

Draft SDTMIG 3.1.4 – Batch 2 Death Details domain - DD

Short summary from Stefan Bordasch



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Death Details domain - Definition

- Defined as **Findings** domain: “One record per finding per subject”

dd.xpt, Death Details — Findings, Version 3.1.4. One record per finding per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DD	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DDSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DDTESTCD	Death Detail Assessment Short Name	Char	*	Topic	Short name of the measurement, test, or examination described in DDTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DDTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., “1TEST” is not valid). DDTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: DIAGPRIM, DIAGSEC, DTHWIT	Req
DDTEST	Death Detail Assessment	Char	*	Synonym Qualifier	Long name for DDTESTCD. The value in DDTEST cannot be longer than 40 characters. Examples: Primary Diagnosis, Secondary Diagnosis, Was Death Witnessed?	Req
DDORRES	Result or Finding as Collected	Char		Result Qualifier	Result of the test defined in DDTEST, as originally received or collected.	Exp
DDSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result or finding copied or derived from DDORRES in a standard format.	Exp
DDRESCAT	Result Category	Char	*	Variable Qualifier	Used to categorize the result of a finding. Examples: TREATMENT RELATED, NONTREATMENT RELATED, UNDETERMINED, ACCIDENTAL	Perm
DDEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation.	Perm
EPOCH	Epoch	Char		Timing	Epoch during which the death occurred.	Perm
DDDTCC	Date/Time of Collection	Char	ISO 8601	Timing	Date/time of collection of the diagnosis or other death assessment data, in ISO 8601 format. This is not necessarily the date of death.	Perm
DDDY	Study Day of Collection	Num		Timing	Study day of the collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

Death Details domain - Assumptions

- Domain should capture information about the death like
 - Cause of Death
 - Primary and Secondary Cause
 - Location of Death
 - Wheater it was witnessed
- Intention to collect this information on a designated CRF page
 - Do not derive from other information, e.g. AE or DS domain
 - Should be in addition to that other domains – linked in RELREC
- No extra Controlled Terminology in place for DDTESTCD / DDTEST

Death Details domain - Examples

- DD domain example

Row	STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES	DSSTRESC	DDTIC
1	ABC123	DD	ABC12301001	1	PRCDTH	Primary Cause of Death	SUDDEN CARDIAC DEATH	SUDDEN CARDIAC DEATH	2011-01-12
2	ABC123	DD	ABC12301001	2	LOCPTH	Location of Death	HOME	HOME	2011-01-12
3	ABC123	DD	ABC12301002	1	PRCDTH	Primary Cause of Death	UNKNOWN	UNKNOWN	2011-03-15
4	ABC123	DD	ABC12301002	2	LOCPTH	Location of Death	UNKNOWN	UNKNOWN	2011-03-15
5	ABC123	DD	ABC12301023	1	PRCDTH	Primary Cause of Death	CARDIAC ARRHYTHMIA	CARDIAC ARRHYTHMIA	2011-09-09
6	ABC123	DD	ABC12301023	2	SECDTH	Secondary Cause of Death	CHF	CONGESTIVE HEART FAILURE	2011-09-09
7	ABC123	DD	ABC12301023	3	LOCPTH	Location of Death	MEMORIAL HOSPITAL	HOSPITAL	2011-09-09

- ...and as combination for a RELREC entry

Death Details (DD) Dataset

Row	STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES	DSSTRESC	DDTIC
1	ABC123	DD	ABC12301001	1	PRCDTH	Primary Cause of Death	SUDDEN CARDIAC DEATH	SUDDEN CARDIAC DEATH	2011-01-12

4	ABC123	DS	ABC12301001	4	SUDDEN CARDIAC DEATH	DEATH	DISPOSITION EVENT	TREATMENT PHASE	2011-01-10	2011-01-10
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Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AESTDTC	AEENDTC	AEDECOD	AEBODSYS	AEOUT	AESER	AESDTH
1	ABC123	AE	ABC123010014	6	SUDDEN CARDIAC DEATH	2011-01-10	2011-01-10	SUDDEN CARDIAC DEATH	CARDIOVASCULAR SYSTEM	FATAL	Y	Y

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC123	DS	ABC12301001	DSSEQ	4		1
2	ABC123	AE	ABC12301001	AESEQ	6		1
3	ABC123	DD	ABC12301001	DDSEQ	1		1

Draft SDTMIG 3.1.4 – Batch 2 Subject Status domain - SS

Short summary from Stefan Bordasch



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Subject Status domain - Definition

- Defined as **Findings** domain: “One record per finding per visit per subject”

SS.xpt, Subject Status — Findings, Version 3.1.4. One record per finding per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
SSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
SSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the procedure or test page.	Perm
SSTESTCD	Status Short Name	Char	(SSTESTCD)	Topic	Short name of the status assessment described in SSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in SSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., “1TEST”). SSTESTCD cannot contain characters other than letters, numbers, or underscores. Example: SURVSTAT	Req
SSTEST	Status Name	Char	(SSTEST)	Synonym Qualifier	Verbatim name of the status assessment used to obtain the finding. The value in SSTEST cannot be longer than 40 characters. Example: Survival Status	Req
SSCAT	Category for Test	Char	*	Grouping Qualifier	Used to categorize observations across subjects.	Perm
SSSCAT	Subcategory for Test	Char	*	Grouping Qualifier	A further categorization.	Perm
SSORRES	Result or Finding	Char		Result Qualifier	Result of the status assessment finding as originally received or collected.	Exp
SSSTRESC	Character Result/Finding in Std Format	Char	(SSSTRESC)	Result Qualifier	Contains the result value for all findings, copied or derived from SSORRES in a standard format.	Exp
SSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a status assessment was not done. Should be null if a result exists in SSORRES.	Perm
SSREASND	Reason Assessment Not Performed	Char		Record Qualifier	Describes why an assessment was not performed. Example: SUBJECT REFUSED. Used in conjunction with SSSTAT when value is NOT DONE.	Perm

Subject Status domain – Definition (2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
SSEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: CAREGIVER, ADJUDICATION COMMITTEE, FRIEND.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the assessment. Example: FOLLOW-UP.	Perm
SSDTC	Date/Time of Test	Char	ISO 8601	Timing		Exp
SSDY	Study Day of Test	Num		Timing	1. Study day of the test, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

Subject Status domain - Assumptions

- SS domain is about “accommodate repeated survival questions where mortality is assessed many times during an ongoing study follow-up period”
- Domain is for data relating to the subject status, not for assessments
- Expected information:
 - Status Collection Date
 - Status Question
 - Status Response
- Controlled Terminology terms not part of latest SDTM Terminology file

Subject Status domain - Example


- SS domain example

SS.xpt

Row	STUDYID	DOMAIN	USUBJID	SSSEQ	SSTESTCD	SSTEST	SSORRES	SSSTRESC	VISITNUM	VISIT	SSDTC
1	XYZ	SS	XYZ-333-009	1	SURVSTAT	Survival Status	ALIVE	ALIVE	10	MONTH 1	2010-04-15
2	XYZ	SS	XYZ-333-009	2	SURVSTAT	Survival Status	ALIVE	ALIVE	20	MONTH 2	2010-05-12
3	XYZ	SS	XYZ-333-009	3	SURVSTAT	Survival Status	ALIVE	ALIVE	30	MONTH 3	2010-06-15
4	XYZ	SS	XYZ-428-021	1	SURVSTAT	Survival Status	ALIVE	ALIVE	10	MONTH 1	2010-08-03
5	XYZ	SS	XYZ-428-021	2	SURVSTAT	Survival Status	DEAD	DEAD	20	MONTH 2	2010-09-06

Subject Status domain – how to use

- Regardless of the method of contact, the information should be stored in the appropriate topic-based domain
- Don't enter per FUP visit a line in DS domain for the actual status – only the final result
- The visit of each SS entry has to be defined in TV domain and has to appear in SV domain
- For the case that the subject has died...
 - Store the survival status in SS domain, SSORRES = DEAD
 - In DS create a line for final result of Follow-Up epoch
 - In DM set the Death Flag DTHFL=Y and enter the Death Date in DTHDTC
 - Depending on the protocol about the FUP period an AE entry has to exist

A faint, dark blue world map is visible in the background of the top half of the slide. The map shows the continents of North America, South America, Europe, Africa, and Asia.

For further information,
please contact your marketing manager

Thank you