

Code	Domain	Class	Description	Status
AD	Analysis Datasets	Not Applicable	Added as a "restricted prefix" and variable naming prefix - see <a href="#">Appendix D</a> . Do not use as a Domain Code.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
AE	Adverse Events	Events	See <a href="#">Section 6.2.1.1</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
CE	Clinical Events	Events	See <a href="#">Section 6.2.5.1</a> , Assumption 1	Will be added to list of controlled terms on CDISC website.
CM	Concomitant Medications	Interventions	See <a href="#">Section 6.1.1.1</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
CO	Comments	Special Purpose	See <a href="#">Section 5.2.1.1</a> .	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
DA	Drug Accountability	Findings	Data regarding the accountability of study drug, such as information on the receipt, dispensing, return, and packaging. See <a href="#">Section 6.3.8.1</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
DM	Demographics	Special Purpose	Demographics includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects. See <a href="#">SDTM 2.2.6</a> .	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
DS	Disposition	Events	See <a href="#">Section 6.2.2.1</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
DV	Protocol Deviations	Events	See <a href="#">Section 6.2.4.1</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
EG	Electrocardiogram Test Results	Findings	See <a href="#">Section 6.3.1.1</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
EX	Exposure	Interventions	See <a href="#">Section 6.1.2.1</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
FA	Findings About	Findings	See <a href="#">Section 6.4.5</a> , Assumption 1.	Will be added to list of controlled terms on CDISC website.
IE	Inclusion/ Exclusion Criterion not met	Findings	See <a href="#">Section 6.3.2.1</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>

Code	Domain	Class	Description	Status
LB	Laboratory Data	Findings	See <a href="#">Section 6.3.3.1</a> , Assumption 1. Does not include microbiology or PK data, which are stored in separate domains.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
MB	Microbiology Specimen	Findings	Microbiology Specimen findings, including gram stain results, and organisms found. See <a href="#">Section 6.3.9.2</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
MH	Medical History	Events	See <a href="#">Section 6.2.3.1</a> , Assumption 1	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
MS	Microbiology Susceptibility Test	Findings	Microbiology Susceptibility Test results, plus results of any other organism-related tests. See <a href="#">Section 6.3.9.3</a> , Assumption 1.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
PC	Pharmacokinetic Concentration	Findings	Concentrations of drugs/metabolites in fluids or tissues as a function of time.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
PE	Physical Examination	Findings	See <a href="#">Section 6.3.4.1</a> , Assumption 1. Does not include vital signs measurements, which are stored in the VS domain.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
PP	Pharmacokinetic Parameters	Findings	Pharmacokinetic parameters derived from pharmacokinetic concentration-time (PC) data.	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
QS	Questionnaires	Findings	See <a href="#">Section 6.3.5.1</a> , Assumption 1	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
SC	Subject Characteristics	Findings	See <a href="#">Section 6.3.6.1</a> Assumption 1	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
SE	Subject Elements	Special Purpose	See <a href="#">Section 5.3.1</a>	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
SU	Substance Use	Interventions	See <a href="#">Section 6.1.3.1</a> , Assumption 1	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
SV	Subject Visits	Special Purpose	See <a href="#">Section 5.3.2</a>	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
TA	Trial Arms	Trial Design	See <a href="#">Section 7.2.1</a>	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>
TE	Trial Elements	Trial Design	See <a href="#">Section 7.3.1</a>	Included as a value in the list of controlled terms, codelist Domain Abbreviation (C66734) at <a href="http://www.cancer.gov/cancertopics/terminologyresources/CDISC">http://www.cancer.gov/cancertopics/terminologyresources/CDISC</a>

**DM Example 1 – General Demographics**

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	SITEID	INVNAM	BIRTHDTC	AGE	AGEU
1	ABC123	DM	ABC12301001	001	2006-01-12	2006-03-10	01	JOHNSON, M	1948-12-13	57	YEARS
2	ABC123	DM	ABC12301002	002	2006-01-15	2006-02-28	01	JOHNSON, M	1955-03-22	50	YEARS
3	ABC123	DM	ABC12301003	003	2006-01-16	2006-03-19	01	JOHNSON, M	1938-01-19	68	YEARS
4	ABC123	DM	ABC12301004	004			01	JOHNSON, M	1941-07-02		
5	ABC123	DM	ABC12302001	001	2006-02-02	2006-03-31	02	GONZALEZ, E	1950-06-23	55	YEARS
6	ABC123	DM	ABC12302002	002	2006-02-03	2006-04-05	02	GONZALEZ, E	1956-05-05	49	YEARS

Row	SEX	RACE	ETHNIC	ARMCD	ARM	COUNTRY
1 (cont)	M	WHITE	HISPANIC OR LATINO	A	Drug A	USA
2 (cont)	M	WHITE	NOT HISPANIC OR LATINO	P	Placebo	USA
3 (cont)	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	P	Placebo	USA
4 (cont)	M	ASIAN	NOT HISPANIC OR LATINO	SCRNFAIL	Screen Failure	USA
5 (cont)	F	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	P	Placebo	USA
6 (cont)	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO	A	Drug A	USA

Row	STUDYID	DOMAIN	USUBJID	COSEQ	RDOMAIN	IDVAR	IDVARVAL	COREF	COVAL	COVAL1	COVAL2	COEVAL	VISIT	CODTC
1	1234	CO	AB-99	1					Comment text			PRINCIPAL INVESTIGATOR		2003-11-08
2	1234	CO	AB-99	2	PE			VISIT 7	Comment text			PRINCIPAL INVESTIGATOR		2004-01-14
3	1234	CO	AB-99	3	AE	AEQ	7	PAGE 650	First 200 characters	Next 200 characters	Remaining text	PRINCIPAL INVESTIGATOR		
4	1234	CO	AB-99	4	EX	EXGRP	COMBO1	PAGE 320-355	First 200 characters	Remaining text		PRINCIPAL INVESTIGATOR		
5	1234	CO	AB-99	5	VS	VSGRP	VS2		Comment text			PRINCIPAL INVESTIGATOR		
6	1234	CO	AB-99	6	SV	VISITNUM	4		Comment Text			PRINCIPAL INVESTIGATOR		
7	1234	CO	AB-99	7				VISIT 4	Comment Text			PRINCIPAL INVESTIGATOR		
8	1234	CO	AB-99	8					Comment Text			PRINCIPAL INVESTIGATOR	4	

se.xpt

Row	USUBJID	SESEQ	ETCD	SESTDTC	SEENDTC	SEUPDES	TAETORD	EPOCH
1	789	1	SCREEN	2006-06-01	2006-06-03T10:32		1	SCREEN
2	789	2	IV	2006-06-03T10:32	2006-06-10T09:47		2	FIRST TREATMENT
3	789	3	ORAL	2006-06-10T09:47	2006-06-17		3	SECOND TREATMENT
4	789	4	FOLLOWUP	2006-06-17	2006-06-17		4	FOLLOW-UP
5	790	1	SCREEN	2006-06-01	2006-06-03T10:14		1	SCREEN
6	790	2	IV	2006-06-03T10:14	2006-06-10T10:32		3	FIRST TREATMENT
7	790	3	ORAL	2006-06-10T10:32	2006-06-17		2	SECOND TREATMENT
8	790	4	FOLLOWUP	2006-06-17	2006-06-17		4	FOLLOW-UP

Row	STUDYID	DOMAIN	USUBJID	VISITNUM	VISIT	VISITDY	SVSTDTC	SVENDTC	SVSTDY	SVENDY	SVUPDES
1	123456	SV	101	1	SCREEN	-7	2006-01-15	2006-01-20	-6	-1	
2	123456	SV	101	2	DAY 1	1	2006-01-21	2006-01-21	1	1	
3	123456	SV	101	3	WEEK 1	8	2006-01-27	2006-01-27	7	7	
4	123456	SV	101	4	WEEK 2	15	2006-02-04	2006-02-04	15	15	
5	123456	SV	101	4.1			2006-02-07	2006-02-07	18	18	Evaluation of AE
6	123456	SV	101	8	FOLLOW-UP	71	2006-02-15	2006-02-15	26	26	

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMDOSE	CMDOSU	CMDOSFRQ	CMSTDTC	CMENDTC
1	ABC	CM	ABC-0001	1	ASPIRIN	100	MG	ONCE	2004-01-01	2004-01-01
2	ABC	CM	ABC-0001	2	ASPIRIN	100	MG	ONCE	2004-01-02	2004-01-02
3	ABC	CM	ABC-0001	3	ASPIRIN	100	MG	ONCE	2004-01-03	2004-01-03
4	ABC	CM	ABC-0001	4	ASPIRIN	100	MG	ONCE	2004-01-07	2004-01-07
5	ABC	CM	ABC-0001	5	ASPIRIN	100	MG	ONCE	2004-01-07	2004-01-07
6	ABC	CM	ABC-0001	6	ASPIRIN	100	MG	ONCE	2004-01-09	2004-01-09
7	ABC	CM	ABC-0002	1	ASPIRIN	100	MG	Q24H	2004-01-01	2004-01-03
8	ABC	CM	ABC-0002	2	ASPIRIN	100	MG	BID	2004-01-07	2004-01-07
9	ABC	CM	ABC-0002	3	ASPIRIN	100	MG	Q24H	2004-01-09	2004-01-09
10	ABC	CM	ABC-0003	1	ASPIRIN	100	MG	PRN	2004-01-01	2004-01-09

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXGRPID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ
1	56789	EX	56789001	1	1	DRUG A	20	mg	CAPSULE	Q24H
2	56789	EX	56789001	2	1	DRUG A	20	mg	CAPSULE	Q24H
3	56789	EX	56789001	3	1	DRUG A	20	mg	CAPSULE	Q24H
4	56789	EX	56789001	4	2	DRUG B	30	mg	TABLET, COATED	Q24H
5	56789	EX	56789001	5	2	DRUG B	30	mg	TABLET, COATED	Q24H
6	56789	EX	56789001	6	2	DRUG B	30	mg	TABLET, COATED	Q24H
7	56789	EX	56789003	1	1	DRUG B	30	mg	TABLET, COATED	Q24H
8	56789	EX	56789003	2	1	DRUG B	30	mg	TABLET, COATED	Q24H
9	56789	EX	56789003	3	1	DRUG B	30	mg	TABLET, COATED	Q24H
10	56789	EX	56789003	4	2	DRUG A	20	mg	CAPSULE	Q24H
11	56789	EX	56789003	5	2	DRUG A	20	mg	CAPSULE	Q24H
12	56789	EX	56789003	6	2	DRUG A	20	mg	CAPSULE	Q24H

Row	EXDOSTOT	EXROUTE	EXSTDTC	EXENDTC	EXSTDY	EXENDY	EXTPT	EXTPTREF
1 (cont)	20	ORAL	2002-07-01T07:30	2002-07-01T07:30	1	1	30 MINUTES PRIOR	STD BREAKFAST
2 (cont)	20	ORAL	2002-07-02T07:30	2002-07-02T07:30	2	2	30 MINUTES PRIOR	STD BREAKFAST
3 (cont)	20	ORAL	2002-07-03T07:32	2002-07-03T07:32	3	3	30 MINUTES PRIOR	STD BREAKFAST
4 (cont)	30	ORAL	2002-07-09T07:30	2002-07-09T07:30	9	9	30 MINUTES PRIOR	STD BREAKFAST
5 (cont)	30	ORAL	2002-07-10T07:30	2002-07-10T07:30	10	10	30 MINUTES PRIOR	STD BREAKFAST
6 (cont)	30	ORAL	2002-07-11T07:34	2002-07-11T07:34	11	11	30 MINUTES PRIOR	STD BREAKFAST
7 (cont)	30	ORAL	2002-07-03T07:30	2002-07-03T07:30	1	1	30 MINUTES PRIOR	STD BREAKFAST
8 (cont)	30	ORAL	2002-07-04T07:24	2002-07-04T07:24	2	2	30 MINUTES PRIOR	STD BREAKFAST
9 (cont)	30	ORAL	2002-07-05T07:24	2002-07-05T07:24	3	3	30 MINUTES PRIOR	STD BREAKFAST
10 (cont)	20	ORAL	2002-07-11T07:30	2002-07-11T07:30	9	9	30 MINUTES PRIOR	STD BREAKFAST
11 (cont)	20	ORAL	2002-07-12T07:43	2002-07-12T07:43	10	10	30 MINUTES PRIOR	STD BREAKFAST
12 (cont)	20	ORAL	2002-07-13T07:38	2002-07-13T07:38	11	11	30 MINUTES PRIOR	STD BREAKFAST

Row	STUDYID	DOMAIN	USUBJID	SUSEQ	SUTRT	SUCAT	SUSTAT	SUREASND	SUDOSE	SUDOSU	SUDOSFRQ
1	1234	SU	1234005	1	CIGARETTES	TOBACCO			2	PACK	PER DAY
2	1234	SU	1234005	2	COFFEE	CAFFEINE			3	CUP	PER DAY
3	1234	SU	1234006	1	CIGARETTES	TOBACCO			1	PACK	PER DAY
4	1234	SU	1234006	2	TEA	CAFFEINE			1	CUP	PER DAY
5	1234	SU	1234006	3	COFFEE	CAFFEINE			2	CUP	PER DAY
6	1234	SU	1234007	1	CIGARETTES	TOBACCO	NOT DONE	Subject left office before CRF was completed			
7	1234	SU	1234007	2	CAFFEINE	CAFFEINE	NOT DONE	Subject left office before CRF was completed			

Row	SUSTDTC	SUENDTC	SUSTTPT	SUSTRPT	SUENTPT	SUENRPT
1 (cont)			2006-01-01	BEFORE	2006-01-01	ONGOING
2 (cont)	2006-01-01	2006-01-01				
3 (cont)		2003	2006-03-15	BEFORE		
4 (cont)	2006-03-15	2006-03-15				
5 (cont)	2006-03-15	2006-03-15				
6 (cont)						
7 (cont)						

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AESTDTC	AEENDTC	AEMODIFY	AEDECOD
1	ABC123	AE	123101	1	POUNDING HEADACHE	2005-10-12	2005-10-12	HEADACHE	Headache
2	ABC123	AE	123101	2	BACK PAIN FOR 6 HOURS	2005-10-13T13:05	2005-10-13T19:00	BACK PAIN	Back pain
3	ABC123	AE	123101	3	PULMONARY EMBOLISM	2005-10-21			Pulmonary embolism

Row	AEBODSYS	AESEV	AESER	AEACN	AEREL
1 (cont)	Nervous system disorders	SEVERE	N	NOT APPLICABLE	DEFINITELY NOT RELATED
2 (cont)	Musculoskeletal and connective tissue disorders	MODERATE	N	DOSE REDUCED	PROBABLY RELATED
3 (cont)	Vascular disorders	MODERATE	Y	DOSE REDUCED	PROBABLY NOT RELATED

Row	AEOUT	AESCONG	AESDISAB	AESDTH	AESHOSP	AESLIFE	AESMIE	AESTDY	AEENDY	AEENRF
1 (cont)	RECOVERED/RESOLVED							-1	-1	
2 (cont)	RECOVERED/RESOLVED							1	1	
3 (cont)	RECOVERING/RESOLVING				Y	Y		9		AFTER

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
1	ABC123	DS	123101	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-21	2003-09-21
2	ABC123	DS	123101	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2003-09-29	2003-09-29
3	ABC123	DS	123101	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2003-09-30	2003-09-30
4	ABC123	DS	123101	4	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT PHASE	2003-10-31	2003-10-31
5	ABC123	DS	123101	5	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2003-11-15	2003-11-15
6	ABC123	DS	123102	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-11-21	2003-11-21
7	ABC123	DS	123102	2	SUBJECT DENIED MRI PROCEDURE	PROTOCOL VIOLATION	DISPOSITION EVENT	SCREENING	2003-11-22	2003-11-20
8	ABC123	DS	123103	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-15	2003-09-15
9	ABC123	DS	123103	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2003-09-22	2003-09-22
10	ABC123	DS	123103	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2003-09-30	2003-09-30
11	ABC123	DS	123103	4	SUBJECT MOVED	LOST TO FOLLOW-UP	DISPOSITION EVENT	TREATMENT PHASE	2003-10-31	2003-10-31
12	ABC123	DS	123104	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-15	2003-09-15
13	ABC123	DS	123104	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2003-09-22	2003-09-22
14	ABC123	DS	123104	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2003-09-30	2003-09-30
15	ABC123	DS	123104	4	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT PHASE	2003-10-15	2003-10-15
16	ABC123	DS	123104	5	AUTOMOBILE ACCIDENT	DEATH	DISPOSITION EVENT	FOLLOW-UP	2003-10-31	2003-10-29
17	ABC123	DS	123105	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-28	2003-09-28
18	ABC123	DS	123105	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2003-10-02	2003-10-02
19	ABC123	DS	123105	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2003-10-02	2003-10-02
20	ABC123	DS	123105	4	ANEMIA	ADVERSE EVENT	DISPOSITION EVENT	TREATMENT PHASE	2003-10-17	2003-10-17
21	ABC123	DS	123105	5	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2003-11-02	2003-11-02

**Disposition (DS) Dataset****Row 1:** Shows that Subject died of heart failure.

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
1	ABC123	DS	123102	1	Heart Failure	DEATH	DISPOSITION EVENT	TREATMENT PHASE	2003-09-29	2003-09-29

**Adverse Event (AE) Dataset:****Row 1:** Shows that Subject died due to heart failure.

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AESTDTC	AEENDTC	AEDECOD	AEBODSYS	AESEV	AESER	AEACN
1	ABC123	AE	123102	1	Heart Failure	2003-09-29	2003-09-29	HEART FAILURE	CARDIOVASCULAR SYSTEM	SEVERE	Y	NOT APPLICABLE

Row	AEREL	AEOUT	AESCAN	AESCONG	AESDISAB	AESDTH	AESHOSP	AESLIFE	AESOD	AESMIE
1 (cont)	DEFINITELY NOT RELATED	FATAL	N	N	N	Y	N	N	N	N

**RELREC Dataset****Rows 1, 2:** Show that the subject's disposition status that is related to the AE record.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC123	DS	123102	DSSEQ	1		1
2	ABC123	AE	123102	AESEQ	1		1

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD	MHCAT	MHSCAT	MHBODSYS	MHSTDTC	MHENRPT	MHENTPT
1	ABC123	MH	123101	1	ASTHMA	Asthma	GENERAL MEDICAL HISTORY	RESPIRATORY	Respiratory system disorders		ONGOING	2004-09-18
2	ABC123	MH	123101	2	FREQUENT HEADACHES	Headache	GENERAL MEDICAL HISTORY	CNS	Central and peripheral nervous system disorders		ONGOING	2004-09-18
3	ABC123	MH	123101	3	BROKEN LEG	Bone fracture	GENERAL MEDICAL HISTORY	OTHER	Musculoskeletal system disorders		BEFORE	2004-09-18
4	ABC123	MH	123101	4	ISCHEMIC STROKE		PRIMARY DIAGNOSIS			2004-09-17T07:30		
5	ABC123	MH	123101	5	CHF	Cardiac failure congestive	CARDIAC MEDICAL HISTORY		Cardiac disorders	2004-06		



Row	STUDYID	DOMAIN	USUBJID	DVSEQ	DVTERM	DVDECOD	EPOCH	DVSTDTC
1	ABC123	DV	123101	1	IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED.	TREATMENT DEVIATION	TREATMENT PHASE	2003-09-21
2	ABC123	DV	123103	1	DRUG XXX ADMINISTERED DURING STUDY TREATMENT PERIOD	EXCLUDED CONCOMITANT MEDICATION	TREATMENT PHASE	2003-10-30
3	ABC123	DV	123103	2	VISIT 3 DOSE <15 MG	TREATMENT DEVIATION	TREATMENT PHASE	2003-10-30
4	ABC123	DV	123104	1	TOOK ASPIRIN	PROHIBITED MEDS	TREATMENT PHASE	2003-11-30

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CEPRES	CEOCCUR	CESTDTC
1	ABC123	CE	123	1	Rash	Y	Y	2006-05-03
2	ABC123	CE	123	2	Wheezing	Y	Y	2006-05-03
3	ABC123	CE	123	3	Edema	Y	Y	2006-05-06

eg.xpt

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGCAT	EGREFID	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU
1	XYZ	EG	XYZ-US-701-002	1	MEASUREMENT	334PT89	HRMEAN	Summary (Mean) Heart Rate	SUPINE	62	BEATS/MIN
2	XYZ	EG	XYZ-US-701-002	2	INTERVAL	334PT89	PRMEAN	Summary (Mean) PR Duration	SUPINE	0.15	sec
3	XYZ	EG	XYZ-US-701-002	3	INTERVAL	334PT89	QRS DUR	Summary (Mean) QRS Duration	SUPINE	0.103	sec
4	XYZ	EG	XYZ-US-701-002	4	INTERVAL	334PT89	QTMEAN	Summary (Mean) QT Duration	SUPINE	0.406	sec
5	XYZ	EG	XYZ-US-701-002	5	INTERVAL	334PT89	QTcB	QTcB – Bazett's Correction Formula	SUPINE		
6	XYZ	EG	XYZ-US-701-002	6	INTERVAL	334PT89	QTcF	QTcF – Fridericia's Correction Formula	SUPINE		
7	XYZ	EG	XYZ-US-701-002	7	FINDING	334PT89	RHYRATE	Rhythm and Rate	SUPINE	ATRIAL FIBRILLATION	
8	XYZ	EG	XYZ-US-701-002	8	FINDING	334PT89	RHYRATE	Rhythm and Rate	SUPINE	ATRIAL FLUTTER	
9	XYZ	EG	XYZ-US-701-002	9	FINDING	334PT89	QTABN	QT Abnormalities	SUPINE	PROLONGED QT	
10	XYZ	EG	XYZ-US-701-002	10	FINDING	334PT89	VCABN	Ventricular Conduction Abnormalities	SUPINE	LEFT VENTRICULAR HYPERTROPHY	
11	XYZ	EG	XYZ-US-701-002	11		334PT89	TECHPROB	Technical Problems	SUPINE	INCORRECT ELECTRODE PLACEMENT	
12	XYZ	EG	XYZ-US-701-002	12		334PT89	INTP	Interpretation	SUPINE	ABNORMAL	

Row	EGSTRESC	EGSTRESN	EGSTRESU	EGXFN	EGNAM	EGDRVFL	EGEVAL	VISITNUM	VISIT	EGDTC	EGDY
1 (cont)	62	62	BEATS/MIN	PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
2 (cont)	150	150	msec	PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
3 (cont)	103	103	msec	PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
4 (cont)	406	406	msec	PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
5 (cont)	469	469	msec	PQW436789-07.xml	Test Lab	Y		1	Screening 1	2003-04-15T11:58	-36
6 (cont)	446	446	msec	PQW436789-07.xml	Test Lab	Y		1	Screening 1	2003-04-15T11:58	-36
7 (cont)	ATRIAL FIBRILLATION			PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
8 (cont)	ATRIAL FLUTTER			PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
9 (cont)	PROLONGED QT			PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36

Row	STUDYID	DOMAIN	USUBJID	IESEQ	IESPID	IETESTCD	IETEST	IECAT	IEORRES	IESTRESC
1	XYZ	IE	XYZ-0007	1	17	EXCL17	Ventricular Rate	EXCLUSION	Y	Y
2	XYZ	IE	XYZ-0007	2	3	INCL03	Acceptable mammogram from local radiologist?	INCLUSION	N	N
3	XYZ	IE	XYZ-0047	1	3	INCL03	Acceptable mammogram from local radiologist?	INCLUSION	N	N
4	XYZ	IE	XYZ-0096	1	3	INCL03	Acceptable mammogram from local radiologist?	INCLUSION	N	N

Row	VISITNUM	VISIT	VISITDY	IEDTC	IEDY
1 (cont)	1	WEEK -8	-56	1999-01-10	-58
2 (cont)	1	WEEK -8	-56	1999-01-10	-58
3 (cont)	1	WEEK -8	-56	1999-01-12	-56
4 (cont)	1	WEEK -8	-56	1999-01-13	-55

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBORNULO	LBORNRHI	LBSTRESC	LBSTRESN
1	ABC	LB	ABC-001-001	1	ALB	Albumin	CHEMISTRY		30	g/L	35	50	3.0	3.0
2	ABC	LB	ABC-001-001	2	ALP	Alkaline Phosphatase	CHEMISTRY		398	IU/L	40	160	398	398
3	ABC	LB	ABC-001-001	3	ALP	Alkaline Phosphatase	CHEMISTRY		350	IU/L	40	160	350	350
4	ABC	LB	ABC-001-001	4	ALP	Alkaline Phosphatase	CHEMISTRY						374	374
5	ABC	LB	ABC-001-001	5	WBC	Leukocytes	HEMATOLOGY		5.9	10 <sup>9</sup> /L	4	11	5.9	5.9
6	ABC	LB	ABC-001-001	6	LYMLE	Lymphocytes	HEMATOLOGY	DIFFERENTIAL	6.7	%	25	40	6.7	6.7
7	ABC	LB	ABC-001-001	7	NEUT	Neutrophils	HEMATOLOGY	DIFFERENTIAL	5.1	10 <sup>9</sup> /L	2	8	5.1	5.1
8	ABC	LB	ABC-001-001	8	PH	pH	URINALYSIS		7.5		5.0	9.0	7.5	
9	ABC	LB	ABC-001-001	9	ALB	Albumin	CHEMISTRY							
10	ABC	LB	ABC-001-001	10	CHOL	Cholesterol	CHEMISTRY		229	mg/dL	0	<200	229	229
11	ABC	LB	ABC-001-001	11	WBC	Leukocytes	HEMATOLOGY		5.9	10 <sup>9</sup> /L	4	11	5.9	5.9
12	ABC	LB	ABC-001-001	12	PROT	Protein	URINALYSIS		MODERATE				MODERATE	

Note that the use of 10<sup>9</sup> as a unit is not a standard representation.

Row	LBSTRESU	LBSTNRLO	LBSTNRHI	LBSTRNRC	LBNRIND	LBSTAT	LBREASND	LBBLFL	LBFAST	LBDRVFL	VISITNUM	VISIT	LBDMC
1 (cont)	g/dL	3.5	5		LOW			Y	Y		1	Week 1	1999-06-19
2 (cont)	units/L	40	160						Y		1	Week 1	1999-06-19
3 (cont)	units/L	40	160						Y		1	Week 1	1999-06-20
4 (cont)	units/L	40	160					Y	Y	Y	1	Week 1	1999-06-19
5 (cont)	10 <sup>3</sup> /uL	4	11					Y	Y		1	Week 1	1999-06-19
6 (cont)	%	25	40		LOW			Y	Y		1	Week 1	1999-06-19
7 (cont)	10 <sup>9</sup> /L	2	8					Y	Y		1	Week 1	1999-06-19
8 (cont)		5.00	9.00					Y	Y		1	Week 1	1999-06-19
9 (cont)						NOT DONE	INSUFFICIENT SAMPLE				2	Week 2	1999-07-21
10 (cont)	mg/dL	0	199								2	Week 2	1999-07-21
11 (cont)	10 <sup>3</sup> /uL	4	11						Y		2	Week 2	1999-07-21
12 (cont)				NEGATIVE to TRACE	ABNORMAL						2	Week 2	1999-07-21

supplb.xpt

Row 1, 6: The SUPPLB dataset example shows clinical significance assigned by the investigator for test results where LBNRIND (reference range indicator) is populated.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	LB	ABC-001-001	LBSEQ	1	LBCLSIG	Clinical Significance	N	CRF	INVESTIGATOR
2	ABC	LB	ABC-001-001	LBSEQ	6	LBCLSIG	Clinical Significance	N	CRF	INVESTIGATOR

Row	STUDYID	DOMAIN	USUBJID	PESEQ	PESPID	PETESTCD	PETEST	PECAT	PELOC	PEBODSYS
1	ABC	PE	ABC-001-001	1	1	HEAD	Head	GENERAL		
2	ABC	PE	ABC-001-001	2	1	RESP	Respiratory	GENERAL		
3	ABC	PE	ABC-001-001	3	1	ENT	Ear/nose/throat	GENERAL		
4	ABC	PE	ABC-001-001	4	1	SKIN	Skin	GENERAL	FACE	SKIN
5	ABC	PE	ABC-001-001	5	2	SKIN	Skin	GENERAL	HANDS	SKIN
6	ABC	PE	ABC-001-001	6	3	SKIN	Skin	GENERAL	LEFT ARM	SKIN
7	ABC	PE	ABC-001-001	7	1	CV	Cardiovascular	GENERAL		CARDIOVASCULAR
8	ABC	PE	ABC-001-001	8	1	FUNDOSCP	Fundoscopy	OPHTHAMOLOGIC		
9	ABC	PE	ABC-001-001	9	1	RESP	Respiratory	GENERAL		
10	ABC	PE	ABC-001-001	10	1	ENT	Ear/nose/throat	GENERAL		
11	ABC	PE	ABC-001-001	11	1	NECK	Neck	GENERAL		
12	ABC	PE	ABC-001-001	12	1	CARDIO	Cardiovascular	GENERAL		
13	ABC	PE	ABC-001-001	13	1	FUNDOSCP	Fundoscopy	OPHTHAMOLOGIC		

Row	PEORRES	PESTRESC	PESTAT	PEREASND	VISITNUM	VISIT	VISITDY	PEDTC	PEDY
1 (cont)	NORMAL	NORMAL			1	BASELINE	1	1999-06-06	-3
2 (cont)			NOT DONE	INVESTIGATOR ERROR	1	BASELINE	1	1999-06-06	-3
3 (cont)	NORMAL	NORMAL			1	BASELINE	1	1999-06-06	-3
4 (cont)	ACNE	ACNE NOS			1	BASELINE	1	1999-06-06	-3
5 (cont)	ALLERGIC REACTION	DERMATITIS			1	BASELINE	1	1999-06-06	-3
6 (cont)	SKINRASH	RASH			1	BASELINE	1	1999-06-06	-3
7 (cont)	HEART MURMUR	CARDIAC MURMUR			1	BASELINE	1	1999-06-06	-3
8 (cont)	NORMAL	NORMAL			1	BASELINE	1	1999-06-06	-3
9 (cont)	NORMAL	NORMAL			2	VISIT 1	45	1999-07-21	45
10 (cont)	NORMAL	NORMAL			2	VISIT 1	45	1999-07-21	45
11 (cont)	NORMAL	NORMAL			2	VISIT 1	45	1999-07-21	45
12 (cont)	NORMAL	NORMAL			2	VISIT 1	45	1999-07-21	45
13 (cont)	NORMAL	NORMAL			2	VISIT 1	45	1999-07-21	45

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT
1	STUDYX	QS	P0001	1	GH1	Health	SF36	GENERAL HEALTH
2	STUDYX	QS	P0001	2	GH11A	Sick a little easier	SF36	GENERAL HEALTH
3	STUDYX	QS	P0001	3	GH11B	Healthy as anybody	SF36	GENERAL HEALTH
4	STUDYX	QS	P0001	4	GH11C	Expect health to get worse	SF36	GENERAL HEALTH
5	STUDYX	QS	P0001	5	GH	SF-36 General health perceptions	SF36	GENERAL HEALTH
6	STUDYX	QS	P0001	6	GHINDEX	SF-36 General health perceptions (0-100)	SF36	GENERAL HEALTH
7	STUDYX	QS	P0001	7	RP4A	Phys. Health-cut down time spent	SF36	ROLE-PHYSICAL
8	STUDYX	QS	P0001	8	RP4B	Phys. Health-accomplished less	SF36	ROLE-PHYSICAL
9	STUDYX	QS	P0001	9	RP4C	Phys. Health-limit kind of work	SF36	ROLE-PHYSICAL
10	STUDYX	QS	P0001	10	RP	SF-36 Role-physical	SF36	ROLE-PHYSICAL
11	STUDYX	QS	P0001	11	RPINDEX	SF-36 Role-physical (0-100)	SF36	ROLE-PHYSICAL

Row	QSORRES	QSSTRESC	QSSTRESN	QSBLFL	QSDRVFL	VISITNUM	VISIT	QSDTC	QSDY
1 (cont)	VERY GOOD	4.4	4.4	Y		2	BASELINE	2001-03-28	-2
2 (cont)	MOSTLY FALSE	4	4	Y		2	BASELINE	2001-03-28	-2
3 (cont)	MOSTLY TRUE	4	4	Y		2	BASELINE	2001-03-28	-2
4 (cont)	DEFINITELY FALSE	5	5	Y		2	BASELINE	2001-03-28	-2
5 (cont)		21.4	21.4	Y	Y	2	BASELINE	2001-03-28	-2
6 (cont)		82	82	Y	Y	2	BASELINE	2001-03-28	-2
7 (cont)	NO	2	2	Y		2	BASELINE	2001-03-28	-2
8 (cont)	NO	2	2	Y		2	BASELINE	2001-03-28	-2
9 (cont)	NO	2	2	Y		2	BASELINE	2001-03-28	-2
10 (cont)		8	8	Y	Y	2	BASELINE	2001-03-28	-2
11 (cont)		100	100	Y	Y	2	BASELINE	2001-03-28	-2

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCTESTCD	SCTEST	SCORRES	SCSTRESC	SCDTC
1	ABC	SC	ABC-001-001	1	EYECD	Eye Color	BROWN	BROWN	1999-06-19
2	ABC	SC	ABC-001-001	2	SUBJINIT	Subject Initials	HLT	HLT	1999-06-19
3	ABC	SC	ABC-001-002	1	EYECD	Eye Color	BLUE	BLUE	1999-03-19
4	ABC	SC	ABC-001-002	2	SUBJINIT	Subject Initials	BAM	BAM	1999-03-19
5	ABC	SC	ABC-001-003	1	EYECD	Eye Color	GREEN	GREEN	1999-05-03
6	ABC	SC	ABC-001-003	2	SUBJINIT	Subject Initials	ALM	ALM	1999-05-03
7	ABC	SC	ABC-002-001	1	EYECD	Eye Color	HAZEL	HAZEL	1999-06-14
8	ABC	SC	ABC-002-001	2	SUBJINIT	Subject Initials	CQH	CQH	1999-06-14

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
1	ABC	VS	ABC-001-001	1	SYSBP	Systolic Blood Pressure	SITTING	154	mmHg	154	154	mmHg
2	ABC	VS	ABC-001-001	2	SYSBP	Systolic Blood Pressure	SITTING	152	mmHg	152	152	mmHg
3	ABC	VS	ABC-001-001	3	SYSBP	Systolic Blood Pressure	SITTING			153	153	mmHg
4	ABC	VS	ABC-001-001	4	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg
5	ABC	VS	ABC-001-001	5	DIABP	Diastolic Blood Pressure	SITTING	48	mmHg	48	48	mmHg
6	ABC	VS	ABC-001-001	6	DIABP	Diastolic Blood Pressure	SITTING			46	46	mmHg
7	ABC	VS	ABC-001-001	7	PULSE	Pulse Rate	SITTING	72	bpm	72	72	bpm
8	ABC	VS	ABC-001-001	8	TEMP	Temperature		34.7	C	34.7	34.7	C
9	ABC	VS	ABC-001-001	9	TEMP	Temperature		36.2	C	36.2	36.2	C
10	ABC	VS	ABC-001-001	10	WEIGHT	Weight	STANDING	90.5	kg	90.5	90.5	kg
11	ABC	VS	ABC-001-001	11	HEIGHT	Height	STANDING	157	cm	157	157	cm
12	ABC	VS	ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	95	mmHg	95	95	mmHg
13	ABC	VS	ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg
14	ABC	VS	ABC-001-001	14	TEMP	Temperature		97.16	F	36.2	36.2	C
15	ABC	VS	ABC-001-001	15	WEIGHT	Weight						

Row	VSSTAT	VSREASND	VSLOC	VSBLFL	VSDRVFL	VISIT	VISITNUM	VISITDY	VSDTC	VSDY	VSTPT	VSTPTNUM
1 (cont)			LEFT ARM			BASELINE	1	1	1999-06-19T08:45	1	BASELINE 1	1
2 (cont)			LEFT ARM			BASELINE	1	1	1999-06-19T09:00	1	BASELINE 2	2
3 (cont)			LEFT ARM	Y	Y	BASELINE	1	1	1999-06-19	1		
4 (cont)			LEFT ARM			BASELINE	1	1	1999-06-19T08:45	1	BASELINE 1	1
5 (cont)			LEFT ARM			BASELINE	1	1	1999-06-19T09:00	1	BASELINE 2	2
6 (cont)			LEFT ARM	Y	Y	BASELINE	1	1	1999-06-19	1		
7 (cont)			LEFT ARM	Y		BASELINE	1	1	1999-06-19	1		
8 (cont)			MOUTH			BASELINE	1	1	1999-06-19T08:45	1	BASELINE 1	1
9 (cont)			MOUTH	Y		BASELINE	1	1	1999-06-19T09:00	1	BASELINE 2	2
10 (cont)				Y		BASELINE	1	1	1999-06-19	1		
11 (cont)				Y		BASELINE	1	1	1999-06-19	1		
12 (cont)			LEFT ARM			VISIT 2	2	35	1999-07-21	33		
13 (cont)			LEFT ARM			VISIT 2	2	35	1999-07-21	33		
14 (cont)			MOUTH			VISIT 2	2	35	1999-07-21	33		
15 (cont)	NOT DONE	Subject refused				VISIT 2	2	35	1999-07-21	33		

Row	STUDYID	DOMAIN	USUBJID	DASEQ	DAREFID	DASPID	DATESTCD	DATEST	DACAT	DASCAT
1	ABC	DA	ABC/01001	1	XBYCC-E990A	A375827	DISPAMT	Dispensed Amount	Study Medication	Bottle A
2	ABC	DA	ABC/01001	2	XBYCC-E990A	A375827	RETAMT	Returned Amount	Study Medication	Bottle A
3	ABC	DA	ABC/01001	3	XBYCC-E990B	A227588	DISPAMT	Dispensed Amount	Study Medication	Bottle B
4	ABC	DA	ABC/01001	4	XBYCC-E990B	A227588	RETAMT	Returned Amount	Study Medication	Bottle B
5	ABC	DA	ABC/01001	5			DISPAMT	Dispensed Amount	Rescue Medication	
6	ABC	DA	ABC/01001	6			RETAMT	Returned Amount	Rescue Medication	

Row	DAORRES	DAORRESU	DASTRESC	DASTRESN	DASTRESU	VISITNUM	DADTC	EPOCH
1 (cont)	30	TABLETS	30	30	TABLETS	1	2004-06-15	Study Med Period 1
2 (cont)	5	TABLETS	5	5	TABLETS	2	2004-07-15	Study Med Period 1
3 (cont)	15	TABLETS	15	15	TABLETS	1	2004-06-15	Study Med Period 1
4 (cont)	0	TABLETS	0	0	TABLETS	2	2004-07-15	Study Med Period 1
5 (cont)	10	TABLETS	10	10	TABLETS	1	2004-06-15	Study Med Period 1
6 (cont)	10	TABLETS	10	10	TABLETS	2	2004-07-15	Study Med Period 1



Microbiology Example 1 MB dataset

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBGRPID	MBREFID	MBSPID	MBTESTCD	MBTEST	MBORRES	
1	ABC	MB	ABC-001-001	1			SP01		GMNCOC	Gram Negative Cocci	2+ FEW
2	ABC	MB	ABC-001-001	2			SP01		GMNROD	Gram Negative Rods	2+ FEW
3	ABC	MB	ABC-001-001	3	1		SP01	ORG01	ORGANISM	Organism Present	STREPTOCOCCUS PNEUMONIAE PENICILLIN RESISTANT
4	ABC	MB	ABC-001-001	4	2		SP01	ORG02	ORGANISM	Organism Present	KLEBSIELLA PNEUMONIAE
5	ABC	MB	ABC-001-001	5	3		SP02	ORG02	ORGANISM	Organism Present	KLEBSIELLA PNEUMONIAE
6	ABC	MB	ABC-001-001	6			SP03	ORG03	ORGANISM	Organism Present	NO GROWTH

Row	MBSTRESC	MBRESCAT	MBLOC	MBSPEC	MBSPCCND	MBMETHOD	VISITNUM	MBDTC
1 (cont)	FEW		LUNG	SPUTUM	MUCOID	GRAM STAIN	1	2005-06-19T08:00
2 (cont)	FEW		LUNG	SPUTUM	MUCOID	GRAM STAIN	1	2005-06-19T08:00
3 (cont)	STREPTOCOCCUS PNEUMONIAE, PENICILLIN RESISTANT	INFECTING	LUNG	SPUTUM	MUCOID	CULTURE PLATE	1	2005-06-19T08:00
4 (cont)	KLEBSIELLA PNEUMONIAE	COLONIZER	LUNG	SPUTUM	MUCOID	CULTURE PLATE	1	2005-06-19T08:00
5 (cont)	KLEBSIELLA PNEUMONIAE	COLONIZER	LUNG	SPUTUM		CULTURE PLATE	2	2005-06-26T08:00
6 (cont)	NO GROWTH		LUNG	SPUTUM		CULTURE PLATE	3	2005-07-06T08:00

Row	STUDYID	DOMAIN	USUBJID	MSSEQ	MSGRPID	MSTESTCD	MSTEST	MSCAT
1	ABC	MS	ABC-001-001	1	1	EXTGROW	Extent of Growth	GROWTH
2	ABC	MS	ABC-001-001	2	1	DRUGA	Sponsor Drug	SUSCEPTIBILITY
3	ABC	MS	ABC-001-001	3	1	PENICLLN	Penicillin	SUSCEPTIBILITY
4	ABC	MS	ABC-001-001	4	2	EXTGROW	Extent of Growth	GROWTH
5	ABC	MS	ABC-001-001	5	2	DRUGA	Sponsor Drug	SUSCEPTIBILITY
6	ABC	MS	ABC-001-001	6	2	PENICLLN	Penicillin	SUSCEPTIBILITY
7	ABC	MS	ABC-001-001	7	3	PENICLLN	Penicillin	SUSCEPTIBILITY

Row	MSORRES	MSORRESU	MSSTRESC	MSSTRESN	MSSTRESU	MSRESCAT	MSMETHOD	VISITNUM
1 (cont)	IN 2ND QUADRANT		IN 2ND QUADRANT					1
2 (cont)	0.004	mcg/mL	0.004	0.004	mcg/mL	SUSCEPTIBLE	E-TEST	1
3 (cont)	0.023	mcg/mL	0.023	0.023	mcg/mL	RESISTANT	E-TEST	1
4 (cont)	>=30 COLONIES IN 2ND QUADRANT		>=30 COLONIES IN 2ND QUADRANT					1
5 (cont)	0.125	mcg/mL	0.125	0.125	mcg/mL	SUSCEPTIBLE	E-TEST	1
6 (cont)	0.023	mcg/mL	0.023	0.023	mcg/mL	INTERMEDIATE	E-TEST	1
7 (cont'd)	0.026	mcg/mL	0.026	0.026	mcg/mL	INTERMEDIATE	E-TEST	2

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCGRPID	PCREFID	PCTESTCD	PCTEST	PCCAT	PCSPEC	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU
1	ABC-123	PC	123-0001	1	Day 1	A554134-10	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	<0.1	ng/mL	<0.1		ng/mL
2	ABC-123	PC	123-0001	2	Day 1	A554134-10	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	<0.1	ng/mL	<0.1		ng/mL
3	ABC-123	PC	123-0001	3	Day 1	A554134-11	DRGA_MET	Drug A Metabolite	ANALYTE	URINE	<2	ng/mL	<2		ng/mL
4	ABC-123	PC	123-0001	4	Day 1	A554134-11	DRGA_PAR	Drug A Parent	ANALYTE	URINE	<2	ng/mL	<2		ng/mL
5	ABC-123	PC	123-0001	5	Day 1	A554134-11	VOLUME	Volume	SPECIMEN	URINE	3500	mL	100	100	mL
6	ABC-123	PC	123-0001	6	Day 1	A554134-11	PH	PH	SPECIMEN	URINE	5.5		5.5	5.5	
7	ABC-123	PC	123-0001	7	Day 1	A554134-12	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	5.4	ng/mL	5.4	5.4	ng/mL
8	ABC-123	PC	123-0001	8	Day 1	A554134-12	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	4.74	ng/mL	4.74	4.74	ng/mL
9	ABC-123	PC	123-0001	9	Day 1	A554134-13	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	5.44	ng/mL	5.44	5.44	ng/mL
10	ABC-123	PC	123-0001	10	Day 1	A554134-13	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	1.09	ng/mL	1.09	1.09	ng/mL
11	ABC-123	PC	123-0001	11	Day 1	A554134-14	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA					
12	ABC-123	PC	123-0001	12	Day 1	A554134-14	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	<0.1	ng/mL	<0.1		ng/mL
13	ABC-123	PC	123-0001	13	Day 11	A554134-15	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	3.41	ng/mL	3.41	3.41	ng/mL
14	ABC-123	PC	123-0001	14	Day 11	A554134-15	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	<0.1	ng/mL	<0.1		ng/mL
15	ABC-123	PC	123-0001	15	Day 11	A554134-16	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	8.74	ng/mL	8.74	8.74	ng/mL

14.4. PP dataset for example 1

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPGRPID	PPTTESTCD	PPTTEST	PPCAT	PPORRES	PPORRESU
1	ABC-123	PP	ABC-123-0001	1	DAY1_PAR	TMAX	Time to Max Effect	DRUG A PARENT	1.87	h
2	ABC-123	PP	ABC-123-0001	2	DAY1_PAR	CMAX	Max Effect Concentration	DRUG A PARENT	44.5	ug/L
3	ABC-123	PP	ABC-123-0001	3	DAY1_PAR	AUC	Area Under Curve	DRUG A PARENT	294.7	h*mg/L
4	ABC-123	PP	ABC-123-0001	4	DAY1_PAR	THALF_1	Half-life of 1st exp phase	DRUG A PARENT	0.75	h
5	ABC-123	PP	ABC-123-0001	5	DAY1_PAR	THALF_2	Half-life of 2nd exp phase	DRUG A PARENT	4.69	h
6	ABC-123	PP	ABC-123-0001	6	DAY1_PAR	VD	Vol of Distribution	DRUG A PARENT	10.9	L
7	ABC-123	PP	ABC-123-0001	7	DAY1_PAR	CL	Clearance	DRUG A PARENT	1.68	L/h
8	ABC-123	PP	ABC-123-0001	8	DAY1_MET	TMAX	Time to Max Effect	DRUG A METABOLITE	0.94	h
9	ABC-123	PP	ABC-123-0001	9	DAY1_MET	CMAX	Max Effect Concentration	DRUG A METABOLITE	22.27	ug/L
10	ABC-123	PP	ABC-123-0001	10	DAY1_MET	AUC	Area Under Curve	DRUG A METABOLITE	147.35	h*mg/L

(PP dataset for example 1, continued)

Row	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	VISITNUM	VISIT	PPDTC	PPRFTDTC
1 (cont)	1.87	1.87	h	PLASMA	1	DAY 1	2001-03-01	2001-02-01 T08:00
2 (cont)	44.5	44.5	ug/L	PLASMA	1	DAY 1	2001-03-01	2001-02-01 T08:00
3 (cont)	294.7	294.7	h.mg/L	PLASMA	1	DAY 1	2001-03-01	2001-02-01 T08:00
4 (cont)	0.75	0.75	h	PLASMA	1	DAY 1	2001-03-01	2001-02-01 T08:00
5 (cont)	4.69	4.69	h	PLASMA	1	DAY 1	2001-03-01	2001-02-01 T08:00
6 (cont)	10.9	10.9	L	PLASMA	1	DAY 1	2001-03-01	2001-02-01 T08:00
7 (cont)	1.68	1.68	L/h		1	DAY 1	2001-03-01	2001-02-01 T08:00
8 (cont)	0.94	0.94	h	PLASMA	1	DAY 1	2001-03-01	2001-02-01 T08:00
9 (cont)	22.27	22.27	ug/L	PLASMA	1	DAY 1	2001-03-01	2001-02-01 T08:00
10 (cont)	147.35	147.35	h.mg/L	PLASMA	1	DAY 1	2001-03-01	2001-02-01 T08:00

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STUDYID	DOMAIN	USUBJID	CESEQ	CESPID	CETERM	CEDECOD	CESTDTC
ABC	CE	ABC-123	1	90567	Migraine	Migraine	2007-05-16T10:30

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Row	STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FACAT
1	ABC	FA	ABC-123	1	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS
2	ABC	FA	ABC-123	2	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS
3	ABC	FA	ABC-123	3	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS
4	ABC	FA	ABC-123	4	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS
5	ABC	FA	ABC-123	6	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS
6	ABC	FA	ABC-123	7	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS
7	ABC	FA	ABC-123	8	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS
8	ABC	FA	ABC-123	9	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS
9	ABC	FA	ABC-123	10	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS
10	ABC	FA	ABC-123	12	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS
11	ABC	FA	ABC-123	13	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS
12	ABC	FA	ABC-123	14	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS
13	ABC	FA	ABC-123	15	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS
14	ABC	FA	ABC-123	16	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS
15	ABC	FA	ABC-123	18	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS

Row	FAORRES	FASTRESC	FADTC	FATPT	FAELTM	FATPTREF
1 (cont'd)	SEVERE	SEVERE	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
2 (cont'd)	Y	Y	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
3 (cont'd)	N	N	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
4 (cont'd)	Y	Y	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
5 (cont'd)	Y	Y	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
6 (cont'd)	MODERATE	MODERATE	2007-05-16	30M POST-DOSE	PT30M	DOSING
7 (cont'd)	Y	Y	2007-05-16	30M POST-DOSE	PT30M	DOSING
8 (cont'd)	N	N	2007-05-16	30M POST-DOSE	PT30M	DOSING
9 (cont'd)	N	N	2007-05-16	30M POST-DOSE	PT30M	DOSING
10 (cont'd)	Y	Y	2007-05-16	30M POST-DOSE	PT30M	DOSING
11 (cont'd)	MILD	MILD	2007-05-16	90M POST-DOSE	PT90M	DOSING
12 (cont'd)	N	N	2007-05-16	90M POST-DOSE	PT90M	DOSING
13 (cont'd)	N	N	2007-05-16	90M POST-DOSE	PT90M	DOSING
14 (cont'd)	N	N	2007-05-16	90M POST-DOSE	PT90M	DOSING
15 (cont'd)	N	N	2007-05-16	90M POST-DOSE	PT90M	DOSING

**RELREC**

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC	CE		CESPID		ONE	1
ABC	FA		FASPID		MANY	1

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STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FADTC
ABC	FA	ABC -US-701-002	1	798654	REAS	Reason	Bone Fracture	BONE FRACTURE ASSESSMENT - HISTORY	FALL	2006-04-10
ABC	FA	ABC -US-701-002	2	798654	OUT	Outcome	Bone Fracture	BONE FRACTURE ASSESSMENT - HISTORY	COMPLICATIONS	2006-04-10
ABC	FA	ABC -US-701-002	3	798654	OCCUR	Occurrence	Complications	BONE FRACTURE ASSESSMENT	Y	2006-04-10
ABC	FA	ABC -US-701-002	4	798654	OCCUR	Occurrence	Therapeutic Measure	BONE FRACTURE ASSESSMENT	Y	2006-04-10

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STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
ABC	FA	ABC -US-701-002	FASEQ	1	FATYP	FA Type	MOST RECENT	CRF	
ABC	FA	ABC -US-701-002	FASEQ	2	FATYP	FA Type	MOST RECENT	CRF	
ABC	FA	ABC -US-701-002	FASEQ	3	FATYP	FA Type	MOST RECENT	CRF	
ABC	FA	ABC -US-701-002	FASEQ	4	FATYP	FA Type	MOST RECENT	CRF	

#### Current Fractures Having Event Records

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STUDYID	DOMAIN	USUBJID	CESEQ	CESPID	CETERM	CELOC	CEOUT	CECONTRT	CESTDTC
ABC	CE	ABC -US-701-002	1	1	Fracture	ARM	NORMAL HEALING	Y	2006-07-03
ABC	CE	ABC -US-701-002	2	2	Fracture	LEG	COMPLICATIONS	N	2006-10-15

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STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
ABC	CE	ABC -US-701-002	CESPID	1	REAS	Reason	FALL	CRF	
ABC	CE	ABC -US-701-002	CESPID	2	REAS	Reason	OTHER TRAUMA	CRF	
ABC	CE	ABC -US-701-002	CESPID	2	OUT	Outcome	COMPLICATIONS	CRF	

Trial Arms Dataset for Example Trial 1

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
1	EX1	TA	P	Placebo	1	SCRN	Screen			Screen
2	EX1	TA	P	Placebo	2	RI	Run-In	Randomized to Placebo		Run-In
3	EX1	TA	P	Placebo	3	P	Placebo			Treatment
4	EX1	TA	A	A	1	SCRN	Screen			Screen
5	EX1	TA	A	A	2	RI	Run-In	Randomized to Drug A		Run-In
6	EX1	TA	A	A	3	A	Drug A			Treatment
7	EX1	TA	B	B	1	SCRN	Screen			Screen
8	EX1	TA	B	B	2	RI	Run-In	Randomized to Drug B		Run-In
9	EX1	TA	B	B	3	B	Drug B			Treatment

Trial Elements Dataset for Example Trial 1

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EX1	TE	SCRN	Screen	Informed consent	1 week after start of Element	P7D
2	EX1	TE	RI	Run-In	Eligibility confirmed	2 weeks after start of Element	P14D
3	EX1	TE	P	Placebo	First dose of study drug, where drug is placebo	2 weeks after start of Element	P14D
4	EX1	TE	A	Drug A	First dose of study drug, where drug is Drug A	2 weeks after start of Element	P14D
5	EX1	TE	B	Drug B	First dose of study drug, where drug is Drug B	2 weeks after start of Element	P14D

Trial Visits Dataset for Example Trial 1 with explicitly scheduled starts and ends of Visits

Row	STUDYID	DOMAIN	VISITNUM	TVSTRL	TVENRL
1	EX1	TV	1	Start of Screen Epoch	1 hour after start of Visit
2	EX1	TV	2	30 minutes before end of Screen Epoch	30 minutes after start of Run-in Epoch
3	EX1	TV	3	30 minutes before end of Run-in Epoch	1 hour after start of Treatment Epoch
4	EX1	TV	4	1 week after start of Treatment Epoch	1 hour after start of Visit
5	EX1	TV	5	2 weeks after start of Treatment Epoch	1 hour after start of Visit

Row	STUDYID	DOMAIN	IETESTCD	IETEST	IECAT	TIVERS
1	XYZ	TI	INCL01	Has disease under study	INCLUSION	1
2	XYZ	TI	INCL02	Age 21 or greater	INCLUSION	1
3	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	1
4	XYZ	TI	INCL01	Has disease under study	INCLUSION	2.2
5	XYZ	TI	INCL02A	Age 18 or greater	INCLUSION	2.2
6	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	2.2

Row	STUDYID	DOMAIN	TSSEQ	TSARMCD	TSPARM	TSVAL
1	XYZ	TS	1	AGESPAN	Age Span	ADULT (18-65)
2	XYZ	TS	2	AGESPAN	Age Span	ELDERLY (> 65)
3	XYZ	TS	1	AGEMAX	Planned Maximum Age of Subjects	70
4	XYZ	TS	1	AGEMIN	Planned Minimum Age of Subjects	18
5	XYZ	TS	1	AGEU	Age Unit	YEARS
6	XYZ	TS	1	COMPTRT	Comparative Treatment Name	PLACEBO
7	XYZ	TS	1	DESIGN	Description of Trial Design	PARALLEL
8	XYZ	TS	1	INDIC	Trial Indication	Asthma
9	XYZ	TS	1	OBJPRIM	Trial Primary Objective	Reduce the incidence of exacerbations of asthma
10	XYZ	TS	1	RANDOM	Trial is Randomized	Y

**suppdm.xpt: Supplemental Qualifiers for DM**

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	1996001	DM	99-401			ITT	Intent to Treat	Y	DERIVED	SPONSOR
2	1996001	DM	99-401			PPROT	Per Protocol Set	N	DERIVED	SPONSOR

*Example 2*

The two rows of *suppae.xpt* add qualifying information to adverse event data (RDOMAIN=AE). IDVAR defines the key variable used to link this information to the AE data (AESEQ). IDVARVAL specifies the value of the key variable within the parent AE record that the SUPPAE record applies to. The remaining columns specify the supplemental variables' names (AESOSP and AETRTEM), labels, values, origin, and who made the evaluation.

**suppae.xpt: Supplemental Qualifiers for AE**

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	1996001	AE	99-401	AESEQ	1	AESOSP	Other Medically Important SAE	Spontaneous Abortion	CRF	
2	1996001	AE	99-401	AESEQ	1	AETRTEM	Treatment Emergent Flag	N	DERIVED	SPONSOR