

**Marfan Data Codebook**  
**Form A200: Adverse Event Form**  
**(raw data)**

**DATE CREATED 13SEP18**

**Number of Observations: 1212**

**Number of Variables: 304**

**Organization of file: Up to 52 Records per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
A1. Study random identification number	RANDOM_ID			1212(0)			144508.00-145870.00
A2. Event number	AE_NUM	1	409(33.7)				
		2	258(21.3)				
		3	157(13.0)				
		4	96(7.9)				
		5	72(5.9)				
		6	56(4.6)				
		7	37(3.1)				
		8	30(2.5)				
		9	19(1.6)				
		10	10(0.8)				
		11	7(0.6)				
		12	4(0.3)				
		13	4(0.3)				
		14	4(0.3)				
		15	4(0.3)				

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		16	4(0.3)				
		17	4(0.3)				
		18	4(0.3)				
		19	4(0.3)				
		20	4(0.3)				
		21	3(0.2)				
		22	3(0.2)				
		23	3(0.2)				
		24	4(0.3)				
		25	2(0.2)				
		26	2(0.2)				
		27	2(0.2)				
		28	2(0.2)				
		29	1(0.1)				
		30	2(0.2)				
		32	1(0.1)				
A2a. Form type	FORM_TYPE	Follow-up	438(36.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		Initial	774(63.9)				
A2a1. Did anything change since the initial form was completed?	FORM_CHANGE	1:Yes	74(6.1)				
		2:No	364(30.0)				
		Skipped	774(63.9)				
A3. Onset Age	ONSET_AGE			774(438)	11.84(6.04)	11.60(6.70,15.80)	0.80-26.90
A4. Age when initiated	INITIATED_AGE			774(438)	12.01(6.04)	11.80(7.00,15.90)	0.90-27.10
A6. AE during musculoskeletal ancillary study measurements	ANCILLARY_AE	<i>Missing</i>	68(5.6)				
		NO	711(58.7)				
		SKIPPED	431(35.6)				
		YES	2(0.2)				
A7. First reported while completing A116	REPORT_A116	<i>Missing</i>	152(12.5)				
		NO	224(18.5)				
		SKIPPED	419(34.6)				
		YES	417(34.4)				

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A7a. Age when A116 where AE first identified or reported	A116_AGE			417(795)	11.75(5.97)	11.60(6.80,15.40)	1.90-27.10
B1. Is this AE related to a previously reported AE?	RELATED	1:Yes	69(5.7)				
		2:No	705(58.2)				
		Skipped	438(36.1)				
B1a. If YES, specify AE event #	PRIORNO	1	20(1.7)				
		2	10(0.8)				
		3	11(0.9)				
		4	5(0.4)				
		5	7(0.6)				
		6	2(0.2)				
		7	4(0.3)				
		8	1(0.1)				
		9	1(0.1)				
		10	1(0.1)				
		11	1(0.1)				
		17	1(0.1)				

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		18	1(0.1)				
		19	1(0.1)				
		21	1(0.1)				
		23	1(0.1)				
		27	1(0.1)				
		Skipped	1143(94.3)				
B2. Event code (CTCAE MedDRA code)	EVTCODE	1000085	15(1.2)				
		1000510	4(0.3)				
		10001497	19(1.6)				
		10001760	5(0.4)				
		10002646	5(0.4)				
		10002855	7(0.6)				
		10003239	6(0.5)				
		10003658	4(0.3)				
		10003815	3(0.2)				
		10003988	16(1.3)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
			1(0.1)				
			7(0.6)				
			38(3.1)				
			12(1.0)				
			1(0.1)				
			1(0.1)				
			4(0.3)				
			6(0.5)				
			4(0.3)				
			7(0.6)				
			1(0.1)				
			5(0.4)				
			19(1.6)				
			1(0.1)				
			9(0.7)				
			48(4.0)				
			5(0.4)				

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			1(0.1)				
			1(0.1)				
			11(0.9)				
			3(0.2)				
			17(1.4)				
			1(0.1)				
			2(0.2)				
			1(0.1)				
			31(2.6)				
			1(0.1)				
			1(0.1)				
			1(0.1)				
			2(0.2)				
			2(0.2)				
			1(0.1)				
			56(4.6)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		10020413	2(0.2)				
		10020755	4(0.3)				
		10020782	1(0.1)				
		10021099	3(0.2)				
		10021113	1(0.1)				
		10021143	1(0.1)				
		10022004	1(0.1)				
		10022437	22(1.8)				
		10023212	2(0.2)				
		10023215	1(0.1)				
		10023644	1(0.1)				
		10024119	1(0.1)				
		10025182	1(0.1)				
		10027175	1(0.1)				
		10028411	15(1.2)				
		10028813	5(0.4)				
		10028836	3(0.2)				



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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
			1(0.1)				
			1(0.1)				
			1(0.1)				
			1(0.1)				
			1(0.1)				
			9(0.7)				
			19(1.6)				
			1(0.1)				
			1(0.1)				
			1(0.1)				
			10(0.8)				
			1(0.1)				
			1(0.1)				
			10(0.8)				
			1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		10037087	4(0.3)				
		10037660	12(1.0)				
		10038848	1(0.1)				
		10039722	1(0.1)				
		10040400	1(0.1)				
		10040752	2(0.2)				
		10040756	3(0.2)				
		10042101	8(0.7)				
		10042604	2(0.2)				
		10042667	1(0.1)				
		10042772	23(1.9)				
		10042777	5(0.4)				
		10043607	2(0.2)				
		10044035	1(0.1)				
		10044565	1(0.1)				
		10046543	2(0.2)				
		10046574	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
			7(0.6)				
			1(0.1)				
			2(0.2)				
			2(0.2)				
			1(0.1)				
			10(0.8)				
			1(0.1)				
			1(0.1)				
			2(0.2)				
			1(0.1)				
			1(0.1)				
			1(0.1)				
			1(0.1)				
			4(0.3)				
			1(0.1)				
			2(0.2)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		90004018	2(0.2)				
		90004028	6(0.5)				
		90004038	26(2.1)				
		90004042	17(1.4)				
		90004050	2(0.2)				
		90004058	2(0.2)				
		90004068	11(0.9)				
		90004076	7(0.6)				
		90004078	12(1.0)				
		90004080	4(0.3)				
		90004082	2(0.2)				
		90004084	10(0.8)				
		90004086	1(0.1)				
		90004092	5(0.4)				
		90030006	1(0.1)				
		90030164	1(0.1)				
		90030220	6(0.5)				

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		90030228	1(0.1)				
		90030268	1(0.1)				
		90030304	1(0.1)				
		90030384	2(0.2)				
		90030392	2(0.2)				
		90030418	3(0.2)				
		90030426	3(0.2)				
		90030440	1(0.1)				
		90030454	4(0.3)				
		90030466	2(0.2)				
		90030468	1(0.1)				
		90030474	1(0.1)				
		90030486	3(0.2)				
		90030492	1(0.1)				
		90030496	1(0.1)				
		90030506	4(0.3)				

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		90030508	4(0.3)				
		90030530	1(0.1)				
		90030686	1(0.1)				
		90030964	1(0.1)				
		90030982	3(0.2)				
		Skipped	438(36.1)				
B3. Serious Adverse Event	SAE	1:Yes	95(7.8)				
		2:No	695(57.3)				
		Skipped	422(34.8)				
B3a. Subject death	SAE_DEATH	2:No	95(7.8)				
		Skipped	1117(92.2)				
B3b. Life-threatening	SAE_LIFE	1:Yes	12(1.0)				
		2:No	83(6.8)				
		Skipped	1117(92.2)				
B3c. Required hospitalization or prolonged hospitalization	SAE_HOSP	1:Yes	88(7.3)				
		2:No	7(0.6)				

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		Skipped	1117(92.2)				
B3d. Results in persistent/significant incapacity	SAE_DISABLED	2:No	95(7.8)				
		Skipped	1117(92.2)				
B3e. Results in a congenital anomaly in the offspring	SAE_CONGENIT	1:Yes	2(0.2)				
		2:No	93(7.7)				
		Skipped	1117(92.2)				
B3f. Important medical event	SAE_IMPORTAN	NO	13(1.1)				
		SKIPPED	170(14.0)				
		<i>Version</i>	1025(84.6)				
		YES	4(0.3)				
B4. Severity of event (refer to CTCAE v3.0)	SEVERITY	Grade 1	326(26.9)				
		Grade 2	293(24.2)				
		Grade 3	158(13.0)				
		Grade 4	13(1.1)				
		Skipped	422(34.8)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B5. Expectedness	EXPECTED	Expected	466(38.4)				
		Skipped	422(34.8)				
		Unexpected	324(26.7)				
B6a. Age when last dose of study drug taken	AEDOSE_AGE			379(833)	11.97(5.93)	12.00(6.90,15.60)	0.80-26.10
B6. Relationship to Drug (Causality)	RELAT_DRUG	Not related	460(38.0)				
		Possibly related	350(28.9)				
		Probably related	38(3.1)				
		Skipped	364(30.0)				
B6b. Time	AEDOSE_T						
B6b1. Units	AEDOSE_TU	<i>Missing</i>	4(0.3)				
		24HR	192(15.8)				
		AM	121(10.0)				
		PM	71(5.9)				
		Skipped	824(68.0)				
B6c. Study drug action taken	DRUG_ACTION	No change to study drug	302(24.9)				
		Skipped	824(68.0)				



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		Study drug dosage adjusted	45(3.7)				
		Study drug dosage temporarily stopped	27(2.2)				
		Study drug permanently discontinued	14(1.2)				
B7a. Were any labs, tests or studies done to diagnose/evaluate	ASSESS_LABS	NO	40(3.3)				
		SKIPPED	109(9.0)				
		<i>Version</i>	1025(84.6)				
		YES	38(3.1)				
B7b. Number of labs, tests or studies done	ASSESS_NUM			38(1174)	2.74(2.58)	2.00(1.00,4.00)	1.00-15.00
B7b.1a1.Test Name	ASSESS_NAME_0	basic metabolic panel	2(0.2)				
		Brain MRI	1(0.1)				
		CBC	2(0.2)				
		CBC with differential and platelets	1(0.1)				
		chest x-ray	4(0.3)				
		colonoscopy	2(0.2)				
		Complete blood count	1(0.1)				

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		CT angiogram	1(0.1)				
		CXR	1(0.1)				
		ECG	2(0.2)				
		echocardiogram	1(0.1)				
		EKG	4(0.3)				
		evaluation by ophthalmologist	2(0.2)				
		evaluation by pediatrician	3(0.2)				
		HCG urine test	1(0.1)				
		holter	1(0.1)				
		<i>Missing</i>	149(12.3)				
		orthopedics surgical evaluation	1(0.1)				
		psychologist	1(0.1)				
		Rapid strep	1(0.1)				
		study (protocol) ECHO	1(0.1)				
		Throat swab	1(0.1)				
		urine culture	1(0.1)				

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		<i>Version</i>	1025(84.6)				
		x-ray	3(0.2)				
B7b.1a2.Test Name	ASSESS_NAME_1	abcd and chemistry	2(0.2)				
		blood work	1(0.1)				
		cbc	2(0.2)				
		cbc (complete blood count)	2(0.2)				
		cbcd/cmp	2(0.2)				
		chest xray	1(0.1)				
		cmp	1(0.1)				
		ddimer	1(0.1)				
		eeg	1(0.1)				
		ekg	2(0.2)				
		endoscopy	1(0.1)				
		evaluation by ophthalmology	1(0.1)				
		<i>Missing</i>	164(13.5)				
		multiple labs	2(0.2)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		pap smear	1(0.1)				
		psychiatrist eval.	1(0.1)				
		urinalysis	2(0.2)				
		<i>Version</i>	1025(84.6)				
B7b.1a3.Test Name	ASSESS_NAME_2	blood culture	1(0.1)				
		brain ct	1(0.1)				
		bravo monitor	1(0.1)				
		cbcd/cmp	2(0.2)				
		drug of abuse	2(0.2)				
		echo	1(0.1)				
		esr	1(0.1)				
		<i>Missing</i>	173(14.3)				
		microscopic exam urine	1(0.1)				
		mrsa screen	1(0.1)				
		pap smear	1(0.1)				
		psychiatrist eval (second opinion w/ diff dr.)	1(0.1)				

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		ultrasound	1(0.1)				
		<i>Version</i>	1025(84.6)				
B7b.1a4.Test Name	ASSESS_NAME_3	Basic metabolic panel	1(0.1)				
		Bi-Lateral Knee Xrays	1(0.1)				
		CBCD/CMP	2(0.2)				
		Chemistry	1(0.1)				
		Chest x-ray	1(0.1)				
		Ferritin	1(0.1)				
		<i>Missing</i>	176(14.5)				
		Pap smear	1(0.1)				
		surgical eval. (orthopedic)	1(0.1)				
		Urine analysis	2(0.2)				
		<i>Version</i>	1025(84.6)				
B7b.1a5.Test Name	ASSESS_NAME_4	C4, C3	1(0.1)				
		CBCD/CMP	2(0.2)				
		<i>Missing</i>	181(14.9)				

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		Parvo B19 PCR	1(0.1)				
		Urine Culture	1(0.1)				
		<i>Version</i>	1025(84.6)				
		Xray (profile)	1(0.1)				
B7b.1a6.Test Name	ASSESS_NAME_5	<i>Missing</i>	184(15.2)				
		MRI with sedation	1(0.1)				
		Total complement	1(0.1)				
		urine culture	1(0.1)				
		<i>Version</i>	1025(84.6)				
B7b.1a7.Test Name	ASSESS_NAME_6	EBV	1(0.1)				
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1a8.Test Name	ASSESS_NAME_7	Anti-dnase B	1(0.1)				
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1a9.Test Name	ASSESS_NAME_8	CRP	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1a10.Test Name	ASSESS_NAME_9	<i>Missing</i>	186(15.3)				
		SED rate	1(0.1)				
		<i>Version</i>	1025(84.6)				
B7b.1a11.Test Name	ASSESS_NAME_10	Immuno Complex	1(0.1)				
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1a12.Test Name	ASSESS_NAME_11	CMP	1(0.1)				
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1a13.Test Name	ASSESS_NAME_12	CBC	1(0.1)				
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1a14.Test Name	ASSESS_NAME_13	Coags	1(0.1)				
		<i>Missing</i>	186(15.3)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
	<i>Version</i>		1025(84.6)				
B7b.1b1.Test Age	ASSESS_AGE_0			37(1175)	11.08(5.61)	8.80(6.50,15.80)	2.90-23.40
B7b.1b2.Test Age	ASSESS_AGE_1			23(1189)	12.06(6.14)	11.90(6.70,18.10)	3.00-24.20
B7b.1b3.Test Age	ASSESS_AGE_2			14(1198)	13.70(5.63)	12.80(8.80,19.00)	5.20-23.70
B7b.1b4.Test Age	ASSESS_AGE_3			11(1201)	13.13(6.20)	11.60(8.80,19.00)	5.30-24.30
B7b.1b5.Test Age	ASSESS_AGE_4			6(1206)	10.28(4.93)	8.80(7.20,12.50)	5.30-19.10
B7b.1b6.Test Age	ASSESS_AGE_5			3(1209)	8.33(3.73)	7.20(5.30,12.50)	5.30-12.50
B7b.1b7.Test Age	ASSESS_AGE_6			1(1211)	7.20()	7.20(7.20,7.20)	7.20-7.20
B7b.1b8.Test Age	ASSESS_AGE_7			1(1211)	7.20()	7.20(7.20,7.20)	7.20-7.20
B7b.1b9.Test Age	ASSESS_AGE_8			1(1211)	7.20()	7.20(7.20,7.20)	7.20-7.20
B7b.1b10.Test Age	ASSESS_AGE_9			1(1211)	7.20()	7.20(7.20,7.20)	7.20-7.20
B7b.1b11.Test Age	ASSESS_AGE_10			1(1211)	7.20()	7.20(7.20,7.20)	7.20-7.20
B7b.1b12.Test Age	ASSESS_AGE_11			1(1211)	7.20()	7.20(7.20,7.20)	7.20-7.20
B7b.1b13.Test Age	ASSESS_AGE_12			1(1211)	7.20()	7.20(7.20,7.20)	7.20-7.20
B7b.1b14.Test Age	ASSESS_AGE_13			1(1211)	7.20()	7.20(7.20,7.20)	7.20-7.20
B7b.1b15.Test Age	ASSESS_AGE_14			1(1211)	7.20()	7.20(7.20,7.20)	7.20-7.20



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B7b.1a15.Test Name	ASSESS_NAME_14	ANA	1(0.1)				
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1c1.Result	ASSESS_RESUL_0	acute chest syndrome	1(0.1)				
		acute chest x ray	1(0.1)				
		confirmation of placement of posterior spinal rods	1(0.1)				
		diagnosed as likely a calcified, aggravated nerve	1(0.1)				
		enlarged aortic root	1(0.1)				
		<i>Missing</i>	149(12.3)				
		marfan study echo discovered this finding	1(0.1)				
		mild to moderate cellular dysplasia	1(0.1)				
		negative	4(0.3)				
		normal	9(0.7)				
		normal per mother	1(0.1)				
		not clinically significant	1(0.1)				
		patellar dislocation	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		positive	1(0.1)				
		positive bacteria	1(0.1)				
		right pnemothorax	1(0.1)				
		strept	1(0.1)				
		trigemeny, bigemeny per parent report	1(0.1)				
		uncertain diagnosis	2(0.2)				
		unchanged	1(0.1)				
		unknown	5(0.4)				
		<i>Version</i>	1025(84.6)				
		within normal limits (platelets,wbc,rbc,hgb,hct)	1(0.1)				
		within normal limits (wnl)	1(0.1)				
B7b.1c2.Result	ASSESS_RESUL_1	1.5	1(0.1)				
		cardiomegaly otherwise unchanged. no pneumothorax	1(0.1)				
		diagnosed with ocd	1(0.1)				
		elevated neutrophils	2(0.2)				
		<i>Missing</i>	164(13.5)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		mild nonspecific slowing in the theta frequency	1(0.1)				
		negative	1(0.1)				
		normal	1(0.1)				
		normal	5(0.4)				
		not clinically significant	1(0.1)				
		results within normal limits (reportedly)	2(0.2)				
		see field level comment	2(0.2)				
		unknown	3(0.2)				
		unknown (normal values not provided)	1(0.1)				
		<i>Version</i>	1025(84.6)				
		wnl	1(0.1)				
B7b.1c3.Result	ASSESS_RESUL_2	"diagnosed as neuroma"	1(0.1)				
		Clinically unchanged	1(0.1)				
		elevated eosonphils	2(0.2)				
		<i>Missing</i>	173(14.3)				
		mild chronic sinus disease	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		negative	3(0.2)				
		no growth	1(0.1)				
		unknown	3(0.2)				
		<i>Version</i>	1025(84.6)				
		WNL	1(0.1)				
		yeast present- non cath specimen	1(0.1)				
B7b.1c4.Result	ASSESS_RESUL_3	25	1(0.1)				
		diagnosed as "calcified aggravated nerve"	1(0.1)				
		elevated eosinophils	2(0.2)				
		glucose 121- non fasting	1(0.1)				
		<i>Missing</i>	176(14.5)				
		normal	4(0.3)				
		normal - no fracture	1(0.1)				
		<i>Version</i>	1025(84.6)				
		wnl	1(0.1)				
B7b.1c5.Result	ASSESS_RESUL_4	Elevated eosinophils	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		elevated eosonphils	1(0.1)				
		gram Negetive rod growth	1(0.1)				
		<i>Missing</i>	181(14.9)				
		negative	1(0.1)				
		normal	1(0.1)				
		unknown	1(0.1)				
		<i>Version</i>	1025(84.6)				
B7b.1c6.Result	ASSESS_RESUL_5	72.7	1(0.1)				
		diagnosed as "soft tissue tumor"	1(0.1)				
		<i>Missing</i>	184(15.2)				
		no growth	1(0.1)				
		<i>Version</i>	1025(84.6)				
B7b.1c7.Result	ASSESS_RESUL_6	<i>Missing</i>	186(15.3)				
		negative	1(0.1)				
		<i>Version</i>	1025(84.6)				
B7b.1c8.Result	ASSESS_RESUL_7	<50	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1c9.Result	ASSESS_RESUL_8	0.5	1(0.1)				
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1c10.Result	ASSESS_RESUL_9	7	1(0.1)				
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1c11.Result	ASSESS_RESUL_10	IGA 56.1, IgG 650 C4 14.5 C3 86	1(0.1)				
		<i>Missing</i>	186(15.3)				
		<i>Version</i>	1025(84.6)				
B7b.1c12.Result	ASSESS_RESUL_11	<i>Missing</i>	186(15.3)				
		normal	1(0.1)				
		<i>Version</i>	1025(84.6)				
B7b.1c13.Result	ASSESS_RESUL_12	Lymph 20.2 Neutro 75.8	1(0.1)				
		<i>Missing</i>	186(15.3)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		<i>Version</i>	1025(84.6)				
B7b.1c14.Result	ASSESS_RESUL_13	<i>Missing</i>	186(15.3)				
		normal	1(0.1)				
		<i>Version</i>	1025(84.6)				
B7b.1c15.Result	ASSESS_RESUL_14	<i>Missing</i>	186(15.3)				
		negative	1(0.1)				
		<i>Version</i>	1025(84.6)				
B8. Does the subject have any pre-existing medical conditions	PREEXIST_CON	NO	51(4.2)				
		SKIPPED	109(9.0)				
		<i>Version</i>	1025(84.6)				
		YES	27(2.2)				
B8a. If yes, specify	PREEXIST_SP						
B9a. Action Taken	TX_ACTION	1:Yes	464(38.3)				
		2:No	384(31.7)				
		Skipped	364(30.0)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B9a1. Medical Therapy (non drug)	TX_THERAPY	1:Yes	244(20.1)				
		2:No	220(18.2)				
		Skipped	748(61.7)				
B9a1i. If yes, specify	TX_THERAPY_S						
B9a2. Number of medications administered to treat this AE	TX_MEDSNUM			461(751)	1.42(2.08)	1.00(0.00,2.00)	0.00-17.00
B9.a21.Treatment medication codes, part 1	TX_MEDCODE1_0	02	3(0.2)				
		03	65(5.4)				
		04	1(0.1)				
		07	3(0.2)				
		08	6(0.5)				
		09	2(0.2)				
		10	10(0.8)				
		11	1(0.1)				
		14	2(0.2)				
		15	6(0.5)				



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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		16	18(1.5)				
		18	20(1.7)				
		22	116(9.6)				
		24	6(0.5)				
		99	46(3.8)				
		<i>Missing</i>	907(74.8)				
B9.a22.Treatment medication codes, part 1	TX_MEDCODE1_1	01	1(0.1)				
		02	1(0.1)				
		03	33(2.7)				
		05	1(0.1)				
		07	2(0.2)				
		09	2(0.2)				
		10	7(0.6)				
		11	2(0.2)				
		14	2(0.2)				
		15	3(0.2)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		16	6(0.5)				
		18	6(0.5)				
		19	4(0.3)				
		22	38(3.1)				
		24	1(0.1)				
		99	29(2.4)				
		<i>Missing</i>	1074(88.6)				
B9.a23.Treatment medication codes, part 1	TX_MEDCODE1_2	03	24(2.0)				
		05	2(0.2)				
		07	1(0.1)				
		08	1(0.1)				
		10	3(0.2)				
		16	3(0.2)				
		18	3(0.2)				
		22	15(1.2)				
		24	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		99	10(0.8)				
		<i>Missing</i>	1149(94.8)				
B9.a24.Treatment medication codes, part 1	TX_MEDCODE1_3	02	1(0.1)				
		03	7(0.6)				
		04	1(0.1)				
		05	2(0.2)				
		10	4(0.3)				
		14	1(0.1)				
		15	1(0.1)				
		18	1(0.1)				
		22	17(1.4)				
		25	1(0.1)				
		99	7(0.6)				
		<i>Missing</i>	1169(96.5)				
B9.a25.Treatment medication codes, part 1	TX_MEDCODE1_4	03	5(0.4)				
		05	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		10	2(0.2)				
		13	1(0.1)				
		14	1(0.1)				
		16	4(0.3)				
		18	2(0.2)				
		22	6(0.5)				
		99	4(0.3)				
		<i>Missing</i>	1186(97.9)				
B9.a26.Treatment medication codes, part 1	TX_MEDCODE1_5	02	1(0.1)				
		03	4(0.3)				
		05	2(0.2)				
		07	2(0.2)				
		10	2(0.2)				
		16	2(0.2)				
		18	2(0.2)				
		22	4(0.3)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		99	3(0.2)				
		<i>Missing</i>	1190(98.2)				
B9.a27.Treatment medication codes, part 1	TX_MEDCODE1_6	03	3(0.2)				
		07	1(0.1)				
		10	2(0.2)				
		12	1(0.1)				
		14	1(0.1)				
		16	1(0.1)				
		22	4(0.3)				
		99	3(0.2)				
		<i>Missing</i>	1196(98.7)				
B9.a28.Treatment medication codes, part 1	TX_MEDCODE1_7	01	1(0.1)				
		03	2(0.2)				
		04	1(0.1)				
		10	1(0.1)				

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		14	1(0.1)				
		16	1(0.1)				
		22	1(0.1)				
		99	2(0.2)				
		<i>Missing</i>	1202(99.2)				
B9.a29.Treatment medication codes, part 1	TX_MEDCODE1_8	03	3(0.2)				
		16	1(0.1)				
		22	3(0.2)				
		<i>Missing</i>	1205(99.4)				
B9.a210.Treatment medication codes, part 1	TX_MEDCODE1_9	03	4(0.3)				
		16	1(0.1)				
		99	1(0.1)				
		<i>Missing</i>	1206(99.5)				
B9.a211.Treatment medication codes, part 1	TX_MEDCODE1_10	01	2(0.2)				
		07	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		22	1(0.1)				
		<i>Missing</i>	1208(99.7)				
B9.a212.Treatment medication codes, part 1	TX_MEDCODE1_11	10	1(0.1)				
		22	1(0.1)				
		99	2(0.2)				
		<i>Missing</i>	1208(99.7)				
B9.a213.Treatment medication codes, part 1	TX_MEDCODE1_12	15	1(0.1)				
		18	1(0.1)				
		22	1(0.1)				
		99	1(0.1)				
		<i>Missing</i>	1208(99.7)				
B9.a214.Treatment medication codes, part 1	TX_MEDCODE1_13	03	1(0.1)				
		99	1(0.1)				
		<i>Missing</i>	1210(99.8)				
B9.a215.Treatment medication codes, part 1	TX_MEDCODE1_14	22	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		99	1(0.1)				
		<i>Missing</i>	1210(99.8)				
B9.a216.Treatment medication codes, part 1	TX_MEDCODE1_15	16	1(0.1)				
		22	1(0.1)				
		<i>Missing</i>	1210(99.8)				
B9.a217.Treatment medication codes, part 1	TX_MEDCODE1_16	07	1(0.1)				
		22	1(0.1)				
		<i>Missing</i>	1210(99.8)				
B9.a21.Treatment medication codes, part 2	TX_MEDCODE2_0	00	15(1.2)				
		01	48(4.0)				
		02	6(0.5)				
		03	3(0.2)				
		04	18(1.5)				
		05	12(1.0)				
		06	13(1.1)				



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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		07	2(0.2)				
		08	12(1.0)				
		09	44(3.6)				
		10	2(0.2)				
		11	2(0.2)				
		13	4(0.3)				
		14	2(0.2)				
		15	1(0.1)				
		16	6(0.5)				
		17	1(0.1)				
		18	4(0.3)				
		20	1(0.1)				
		21	1(0.1)				
		22	1(0.1)				
		29	2(0.2)				
		35	2(0.2)				

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*(raw data)*

**DATE CREATED 13SEP18**

**Number of Observations: 1212**

**Number of Variables: 304**

**Organization of file: Up to 52 Records per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		36	2(0.2)				
		37	3(0.2)				
		99	98(8.1)				
		<i>Missing</i>	907(74.8)				
B9.a22.Treatment medication codes, part 2	TX_MEDCODE2_1	00	5(0.4)				
		01	14(1.2)				
		02	5(0.4)				
		03	2(0.2)				
		04	4(0.3)				
		05	4(0.3)				
		06	3(0.2)				
		07	5(0.4)				
		08	7(0.6)				
		09	9(0.7)				
		10	3(0.2)				
		11	1(0.1)				

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**DATE CREATED 13SEP18**

**Number of Observations: 1212**

**Number of Variables: 304**

**Organization of file: Up to 52 Records per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		12	4(0.3)				
		13	1(0.1)				
		15	3(0.2)				
		16	6(0.5)				
		18	3(0.2)				
		19	1(0.1)				
		23	1(0.1)				
		27	1(0.1)				
		99	56(4.6)				
		<i>Missing</i>	1074(88.6)				
B9.a23.Treatment medication codes, part 2	TX_MEDCODE2_2	00	4(0.3)				
		01	7(0.6)				
		02	1(0.1)				
		03	1(0.1)				
		04	2(0.2)				
		05	5(0.4)				

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**Organization of file: Up to 52 Records per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		06	3(0.2)				
		07	1(0.1)				
		08	4(0.3)				
		09	3(0.2)				
		12	1(0.1)				
		13	3(0.2)				
		15	2(0.2)				
		16	4(0.3)				
		99	22(1.8)				
		<i>Missing</i>	1149(94.8)				
B9.a24.Treatment medication codes, part 2	TX_MEDCODE2_3	00	1(0.1)				
		01	4(0.3)				
		02	1(0.1)				
		03	1(0.1)				
		05	4(0.3)				
		06	2(0.2)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		07	1(0.1)				
		08	1(0.1)				
		09	2(0.2)				
		10	1(0.1)				
		13	2(0.2)				
		15	1(0.1)				
		16	2(0.2)				
		18	2(0.2)				
		19	1(0.1)				
		99	17(1.4)				
		<i>Missing</i>	1169(96.5)				
B9.a25.Treatment medication codes, part 2	TX_MEDCODE2_4	00	1(0.1)				
		01	3(0.2)				
		02	1(0.1)				
		04	1(0.1)				
		05	2(0.2)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		06	1(0.1)				
		07	1(0.1)				
		08	1(0.1)				
		09	2(0.2)				
		11	1(0.1)				
		13	1(0.1)				
		15	1(0.1)				
		99	10(0.8)				
		<i>Missing</i>	1186(97.9)				
B9.a26.Treatment medication codes, part 2	TX_MEDCODE2_5	00	2(0.2)				
		01	3(0.2)				
		06	2(0.2)				
		08	2(0.2)				
		09	2(0.2)				
		13	1(0.1)				
		14	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		15	1(0.1)				
		18	1(0.1)				
		99	7(0.6)				
		<i>Missing</i>	1190(98.2)				
B9.a27.Treatment medication codes, part 2	TX_MEDCODE2_6	03	1(0.1)				
		05	2(0.2)				
		06	1(0.1)				
		07	1(0.1)				
		08	1(0.1)				
		12	3(0.2)				
		16	1(0.1)				
		99	6(0.5)				
		<i>Missing</i>	1196(98.7)				
B9.a28.Treatment medication codes, part 2	TX_MEDCODE2_7	01	2(0.2)				
		02	1(0.1)				
		04	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		06	1(0.1)				
		08	1(0.1)				
		15	1(0.1)				
		99	3(0.2)				
		<i>Missing</i>	1202(99.2)				
B9.a29.Treatment medication codes, part 2	TX_MEDCODE2_8	01	2(0.2)				
		15	1(0.1)				
		37	2(0.2)				
		99	2(0.2)				
		<i>Missing</i>	1205(99.4)				
B9.a210.Treatment medication codes, part 2	TX_MEDCODE2_9	06	1(0.1)				
		08	1(0.1)				
		11	1(0.1)				
		15	1(0.1)				
		37	1(0.1)				



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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		99	1(0.1)				
		<i>Missing</i>	1206(99.5)				
B9.a211.Treatment medication codes, part 2	TX_MEDCODE2_10	02	2(0.2)				
		08	1(0.1)				
		12	1(0.1)				
		<i>Missing</i>	1208(99.7)				
B9.a212.Treatment medication codes, part 2	TX_MEDCODE2_11	06	1(0.1)				
		99	3(0.2)				
		<i>Missing</i>	1208(99.7)				
B9.a213.Treatment medication codes, part 2	TX_MEDCODE2_12	01	2(0.2)				
		09	1(0.1)				
		99	1(0.1)				
		<i>Missing</i>	1208(99.7)				
B9.a214.Treatment medication codes, part 2	TX_MEDCODE2_13	14	1(0.1)				
		99	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		<i>Missing</i>	1210(99.8)				
B9.a215.Treatment medication codes, part 2	TX_MEDCODE2_14	07	1(0.1)				
		99	1(0.1)				
		<i>Missing</i>	1210(99.8)				
B9.a31.Age when the procedure	TX_SURG_AGE_0			56(1156)	12.66(6.48)	13.30(7.15,16.70)	2.30-26.00
B9.a32.Age when the procedure	TX_SURG_AGE_1			14(1198)	11.82(4.91)	13.70(8.10,15.00)	2.30-17.70
B9.a33.Age when the procedure	TX_SURG_AGE_2			7(1205)	12.49(5.41)	15.00(8.10,15.90)	2.30-17.70
B9.a34.Age when the procedure	TX_SURG_AGE_3			4(1208)	12.05(6.51)	15.00(8.65,15.45)	2.30-15.90
B9.a35.Age when the procedure	TX_SURG_AGE_4			2(1210)	8.65(8.98)	8.65(2.30,15.00)	2.30-15.00
B9.a36.Age when the procedure	TX_SURG_AGE_5			1(1211)	15.00()	15.00(15.00,15.00)	15.00-15.00
B9.a216.Treatment medication codes, part 2	TX_MEDCODE2_15	06	1(0.1)				
		12	1(0.1)				
		<i>Missing</i>	1210(99.8)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B9.a217.Treatment medication codes, part 2	TX_MEDCODE2_16	12	2(0.2)				
		<i>Missing</i>	1210(99.8)				
B9a3. Number of Surgeries or Procedures performed to treat this AE	TX_SURGNUM			464(748)	0.18(0.62)	0.00(0.00,0.00)	0.00-6.00
B9.a31.Specify name of procedure	TX_SURGNAM_S_0			()	()	(,)	-
B10. Number of medications subject was taking at time of event	MEDS_NUM		371(30.6)				
		0	504(41.6)				
		1	148(12.2)				
		2	78(6.4)				
		3	57(4.7)				
		4	30(2.5)				
		5	4(0.3)				
		6	9(0.7)				
		7	6(0.5)				
		8	2(0.2)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		9	1(0.1)				
		13	1(0.1)				
		29	1(0.1)				
B10.1.Concomitant Medication code,part 1	MEDCODE1_0	01	9(0.7)				
		03	21(1.7)				
		04	10(0.8)				
		06	7(0.6)				
		07	2(0.2)				
		08	7(0.6)				
		09	35(2.9)				
		10	13(1.1)				
		14	1(0.1)				
		15	5(0.4)				
		16	6(0.5)				
		18	28(2.3)				
		22	46(3.8)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		24	47(3.9)				
		25	3(0.2)				
		99	97(8.0)				
		<i>Missing</i>	875(72.2)				
B10.2.Concomitant Medication code,part 1	MEDCODE1_1	01	2(0.2)				
		02	1(0.1)				
		03	8(0.7)				
		04	3(0.2)				
		07	4(0.3)				
		08	7(0.6)				
		09	35(2.9)				
		10	12(1.0)				
		14	1(0.1)				
		16	9(0.7)				
		17	1(0.1)				
		18	4(0.3)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		22	41(3.4)				
		24	14(1.2)				
		25	6(0.5)				
		99	41(3.4)				
		<i>Missing</i>	1023(84.4)				
B10.3.Concomitant Medication code,part 1	MEDCODE1_2	03	1(0.1)				
		04	3(0.2)				
		07	1(0.1)				
		09	22(1.8)				
		10	4(0.3)				
		13	1(0.1)				
		14	1(0.1)				
		15	2(0.2)				
		16	3(0.2)				
		18	7(0.6)				
		22	15(1.2)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		24	8(0.7)				
		99	43(3.5)				
		<i>Missing</i>	1101(90.8)				
B10.4.Concomitant Medication code,part 1	MEDCODE1_3	01	1(0.1)				
		09	17(1.4)				
		10	5(0.4)				
		14	3(0.2)				
		15	4(0.3)				
		16	3(0.2)				
		22	8(0.7)				
		25	2(0.2)				
		99	11(0.9)				
		<i>Missing</i>	1158(95.5)				
B10.5.Concomitant Medication code,part 1	MEDCODE1_4	09	9(0.7)				
		10	4(0.3)				
		16	2(0.2)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		18	1(0.1)				
		22	5(0.4)				
		99	3(0.2)				
		<i>Missing</i>	1188(98.0)				
B10.6.Concomitant Medication code,part 1	MEDCODE1_5	01	1(0.1)				
		07	1(0.1)				
		09	3(0.2)				
		10	2(0.2)				
		18	4(0.3)				
		22	7(0.6)				
		99	2(0.2)				
		<i>Missing</i>	1192(98.3)				
B10.7.Concomitant Medication code,part 1	MEDCODE1_6	03	1(0.1)				
		09	2(0.2)				
		10	2(0.2)				



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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		15	1(0.1)				
		18	2(0.2)				
		22	3(0.2)				
		<i>Missing</i>	1201(99.1)				
B10.8.Concomitant Medication code,part 1	MEDCODE1_7	10	1(0.1)				
		22	4(0.3)				
		<i>Missing</i>	1207(99.6)				
B10.9.Concomitant Medication code,part 1	MEDCODE1_8	04	1(0.1)				
		10	1(0.1)				
		19	1(0.1)				
		<i>Missing</i>	1209(99.8)				
B10.10.Concomitant Medication code,part 1	MEDCODE1_9	15	1(0.1)				
		22	1(0.1)				
		<i>Missing</i>	1210(99.8)				
B10.11.Concomitant Medication code,part 1	MEDCODE1_10	14	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		21	1(0.1)				
		<i>Missing</i>		1210(99.8)			
B10.12.Concomitant Medication code,part 1	MEDCODE1_11	03	1(0.1)				
		22	1(0.1)				
		<i>Missing</i>		1210(99.8)			
B10.13.Concomitant Medication code,part 1	MEDCODE1_12	21	1(0.1)				
		99	1(0.1)				
		<i>Missing</i>		1210(99.8)			
B10.14.Concomitant Medication code,part 1	MEDCODE1_13	99	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.15.Concomitant Medication code,part 1	MEDCODE1_14	99	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.16.Concomitant Medication code,part 1	MEDCODE1_15	16	1(0.1)				
		<i>Missing</i>		1211(99.9)			

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.17.Concomitant Medication code,part 1	MEDCODE1_16	22	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.18.Concomitant Medication code,part 1	MEDCODE1_17	22	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.19.Concomitant Medication code,part 1	MEDCODE1_18	03	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.20.Concomitant Medication code,part 1	MEDCODE1_19	03	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.21.Concomitant Medication code,part 1	MEDCODE1_20	03	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.22.Concomitant Medication code,part 1	MEDCODE1_21	14	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.23.Concomitant Medication code,part 1	MEDCODE1_22	22	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		<i>Missing</i>	1211(99.9)				
B10.24.Concomitant Medication code,part 1	MEDCODE1_23	22	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.25.Concomitant Medication code,part 1	MEDCODE1_24	19	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.26.Concomitant Medication code,part 1	MEDCODE1_25	03	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.27.Concomitant Medication code,part 1	MEDCODE1_26	03	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.28.Concomitant Medication code,part 1	MEDCODE1_27	21	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.29.Concomitant Medication code,part 1	MEDCODE1_28	22	1(0.1)				
		<i>Missing</i>	1211(99.9)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.1.Concomitant Medication code,part 2	MEDCODE2_0	00	14(1.2)				
		01	34(2.8)				
		02	21(1.7)				
		03	8(0.7)				
		04	16(1.3)				
		05	19(1.6)				
		06	3(0.2)				
		08	27(2.2)				
		09	19(1.6)				
		10	9(0.7)				
		12	1(0.1)				
		14	1(0.1)				
		15	2(0.2)				
		36	1(0.1)				
		37	1(0.1)				
		99	161(13.3)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		<i>Missing</i>	875(72.2)				
B10.2.Concomitant Medication code,part 2	MEDCODE2_1	00	8(0.7)				
		01	14(1.2)				
		02	8(0.7)				
		03	7(0.6)				
		04	12(1.0)				
		05	3(0.2)				
		06	7(0.6)				
		08	19(1.6)				
		09	11(0.9)				
		15	1(0.1)				
		17	1(0.1)				
		18	2(0.2)				
		27	2(0.2)				
		37	1(0.1)				
		99	93(7.7)				

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**Number of Observations: 1212**

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**Organization of file: Up to 52 Records per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		<i>Missing</i>	1023(84.4)				
B10.3.Concomitant Medication code,part 2	MEDCODE2_2	00	6(0.5)				
		01	3(0.2)				
		02	2(0.2)				
		04	1(0.1)				
		05	2(0.2)				
		06	1(0.1)				
		08	9(0.7)				
		09	9(0.7)				
		13	1(0.1)				
		15	1(0.1)				
		99	76(6.3)				
		<i>Missing</i>	1101(90.8)				
B10.4.Concomitant Medication code,part 2	MEDCODE2_3	01	5(0.4)				
		02	2(0.2)				
		03	2(0.2)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		05	1(0.1)				
		08	9(0.7)				
		09	4(0.3)				
		99	31(2.6)				
		<i>Missing</i>	1158(95.5)				
B10.5.Concomitant Medication code,part 2	MEDCODE2_4	00	1(0.1)				
		01	1(0.1)				
		05	1(0.1)				
		06	1(0.1)				
		09	3(0.2)				
		13	1(0.1)				
		99	16(1.3)				
		<i>Missing</i>	1188(98.0)				
B10.6.Concomitant Medication code,part 2	MEDCODE2_5	01	1(0.1)				
		02	1(0.1)				



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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		06	1(0.1)				
		07	1(0.1)				
		08	2(0.2)				
		09	3(0.2)				
		12	1(0.1)				
		15	1(0.1)				
		99	9(0.7)				
		<i>Missing</i>	1192(98.3)				
B10.7.Concomitant Medication code,part 2	MEDCODE2_6	01	3(0.2)				
		05	1(0.1)				
		07	1(0.1)				
		08	2(0.2)				
		18	1(0.1)				
		99	3(0.2)				
		<i>Missing</i>	1201(99.1)				
B10.8.Concomitant Medication code,part 2	MEDCODE2_7	06	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		09	2(0.2)				
		15	1(0.1)				
		99	1(0.1)				
		<i>Missing</i>	1207(99.6)				
B10.9.Concomitant Medication code,part 2	MEDCODE2_8	01	1(0.1)				
		02	1(0.1)				
		09	1(0.1)				
		<i>Missing</i>	1209(99.8)				
B10.10.Concomitant Medication code,part 2	MEDCODE2_9	16	1(0.1)				
		99	1(0.1)				
		<i>Missing</i>	1210(99.8)				
B10.11.Concomitant Medication code,part 2	MEDCODE2_10	01	1(0.1)				
		05	1(0.1)				
		<i>Missing</i>	1210(99.8)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.12.Concomitant Medication code,part 2	MEDCODE2_11	06	1(0.1)				
		11	1(0.1)				
		<i>Missing</i>	1210(99.8)				
B10.13.Concomitant Medication code,part 2	MEDCODE2_12	99	2(0.2)				
		<i>Missing</i>	1210(99.8)				
B10.14.Concomitant Medication code,part 2	MEDCODE2_13	99	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.15.Concomitant Medication code,part 2	MEDCODE2_14	99	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.16.Concomitant Medication code,part 2	MEDCODE2_15	06	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.17.Concomitant Medication code,part 2	MEDCODE2_16	01	1(0.1)				
		<i>Missing</i>	1211(99.9)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.18.Concomitant Medication code,part 2	MEDCODE2_17	09	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.19.Concomitant Medication code,part 2	MEDCODE2_18	07	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.20.Concomitant Medication code,part 2	MEDCODE2_19	03	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.21.Concomitant Medication code,part 2	MEDCODE2_20	13	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.22.Concomitant Medication code,part 2	MEDCODE2_21	13	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.23.Concomitant Medication code,part 2	MEDCODE2_22	03	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.24.Concomitant Medication code,part 2	MEDCODE2_23	16	1(0.1)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		<i>Missing</i>	1211(99.9)				
B10.25.Concomitant Medication code,part 2	MEDCODE2_24	03	1(0.1)				
		<i>Missing</i>	1211(99.9)				
B10.1 Start Age	MED_START_AGE_0			49(1163)	8.50(6.43)	5.60(4.60,10.00)	2.00-23.20
B10.2 Start Age	MED_START_AGE_1			37(1175)	8.51(7.15)	4.90(2.00,14.00)	1.00-23.20
B10.3 Start Age	MED_START_AGE_2			27(1185)	6.94(6.76)	5.10(2.00,9.00)	1.00-23.20
B10.4 Start Age	MED_START_AGE_3			16(1196)	7.03(5.69)	4.80(3.35,9.00)	2.00-23.20
B10.5 Start Age	MED_START_AGE_4			5(1207)	5.02(2.78)	4.50(4.50,4.50)	2.00-9.60
B10.6 Start Age	MED_START_AGE_5			4(1208)	5.78(2.55)	4.50(4.50,7.05)	4.50-9.60
B10.7 Start Age	MED_START_AGE_6						
B10.8 Start Age	MED_START_AGE_7						
B10.9 Start Age	MED_START_AGE_8						
B10.10 Start Age	MED_START_AGE_9						
B10.11 Start Age	MED_START_AGE_10						
B10.12 Start Age	MED_START_AGE_11						
B10.13 Start Age	MED_START_AGE_12						

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.14 Start Age	MED_START_AGE_13						
B10.15 Start Age	MED_START_AGE_14						
B10.16 Start Age	MED_START_AGE_15						
B10.17 Start Age	MED_START_AGE_16						
B10.18 Start Age	MED_START_AGE_17						
B10.19 Start Age	MED_START_AGE_18						
B10.20 Start Age	MED_START_AGE_19						
B10.21 Start Age	MED_START_AGE_20						
B10.22 Start Age	MED_START_AGE_21						
B10.23 Start Age	MED_START_AGE_22						
B10.24 Start Age	MED_START_AGE_23						
B10.25 Start Age	MED_START_AGE_24						
B10.26 Start Age	MED_START_AGE_25						
B10.27 Start Age	MED_START_AGE_26						
B10.28 Start Age	MED_START_AGE_27						
B10.29 Start Age	MED_START_AGE_28						

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.26. Concomitant Medication code, part 2	MEDCODE2_25	11	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.27. Concomitant Medication code, part 2	MEDCODE2_26	11	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.28. Concomitant Medication code, part 2	MEDCODE2_27	99	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.29. Concomitant Medication code, part 2	MEDCODE2_28	99	1(0.1)				
		<i>Missing</i>		1211(99.9)			
B10.1. Box checked if start age estimated	MED_START_E_0	<i>Missing</i>					
B10.2. Box checked if start age estimated	MED_START_E_1	<i>Missing</i>		1174(96.9)			
		NO		20(1.7)			
		YES		18(1.5)			
B10.3. Box checked if start age estimated	MED_START_E_2	<i>Missing</i>		1184(97.7)			

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		NO	13(1.1)				
		YES	15(1.2)				
B10.4. Box checked if start age estimated	MED_START_E_3	<i>Missing</i>	1195(98.6)				
		NO	7(0.6)				
		YES	10(0.8)				
B10.5. Box checked if start age estimated	MED_START_E_4	<i>Missing</i>	1207(99.6)				
		YES	5(0.4)				
B10.6. Box checked if start age estimated	MED_START_E_5	<i>Missing</i>	1208(99.7)				
		YES	4(0.3)				
B10.7. Box checked if start age estimated	MED_START_E_6	<i>Missing</i>	1212(100.0)				
B10.8. Box checked if start age estimated	MED_START_E_7	<i>Missing</i>	1212(100.0)				
B10.9. Box checked if start age estimated	MED_START_E_8	<i>Missing</i>	1212(100.0)				
B10.10. Box checked if start age estimated	MED_START_E_9	<i>Missing</i>	1212(100.0)				



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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.11. Box checked if start age estimated	MED_START_E_10	<i>Missing</i>	1212(100.0)				
B10.12. Box checked if start age estimated	MED_START_E_11	<i>Missing</i>	1212(100.0)				
B10.13. Box checked if start age estimated	MED_START_E_12	<i>Missing</i>	1212(100.0)				
B10.14. Box checked if start age estimated	MED_START_E_13	<i>Missing</i>	1212(100.0)				
B10.15. Box checked if start age estimated	MED_START_E_14	<i>Missing</i>	1212(100.0)				
B10.16. Box checked if start age estimated	MED_START_E_15	<i>Missing</i>	1212(100.0)				
B10.17. Box checked if start age estimated	MED_START_E_16	<i>Missing</i>	1212(100.0)				
B10.18. Box checked if start age estimated	MED_START_E_17	<i>Missing</i>	1212(100.0)				
B10.19. Box checked if start age estimated	MED_START_E_18	<i>Missing</i>	1212(100.0)				
B10.20. Box checked if start age estimated	MED_START_E_19	<i>Missing</i>	1212(100.0)				
B10.21. Box checked if start age estimated	MED_START_E_20	<i>Missing</i>	1212(100.0)				
B10.22. Box checked if start age estimated	MED_START_E_21	<i>Missing</i>	1212(100.0)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.23. Box checked if start age estimated	MED_START_E_22	<i>Missing</i>	1212(100.0)				
B10.24. Box checked if start age estimated	MED_START_E_23	<i>Missing</i>	1212(100.0)				
B10.25. Box checked if start age estimated	MED_START_E_24	<i>Missing</i>	1212(100.0)				
B10.1.Stop Age	MED_STOP_AGE_0			5(1207)	15.52(5.12)	18.00(14.00,19.20)	7.20-19.20
B10.2.Stop Age	MED_STOP_AGE_1			8(1204)	15.15(4.42)	16.00(12.20,19.15)	7.30-19.20
B10.3.Stop Age	MED_STOP_AGE_2			2(1210)	12.20(9.76)	12.20(5.30,19.10)	5.30-19.10
B10.4.Stop Age	MED_STOP_AGE_3			1(1211)	19.10()	19.10(19.10,19.10)	19.10-19.10
B10.5.Stop Age	MED_STOP_AGE_4			1(1211)	5.30()	5.30(5.30,5.30)	5.30-5.30
B10.6.Stop Age	MED_STOP_AGE_5			1(1211)	5.30()	5.30(5.30,5.30)	5.30-5.30
B10.7.Stop Age	MED_STOP_AGE_6						
B10.8.Stop Age	MED_STOP_AGE_7						
B10.9.Stop Age	MED_STOP_AGE_8						
B10.10.Stop Age	MED_STOP_AGE_9						
B10.11.Stop Age	MED_STOP_AGE_10						
B10.12.Stop Age	MED_STOP_AGE_11						

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.13.Stop Age	MED_STOP_AGE_12						
B10.14.Stop Age	MED_STOP_AGE_13						
B10.15.Stop Age	MED_STOP_AGE_14						
B10.16.Stop Age	MED_STOP_AGE_15						
B10.17.Stop Age	MED_STOP_AGE_16						
B10.18.Stop Age	MED_STOP_AGE_17						
B10.19.Stop Age	MED_STOP_AGE_18						
B10.20.Stop Age	MED_STOP_AGE_19						
B10.21.Stop Age	MED_STOP_AGE_20						
B10.22.Stop Age	MED_STOP_AGE_21						
B10.23.Stop Age	MED_STOP_AGE_22						
B10.24.Stop Age	MED_STOP_AGE_23						
B10.25.Stop Age	MED_STOP_AGE_24						
B10.26.Stop Age	MED_STOP_AGE_25						
B10.27.Stop Age	MED_STOP_AGE_26						
B10.28.Stop Age	MED_STOP_AGE_27						
B10.29.Stop Age	MED_STOP_AGE_28						

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.26. Box checked if start age estimated	MED_START_E_25	<i>Missing</i>					
B10.27. Box checked if start age estimated	MED_START_E_26	<i>Missing</i>	1212(100.0)				
B10.28. Box checked if start age estimated	MED_START_E_27	<i>Missing</i>	1212(100.0)				
B10.29. Box checked if start age estimated	MED_START_E_28	<i>Missing</i>	1212(100.0)				
B10.1. Box checked if start age estimated	MED_STOP_E_0	<i>Missing</i>	1162(95.9)				
		NO	42(3.5)				
		YES	8(0.7)				
B10.2. Box checked if start age estimated	MED_STOP_E_1	<i>Missing</i>	1174(96.9)				
		NO	30(2.5)				
		YES	8(0.7)				
B10.3. Box checked if start age estimated	MED_STOP_E_2	<i>Missing</i>	1184(97.7)				
		NO	24(2.0)				
		YES	4(0.3)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.4. Box checked if start age estimated	MED_STOP_E_3	<i>Missing</i>	1195(98.6)				
		NO	13(1.1)				
		YES	4(0.3)				
B10.5. Box checked if start age estimated	MED_STOP_E_4	<i>Missing</i>	1207(99.6)				
		NO	5(0.4)				
B10.6. Box checked if start age estimated	MED_STOP_E_5	<i>Missing</i>	1208(99.7)				
		NO	4(0.3)				
B10.7. Box checked if start age estimated	MED_STOP_E_6	<i>Missing</i>	1212(100.0)				
B10.8. Box checked if start age estimated	MED_STOP_E_7	<i>Missing</i>	1212(100.0)				
B10.9. Box checked if start age estimated	MED_STOP_E_8	<i>Missing</i>	1212(100.0)				
B10.10. Box checked if start age estimated	MED_STOP_E_9	<i>Missing</i>	1212(100.0)				
B10.11. Box checked if start age estimated	MED_STOP_E_10	<i>Missing</i>	1212(100.0)				
B10.12. Box checked if start age estimated	MED_STOP_E_11	<i>Missing</i>	1212(100.0)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.13. Box checked if start age estimated	MED_STOP_E_12	<i>Missing</i>	1212(100.0)				
B10.14. Box checked if start age estimated	MED_STOP_E_13	<i>Missing</i>	1212(100.0)				
B10.15. Box checked if start age estimated	MED_STOP_E_14	<i>Missing</i>	1212(100.0)				
B10.16. Box checked if start age estimated	MED_STOP_E_15	<i>Missing</i>	1212(100.0)				
B10.17. Box checked if start age estimated	MED_STOP_E_16	<i>Missing</i>	1212(100.0)				
B10.18. Box checked if start age estimated	MED_STOP_E_17	<i>Missing</i>	1212(100.0)				
B10.19. Box checked if start age estimated	MED_STOP_E_18	<i>Missing</i>	1212(100.0)				
B10.20. Box checked if start age estimated	MED_STOP_E_19	<i>Missing</i>	1212(100.0)				
B10.21. Box checked if start age estimated	MED_STOP_E_20	<i>Missing</i>	1212(100.0)				
B10.22. Box checked if start age estimated	MED_STOP_E_21	<i>Missing</i>	1212(100.0)				
B10.23. Box checked if start age estimated	MED_STOP_E_22	<i>Missing</i>	1212(100.0)				
B10.24. Box checked if start age estimated	MED_STOP_E_23	<i>Missing</i>	1212(100.0)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
B10.25. Box checked if start age estimated	MED_STOP_E_24	<i>Missing</i>	1212(100.0)				
B10.26. Box checked if start age estimated	MED_STOP_E_25	<i>Missing</i>	1212(100.0)				
B10.27. Box checked if start age estimated	MED_STOP_E_26	<i>Missing</i>	1212(100.0)				
B10.28. Box checked if start age estimated	MED_STOP_E_27	<i>Missing</i>	1212(100.0)				
B12b. Death Age	DEATH_AGE			1(1211)	2.30()	2.30(2.30,2.30)	2.30-2.30
B10.29. Box checked if start age estimated	MED_STOP_E_28	<i>Missing</i>	1212(100.0)				
B11a. Outcome	OUTCOME	Continuing	435(35.9)				
		Resolved	721(59.5)				
		Resolved with sequelae	56(4.6)				
B11b. Resolution Age	RESOL_AGE			777(435)	12.42(5.98)	12.20(7.50,16.20)	0.90-27.80
B12. Did the patient die?	DEATH	1:Yes	1(0.1)				
		2:No	776(64.0)				
		Skipped	435(35.9)				
B12a. How is this AE related to the cause of death?	DTHRELAT_RSN	Contributing	1(0.1)				

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**Number of Variables: 304**

**Organization of file: Up to 52 Records per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		Skipped	1211(99.9)				
B13. Did event code from question B2 change?	EVTCD_CHANGE	1:Yes	11(0.9)				
		2:No	766(63.2)				
		Skipped	435(35.9)				
B13a. Updated event code (CTCAE MedDRA code)	UPD_EVTCODE	10002855	1(0.1)				
		10012378	1(0.1)				
		10012745	1(0.1)				
		10016256	1(0.1)				
		10042604	1(0.1)				
		10043607	1(0.1)				
		10046459	1(0.1)				
		10046574	1(0.1)				
		10048038	1(0.1)				
		90004028	1(0.1)				
		90030418	1(0.1)				
		Skipped	1201(99.1)				



**Marfan Data Codebook**  
**Form A200: Adverse Event Form**  
**(raw data)**

**DATE CREATED 13SEP18**

**Number of Observations: 1212**

**Number of Variables: 304**

**Organization of file: Up to 52 Records per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
Form version	VER_ID	A	68(5.6)				
		B	84(6.9)				
		C	873(72.0)				
		D	187(15.4)				