VISFYN	Field Null		VISF.VISFYN IS NULL	"A1. Was the visit completed?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619889	SYSQ_5499	VISF.VISFDAT	Field Null		VISF.VISFDAT IS NULL	"A1a. Date of contact" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619892	SYSQ_5500	VISF.VISFDAT	Future Date		VISF.VISFDAT > Today	"A1a. Date of contact" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619894	SYSQ_5501	VISF.VISFTYP	Field Null		VISF.VISFTYP IS NULL	"A1b. Type of follow-up" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619895	SYSQ_5502	VISF.VISFTYPO	Field Null		VISF.VISFTYPO IS NULL	"A1b1. Specify the other follow-up type" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0

System Queries														
sysq-619898	SYSQ_55503	VISF.VISFMASK	Field Null		VISF.VISFMASK IS NULL	"A1c. Was masking maintained since last visit through the completion of this visit and all associated assessments?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619899	SYSQ_55504	VISF.VISFNREAS	Field Null		VISF.VISFNREAS IS NULL	"A1d. If No, Reason" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619901	SYSQ_55505	VISF.VISFAEYN	Field Null		VISF.VISFAEYN IS NULL	"A2. Were there any <u>changes to existing adverse events</u> or <u>new adverse events</u> experienced since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619904	SYSQ_55506	VISF.VISFSMYN	Field Null		VISF.VISFSMYN IS NULL	"A3. Were there any changes to study medication since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619905	SYSQ_55507	VISF.VISFSMCHG	Field Null		VISF.VISFSMCHG IS NULL	"A3a. Type of change" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:42	0	0	0	0	0	0
sysq-619908	SYSQ_55508	VISF.VISFCMYN	Field Null		VISF.VISFCMYN IS NULL	"A4. Were there any <u>changes to existing or the addition of <u>new concomitant medications, non-prescription medication, vitamins or herbal supplements</u> since last visit?</u>" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619909	SYSQ_55509	VISF.VISFAMHX	Field Null		VISF.VISFAMHX IS NULL	"B1. Have there been any updates to the participant's family history of premature CVD since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619912	SYSQ_55510	VISF.VISFHXCHG	Field Null		VISF.VISFHXCHG IS NULL	"B1a. Did the total number of the participant's biological relatives with premature CVD change?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619914	SYSQ_55511	VISF.VISFHXNUM	Field Null		VISF.VISFHXNUM IS NULL	"B1a1. Total number of biological relatives with premature CVD" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0

System Queries														
sysq-619915	SYSQ_5512	VISF.SYMMUSCL	Field Null		VISF.SYMMUSCL IS NULL	"C1. Unexplained and/or persistent muscle pain, tenderness or weakness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619918	SYSQ_5513	VISF.SYMUSCINJ	Field Null		VISF.SYMUSCINJ IS NULL	"C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent usual physical activity or any recent trauma or injury?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619920	SYSQ_5514	VISF.SYMUSDAT	Field Null		VISF.SYMUSDAT IS NULL	"C1b. Date of first new muscle symptom" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619922	SYSQ_5515	VISF.SYMUSDAT	Future Date		VISF.SYMUSDAT > Today	"C1b. Date of first new muscle symptom" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619924	SYSQ_5516	VISF.SYMURINE	Field Null		VISF.SYMURINE IS NULL	"C2. Brown or red urine" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619925	SYSQ_5517	VISF.SYMFATIG	Field Null		VISF.SYMFATIG IS NULL	"C3. Appearance of fatigue" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619927	SYSQ_5518	VISF.SYMNAUS	Field Null		VISF.SYMNAUS IS NULL	"C4. Nausea and/or Vomiting" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619930	SYSQ_5519	VISF.SYMPAIN	Field Null		VISF.SYMPAIN IS NULL	"C5. Right upper quadrant pain or tenderness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619931	SYSQ_5520	VISF.SYMEOSIN	Field Null		VISF.SYMEOSIN IS NULL	"C6. Eosinophilia (> 5%)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0

System Queries														
sysq-619933	SYSQ_5521	VISF.SYMLIVER	Field Null		VISF.SYMLIVER IS NULL	"C7. Elevations in liver enzymes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619935	SYSQ_5522	VISF.SYMJAUND	Field Null		VISF.SYMJAUND IS NULL	"C8. Yellow skin or eye discoloration (jaundice)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:43	0	0	0	0	0	0
sysq-619938	SYSQ_5523	VISF.SYMTHRST	Field Null		VISF.SYMTHRST IS NULL	"C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619940	SYSQ_5524	VISF.SYMRASH	Field Null		VISF.SYMRASH IS NULL	"C10. Rash and itching" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619942	SYSQ_5525	VISF.SYMDIAR	Field Null		VISF.SYMDIAR IS NULL	"C11. Diarrhea" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619944	SYSQ_5526	VISF.SYMCONST	Field Null		VISF.SYMCONST IS NULL	"C12. Constipation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619945	SYSQ_5527	VISF.PREG_CON	Field Null		VISF.PREG_CON IS NULL	"D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619948	SYSQ_5528	VISF.ABS_CONTRA	Field Null		VISF.ABS_CONTRA IS NULL	"D2. Did subject confirm abstinence or use of contraceptives measures?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619949	SYSQ_5529	VISF.LIFESTYN	Field Null		VISF.LIFESTYN IS NULL	"E1. Preventive Cardiology Lifestyle Screener Questionnaire" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619951	SYSQ_5530	VISF.PSQIYN	Field Null		VISF.PSQIYN IS NULL	"E2. Pittsburgh Sleep Quality Index" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0

System Queries														
sysq-619953	SYSQ_5531	VISF.FBITYN	Field Null		VISF.FBITYN IS NULL	"E3. Was data obtained from the Fitbit physical activity tracker device?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619955	SYSQ_5532	VISF.TANSYN	Field Null		VISF.TANSYN IS NULL	"E4. Tanner staging (self report)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619957	SYSQ_5533	VISF.LABYN	Field Null		VISF.LABYN IS NULL	"E5. Labs" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619959	SYSQ_5534	VISF.ANTHROPYN	Field Null		VISF.ANTHROPYN IS NULL	"E6. Anthropometry, blood pressure measurements" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619962	SYSQ_5535	VISF.VASCMYN	Field Null		VISF.VASCMYN IS NULL	"E7. Vascular measures (PWV, CIMT, carotid stiffness)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-620295	SYSQ_5765	VISF.VISFSMTRT	Field Null		VISF.VISFSMTRT IS NULL	"A3. Did subject start study medication treatment since being randomized?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620296	SYSQ_5766	VISF.VISFSMDAT	Field Null		VISF.VISFSMDAT IS NULL	"A3a. Date First Dose taken" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0
sysq-620299	SYSQ_5767	VISF.VISFSMDAT	Future Date		VISF.VISFSMDAT > Today	"A3a. Date First Dose taken" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:57	0	0	0	0	0	0

System Queries														
sysq-620497	SYSQ_5898	VISF.VISFDAT	Other / Cross Page	1 Month +/- 2 weeks post randomization (16 – 44 days) - new query	VISITID = 30 AND (FUNCTION-DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 16 OR FUNCTION-DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 44)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620498	SYSQ_5899	VISF.VISFDAT	Other / Cross Page	3 Month +/- 2 weeks post randomization (76 – 104 days) - new query	VISITID = 40 AND (FUNCTION-DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 76 OR FUNCTION-DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 104)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620499	SYSQ_5900	VISF.VISFDAT	Other / Cross Page	6 Month +/- 4 weeks post randomization (152 – 208 days) - new query	VISITID = 50 AND (FUNCTION-DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 152 OR FUNCTION-DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 208)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
sysq-620500	SYSQ_5901	VISF.VISFDAT	Other / Cross Page	9 Month +/- 4 weeks post randomization (242 – 298 days) - new query	VISITID = 60 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 242 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 298)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620501	SYSQ_5902	VISF.VISFDAT	Other / Cross Page	12 Month +/- 4 weeks post randomization (337 – 393 days) - new query	VISITID = 70 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 337 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 393)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0
sysq-620502	SYSQ_5903	VISF.VISFDAT	Other / Cross Page	18 Month +/- 4 weeks post randomization (519 – 575 days) - new query	VISITID = 80 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 519 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 575)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

System Queries														
sysq-620503	SYSQ_5904	VISF.VISFDAT	Other / Cross Page	24 Month +/- 6 weeks post randomization (688 – 772 days) - new query	VISITID = 90 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 688 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 772)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0

pVISF_8

Page

(Visit ID = 620585, Page ID =)

Unique Identifier page-620585-620585-620585-

SECTION A: VISIT DETAILS			
SDV	* A1. Was the visit completed?	○ Yes ○ No	VISF.VISFYN
SDV	* A1a. Date of contact		VISF.VISFDAT
SDV	* A1b. Type of follow-up	○ Clinic/office visit ○ Telephone contact with subject ○ Parent/guardian contact ○ Other	VISF.VISFTYP
SDV	* A1b1. Specify the other follow-up type		VISF.VISFTYPO
SDV	* A1c. Was masking maintained since last visit through the completion of this visit and all associated assessments?	○ Yes ○ No	VISF.VISFMASK
	If No, please complete an UNMASK (Unmasking Form) in the LOG (Addable Log Pages) Visit. Complete 1 UNMASK form per individual (participant, study staff member or non-study staff member) who was unmasked.		
SDV	* A1d. If No, Reason	○ Missed Visit ○ Subject Withdrawn	VISF.VISFNREAS
SDV	* A2. Were there any changes to existing adverse events or new adverse events experienced since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFAEYN
	If Yes, please update and/or create a new AE (Adverse Events) Form in the LOG (Addable Log Pages) Visit.		
SDV	* A3. Did subject start study medication treatment since being randomized?	○ Yes ○ No	VISF.VISFSMTRT
SDV	* A3a. Date First Dose taken		VISF.VISFSMDAT
SDV	* A3b. Were there any changes to study medication since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFSMYN

SDV	* A3c. Type of change	○ Temporarily stopped ○ Permanently discontinued ○ Other	VISF.VISFS MCHG

If Temporarily Stopped, please complete the TDIS (Temporary Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.

If Permanently Discontinued, please complete the PDIS (Permanent Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.

SDV	* A4. Were there any changes to existing or the addition of new concomitant medications, non-prescription medication, vitamins or herbal supplements since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFC MYN

If Yes, please update and/or create a new CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit.

SECTION B: FAMILY HISTORY

Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).

SDV	* B1. Have there been any updates to the participant's family history of premature CVD since last visit?	○ Yes ○ No ○ Unknown	VISF.VISFA MHX

If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.

SDV	* B1a. Did the total number of the participant's biological relatives with premature CVD change?	○ Yes ○ No	VISF.VISFH XCHG
SDV	* B1a1. Total number of biological relatives with premature CVD		VISF.VISFH XNUM (format xx)

SECTION C: SYMPTOMS ASSESSMENT

Has the participant experienced any of the following symptoms since last visit...

SDV	* C1. Unexplained and/or persistent muscle pain, tenderness or weakness	○ Yes ○ No ○ Unknown	VISF.SYMM USCL

SDV	* C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	○ Yes ○ No ○ Unknown	VISF.SYMUSCINJ
SDV	* C1b. Date of first new muscle symptom		VISF.SYMUSDAT
SDV	* C2. Brown or red urine	○ Yes ○ No ○ Unknown	VISF.SYMURINE
SDV	* C3. Appearance of fatigue	○ Yes ○ No ○ Unknown	VISF.SYMFATIG
SDV	* C4. Nausea and/or Vomiting	○ Yes ○ No ○ Unknown	VISF.SYMNAUS
SDV	* C5. Right upper quadrant pain or tenderness	○ Yes ○ No ○ Unknown	VISF.SYMPAIN
SDV	* C6. Eosinophilia (> 5%)	○ Yes ○ No ○ Unknown	VISF.SYMEOSIN
SDV	* C7. Elevations in liver enzymes	○ Yes ○ No ○ Unknown	VISF.SYMLIVER
SDV	* C8. Yellow skin or eye discoloration (jaundice)	○ Yes ○ No ○ Unknown	VISF.SYMJAUND
SDV	* C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	○ Yes ○ No ○ Unknown	VISF.SYMTHRST
SDV	* C10. Rash and itching	○ Yes ○ No ○ Unknown	VISF.SYMRASH
SDV	* C11. Diarrhea	○ Yes ○ No ○ Unknown	VISF.SYMDIAR
SDV	* C12. Constipation	○ Yes ○ No ○ Unknown	VISF.SYMCONST
SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING			

SDV	* D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	○ Yes ○ No	VISF.PREG_CON
SDV	* D2. Did subject confirm abstinence or use of contraceptives measures?	○ Yes ○ No	VISF.ABS_CONTRA
SECTION E: ASSESSMENTS			
	Select "Yes" or "No" to indicate whether the assessment was performed at this followup visit.		
SDV	* E1. Preventive Cardiology Lifestyle Screener Questionnaire	○ Yes ○ No	VISF.LIFESTYN
SDV	* E2. Pittsburgh Sleep Quality Index	○ Yes ○ No	VISF.PSQIYN
SDV	* E3. Was data obtained from the Fitbit physical activity tracker device?	○ Yes ○ No	VISF.FBITYN
SDV	* E4. Tanner staging (self report)	○ Yes ○ No	VISF.TANSYN
SDV	* E5. Labs	○ Yes ○ No	VISF.LABYN
SDV	* E6. Anthropometry, blood pressure measurements	○ Yes ○ No	VISF.ANTHROPYN
SDV	* E7. Vascular measures (PWV, CIMT, carotid stiffness)	○ Yes ○ No	VISF.VASCMYN

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-620585	Section Header	0	SECTION A: VISIT DETAILS											
Page-2-620585	Radiolist Horizontal	0	A1. Was the visit completed?	VISF.VISFYN	Yes				cYN					
Page-3-620585	Date	1	A1a. Date of contact	VISF.VISFDAT	Yes									
-- Page Dynamics (VISF. VISFDAT): Show When: VISF.VISFYN = 1														

Page Information														
Page-4-620585	Radiolist	1	A1b. Type of follow-up	VISF.VISFTYP	Yes				cVISFTYPE					
-- Page Dynamics (VISF. VISFTYP): Show When: VISF.VISFYN = 1														
Page-5-620585	Text Field	2	A1b1. Specify the other follow-up type	VISF.VISFTYPO	Yes					100	50			
-- Page Dynamics (VISF. VISFTYPO): Show When: VISF.VISFYN = 1 AND VISF.VISFTYP = 99														
Page-6-620585	Radiolist Horizontal	1	A1c. Was masking maintained since last visit through the completion of this visit and all associated assessments?	VISF.VISFMASK	Yes				cYN					
-- Page Dynamics (VISF. VISFMASK): Show When: VISF.VISFYN = 1														
Page-7-620585	Help Text Line	1	If No, please complete an UNMASK (Unmasking Form) in the LOG (Addable Log Pages) Visit. Complete 1 UNMASK form per individual (participant, study staff member or non-study staff member) who was unmasked.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFMASK = 0														
Page-8-620585	Radiolist	2	A1d. If No, Reason	VISF.VISFNREAS	Yes				cVISFNREAS					
-- Page Dynamics (VISF. VISFNREAS): Show When: VISF.VISFYN = 0														
Page-9-620585	Radiolist Horizontal	0	A2. Were there any <u>changes to existing adverse events</u> or <u>new adverse events</u> experienced since last visit?	VISF.VISFAEYN	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFAEYN): Show When: VISF.VISFYN = 1														
Page-10-620585	Help Text Line	1	If Yes, please update and/or create a new AE (Adverse Events) Form in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFAEYN = 1														
Page-11-620585	Radiolist	0	A3. Did subject start study medication treatment since being randomized?	VISF.VISFSMTRT	Yes				cYN					
-- Page Dynamics (VISF. VISFSMTRT): Show When: VISF.VISFYN = 1 AND VISITID = 30														
Page-12-620585	Date	1	A3a. Date First Dose taken	VISF.VISFSMDAT	Yes									
-- Page Dynamics (VISF. VISFSMDAT): Show When: VISF.VISFYN = 1 AND VISF.VISFSMTRT = 1 AND VISITID = 30														

Page Information														
Page-13-620585	Radiolist Horizontal	0	A3b. Were there any changes to study medication since last visit?	VISF.VISFSMYN	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFSMYN): Show When: VISF.VISFYN = 1														
Page-14-620585	Radiolist Horizontal	1	A3c. Type of change	VISF.VISFSMCHG	Yes				cStudyMedChg					
-- Page Dynamics (VISF. VISFSMCHG): Show When: VISF.VISFYN = 1 AND VISF.VISFSMYN = 1														
Page-15-620585	Help Text Line	1	If Temporarily Stopped, please complete the TDIS (Temporary Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFSMCHG = 1														
Page-16-620585	Help Text Line	1	If Permanently Discontinued, please complete the PDIS (Permanent Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFSMCHG = 2														
Page-17-620585	Radiolist Horizontal	0	A4. Were there any <u>changes to existing or the addition of <u>new concomitant medications, non-prescription medication, vitamins or herbal supplements</u> since last visit?	VISF.VISFCMYN	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFCMYN): Show When: VISF.VISFYN = 1														
Page-18-620585	Help Text Line	1	If Yes, please update and/or create a new CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFCMYN = 1														
Page-19-620585	Section Header	0	SECTION B: FAMILY HISTORY											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														

Page Information														
Page-20-620585	Help Text Line	0	Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-21-620585	Radiolist Horizontal	0	B1. Have there been any updates to the participant's family history of premature CVD since last visit?	VISF. VISFAMHX	Yes				cYNUNK					
-- Page Dynamics (VISF. VISFAMHX): Show When: VISF.VISFYN = 1														
Page-22-620585	Help Text Line	1	If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1 AND VISF.VISFAMHX = 1														
Page-23-620585	Radiolist Horizontal	1	B1a. Did the total number of the participant's biological relatives with premature CVD change?	VISF. VISFHXCHG	Yes				cYN					
-- Page Dynamics (VISF. VISFHXCHG): Show When: VISF.VISFYN = 1 AND VISF.VISFAMHX = 1														
Page-24-620585	Numeric	2	B1a1. Total number of biological relatives with premature CVD	VISF. VISFHXNUM	Yes							2	0	
-- Page Dynamics (VISF. VISFHXNUM): Show When: VISF.VISFAMHX = 1 AND VISF.VISFHXCHG = 1														
Page-25-620585	Section Header	0	SECTION C: SYMPTOMS ASSESSMENT											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-26-620585	Help Text Line	0	Has the participant experienced <u>any of the following symptoms</u> since last visit...											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														

Page Information														
Page-27-620585	Radiolist Horizontal	0	C1. Unexplained and/or persistent muscle pain, tenderness or weakness	VISF.SYMMUSCL	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMMUSCL): Show When: VISF.VISFYN = 1														
Page-28-620585	Radiolist Horizontal	1	C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	VISF.SYMUSCINJ	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMUSCINJ): Show When: VISF.VISFYN = 1 AND VISF.SYMMUSCL = 1														
Page-29-620585	Date	1	C1b. Date of first new muscle symptom	VISF.SYMUSDAT	Yes									Enter the date of the first new symptom
-- Page Dynamics (VISF. SYMUSDAT): Show When: VISF.VISFYN = 1 AND VISF.SYMMUSCL = 1														
Page-30-620585	Radiolist Horizontal	0	C2. Brown or red urine	VISF.SYMURINE	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMURINE): Show When: VISF.VISFYN = 1														
Page-31-620585	Radiolist Horizontal	0	C3. Appearance of fatigue	VISF.SYMFATIG	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMFATIG): Show When: VISF.VISFYN = 1														
Page-32-620585	Radiolist Horizontal	0	C4. Nausea and/or Vomiting	VISF.SYMNAUS	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMNAUS): Show When: VISF.VISFYN = 1														
Page-33-620585	Radiolist Horizontal	0	C5. Right upper quadrant pain or tenderness	VISF.SYMPAIN	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMPAIN): Show When: VISF.VISFYN = 1														
Page-34-620585	Radiolist Horizontal	0	C6. Eosinophilia (> 5%)	VISF.SYMEOSIN	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMEOSIN): Show When: VISF.VISFYN = 1														
Page-35-620585	Radiolist Horizontal	0	C7. Elevations in liver enzymes	VISF.SYMLIVER	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMLIVER): Show When: VISF.VISFYN = 1														
Page-36-620585	Radiolist Horizontal	0	C8. Yellow skin or eye discoloration (jaundice)	VISF.SYMJAUND	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMJAUND): Show When: VISF.VISFYN = 1														
Page-37-620585	Radiolist Horizontal	0	C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	VISF.SYMTHRST	Yes				cYNUNK					

Page Information														
-- Page Dynamics (VISF. SYMTHRST): Show When: VISF.VISFYN = 1														
Page-38-620585	Radiolist Horizontal	0	C10. Rash and itching	VISF.SYMRASH	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMRASH): Show When: VISF.VISFYN = 1														
Page-39-620585	Radiolist Horizontal	0	C11. Diarrhea	VISF.SYMDIAR	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMDIAR): Show When: VISF.VISFYN = 1														
Page-40-620585	Radiolist Horizontal	0	C12. Constipation	VISF.SYMCONST	Yes				cYNUNK					
-- Page Dynamics (VISF. SYMCONST): Show When: VISF.VISFYN = 1														
Page-41-620585	Section Header	0	SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-42-620585	Radiolist Horizontal	0	D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	VISF.PREG_CON	Yes				cYN					
-- Page Dynamics (VISF. PREG_CON): Show When: VISF.VISFYN = 1														
Page-43-620585	Radiolist Horizontal	0	D2. Did subject confirm abstinence or use of contraceptives measures?	VISF.ABS_CONTRA	Yes				cYN					
-- Page Dynamics (VISF. ABS_CONTRA): Show When: VISF.VISFYN = 1														
Page-44-620585	Section Header	0	SECTION E: ASSESSMENTS											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-45-620585	Help Text Line	0	Select "Yes" or "No" to indicate whether the assessment was performed at this followup visit.											
-- Page Dynamics (.): Show When: VISF.VISFYN = 1														
Page-46-620585	Radiolist Horizontal	0	E1. Preventive Cardiology Lifestyle Screener Questionnaire	VISF.LIFESTYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. LIFESTYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														
Page-47-620585	Radiolist Horizontal	0	E2. Pittsburgh Sleep Quality Index	VISF.PSQIYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. PSQIYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														

Page Information														
Page-48-620585	Radiolist Horizontal	0	E3. Was data obtained from the Fitbit physical activity tracker device?	VISF.FBITYN	Yes				cYN					At 1, 6, 12 and 24 Months. Must be worn for at least 7 days (5 weekdays, 2 weekend days) prior to visit.
-- Page Dynamics (VISF. FBITYN): Show When: VISF.VISFYN = 1 AND (VISITID = 30 OR VISITID = 50 OR VISITID = 70 OR VISITID = 90)														
Page-49-620585	Radiolist Horizontal	0	E4. Tanner staging (self report)	VISF.TANSYN	Yes				cYN					At 6, 12 and 24 Months
-- Page Dynamics (VISF. TANSYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90)														
Page-50-620585	Radiolist Horizontal	0	E5. Labs	VISF.LABYN	Yes				cYN					This includes samples collected for local testing (and results) and core lab/biorepository. Please enter "Yes" if samples were collected for either local testing and/or core lab/biorepository testing.
-- Page Dynamics (VISF. LABYN): Show When: VISF.VISFYN = 1														
Page-51-620585	Radiolist Horizontal	0	E6. Anthropometry, blood pressure measurements	VISF.ANTHROPYN	Yes				cYN					At 3, 6, 12, 18 and 24 Months
-- Page Dynamics (VISF. ANTHROPYN): Show When: VISF.VISFYN = 1 AND (VISITID = 40 OR VISITID = 50 OR VISITID = 70 OR VISITID = 80 OR VISITID = 90)														
Page-52-620585	Radiolist Horizontal	0	E7. Vascular measures (PWV, CIMT, carotid stiffness)	VISF.VASCMYN	Yes				cYN					At 6, 12, 18 and 24 Months
-- Page Dynamics (VISF. VASCMYN): Show When: VISF.VISFYN = 1 AND (VISITID = 50 OR VISITID = 70 OR VISITID = 90 OR VISITID = 80)														

System Queries														
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-620586	SYSQ_5481	VISF.VISFYN	Other / Cross Page		VISF.VISFYN <> 1	If visit was not completed, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0

System Queries														
sysq-620587	SYSQ_5482a	VISF.VISFMASK	Other / Cross Page		VISF.VISFMASK <> 1	If masking was not maintained since last visit and including this visit, please complete a corresponding UNMASK (Unmasking Form).	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620588	SYSQ_5483a	VISF.VISFAEYN	Other / Cross Page		VISF.VISFAEYN = 1	Please complete a corresponding AE (Adverse Events) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620589	SYSQ_5484a	VISF.VISFCMYN	Other / Cross Page		VISF.VISFCMYN = 1	Please update and/or complete the corresponding CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620590	SYSQ_5485a	VISF.VISFAMHX	Other / Cross Page		VISF.VISFAMHX = 1	Please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620591	SYSQ_5486a	VISF.VISFSMCHG	Other / Cross Page		VISF.VISFSMCHG = 1	Please complete a TDIS (Temporary Discontinuation of Study Drug) Form in the SDV (Study Drug) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620592	SYSQ_5487a	VISF.VISFSMCHG	Other / Cross Page		VISF.VISFSMCHG = 2	Please complete a PDIS (Permanent Discontinuation of Study Drug) Form in the SDV (Study Drug) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0

System Queries														
sysq-620593	SYSQ_5488a	VISF.SYMMUSCL	Other / Cross Page		(Field[VISF.SYMMUSCL] = '1') Or ((Field[VISF.SYMURINE] = '1') Or ((Field[VISF.SYMFATIG] = '1') Or ((Field[VISF.SYMNAUS] = '1') Or ((Field[VISF.SYMPAIN] = '1') Or ((Field[VISF.SYMEOSIN] = '1') Or ((Field[VISF.SYMLIVER] = '1') Or ((Field[VISF.SYMJAUND] = '1') Or ((Field[VISF.SYMTHRST] = '1') Or ((Field[VISF.SYMRASH] = '1') Or ((Field[VISF.SYMDIAR] = '1') Or (Field[VISF.SYMCONST] = '1'))))))))))	Symptoms are reported during this reporting period/since last visit. If these are new or worsening symptoms since last visit, then please report on the corresponding AE (Adverse Events) Form(s).	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620594	SYSQ_5489	VISF.PREG_CON	Other / Cross Page		VISF.PREG_CON <> 1 AND 10-40-DM.SEX = 2	Pregnancy/contraception counseling is required at this visit. If not done, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620595	SYSQ_5490	VISF.ABS_CONTRA	Other / Cross Page		VISF.ABS_CONTRA <> 1 AND 10-40-DM.SEX = 2	Use of oral contraceptives or abstinence is required to be verified at this visit. If not verified, please complete a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620596	SYSQ_5491	VISF.LIFESTYN	Other / Cross Page		VISF.LIFESTYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620597	SYSQ_5492	VISF.PSQIYN	Other / Cross Page		VISF.PSQIYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0

System Queries														
sysq-620598	SYSQ_5493	VISF.FBITYN	Other / Cross Page		VISF.FBITYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620599	SYSQ_5494	VISF.TANSYN	Other / Cross Page		VISF.TANSYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620600	SYSQ_5495	VISF.LABYN	Other / Cross Page		VISF.LABYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620601	SYSQ_5496	VISF.ANTHROPYN	Other / Cross Page		VISF.ANTHROPYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620602	SYSQ_5497	VISF.VASCMYN	Other / Cross Page		VISF.VASCMYN = 0	If not done, please submit a corresponding DV (Protocol Deviation) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620603	SYSQ_5498	VISF.VISFYN	Field Null		VISF.VISFYN IS NULL	"A1. Was the visit completed?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:29	0	0	0	0	0	0
sysq-620604	SYSQ_5499	VISF.VISFDAT	Field Null		VISF.VISFDAT IS NULL	"A1a. Date of contact" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620605	SYSQ_5500	VISF.VISFDAT	Future Date		VISF.VISFDAT > Today	"A1a. Date of contact" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620606	SYSQ_5501	VISF.VISFTYP	Field Null		VISF.VISFTYP IS NULL	"A1b. Type of follow-up" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620607	SYSQ_5502	VISF.VISFTYPO	Field Null		VISF.VISFTYPO IS NULL	"A1b1. Specify the other follow-up type" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0

System Queries														
sysq-620608	SYSQ_55503	VISF.VISFMASK	Field Null		VISF.VISFMASK IS NULL	"A1c. Was masking maintained since last visit through the completion of this visit and all associated assessments?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620609	SYSQ_55504	VISF.VISFNREAS	Field Null		VISF.VISFNREAS IS NULL	"A1d. If No, Reason" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620610	SYSQ_55505	VISF.VISFAEYN	Field Null		VISF.VISFAEYN IS NULL	"A2. Were there any <u>changes to existing adverse events</u> or <u>new adverse events</u> experienced since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620611	SYSQ_55506	VISF.VISFSMYN	Field Null		VISF.VISFSMYN IS NULL	"A3. Were there any changes to study medication since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620612	SYSQ_55507	VISF.VISFSMCHG	Field Null		VISF.VISFSMCHG IS NULL	"A3a. Type of change" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620613	SYSQ_55508	VISF.VISFCMYN	Field Null		VISF.VISFCMYN IS NULL	"A4. Were there any <u>changes to existing or the addition of <u>new concomitant medications, non-prescription medication, vitamins or herbal supplements</u> since last visit?</u>" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620614	SYSQ_55509	VISF.VISFAMHX	Field Null		VISF.VISFAMHX IS NULL	"B1. Have there been any updates to the participant's family history of premature CVD since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620615	SYSQ_55510	VISF.VISFHXCHG	Field Null		VISF.VISFHXCHG IS NULL	"B1a. Did the total number of the participant's biological relatives with premature CVD change?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620616	SYSQ_55511	VISF.VISFHXNUM	Field Null		VISF.VISFHXNUM IS NULL	"B1a1. Total number of biological relatives with premature CVD" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0

System Queries														
sysq-620617	SYSQ_5512	VISF.SYMMUSCL	Field Null		VISF.SYMMUSCL IS NULL	"C1. Unexplained and/or persistent muscle pain, tenderness or weakness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620618	SYSQ_5513	VISF.SYMUSCINJ	Field Null		VISF.SYMUSCINJ IS NULL	"C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent usual physical activity or any recent trauma or injury?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620619	SYSQ_5514	VISF.SYMUSDAT	Field Null		VISF.SYMUSDAT IS NULL	"C1b. Date of first new muscle symptom" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620620	SYSQ_5515	VISF.SYMUSDAT	Future Date		VISF.SYMUSDAT > Today	"C1b. Date of first new muscle symptom" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620621	SYSQ_5516	VISF.SYMURINE	Field Null		VISF.SYMURINE IS NULL	"C2. Brown or red urine" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620622	SYSQ_5517	VISF.SYMFATIG	Field Null		VISF.SYMFATIG IS NULL	"C3. Appearance of fatigue" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620623	SYSQ_5518	VISF.SYMNAUS	Field Null		VISF.SYMNAUS IS NULL	"C4. Nausea and/or Vomiting" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620624	SYSQ_5519	VISF.SYMPAIN	Field Null		VISF.SYMPAIN IS NULL	"C5. Right upper quadrant pain or tenderness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620625	SYSQ_5520	VISF.SYMEOSIN	Field Null		VISF.SYMEOSIN IS NULL	"C6. Eosinophilia (> 5%)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0

System Queries														
sysq-620626	SYSQ_5521	VISF.SYMLIVER	Field Null		VISF.SYMLIVER IS NULL	"C7. Elevations in liver enzymes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620627	SYSQ_5522	VISF.SYMJAUND	Field Null		VISF.SYMJAUND IS NULL	"C8. Yellow skin or eye discoloration (jaundice)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620628	SYSQ_5523	VISF.SYMTHRST	Field Null		VISF.SYMTHRST IS NULL	"C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620629	SYSQ_5524	VISF.SYMRASH	Field Null		VISF.SYMRASH IS NULL	"C10. Rash and itching" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620630	SYSQ_5525	VISF.SYMDIAR	Field Null		VISF.SYMDIAR IS NULL	"C11. Diarrhea" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620631	SYSQ_5526	VISF.SYMCONST	Field Null		VISF.SYMCONST IS NULL	"C12. Constipation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620632	SYSQ_5527	VISF.PREG_CON	Field Null		VISF.PREG_CON IS NULL	"D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620633	SYSQ_5528	VISF.ABS_CONTRA	Field Null		VISF.ABS_CONTRA IS NULL	"D2. Did subject confirm abstinence or use of contraceptives measures?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:30	0	0	0	0	0	0
sysq-620634	SYSQ_5529	VISF.LIFESTYN	Field Null		VISF.LIFESTYN IS NULL	"E1. Preventive Cardiology Lifestyle Screener Questionnaire" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620635	SYSQ_5530	VISF.PSQIYN	Field Null		VISF.PSQIYN IS NULL	"E2. Pittsburgh Sleep Quality Index" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0

System Queries														
sysq-620636	SYSQ_5531	VISF.FBITYN	Field Null		VISF.FBITYN IS NULL	"E3. Was data obtained from the Fitbit physical activity tracker device?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620637	SYSQ_5532	VISF.TANSYN	Field Null		VISF.TANSYN IS NULL	"E4. Tanner staging (self report)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620638	SYSQ_5533	VISF.LABYN	Field Null		VISF.LABYN IS NULL	"E5. Labs" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620639	SYSQ_5534	VISF.ANTHROPYN	Field Null		VISF.ANTHROPYN IS NULL	"E6. Anthropometry, blood pressure measurements" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620640	SYSQ_5535	VISF.VASCMYN	Field Null		VISF.VASCMYN IS NULL	"E7. Vascular measures (PWV, CIMT, carotid stiffness)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620641	SYSQ_5765	VISF.VISFSMTRT	Field Null		VISF.VISFSMTRT IS NULL	"A3. Did subject start study medication treatment since being randomized?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620642	SYSQ_5766	VISF.VISFSMDAT	Field Null		VISF.VISFSMDAT IS NULL	"A3a. Date First Dose taken" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620643	SYSQ_5767	VISF.VISFSMDAT	Future Date		VISF.VISFSMDAT > Today	"A3a. Date First Dose taken" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0

System Queries														
sysq-620644	SYSQ_5898	VISF.VISFDAT	Other / Cross Page		VISITID = 30 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 16 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 44)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620645	SYSQ_5899	VISF.VISFDAT	Other / Cross Page		VISITID = 40 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 76 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 104)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620646	SYSQ_5900	VISF.VISFDAT	Other / Cross Page		VISITID = 50 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 152 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 208)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0

System Queries														
sysq-620647	SYSQ_5901	VISF.VISFDAT	Other / Cross Page		VISITID = 60 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 242 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 298)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620648	SYSQ_5902	VISF.VISFDAT	Other / Cross Page		VISITID = 70 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 337 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 393)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0
sysq-620649	SYSQ_5903	VISF.VISFDAT	Other / Cross Page		VISITID = 80 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 519 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 575)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0

System Queries														
sysq-620650	SYSQ_5904	VISF.VISFDAT	Other / Cross Page		VISITID = 90 AND (FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) < 688 OR FUNCTION--DATE_COMPARE(20-140-RAND.RANDDAT, VISF.VISFDAT) > 772)	Visit date is not within the expected range. Please confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 16:52:31	0	0	0	0	0	0

pVISU

Page

(Visit ID = 618822, Page ID =)

Unique Identifier page-618822-618822-618822-

SECTION A: VISIT DETAILS			
SDV	* A1. Date of contact		VISU.VISUDAT
SDV	* A2. Type:	○ Clinic/office visit ○ Telephone contact with subject ○ Parent/guardian contact ○ Other	VISU.VISUTYP
SDV	* A2a. Specify other visit type:		VISU.VISUTYPO
SDV	* A3. Visit/call conducted by:	○ Site Coordinator ○ Investigator ○ Other	VISU.VISUPERS
SDV	* A3a. Specify other study member who conducted the visit/call:		VISU.VISUPOTH
SDV	* A4. Reason for visit/call:		VISU.VISUREAS
SDV	* A5. Was masking maintained since last visit through the completion of this visit and all associated assessments? ***If No, please complete an UNMASK (Unmasking Form) in the LOG (Addable Log Pages) Visit. Complete 1 UNMASK form per individual (participant, study staff member or non-study staff member) who was unmasked.***	○ Yes ○ No	VISU.VISUMASK
SDV	* A6. Were there any changes to adverse events since last visit? ***If Yes, please update and/or create a new AE (Adverse Events) Form in the LOG (Addable Log Pages) Visit.***	○ Yes ○ No ○ Not assessed	VISU.VISUAEYN
SDV	* A7. Were there any changes to study medication since last visit?	○ Yes ○ No ○ Not assessed	VISU.VISUSMYN

SDV	* A7a. Type of change	○ Temporarily stopped ○ Permanently discontinued ○ Other	VISU.VISUSMCHG

If Temporarily Stopped, please complete the TDIS (Temporary Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.

If Permanently Discontinued, please complete the PDIS (Permanent Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.

SDV	* A8. Were there any changes to concomitant medications since last visit?	○ Yes ○ No ○ Not assessed	VISU.VISUCMYN

If Yes, please update and/or create a new CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit.

SECTION B: FAMILY HISTORY

Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).

SDV	* B1. Have there been any updates to the participant's family history of premature CVD since last visit?	○ Yes ○ No ○ Not assessed	VISU.VISUFAMHX

If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.

SDV	* B1a. Did the total number of the participant's biological relatives with premature CVD change?	○ Yes ○ No	VISU.VISUHXCHG
SDV	* B1a1. Total number of biological relatives with premature CVD		VISU.VISUHXNUM (format xx)

SECTION C: SYMPTOMS ASSESSMENT

Has the participant experienced any of the following symptoms since last visit...

SDV	* C1. Unexplained and/or persistent muscle pain, tenderness or weakness	○ Yes ○ No ○ Not assessed	VISU.SYMMUSCL
SDV	* C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	○ Yes ○ No ○ Not assessed	VISU.SYMUSCINJ
SDV	* C1b. Date of first new muscle symptom		VISU.SYMUSDAT

SDV	* C2. Brown or red urine	○ Yes ○ No ○ Not assessed	VISU.SYMURINE
SDV	* C3. Appearance of fatigue	○ Yes ○ No ○ Not assessed	VISU.SYMFATIG
SDV	* C4. Nausea and/or Vomiting	○ Yes ○ No ○ Not assessed	VISU.SYMNAUS
SDV	* C5. Right upper quadrant pain or tenderness	○ Yes ○ No ○ Not assessed	VISU.SYMPAIN
SDV	* C6. Eosinophilia (> 5%)	○ Yes ○ No ○ Not assessed	VISU.SYMEOSIN
SDV	* C7. Elevations in liver enzymes	○ Yes ○ No ○ Not assessed	VISU.SYMLIVER
SDV	* C8. Yellow skin or eye discoloration (jaundice)	○ Yes ○ No ○ Not assessed	VISU.SYMJAUND
SDV	* C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	○ Yes ○ No ○ Not assessed	VISU.SYMTHRST
SDV	* C10. Rash and itching	○ Yes ○ No ○ Not assessed	VISU.SYMRASH
SDV	* C11. Diarrhea	○ Yes ○ No ○ Not assessed	VISU.SYMDIAR
SDV	* C12. Constipation	○ Yes ○ No ○ Not assessed	VISU.SYMCONST
SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING			
SDV	* D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	○ Yes ○ No ○ Not assessed	VISU.PREGCONS
SDV	* D2. Did subject confirm abstinence or use of contraceptives measures?	○ Yes ○ No ○ Not assessed	VISU.ABSTINYN

SECTION E: ASSESSMENTS

Select "Yes" or "No" for each to indicate whether the assessment was performed at this unscheduled visit.

SDV	* E1. Preventive Cardiology Lifestyle Screener Questionnaire	○ Yes ○ No	VISU.LIFESTYN
SDV	* E2. Pittsburgh Sleep Quality Index	○ Yes ○ No	VISU.PSQIYN
SDV	* E3. Data from Fitbit physical activity tracker device?	○ Yes ○ No	VISU.FBITYN
SDV	* E4. Tanner staging (self report)	○ Yes ○ No	VISU.TANSYN
SDV	* E5. Labs	○ Yes ○ No	VISU.LABYN
SDV	* E6. Anthropometry, blood pressure measurements	○ Yes ○ No	VISU.ANTHROPYN
SDV	* E7. Vascular measures (PWV, CIMT, carotid stiffness)	○ Yes ○ No	VISU.VASCMYN

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618822	Section Header	0	SECTION A: VISIT DETAILS											
Page-2-618822	Date	0	A1. Date of contact	VISU.VISUDAT	Yes									
Page-3-618822	Radiolist	0	A2. Type:	VISU.VISUTYP	Yes				cVISFTYPE					If visit type was an Clinic/office visit or Other, please complete the questions that will appear below on this form.
Page-4-618822	Text Field	1	A2a. Specify other visit type:	VISU.VISUTYPO	Yes					100	50			
-- Page Dynamics (VISU. VISUTYPO): Show When: VISU.VISUTYP = 99														

Page Information														
Page-5-618822	Radiolist Horizontal	0	A3. Visit/call conducted by:	VISU.VISUPERS	Yes				cVISUPERS					
Page-6-618822	Text Field	1	A3a. Specify other study member who conducted the visit/call:	VISU.VISUPOTH	Yes					100	50			
-- Page Dynamics (VISU. VISUPOTH): Show When: VISU.VISUPERS = 99														
Page-7-618822	Text Field	0	A4. Reason for visit/call:	VISU.VISUREAS	Yes					200	99			
Page-8-618822	Radiolist Horizontal	0	A5. Was masking maintained since last visit through the completion of this visit and all associated assessments?	VISU.VISUMASK	Yes				cYN					
-- Page Dynamics (VISU. VISUMASK): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-9-618822	Help Text Line	1	If No, please complete an UNMASK (Unmasking Form) in the LOG (Addable Log Pages) Visit. Complete 1 UNMASK form per individual (participant, study staff member or non-study staff member) who was unmasked.											
-- Page Dynamics (.): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.VISUMASK = 0														
Page-10-618822	Radiolist Horizontal	0	A6. Were there any changes to adverse events since last visit?	VISU.VISUAEYN	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. VISUAEYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-11-618822	Help Text Line	1	If Yes, please update and/or create a new AE (Adverse Events) Form in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.VISUAEYN = 1														
Page-12-618822	Radiolist Horizontal	0	A7. Were there any changes to study medication since last visit?	VISU.VISUSMYN	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. VISUSMYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-13-618822	Radiolist Horizontal	1	A7a. Type of change	VISU.VISUSMCHG	Yes				cStudyMedChg					
-- Page Dynamics (VISU. VISUSMCHG): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.VISUSMYN = 1														
Page-14-618822	Help Text Line	1	If Temporarily Stopped, please complete the TDIS (Temporary Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.											

Page Information														
-- Page Dynamics (.): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.VISUSMYN = 1 AND VISU.VISUSMCHG = 1														
Page-15-618822	Help Text Line	1	If Permanently Discontinued, please complete the PDIS (Permanent Discontinuation of Study Drug) form in the SDV (Study Drug) Visit.											
-- Page Dynamics (.): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.VISUSMYN = 1 AND VISU.VISUSMCHG = 2														
Page-16-618822	Radiolist Horizontal	0	A8. Were there any changes to concomitant medications since last visit?	VISU.VISUCMYN	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. VISUCMYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-17-618822	Help Text Line	1	If Yes, please update and/or create a new CMED (Concomitant Medications) Form in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.VISUCMYN = 1														
Page-18-618822	Section Header	0	SECTION B: FAMILY HISTORY											
-- Page Dynamics (.): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-19-618822	Help Text Line	0	Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).											
-- Page Dynamics (.): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-20-618822	Radiolist Horizontal	0	B1. Have there been any updates to the participant's family history of premature CVD since last visit?	VISU.VISUFAMHX	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. VISUFAMHX): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														

Page Information														
Page-21-618822	Help Text Line	1	If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.											
-- Page Dynamics (.): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.VISUFAMHX = 1														
Page-22-618822	Radiolist Horizontal	1	B1a. Did the total number of the participant's biological relatives with premature CVD change?	VISU.VISUHXCHG	Yes				cYN					
-- Page Dynamics (VISU. VISUHXCHG): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.VISUFAMHX = 1														
Page-23-618822	Numeric	2	B1a1. Total number of biological relatives with premature CVD	VISU.VISUHXNUM	Yes							2	0	
-- Page Dynamics (VISU. VISUHXNUM): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.VISUFAMHX = 1 AND VISU.VISUHXCHG = 1														
Page-24-618822	Section Header	0	SECTION C: SYMPTOMS ASSESSMENT											
-- Page Dynamics (.): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-25-618822	Help Text Line	0	Has the participant experienced <u>any of the following symptoms</u> since last visit...											
-- Page Dynamics (.): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-26-618822	Radiolist Horizontal	0	C1. Unexplained and/or persistent muscle pain, tenderness or weakness	VISU.SYMMUSCL	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMMUSCL): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-27-618822	Radiolist Horizontal	1	C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	VISU.SYMUSCINJ	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMUSCINJ): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.SYMMUSCL = 1														
Page-28-618822	Date	1	C1b. Date of first new muscle symptom	VISU.SYMUSDAT	Yes									Enter the date of the first new symptom
-- Page Dynamics (VISU. SYMUSDAT): Show When: (VISU.VISUTYP = 1 OR VISU.VISUTYP = 99) AND VISU.SYMMUSCL = 1														
Page-29-618822	Radiolist Horizontal	0	C2. Brown or red urine	VISU.SYMURINE	Yes				cYNNotAssessed					

Page Information														
-- Page Dynamics (VISU. SYMURINE): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-30-618822	Radiolist Horizontal	0	C3. Appearance of fatigue	VISU.SYMFATIG	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMFATIG): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-31-618822	Radiolist Horizontal	0	C4. Nausea and/or Vomiting	VISU.SYMNAUS	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMNAUS): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-32-618822	Radiolist Horizontal	0	C5. Right upper quadrant pain or tenderness	VISU.SYMPAIN	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMPAIN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-33-618822	Radiolist Horizontal	0	C6. Eosinophilia (> 5%)	VISU.SYMEOSIN	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMEOSIN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-34-618822	Radiolist Horizontal	0	C7. Elevations in liver enzymes	VISU.SYMLIVER	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMLIVER): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-35-618822	Radiolist Horizontal	0	C8. Yellow skin or eye discoloration (jaundice)	VISU.SYMJAUND	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMJAUND): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-36-618822	Radiolist Horizontal	0	C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	VISU.SYMTHRST	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMTHRST): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-37-618822	Radiolist Horizontal	0	C10. Rash and itching	VISU.SYMRASH	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMRASH): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-38-618822	Radiolist Horizontal	0	C11. Diarrhea	VISU.SYMDIAR	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMDIAR): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-39-618822	Radiolist Horizontal	0	C12. Constipation	VISU.SYMCONST	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. SYMCONST): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-40-618822	Section Header	0	SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING											
-- Page Dynamics (.): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														

Page Information														
Page-41-618822	Radiolist Horizontal	0	D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	VISU.PREGCONS	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. PREGCONS): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-42-618822	Radiolist Horizontal	0	D2. Did subject confirm abstinence or use of contraceptives measures?	VISU.ABSTINYN	Yes				cYNNotAssessed					
-- Page Dynamics (VISU. ABSTINYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-43-618822	Section Header	0	SECTION E: ASSESSMENTS											
-- Page Dynamics (.): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-44-618822	Help Text Line	0	Select "Yes" or "No" for each to indicate whether the assessment was performed at this unscheduled visit.											
-- Page Dynamics (.): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-45-618822	Radiolist Horizontal	0	E1. Preventive Cardiology Lifestyle Screener Questionnaire	VISU.LIFESTYN	Yes				cYN					If Yes, complete the specific assessment that will be triggered within this unscheduled visit.
-- Page Dynamics (VISU. LIFESTYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-46-618822	Radiolist Horizontal	0	E2. Pittsburgh Sleep Quality Index	VISU.PSQIYN	Yes				cYN					If Yes, complete the specific assessment that will be triggered within this unscheduled visit.
-- Page Dynamics (VISU. PSQIYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-47-618822	Radiolist Horizontal	0	E3. Data from Fitbit physical activity tracker device?	VISU.FBITYN	Yes				cYN					If Yes, complete the specific assessment that will be triggered within this unscheduled visit.
-- Page Dynamics (VISU. FBITYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99														
Page-48-618822	Radiolist Horizontal	0	E4. Tanner staging (self report)	VISU.TANSYN	Yes				cYN					If Yes, complete the specific assessment that will be triggered within this unscheduled visit.

Page Information													
-- Page Dynamics (VISU. TANSYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99													
Page-49-618822	Radiolist Horizontal	0	E5. Labs	VISU.LABYN	Yes				cYN				If Yes, complete the specific assessment that will be triggered within this unscheduled visit. This includes samples collected for local testing (and results) and core lab/biorepository. Please enter "Yes" if samples were collected for either local testing and/or core lab/biorepository testing.
-- Page Dynamics (VISU. LABYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99													
Page-50-618822	Radiolist Horizontal	0	E6. Anthropometry, blood pressure measurements	VISU.ANTHROPYN	Yes				cYN				If Yes, complete the specific assessment that will be triggered within this unscheduled visit.
-- Page Dynamics (VISU. ANTHROPYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99													
Page-51-618822	Radiolist Horizontal	0	E7. Vascular measures (PWV, CIMT, carotid stiffness)	VISU.VASCMYN	Yes				cYN				If Yes, complete the specific assessment that will be triggered within this unscheduled visit.
-- Page Dynamics (VISU. VASCMYN): Show When: VISU.VISUTYP = 1 OR VISU.VISUTYP = 99													

System Queries

Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph
sysq-619850	SYSQ_5482b	VISU.VISUMASK	Other / Cross Page		VISU.VISUMASK <> 1	If masking was not maintained since last visit and including this visit, please complete a corresponding UNMASK (Unmasking Form).	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:40	0	0	0	0	0	0

System Queries														
sysq-619853	SYSQ_5483b	VISU.VISUAEYN	Other / Cross Page		VISU.VISUAEYN = 1	Please complete a corresponding AE (Adverse Events) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619856	SYSQ_5484b	VISU.VISUCMYN	Other / Cross Page		VISU.VISUCMYN = 1	Please update and/or complete the corresponding CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619859	SYSQ_5485b	VISU.VISUFAMHX	Other / Cross Page		VISU.VISUFAMHX = 1	Please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619862	SYSQ_5486b	VISU.VISUSMCHG	Other / Cross Page		VISU.VISUSMCHG = 1	Please complete a TDIS (Temporary Discontinuation of Study Drug) Form in the SDV (Study Drug) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619865	SYSQ_5487b	VISU.VISUSMCHG	Other / Cross Page		VISU.VISUSMCHG = 2	Please complete a PDIS (Permanent Discontinuation of Study Drug) Form in the SDV (Study Drug) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0

System Queries														
sysq-619868	SYSQ_5488b	VISU.SYMMUSCL	Other / Cross Page		(Field[VISU.SYMMUSCL] = '1') Or ((Field[VISU.SYMURINE] = '1') Or ((Field[VISU.SYMFATIG] = '1') Or ((Field[VISU.SYMNAUS] = '1') Or ((Field[VISU.SYMPAIN] = '1') Or ((Field[VISU.SYMEOSIN] = '1') Or ((Field[VISU.SYMLIVER] = '1') Or ((Field[VISU.SYMJAUND] = '1') Or ((Field[VISU.SYMTHRST] = '1') Or ((Field[VISU.SYMRASH] = '1') Or ((Field[VISU.SYMDIAR] = '1') Or (Field[VISU.SYMCONST] = '1'))))))))))	Symptoms are reported during this reporting period/since last visit. If these are new or worsening symptoms since last visit, then please report on the corresponding AE (Adverse Events) Form(s).	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:41	0	0	0	0	0	0
sysq-619963	SYSQ_5536	VISU.VISUDAT	Field Null		VISU.VISUDAT IS NULL	"A1. Date of contact" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619964	SYSQ_5537	VISU.VISUDAT	Future Date		VISU.VISUDAT > Today	"A1. Date of contact" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619965	SYSQ_5538	VISU.VISUTYP	Field Null		VISU.VISUTYP IS NULL	"A2. Type:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:44	0	0	0	0	0	0
sysq-619966	SYSQ_5539	VISU.VISUTYPO	Field Null		VISU.VISUTYPO IS NULL	"A2a. Specify other visit type:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0

System Queries														
sysq-619967	SYSQ_5540	VISU.VISUPERS	Field Null		VISU.VISUPERS IS NULL	"A3. Visit/call conducted by:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619968	SYSQ_5541	VISU.VISUPOTH	Field Null		VISU.VISUPOTH IS NULL	"A3a. Specify other study member who conducted the visit/call:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619969	SYSQ_5542	VISU.VISUREAS	Field Null		VISU.VISUREAS IS NULL	"A4. Reason for visit/call:" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619970	SYSQ_5543	VISU.VISUMASK	Field Null		VISU.VISUMASK IS NULL	"A5. Was masking maintained since last visit through the completion of this visit and all associated assessments?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619971	SYSQ_5544	VISU.VISUAEYN	Field Null		VISU.VISUAEYN IS NULL	"A6. Were there any changes to adverse events since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619972	SYSQ_5545	VISU.VISUSMYN	Field Null		VISU.VISUSMYN IS NULL	"A7. Were there any changes to study medication since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619973	SYSQ_5546	VISU.VISUSMCHG	Field Null		VISU.VISUSMCHG IS NULL	"A7a. Type of change" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619974	SYSQ_5547	VISU.VISUCMYN	Field Null		VISU.VISUCMYN IS NULL	"A8. Were there any changes to concomitant medications since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619975	SYSQ_5548	VISU.VISUFAMHX	Field Null		VISU.VISUFAMHX IS NULL	"B1. Have there been any updates to the participant's family history of premature CVD since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619976	SYSQ_5549	VISU.VISUHXCHG	Field Null		VISU.VISUHXCHG IS NULL	"B1a. Did the total number of the participant's biological relatives with premature CVD change?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0

System Queries														
sysq-619977	SYSQ_5550	VISU.VISUHXNUM	Field Null		VISU.VISUHXNUM IS NULL	"B1a1. Total number of biological relatives with premature CVD" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619978	SYSQ_5551	VISU.SYMMUSCL	Field Null		VISU.SYMMUSCL IS NULL	"C1. Unexplained and/or persistent muscle pain, tenderness or weakness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619979	SYSQ_5552	VISU.SYMUSCINJ	Field Null		VISU.SYMUSCINJ IS NULL	"C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent usual physical activity or any recent trauma or injury?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619980	SYSQ_5553	VISU.SYMUSDAT	Field Null		VISU.SYMUSDAT IS NULL	"C1b. Date of first new muscle symptom" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:45	0	0	0	0	0	0
sysq-619981	SYSQ_5554	VISU.SYMUSDAT	Future Date		VISU.SYMUSDAT > Today	"C1b. Date of first new muscle symptom" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619982	SYSQ_5555	VISU.SYMURINE	Field Null		VISU.SYMURINE IS NULL	"C2. Brown or red urine" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619983	SYSQ_5556	VISU.SYMFATIG	Field Null		VISU.SYMFATIG IS NULL	"C3. Appearance of fatigue" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619984	SYSQ_5557	VISU.SYMNAUS	Field Null		VISU.SYMNAUS IS NULL	"C4. Nausea and/or Vomiting" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619985	SYSQ_5558	VISU.SYMPAIN	Field Null		VISU.SYMPAIN IS NULL	"C5. Right upper quadrant pain or tenderness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0

System Queries														
sysq-619986	SYSQ_5559	VISU.SYMEOSIN	Field Null		VISU.SYMEOSIN IS NULL	"C6. Eosinophilia (> 5%)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619987	SYSQ_5560	VISU.SYMLIVER	Field Null		VISU.SYMLIVER IS NULL	"C7. Elevations in liver enzymes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619988	SYSQ_5561	VISU.SYMJAUND	Field Null		VISU.SYMJAUND IS NULL	"C8. Yellow skin or eye discoloration (jaundice)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619989	SYSQ_5562	VISU.SYMTHRST	Field Null		VISU.SYMTHRST IS NULL	"C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619990	SYSQ_5563	VISU.SYMRASH	Field Null		VISU.SYMRASH IS NULL	"C10. Rash and itching" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619991	SYSQ_5564	VISU.SYMDIAR	Field Null		VISU.SYMDIAR IS NULL	"C11. Diarrhea" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619992	SYSQ_5565	VISU.SYMCONST	Field Null		VISU.SYMCONST IS NULL	"C12. Constipation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619993	SYSQ_5566	VISU.PREGCONS	Field Null		VISU.PREGCONS IS NULL	"D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619994	SYSQ_5567	VISU.ABSTINYN	Field Null		VISU.ABSTINYN IS NULL	"D2. Did subject confirm abstinence or use of contraceptives measures?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619995	SYSQ_5568	VISU.LIFESTYN	Field Null		VISU.LIFESTYN IS NULL	"E1. Preventive Cardiology Lifestyle Screener Questionnaire" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0

System Queries														
sysq-619996	SYSQ_5569	VISU.PSQIYN	Field Null		VISU.PSQIYN IS NULL	"E2. Pittsburgh Sleep Quality Index" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619997	SYSQ_5570	VISU.FBITYN	Field Null		VISU.FBITYN IS NULL	"E3. Data from Fitbit physical activity tracker device?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619998	SYSQ_5571	VISU.TANSYN	Field Null		VISU.TANSYN IS NULL	"E4. Tanner staging (self report)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-619999	SYSQ_5572	VISU.LABYN	Field Null		VISU.LABYN IS NULL	"E5. Labs" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-620000	SYSQ_5573	VISU.ANTHROPYN	Field Null		VISU.ANTHROPYN IS NULL	"E6. Anthropometry, blood pressure measurements" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0
sysq-620001	SYSQ_5574	VISU.VASCMYN	Field Null		VISU.VASCMYN IS NULL	"E7. Vascular measures (PWV, CIMT, carotid stiffness)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:46	0	0	0	0	0	0

pVIS_4

Page

(Visit ID = 618823, Page ID =)

Unique Identifier page-618823-618823-618823-

SECTION A: VISIT DETAILS			
SDV	* A1. Date of visit		VIS.VISDAT
SDV	* A2. Were there any adverse events experienced since last visit?	○ Yes ○ No	VIS.VISAEYN
	If Yes, please complete AE (Adverse Events) Form(s) in the LOG (Addable Log Pages) Visit.		
SDV	* A3. Is the subject taking any concomitant medications, non-prescription medication, vitamins or herbal supplements?	○ Yes ○ No	VIS.VISCMDYN
	If Yes, please complete CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.		
SECTION B: FAMILY HISTORY			
	Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).		
SDV	* B1. Does the participant have any biological relatives with a history of premature CVD?	○ Yes ○ No ○ Unknown	VIS.VISFHXYN
	If Yes, please complete CVDFHX (Family History of CVD) Form(s) in the LOG (Addable Log Pages) Visit for each of the participants biological relatives with history of premature CVD.		
SDV	* B1a. How many biological relatives does the participant have with premature CVD?		VIS.VISFHXNUM (format xx)
SDV	* B2. Have there been any updates to the participant's family history of premature CVD since last visit?	○ Yes ○ No	VIS.VISFHXCHG
	If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.		

SDV	* B2a. Did the total number of the participant's biological relatives with premature CVD change?	○ Yes ○ No	VIS.VISFHXCTOT
SDV	* B2b. Total number of biological relatives with premature CVD		VIS.VISFHXCNUM (format xx)
SECTION C: SYMPTOMS ASSESSMENT			
	Has the participant experienced any of the following symptoms during this reporting period...		
	For the Baseline Visit, please report any symptoms experienced since last visit.		
SDV	* C1. Unexplained and/or persistent muscle pain, tenderness or weakness	○ Yes ○ No ○ Unknown	VIS.SYMMUSCL
SDV	* C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	○ Yes ○ No ○ Unknown	VIS.SYMUSCINJ
SDV	* C1b. Date of first new muscle symptom		VIS.SYMUSDAT
SDV	* C2. Brown or red urine	○ Yes ○ No ○ Unknown	VIS.SYMURINE
SDV	* C3. Appearance of fatigue	○ Yes ○ No ○ Unknown	VIS.SYMFATIG
SDV	* C4. Nausea and/or Vomiting	○ Yes ○ No ○ Unknown	VIS.SYMNAUS
SDV	* C5. Right upper quadrant pain or tenderness	○ Yes ○ No ○ Unknown	VIS.SYMPAIN
SDV	* C6. Eosinophilia (> 5%)	○ Yes ○ No ○ Unknown	VIS.SYMEOSIN
SDV	* C7. Elevations in liver enzymes	○ Yes ○ No ○ Unknown	VIS.SYMLIVER
SDV	* C8. Yellow skin or eye discoloration (jaundice)	○ Yes ○ No ○ Unknown	VIS.SYMJAUND

SDV	* C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	○ Yes ○ No ○ Unknown	VIS.SYMTHRST
SDV	* C10. Rash and itching	○ Yes ○ No ○ Unknown	VIS.SYMRASH
SDV	* C11. Diarrhea	○ Yes ○ No ○ Unknown	VIS.SYMDIAR
SDV	* C12. Constipation	○ Yes ○ No ○ Unknown	VIS.SYMCONST
SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING			
SDV	* D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	○ Yes ○ No	VIS.PREG_CON
SDV	* D2. Did subject confirm abstinence or use of contraceptives measures?	○ Yes ○ No	VIS.ABS_CONTRA

Page Information

Unique Identifier	Type	Indent	Display text	Reporting / Export	SDV		Empty State	MedCod	Codelist	Max Length	Size	Before Dec	After Dec	Help Text
Page-1-618823	Section Header	0	SECTION A: VISIT DETAILS											
Page-2-618823	Date	0	A1. Date of visit	VIS.VISDAT	Yes									
Page-3-618823	Radiolist Horizontal	0	A2. Were there any adverse events experienced since last visit?	VIS.VISAEYN	Yes				cYN					
-- Page Dynamics (VIS. VISAEYN): Show When: VISITID = 20														
Page-4-618823	Help Text Line	1	If Yes, please complete AE (Adverse Events) Form(s) in the LOG (Addable Log Pages) Visit.											
-- Page Dynamics (.): Show When: VISITID = 20 AND VIS.VISAEYN = 1														

Page Information															
Page-5-618823	Radiolist Horizontal	0	A3. Is the subject taking any concomitant medications, non-prescription medication, vitamins or herbal supplements?	VIS. VISCMDYN	Yes				cYN					
-- Page Dynamics (VIS. VISCMDYN): Show When: VISITID = 20															
Page-6-618823	Help Text Line	1	If Yes, please complete CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.												
-- Page Dynamics (.): Show When: VISITID = 20 AND VIS.VISCMDYN = 1															
Page-7-618823	Section Header	0	SECTION B: FAMILY HISTORY												
Page-8-618823	Help Text Line	0	Per the protocol, premature CVD is defined as myocardial infarction, angina, stroke, or CVD procedures (CABG, coronary artery angioplasty and/or stent placement) occurring before the age of 55 years in male relatives and before the age of 65 years in female relatives, in first degree (parents, siblings) and second degree (aunts, uncles and grandparents).												
Page-9-618823	Radiolist	0	B1. Does the participant have any biological relatives with a history of premature CVD?	VIS. VISFHXYN	Yes				cYNUNK					Screening visit only
-- Page Dynamics (VIS. VISFHXYN): Show When: VISITID = 10															
Page-10-618823	Help Text Line	1	If Yes, please complete CVDFHX (Family History of CVD) Form(s) in the LOG (Addable Log Pages) Visit for each of the participants biological relatives with history of premature CVD.												
-- Page Dynamics (.): Show When: VIS.VISFHXYN = 1 AND VISITID = 10															
Page-11-618823	Numeric	1	B1a. How many biological relatives does the participant have with premature CVD?	VIS. VISFHXNUM	Yes							2	0		
-- Page Dynamics (VIS. VISFHXNUM): Show When: VIS.VISFHXYN = 1 AND VISITID = 10															
Page-12-618823	Radiolist Horizontal	0	B2. Have there been any updates to the participant's family history of premature CVD since last visit?	VIS. VISFHXCHG	Yes				cYN					Baseline visit only
-- Page Dynamics (VIS. VISFHXCHG): Show When: VISITID = 20															

Page Information														
Page-13-618823	Help Text Line	1	If Yes, please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.											
-- Page Dynamics (.): Show When: VIS.VISFHXCHG = 1 AND VISITID = 20														
Page-14-618823	Radiolist Horizontal	1	B2a. Did the total number of the participant's biological relatives with premature CVD change?	VIS.VISFHXCTOT	Yes				cYN					
-- Page Dynamics (VIS. VISFHXCTOT): Show When: VIS.VISFHXCHG = 1 AND VISITID = 20														
Page-15-618823	Numeric	1	B2b. Total number of biological relatives with premature CVD	VIS.VISFHXCNUM	Yes							2	0	
-- Page Dynamics (VIS. VISFHXCNUM): Show When: VIS.VISFHXCHG = 1 AND VIS.VISFHXCTOT = 1 AND VISITID = 20														
Page-16-618823	Section Header	0	SECTION C: SYMPTOMS ASSESSMENT											
Page-17-618823	Help Text Line	0	Has the participant experienced <u>any of the following symptoms</u> during this reporting period...											
Page-18-618823	Help Text Line	0	For the <u>Baseline Visit</u>, please report any symptoms experienced since last visit.											
-- Page Dynamics (.): Show When: VISITID = 20														
Page-19-618823	Radiolist Horizontal	0	C1. Unexplained and/or persistent muscle pain, tenderness or weakness	VIS.SYMMUSCL	Yes				cYNUNK					
Page-20-618823	Radiolist Horizontal	1	C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent physical activity or any recent trauma or injury?	VIS.SYMUSCINJ	Yes				cYNUNK					
-- Page Dynamics (VIS. SYMUSCINJ): Show When: VIS.SYMMUSCL = 1														
Page-21-618823	Date	1	C1b. Date of first new muscle symptom	VIS.SYMUSDAT	Yes									Enter the date of the first new symptom
-- Page Dynamics (VIS. SYMUSDAT): Show When: VIS.SYMMUSCL = 1														
Page-22-618823	Radiolist Horizontal	0	C2. Brown or red urine	VIS.SYMURINE	Yes				cYNUNK					

Page Information														
Page-23-618823	Radiolist Horizontal	0	C3. Appearance of fatigue	VIS.SYMFATIG	Yes				cYNUNK					
Page-24-618823	Radiolist Horizontal	0	C4. Nausea and/or Vomiting	VIS.SYMNAUS	Yes				cYNUNK					
Page-25-618823	Radiolist Horizontal	0	C5. Right upper quadrant pain or tenderness	VIS.SYMPAIN	Yes				cYNUNK					
Page-26-618823	Radiolist Horizontal	0	C6. Eosinophilia (> 5%)	VIS.SYMEOSIN	Yes				cYNUNK					
Page-27-618823	Radiolist Horizontal	0	C7. Elevations in liver enzymes	VIS.SYMLIVER	Yes				cYNUNK					
Page-28-618823	Radiolist Horizontal	0	C8. Yellow skin or eye discoloration (jaundice)	VIS.SYMJAUND	Yes				cYNUNK					
Page-29-618823	Radiolist Horizontal	0	C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst	VIS.SYMTHRST	Yes				cYNUNK					
Page-30-618823	Radiolist Horizontal	0	C10. Rash and itching	VIS.SYMRASH	Yes				cYNUNK					
Page-31-618823	Radiolist Horizontal	0	C11. Diarrhea	VIS.SYMDIAR	Yes				cYNUNK					
Page-32-618823	Radiolist Horizontal	0	C12. Constipation	VIS.SYMCONST	Yes				cYNUNK					
Page-33-618823	Section Header	0	SECTION D: PREGNANCY/CONTRACEPTIVE COUNSELING											
Page-34-618823	Radiolist Horizontal	0	D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?	VIS.PREG_CON	Yes				cYN					
Page-35-618823	Radiolist Horizontal	0	D2. Did subject confirm abstinence or use of contraceptives measures?	VIS.ABS_CONTRA	Yes				cYN					

System Queries													
Unique Identifier	Name	Table/Col	Type	Description	Conditions	Error Message	Active	Last Mod (GMT)	Total	Open	Ans	Closed	Mark Del	Orph

System Queries														
sysq-618890	SYSQ_4898	VIS.VISDAT	Other / Cross Page		VISITID = 10 AND 10-20-ICF.ICF_DT > VIS.VISDAT	This date is prior to the informed consent date. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:08	0	0	0	0	0	0
sysq-618892	SYSQ_4899	VIS.VISDAT	Other / Cross Page		VISITID = 20 AND (FUNCTION-DATE_COMPARE(10-10-VIS.VISDAT, VIS.VISDAT) < 0 OR FUNCTION-DATE_COMPARE(10-10-VIS.VISDAT, VIS.VISDAT) > 42)	This date is not within 6 weeks of the screening visit. Please review and confirm.		Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618894	SYSQ_4900	VIS.VISAEYN	Other / Cross Page		VIS.VISAEYN = 1 AND VISITID = 20	Please complete a corresponding AE (Adverse Events) form.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618896	SYSQ_4901	VIS.VISFHXYN	Other / Cross Page		VIS.VISFHXYN = 1	Please complete the corresponding CVDFHX (Family History of CVD) Form(s) in the LOG (Addable Log Pages) Visit for each of the participants biological relatives with history of premature CVD.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618898	SYSQ_4902	VIS.VISCMDYN	Other / Cross Page		VIS.VISCMDYN = 1 AND VISITID = 20	Please complete the corresponding CMED (Concomitant Medications) Form(s) in the LOG (Addable Log Pages) Visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-618899	SYSQ_4903	VIS.VISFHXCHG	Other / Cross Page		VIS.VISFHXCHG = 1 AND VISITID = 20	Please update and/or create a new CVDFHX (Family History of CVD) Form in the LOG (Addable Log Pages) Visit for any changes to the participant's biological relatives with premature CVD since last visit.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0

System Queries														
sysq-618902	SYSQ_4904	VIS.SYMMUSCL	Other / Cross Page		(VIS.SYMMUSCL = 1 OR VIS.SYMURINE = 1 OR VIS.SYMFATIG = 1 OR VIS.SYMNAUS = 1 OR VIS.SYMPAIN = 1 OR VIS.SYMEOSIN = 1 OR VIS.SYMLIVER = 1 OR VIS.SYMJAUND = 1 OR VIS.SYMTHRST = 1 OR VIS.SYMRASH = 1 OR VIS.SYMDIAR = 1 OR VIS.SYMCONST = 1) AND VISITID = 20	Symptoms are reported during this reporting period/since last visit. If these are new or worsening symptoms since last visit, then please report on the corresponding AE (Adverse Events) Form(s).	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:09	0	0	0	0	0	0
sysq-619161	SYSQ_5035	VIS.SYMUSDAT	Other / Cross Page		VISITID = 20 AND FUNCTION-DATE_COMPARE(VIS.SYMUSDAT, 10-10-VIS.VISDAT) >= 0	Date of first new muscle symptom since previous reporting period is either the same as or prior to the last reporting period (screening visit). Please clarify.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619164	SYSQ_5036	VIS.VISDAT	Field Null		VIS.VISDAT IS NULL	"A1. Date of visit" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619165	SYSQ_5037	VIS.VISDAT	Future Date		VIS.VISDAT > Today	"A1. Date of visit" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619167	SYSQ_5038	VIS.VISAEYN	Field Null		VIS.VISAEYN IS NULL	"A2. Were there any adverse events experienced since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619170	SYSQ_5039	VIS.VISCMDYN	Field Null		VIS.VISCMDYN IS NULL	"A3. Is the subject taking any concomitant medications, non-prescription medication, vitamins or herbal supplements?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0

System Queries														
sysq-619172	SYSQ_5040	VIS.VISFHXYN	Field Null		VIS.VISFHXYN IS NULL	"B1. Does the participant have any biological relatives with a history of premature CVD?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619174	SYSQ_5041	VIS.VISFHXNUM	Field Null		VIS.VISFHXNUM IS NULL	"B1a. How many biological relatives does the participant have with premature CVD?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619176	SYSQ_5042	VIS.VISFHXNUM	Range		VIS.VISFHXNUM <= 0 OR VIS.VISFHXNUM > 20	"B1a. How many biological relatives does the participant have with premature CVD?" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619177	SYSQ_5043	VIS.VISFHXCHG	Field Null		VIS.VISFHXCHG IS NULL	"B2. Have there been any updates to the participant's family history of premature CVD since last visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619179	SYSQ_5044	VIS.VISFHXCTOT	Field Null		VIS.VISFHXCTOT IS NULL	"B2a. Did the total number of the participant's biological relatives with premature CVD change?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619182	SYSQ_5045	VIS.VISFHXCNUM	Field Null		VIS.VISFHXCNUM IS NULL	"B2b. Total number of biological relatives with premature CVD" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619183	SYSQ_5046	VIS.SYMMUSCL	Field Null		VIS.SYMMUSCL IS NULL	"C1. Unexplained and/or persistent muscle pain, tenderness or weakness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:18	0	0	0	0	0	0
sysq-619186	SYSQ_5047	VIS.SYMUSCINJ	Field Null		VIS.SYMUSCINJ IS NULL	"C1a. Is the Unexplained and/or persistent muscle pain, tenderness or weakness associated with recent usual physical activity or any recent trauma or injury?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619188	SYSQ_5048	VIS.SYMUSDAT	Field Null		VIS.SYMUSDAT IS NULL	"C1b. Date of first new muscle symptom" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0

System Queries														
sysq-619189	SYSQ_5049	VIS.SYMUSDAT	Future Date		VIS.SYMUSDAT > Today	"C1b. Date of first new muscle symptom" cannot be in the future.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619191	SYSQ_5050	VIS.SYMURINE	Field Null		VIS.SYMURINE IS NULL	"C2. Brown or red urine" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619193	SYSQ_5051	VIS.SYMFATIG	Field Null		VIS.SYMFATIG IS NULL	"C3. Appearance of fatigue" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619196	SYSQ_5052	VIS.SYMNAUS	Field Null		VIS.SYMNAUS IS NULL	"C4. Nausea and/or Vomiting" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619197	SYSQ_5053	VIS.SYMPAIN	Field Null		VIS.SYMPAIN IS NULL	"C5. Right upper quadrant pain or tenderness" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619199	SYSQ_5054	VIS.SYMEOSIN	Field Null		VIS.SYMEOSIN IS NULL	"C6. Eosinophilia (> 5%)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619201	SYSQ_5055	VIS.SYMLIVER	Field Null		VIS.SYMLIVER IS NULL	"C7. Elevations in liver enzymes" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619204	SYSQ_5056	VIS.SYMJAUND	Field Null		VIS.SYMJAUND IS NULL	"C8. Yellow skin or eye discoloration (jaundice)" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619206	SYSQ_5057	VIS.SYMTHRST	Field Null		VIS.SYMTHRST IS NULL	"C9. Frequent or night-time urination, excessive fatigue and/or excessive thirst" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619208	SYSQ_5058	VIS.SYMRASH	Field Null		VIS.SYMRASH IS NULL	"C10. Rash and itching" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0

System Queries														
sysq-619210	SYSQ_5059	VIS.SYMDIAR	Field Null		VIS.SYMDIAR IS NULL	"C11. Diarrhea" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619212	SYSQ_5060	VIS.SYMCONST	Field Null		VIS.SYMCONST IS NULL	"C12. Constipation" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619213	SYSQ_5061	VIS.PREG_CON	Field Null		VIS.PREG_CON IS NULL	"D1. Was pregnancy/contraceptive counseling discussed with the subject at this visit?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619215	SYSQ_5062	VIS.ABS_CONTRA	Field Null		VIS.ABS_CONTRA IS NULL	"D2. Did subject confirm abstinence or use of contraceptives measures?" cannot be empty.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:19	0	0	0	0	0	0
sysq-619218	SYSQ_5063	VIS.VISFHXCNUM	Range		VIS.VISFHXCNUM <= 0 OR VIS.VISFHXCNUM > 20	"B2b. Total number of biological relatives with premature CVD" is not within expected range.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:38:20	0	0	0	0	0	0
sysq-620495	SYSQ_5896	VIS.VISDAT	Other / Cross Page	Protocol v4.1/5.0 update	VISITID = 20 AND (FUNCTION-DATE_COMPARE(10-10-VIS.VISDAT, VIS.VISDAT) < 14 OR FUNCTION-DATE_COMPARE(10-10-VIS.VISDAT, VIS.VISDAT) > 42)	The visit date is either less than 2 weeks or more than 6 weeks from the screening visit. Please review and confirm.	Yes	Horng, Dunstan [DES] 14-SEP-20 14:39:03	0	0	0	0	0	0