

Marfan Data Codebook
A202: Serious Adverse Event Adjudication Form
(raw data)

DATE CREATED 13SEP18

Number of Observations: 92

Number of Variables: 15

Organization of file: Up to Five Records per Patient

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
A1. Random identification number	RANDOM_ID			92(0)			144537.00-145860.00
A2. Adverse Event Number	AE_NUM	1	43(46.7)				
		2	18(19.6)				
		3	10(10.9)				
		4	2(2.2)				
		5	4(4.3)				
		6	6(6.5)				
		7	2(2.2)				
		8	4(4.3)				
		9	1(1.1)				
		23	1(1.1)				
		32	1(1.1)				
A3. A200 Form Type	FORM_TYPE	Initial	50(54.3)				
		Resolution	42(45.7)				
A4. Event onset age from site	ONSET_AGE			92(0)	13.21(6.04)	13.80(8.55,17.90)	0.80-26.00

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A5. Event code from site	EVTCODE_SITE	10000085	1(1.1)				
		10001497	4(4.3)				
		10002646	1(1.1)				
		10002855	1(1.1)				
		10003658	4(4.3)				
		10003815	3(3.3)				
		10008479	3(3.3)				
		10010922	1(1.1)				
		10012174	2(2.2)				
		10012378	5(5.4)				
		10012745	1(1.1)				
		10013573	1(1.1)				
		10015090	1(1.1)				
		10016256	1(1.1)				
		10018854	1(1.1)				
		10019211	1(1.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		10020755	1(1.1)				
		10024119	1(1.1)				
		10033656	1(1.1)				
		10034495	1(1.1)				
		10034719	1(1.1)				
		10035598	1(1.1)				
		10035755	1(1.1)				
		10035762	10(10.9)				
		10037660	2(2.2)				
		10038848	1(1.1)				
		10039722	1(1.1)				
		10040400	1(1.1)				
		10042604	2(2.2)				
		10043607	2(2.2)				
		10044030	1(1.1)				
		10046459	1(1.1)				

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		10046574	1(1.1)				
		10046972	2(2.2)				
		10047302	1(1.1)				
		10048038	2(2.2)				
		10049083	1(1.1)				
		10049582	1(1.1)				
		90004018	1(1.1)				
		90004028	4(4.3)				
		90004058	1(1.1)				
		90004068	1(1.1)				
		90004078	3(3.3)				
		90004084	2(2.2)				
		90004092	3(3.3)				
		90030220	4(4.3)				
		90030304	1(1.1)				
		90030418	2(2.2)				

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		90030468	1(1.1)				
		90030474	1(1.1)				
		90030964	1(1.1)				
A5a. Event name from site	EVTNAME_SITE	aortic dissection	1(1.1)				
		aortic root enlargement	1(1.1)				
		Asthma exacerbation/pneumonia	1(1.1)				
		blood/bone marrow(sickle cell crisis)	1(1.1)				
		cardiac general	1(1.1)				
		cerebral abcess	2(2.2)				
		Infection: viral	1(1.1)				
		Menorrhagia	1(1.1)				
		Mitral valve replacement	1(1.1)				
		pregnancy	1(1.1)				
		Pregnancy	1(1.1)				
		RSV infection	1(1.1)				
		Schizophrenia	1(1.1)				

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		Sexual/Reproductive Function-Other: Pregnancy	1(1.1)				
		SKIPPED	77(83.7)				
B1. Do you agree with the event code/name assigned by the site?	AGREE	NO	15(16.3)				
		YES	77(83.7)				
B1a. If NO, specify new code:	NEW_CODE	10002855	1(1.1)				
		10006485	1(1.1)				
		10011642	1(1.1)				
		10035725	2(2.2)				
		10037660	1(1.1)				
		10046788	1(1.1)				
		10046972	1(1.1)				
		10047895	1(1.1)				
		10048343	2(2.2)				
		10051077	1(1.1)				

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		90030418	1(1.1)				
		90030956	2(2.2)				
		SKIPPED	77(83.7)				
B1b. Event name (if other, specify)	NEW_EVT_NAME	SKIPPED	92(100.0)				
B2. Seriousness of event	SERIOUS	DEATH	1(1.1)				
		LIFE THREATENING	1(1.1)				
		NOT SERIOUS	1(1.1)				
		SERIOUS	89(96.7)				
B3. Was this event expected?	EXPECTED	NO	34(37.0)				
		YES	58(63.0)				
B4. Was this event related to the study drug subject received?	REL_DRUG	NOT RELATED	85(92.4)				
		POSSIBLY RELATED	5(5.4)				
		PROBABLY RELATED	2(2.2)				

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B6. Resolved according to regulatory reporting guidelines?	AE_RESOLVED	NO	1(1.1)				
		YES	91(98.9)				
B9. Is this adjudication final?	ADJ_FINAL	<i>Version</i>	29(31.5)				
		YES	63(68.5)				
Form Version	VER_ID	A	29(31.5)				
		B	48(52.2)				
		C	4(4.3)				
		D	11(12.0)				