



NEW DOMAINS FOR IG 3.3 FROM REVIEW BATCH 2

SM - SUBJECT DISEASE
MILESTONES

TM - TRIAL DISEASE
MILESTONES

03-Mar-2015, 20th German CDISC User Network Meeting
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NEW CONCEPT DISEASE MILESTONES

- Invented during creation of Therapeutic Area User Guide „Diabetes“ v1/2014
from handling of disease history
to handling of timing of events of interest (study related)
- Adding an event of interest to related domains was inconsistent:
 - e.g. a hypoglycemic event was added as **-TPT** to LB (finding)
but as **-TPTREF** to EX (intervention)
 - construction of RELREC to link all related information of those events was insufficient

NEW CONCEPT DISEASE MILESTONES (CONTINUING)

- New timing variables RELMIDS, MIDS, MIDSDTC and domains TM and SM designed
- Variables to be used in related domains, **TM** and **SM** to describe milestones/events on trial/subject basis, no RELREC needed for those events

		OLD			NEW		
Type of data	Domain	Time Point Variable Values			Disease Milestone Timing Variable Values		
		--TPT	--REFIPT	--RFTDTC	RELMIDS	MIDS	MIDSDTC
Hypoglycemic Event	CE	HYPO 1				HYPO 1	
Hypoglycemic Event Symptoms	CE	HYPO 1			DURING	HYPO 1	<date/time>
Glucose	LB	HYPO 1			DURING	HYPO 1	<date/time>
Most recent meal	ML	LAST INTERVENTION PRIOR TO	HYPO 1	<date/time>	LAST INTERVENTION PRIOR TO	HYPO 1	<date/time>
Most recent dose of study medication	EX	LAST INTERVENTION PRIOR TO	HYPO 1	<date/time>	LAST INTERVENTION PRIOR TO	HYPO 1	<date/time>
Findings about the hypoglycemic event	FA	HYPO 1			AT	HYPO 1	<date/time>
Most recent dose of anti-diabetic con med	CM	LAST INTERVENTION PRIOR TO	HYPO 1	<date/time>	LAST INTERVENTION PRIOR TO	HYPO 1	<date/time>
Treatments for the hypoglycemic event	CM	IMMEDIATELY AFTER	HYPO 1	<date/time>	IMMEDIATELY AFTER	HYPO 1	<date/time>

DOMAIN MODEL - TM

TM – Specification for Trial Disease Milestones Domain Model

tm.xpt – Trial Disease Milestones, Type, version 3.x.x. One record per Disease Milestone type.

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	Char	TM	Identifier	Two-character abbreviation for the domain	Req
MIDSTYPE	Disease Milestone Type	Char		Topic	The type of Disease Milestone. Example: HYPOGLYCEMIC EVENT	Req
TMDEF	Disease Milestone Definition	Char		Rule	Definition of the Disease Milestone.	Req
TMRPT	Disease Milestone Repetition Indicator	Char	(NY)	Record Qualifier	Indicates whether this is a Disease Milestone that can occur only once (N) or a type of Disease Milestone that can occur multiple times (Y).	Req

- describe Disease Milestones (events of interest) at trial level
- observations or activities expected to occur
- expected to happen before the study, or during the study
- no current CT

Example TM:

Diabetes trial: initial diagnosis of diabetes and the hypoglycemic events occur during trial have been identified as Disease Milestones of interest.

tm.xpt

Row	STUDYID	DOMAIN	MIDSTYPE	TMDEF	TMRPT
1	XYZ	TM	DIAGNOSIS	Initial diagnosis of diabetes, the first time a physician told the subject they had diabetes.	N
2	XYZ	TM	HYPOGLYCEMIC EVENT	Hypoglycemic Event, the occurrence of a glucose level below [threshold level].	Y

DOMAIN MODEL - SM

SM – Specification for Subject Disease Milestones Domain Model

sm.xpt – Subject Disease Milestones, Type, version 3.x.x. One record per Disease Milestone per subject.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
SMSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records. Should be assigned to be consistent chronological order.	Req
MIDS	Disease Milestone Instance Name	Char		Topic	Name of the specific Disease Milestone. For types of Disease Milestones that can occur multiple times, the name will end with a sequence number. Example: HYPO 1.	Req
MIDSTYPE	Disease Milestone Type	Char		Qualifier	The type of Disease Milestone. Example: HYPOGLYCEMIC EVENT	Req
SMSTDTC	Start Date/Time of Milestone	Char	ISO 8601	Timing	Start date/time of Milestone Instance, if Milestone is an intervention or event, or date of Milestone if Milestone is a finding.	Exp
SMENDTC	End Date/Time of Milestone	Char	ISO 8601	Timing	End date/time of Disease Milestone Instance.	Exp
SMSTDY	Study Day of Start of Milestone	Num		Timing	Study day of start of Disease Milestone Instance, relative to the sponsor-defined RFSTDTC.	Exp
SMENDY	Study Day of End of Milestone	Num		Timing	Study day of end of Disease Milestone Instance, relative to the sponsor-defined RFSTDTC.	Exp

- describe Disease Milestones (events of interest) at subject level
- record the timing per subject of Disease Milestones that have been defined in the Trial Disease Milestones (TM)
- Milestones occurring once (TMRPT = N) use MIDS = MIDSTYPE or abbreviation;
- Milestones occurring multiple times (TMRPT = Y) use MIDS = abbreviation of MIDSTYPE + sequence number.
- start date/time is the critical date/time, and must be populated

EXAMPLES

Example SM:

Subject 1: Initial diagnosis of diabetes in October of 2005; partial date so SMDY is not populated. No end date/time was recorded for this Milestone. Two hypoglycemic events occurred, only start date/times have been collected.

Subject 2: Initial diagnosis diabetes in May 2005, full date. No hypoglycemic events.

Row	STUDYID	DOMAIN	USUBJID	SMSEQ	MIDSTYPE	MIDS	SMSTDTC	SMENDTC	SMSTDY	SMENDY
1	XYZ	SM	001	1	DIAGNOSIS	DIAG	2005-10			
2	XYZ	SM	001	2	HYPOGLYCEMIC EVENT	HYPO 1	2013-09-01T11:00		25	
3	XYZ	SM	001	3	HYPOGLYCEMIC EVENT	HYPO 2	2013-09-24T08:48		50	
4	XYZ	SM	002	1	DIAGNOSIS	DIAG	2010-05-15		-1046	

Example TM:

Row	STUDYID	DOMAIN	MIDSTYPE	TMDEF	TMRPT
1	XYZ	TM	DIAGNOSIS	Initial diagnosis of diabetes, the first time a physician told the subject they had diabetes.	N
2	XYZ	TM	HYPOGLYCEMIC EVENT	Hypoglycemic Event, the occurrence of a glucose level below [threshold level].	Y

Both domains linked by MIDSTYPE.

Example related domains EX, LB:

ex.xpt

STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXCAT	EXDOSE	EXDOSU	EXSTDTC	MIDS	MIDSREL
XYZ	EX	XYZ-001-001	1	DRUG A	HIGHLIGHTED DOSE	10	mg	2013-09-01T07:00	HYPO 1	LAST INTERVENTION PRIOR TO

lb.xpt

STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBTESTCD	LBSTRESN	LBSTRESU	LBSPEC	LBSTDC	MIDS	MIDSREL
XYZ	LB	XYZ-001-001	GLUCOMETER	1	GLUC	3.33	mmol/L	BLOOD	2013-09-01T11:00	HYPO 1	DURING

Related domains linked by MIDS.

THANK YOU