000000174112115214111	YING INFORMATION
A1. Study Identification Number _	
Replaced by blinded subject ID	
subj_id Blinded subject ID	
Blinded site ID <created var=""></created>	
site_id Blinded site ID	
A2. Acrostic Identifier	
Removed to protect privacy	
A3. Date of form completion _	$\frac{1}{M} = \frac{1}{M} = \frac{1}$
Replaced by age	м м о о ү ү ү ү
COMP_AGE <created var=""> Age (yrs) of the subject</created>	t at A3. Date of form completion
A4. Name of person completing form	
Removed to protect privacy	PRINT FULL NAME INITIALS
Section B: ADVERSE	EVENT SUMMARY
B1. Did patient experience any adverse events s	
	since the study consent form was signed?
Y	since the study consent form was signed? ES 1 NO 2
Y	,
ANYA B1. Did patient experience adverse even	ES 1 NO 2 STOP - FORM COMPLETE
ANYA B1. Did patient experience adverse even	ES 1 NO 2 STOP - FORM COMPLETE
ANYA B1. Did patient experience adverse even	ES2 STOP - FORM COMPLETE
ANYA B1. Did patient experience adverse even B2. Number of adverse events	ES2 STOP - FORM COMPLETE
ANYA B1. Did patient experience adverse even B2. Number of adverse events NUMAE B2. Number of adverse events	ES2 STOP - FORM COMPLETE
ANYA E B1. Did patient experience adverse events B2. Number of adverse events NUMAE B2. Number of adverse events Event #1 B3. a. Type of event	ES2 STOP - FORM COMPLETE
ANYA E B1. Did patient experience adverse events B2. Number of adverse events NUMAE B2. Number of adverse events Event #1 B3. a. Type of event VENTRICULAR TACHYCA	NO 2 STOP - FORM COMPLETE nts (1-4)
ANYA E B1. Did patient experience adverse events B2. Number of adverse events NUMAE B2. Number of adverse events Event #1 B3. a. Type of event VENTRICULAR TACHYCARDIA	NO 2 STOP - FORM COMPLETE nts (1-4)
ANYA E B1. Did patient experience adverse events B2. Number of adverse events NUMAE B2. Number of adverse events Event #1 B3. a. Type of event VENTRICULAR TACHYCAR ATRIAL TACHYCARDIA SYNCOPE	NO 2 STOP - FORM COMPLETE 1
ANYA E B1. Did patient experience adverse events B2. Number of adverse events NUMAE B2. Number of adverse events Event #1 B3. a. Type of event VENTRICULAR TACHYCA ATRIAL TACHYCARDIA SYNCOPE	NO2 STOP - FORM COMPLETE 1

	Pediatric Heart Network: F	ontan	Cross-	Secti	ional St	udy			DUN O
	Form F06A: Fontan Adv	erse E	Event S	umm	ary For	m			PHN-0 ⁻
	OTHER								
	1. If OTHER, specify	/:							
									
TYPEVENT_0	B3a. Type of adverse event ((0)							
EVNTSPEC_0	B3a1. If other, specify (0)								
b. Date of	event		/		/_	Y	Y		
Replaced by age									
AEDATE_0_AGE <0	reated var> Age (yrs) of the	subje	ct at I	33b.	Date of	adv	erse	event	(0)

	Tomin Took. Fondan Adverse	Event Summary Form				
Event #1 (continue	ed)					
c. Was treati	ment administered for event?	YES1	NO2 (B3.e)			
AETX_0 B3c. Was						
d. Type of tre	eatment					
	OUTPATIENT, NO INTERV	ENTION REQUIRED .	1(B3.e)			
	OUTPATIENT, INTERVENT	ΓΙΟΝ REQUIRED	2			
	INPATIENT		3			
	Specify treatment or inte	rvention administered	for event			
	· •		· · · · · · · · · · · · · · · · · · ·			
TVTVD5 0 D						
_	3d. Type of treatment (0)					
	•	\\	NO 0			
e. Did the ev			NO2			
AERSLV_0 B3e. D	Oid the adverse event resolve?	(0)				
	1. If YES, date event resolved					
		///				
Replaced by age		M M D D	Y Y Y Y			
	<pre><created var=""> Age (yrs) of the resolved (0)</created></pre>	subject at B3e1. Date	adverse event			
f. Seriousnes	ss of event					
	NOT SERIOUS		1			
	MODERATELY SERIOUS.		2			
	SERIOUS		3			
	If SERIOUS, was a Serio (Form F06B) completed		ification Form			
	,	YES1	NO2			

SAELEVEL_0	B3f. Seriousness of adverse event (0)
AENOTIFM_0	B3f1. Was a Serious AE Form completed? (0)

g. Was the event associated with a study test?

NOT ASSOCIATED 1

POSSIBLY ASSOCIATED.....2

Fontan Adverse Event Summary Form	Form F06A	Version A: 08-20-02	Page 3 of 9
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COMPLETE SERIOUS ADVERSE EVENT NOTIFICATION FORM (F06B)

Form F06A: Fontan Adverse Event Summary Form

PROBABLY ASSOCIATED3

AEASSOC_0 B3g. Was the adverse event associated with a study test (0)

1. If POSSIBLY or PROBABLY ASSOCIATED, specify test:

ECHOCARDIOGRAM......1

CARDIAC MRI......2

ELECTROCARDIOGRAM....3

EXERCISE TEST 4

VENIPUNCTURE5

OTHER......99

a. If OTHER, specify: ____

SPECTEST_0	B3g1. Specify test (0)
SPTSTOTH_0	B3g1a. Type of adverse event (0)

FORMSTAT_ID	Unique form/subject ID
FORM_ID	4 letter code for the form
VER_ID	1 letter code added to form code to make unique form/version
DESTATUS	Form completion

Event	#2
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B4.	a. Type of even	t		
		VENTRICULAR TACHYC	ARDIA	1
		ATRIAL TACHYCARDIA		2
		SYNCOPE		3
		FALL-INDUCED TRAUMA	/BRUISING	4
		SEVERE ANXIETY		5
		VENIPUNCTURE BRUISI	NG	6
		OTHER		99
		1. If OTHER, specify:		
	b. Date of ever	nt		
		ı	и и в	YYYY
	c. Was treatme	ent administered for event?	YES1	NO2 (B4.e)
	d. Type of trea	tment		
		OUTPATIENT, NO INTER	VENTION REQUIR	ED 1(B4.e)
		OUTPATIENT, INTERVEN	NTION REQUIRED.	2
		INPATIENT		3
		1. Specify treatment or int	ervention administe	red for event
				·····
	e. Did the ever	nt resolve?	YES1	NO2
			1. If YES, date ev	vent resolved
			/	/
			M M D	D Y Y Y Y
	f. Seriousness			
		NOT SERIOUS		
		MODERATELY SERIOUS		
		SERIOUS		3
		If SERIOUS, was a Se (Form F06B) complete		t Notification Form
			YES1	NO2
				COMPLETE SERIOUS ADVERSE EVENT NOTIFICATION FORM (F06B)

	g.	Was the ever	nt associated with a study te	est?	
			NOT ASSOCIATED	1	
			POSSIBLY ASSOCIATED	2	
			PROBABLY ASSOCIATED)3	
			1. If POSSIBLY or PROB	ABLY ASSOCIATED, sp	pecify test:
			ECHOCARDIOGR <i>A</i>	AM 1	
			CARDIAC MRI	2	
			ELECTROCARDIO	GRAM 3	
			EXERCISE TEST	4	
			VENIPUNCTURE	5	
			OTHER	99	
			a. If OTHER, speci	ify:	
Even	t #3	3			
B5.	a.	Type of event			
			VENTRICULAR TACHYCA	ARDIA	1
			ATRIAL TACHYCARDIA		2
			SYNCOPE		3
			FALL-INDUCED TRAUMA	/BRUISING	4
			SEVERE ANXIETY		5
			VENIPUNCTURE BRUISIN	NG	6
			OTHER		99
			1. If OTHER, specify: _		
	b.	Date of even	t	M M / D D / Y	<u> </u>
	C.	Was treatme	nt administered for event?	YES1	NO2 (B5.e)

Event #3 ((continued))
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d.	Type of treatment				
	OUTPATIENT, NO INTE	ERVENTION REQUI	RED 1(B5.e)		
	OUTPATIENT, INTERV	ENTION REQUIRED) 2		
	INPATIENT		3		
	1. Specify treatment or	intervention administ	tered for event		
					
۵	Did the event resolve?	VEQ 1	NO2		
€.	Did the event resolve:				
		1. If YES, date			
		/	/		
f.	Seriousness of event				
	NOT SERIOUS		1		
	MODERATELY SERIOL	JS	2		
	SERIOUS		3		
	 If SERIOUS, was a Serious Adverse Event Notification Form (Form F06B) completed for this event? 				
		YES1	NO2		
			COMPLETE SERIOUS ADVERSE EVENT NOTIFICATION FORM (F06B)		
q.	Was the event associated with a study	y test?	(002		
•	NOT ASSOCIATED				
	POSSIBLY ASSOCIATE	ED2			
	PROBABLY ASSOCIAT				
	1. If POSSIBLY or PRO	OBABLY ASSOCIAT	ED, specify test:		
	ECHOCARDIOG				
	CARDIAC MRI	2			
	ELECTROCARD	DIOGRAM 3			
	EXERCISE TES	T 4			
	VENIPUNCTURI	E5			
	OTHER	99			
	a. If OTHER, sp	ecify:	· · · · · · · · · · · · · · · · · · ·		

⊏,	10	nt	#	1
=	ιe	nı	#	4

Б6.	a. Type of ever				
		VENTRICULAR TACHYCA	ARDIA	1	
		ATRIAL TACHYCARDIA		2	
		SYNCOPE		3	
		FALL-INDUCED TRAUMA	/BRUISING	4	
		SEVERE ANXIETY		5	
		VENIPUNCTURE BRUISI	NG	6	
		OTHER		99	
		1. If OTHER, specify:		· · · · · · · · · · · · · · · · · · ·	
	b. Date of eve	nt			
	b. Date of ever		M M D D	/ 	
	c. Was treatm	ent administered for event?	YES1	NO2 (B6.e)	
	d. Type of trea	atment			
	OUTPATIENT, NO INTERVENTION REQUIRED 1(B6.e)				
	OUTPATIENT, INTERVENTION REQUIRED 2				
		INPATIENT		3	
		1. Specify treatment or int	ervention administ	ered for event	
		· · ·			
	e. Did the eve	nt resolve?	YES1	NO2	
			1. If YES, date e	event resolved	
			/	/	
			M M D	D Y Y Y Y	
	f. Seriousness	of event			
		NOT SERIOUS		1	
		MODERATELY SERIOUS		2	
		SERIOUS		3	
	 If SERIOUS, was a Serious Adverse Event Notification Form (Form F06B) completed for this event? 				
			YES1	NO2	
				COMPLETE SERIOUS ADVERSE EVENT NOTIFICATION FORM (F06B)	

Form F06A: Fontan Adverse Event Summary Form

Event #4 (continued)

g. Was the event associated with a study test?		
NOT ASSOCIATED 1		
POSSIBLY ASSOCIATED2		
PROBABLY ASSOCIATED3		
1. If POSSIBLY or PROBABLY ASSOCIATED, specify test:		
ECHOCARDIOGRAM 1		
CARDIAC MRI2		
ELECTROCARDIOGRAM 3		
EXERCISE TEST 4		
VENIPUNCTURE 5		
OTHER99		
a. If OTHER, specify:		