

PP25: SDTM can be customized to different types of nonclinical data using a streamlined decision-making process

Standards Roadmap Team



<http://goo.gl/HxKa13>

Abstract

Project: Demonstrating proof-of-concept for the decision-making process by modeling different nonclinical endpoints to custom SDTM findings domains.

The PhUSE Nonclinical Roadmap Group developed a resource that transforms nonclinical data that is not currently modelled in SEND into an SDTM Custom Domain. In this poster, the group demonstrates how the Custom Domain Resource was used to model Micronucleus, Ocular Irritation, and Motor Activity data. The goal was to demonstrate how three different types of nonclinical data can be modelled in SDTM using a streamlined decision-making process.

Approach

The Study Data Tabulation model (SDTM) is currently only applicable for collected subject or pool-based data, so the data that we are attempting to model will be subject to this restriction. Endpoints in a nonclinical study may consist of several examinations, each of which has its own result. Each result may constitute its own data type, like numerical or descriptive data. Within each of the selected endpoints for modelling, each result (or data) type must be processed through the decision tree to be appropriately represented by the resulting domain structure.

In the Motor Activity study [data courtesy of PDS], we identified one result type:

- Number of crossed photocell per axis, where the data type is an *integer*.

In the Micronucleus study [1], we identified two result types:

- Number of micronucleated erythrocytes per 2000 polychromatic erythrocytes (PCE) examined per animal, where the data type is an *integer*.
- Ratio of polychromatic erythrocytes (PCE) to monochromatic erythrocytes (NCE) determined in at least 500 erythrocytes per animal, where the data type is *float*.

In the Ocular study [2], we identified two result types:

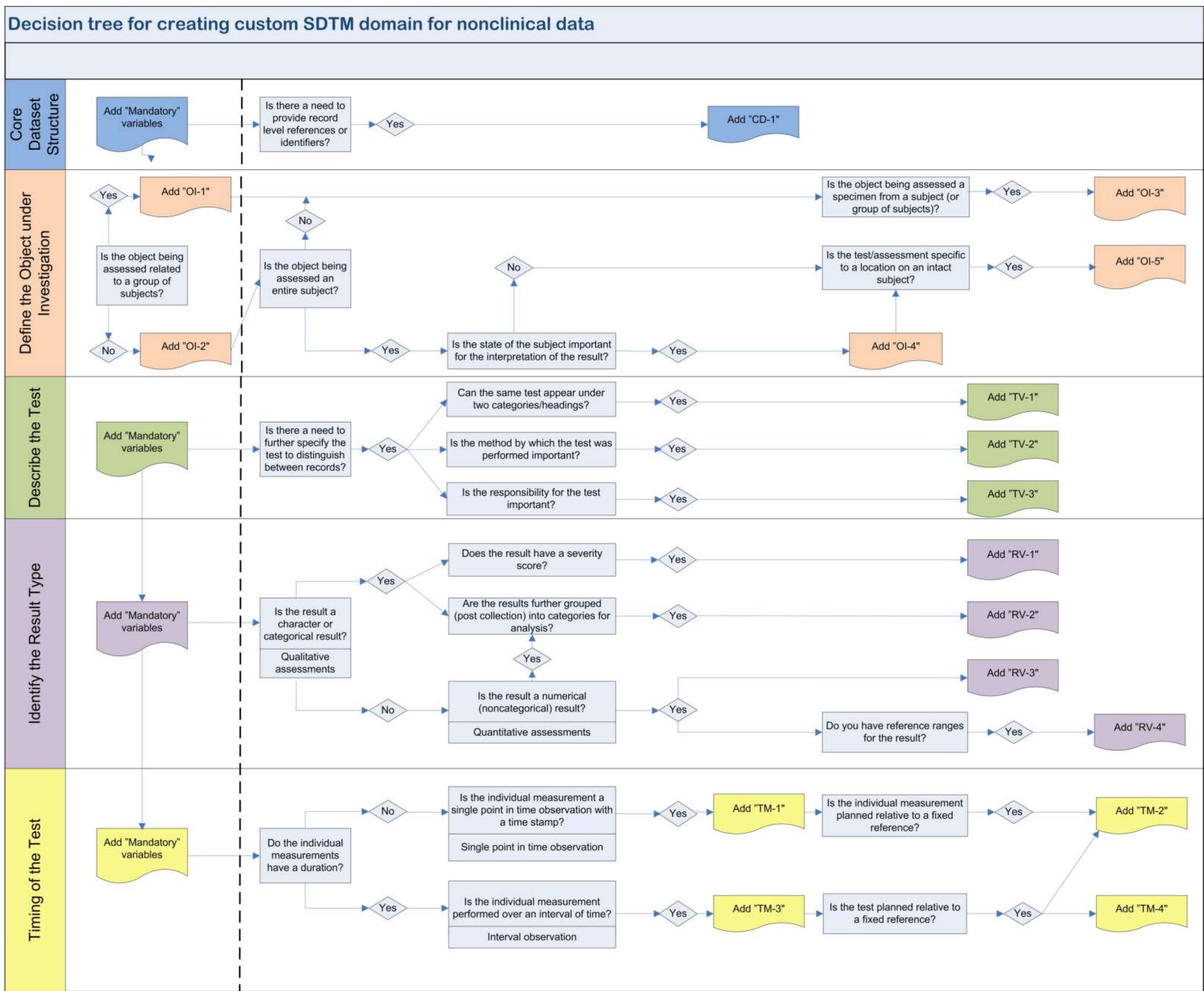
- The Draize scale for scoring of ocular lesions, where the data type is an *integer*.
- The derived weighted sum of all ocular scoring, where the data type is an *integer*.

- Title: "In Vivo Mammalian Cytogenetics – Erythrocyte Micronucleus assay in Mice using Silver Chloride", Study Date: 7/27/05. Accessed at: http://www.epa.gov/opp00001/chem_search/cleared_reviews/csr_PC-072506_27-Jul-05_a.pdf
- Title: "Primary Eye Irritation Study of Alpal CO-436 in New Zealand White Rabbits", Study Date: 9/24/84. Accessed at: <http://www.epa.gov/opp/tscat8e/pubs/8ehq/2011/apr11/8ehq-0411-01708b.pdf>

Summary

The PhUSE Nonclinical Roadmap Group performed a validation of the workflow designed in the decision tree to identify potentially misleading areas within that workflow. The decision tree was used by individuals in the group to create custom SDTM domains for Motor Activity, Micronucleus, and Ocular Irritation data. The outcome was a custom-fitted SDTM domain table for each of the three nonclinical data types, all of which are presented on this poster. Individual experiences in creating these custom domains were discussed among the group, and subsequently, updates were made to the decision-tree to make it more intuitive to use. The decision-tree process presented on this poster has the confidence of the group that it will result in a custom-domain which conforms with the rules of SDTM. The Nonclinical Roadmap Group will gladly accept feedback from the PhUSE community about the execution of the decision tree on other nonclinical data types. A digital version of the three nonclinical custom domain examples can be accessed via the QR code or URL link.

Decision Tree



Ocular Irritation custom domain - OC

Decision based adding of variables		Custom SDTM dataset specification – Ocular Irritation data					
Variable category	Variable group	Variable Name	Variable Label	Type	Controlled Terms (CT), Codelist, or Format	Role	Core (within variable group)
Core Dataset structure	Mandatory	STUDYID	Study Identifier	Char		Identifier	Req
Core Dataset structure	Mandatory	DOMAIN	Domain Abbreviation	Char	XX	Identifier	Req
Object Identifier	OI-2	USUBJID	Unique Subject Identifier	Char		Identifier	Req
Core Dataset structure	Mandatory	--SEQ	Sequence Number	Num		Identifier	Req
Test Variables	Mandatory	--TESTCD	Measurement, Test or Examination Short Name	Char	CT is expected	Topic	Req
Test Variables	Mandatory	--TEST	Measurement, Test or Examination Name	Char	CT is expected	Synonym Qualifier	Req
Result Variables	Mandatory	--ORRES	Result or Finding as Collected	Char		Result Qualifier	Exp
Results Variables	RV-3	--ORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	Exp
Results Variables	Mandatory	--STRESC	Standardized Result in Character Format	Char	CT is expected	Result Qualifier	Exp
Results Variables	RV-3	--STRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Exp
Results Variables	RV-3	--STRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Exp
Result Variables	Mandatory	--STAT	Completion Status	Char	(ND)	Record Qualifier	Perm
Result Variables	Mandatory	--REASND	Reason Not Done	Char		Record Qualifier	Perm
Object Identifier	OI-5	--LOC	Location associated with a result or finding	Char		Record Qualifier	Perm
Result Variables	RV-3	--BLFL	Baseline Flag	Char	(NY)	Record Qualifier	Perm
Results Variables	Mandatory	--EXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Perm
Results Variable	Mandatory	--REASEX	Reason for Exclusion	Char		Record Qualifier	Perm
Timing Variables	Mandatory	VISITDY	Planned Study Day	Num		Timing	Exp
Timing Variables	TM-1	--DTC	Date/Time of Test	Char	ISO 8601	Timing	Exp
Timing Variables	TM-1	--DY	Study Day of Test	Num		Timing	Exp
Timing Variables	TM-2	--TPT	Planned Time Point Name	Char		Timing	Exp
Timing Variables	TM-2	--TPTNUM	Planned Time Point Number	Num		Timing	Exp
Timing Variables	TM-2	--ELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Exp
Timing Variables	TM-2	--TPTREF	Time Point Reference	Char		Timing	Exp
Timing Variables	TM-2	--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Exp



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Motor Activity custom domain - MC

Decision based adding of variables		Custom SDTM dataset specification – Motor Activity data					
Variable category	Variable group	Variable Name	Variable Label	Type	Controlled Terms (CT), Codelist, or Format	Role	Core (within variable group)
Core Dataset structure	Mandatory	STUDYID	Study Identifier	Char		Identifier	Req
Core Dataset structure	Mandatory	DOMAIN	Domain Abbreviation	Char	XX	Identifier	Req
Object Identifier	OI-2	USUBJID	Unique Subject Identifier	Char		Identifier	Req
Core Dataset structure	Mandatory	--SEQ	Sequence Number	Num		Identifier	Req
Test Variables	Mandatory	--TESTCD	Measurement, Test or Examination Short Name	Char	CT is expected	Topic	Req
Test Variables	Mandatory	--TEST	Measurement, Test or Examination Name	Char	CT is expected	Synonym Qualifier	Req
Test Variables	TV-2	--LOC	Location associated with a result or finding	Char		Record Qualifier	Perm
Test Variables	TV-2	--METHOD	Method of Test or Examination	Char		Record Qualifier	Perm
Result Variables	Mandatory	--ORRES	Result or Finding as Collected	Char		Result Qualifier	Exp
Results Variables	RV-3	--ORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	Exp
Results Variables	Mandatory	--STRESC	Standardized Result in Character Format	Char	CT is expected	Result Qualifier	Exp
Results Variables	RV-3	--STRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Exp
Results Variables	RV-3	--STRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Exp
Result Variables	Mandatory	--STAT	Completion Status	Char	(ND)	Record Qualifier	Perm
Result Variables	Mandatory	--REASND	Reason Not Done	Char		Record Qualifier	Perm
Result Variables	RV-3	--BLFL	Baseline Flag	Char	(NY)	Record Qualifier	Exp
Results Variables	Mandatory	--EXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Perm
Results Variable	Mandatory	--REASEX	Reason for Exclusion	Char		Record Qualifier	Perm
Timing Variables	Mandatory	VISITDY	Planned Study Day	Num		Timing	Exp
Timing Variables	TM-2	--STDTC	Start Date/Time of Test	Char	ISO 8601	Timing	Exp
Timing Variables	TM-3	--ENDTC	End Date/Time of Test	Char	ISO 8601	Timing	Perm
Timing Variables	TM-3	--STDY	Study Day of Start of Test	Num		Timing	Exp
Timing Variables	TM-3	--ENDY	Study Day of End of Test	Num		Timing	Perm
Timing Variables	TM-3	--DUR	Duration of Test	Char	ISO 8601	Timing	Perm
Timing Variables	TM-2	--TPT	Planned Time Point Name	Char		Timing	Exp
Timing Variables	TM-2	--TPTNUM	Planned Time Point Number	Num		Timing	Exp
Timing Variables	TM-2	--ELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Exp
Timing Variables	TM-2	--TPTREF	Time Point Reference	Char		Timing	Exp
Timing Variables	TM-2	--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Exp
Timing Variables	TM-4	--EVLINT	Evaluation Interval	Char	ISO 8601	Timing	Perm
Timing Variables	TM-4	--STINT	Planned Start of Assessment Interval	Char	ISO 8601	Timing	Perm
Timing Variables	TM-4	--ENINT	Planned End of Assessment Interval	Char	ISO 8601	Timing	Perm



<http://goo.gl/L42u8x>

Micronucleus custom domain - MN

Decision based adding of variables		Custom SDTM dataset specification – Micronucleus data					
Variable category	Variable group	Variable Name	Variable Label	Type	Controlled Terms (CT), Codelist, or Format	Role	Core (within variable group)
Core Dataset structure	Mandatory	STUDYID	Study Identifier	Char		Identifier	Req
Core Dataset structure	Mandatory	DOMAIN	Domain Abbreviation	Char	XX	Identifier	Req
Object Identifier	OI-2	USUBJID	Unique Subject Identifier	Char		Identifier	Req
Core Dataset structure	Mandatory	--SEQ	Sequence Number	Num		Identifier	Req
Object Identifier	OI-3	--REFID	Reference Identifier	Char		Identifier	Perm
Test Variables	Mandatory	--TESTCD	Measurement, Test or Examination Short Name	Char	CT is expected	Topic	Req
Test Variables	Mandatory	--TEST	Measurement, Test or Examination Name	Char	CT is expected	Synonym Qualifier	Req
Result Variables	Mandatory	--ORRES	Result or Finding as Collected	Char		Result Qualifier	Exp
Results Variables	RV-3	--ORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	Exp
Results Variables	Mandatory	--STRESC	Standardized Result in Character Format	Char	CT is expected	Result Qualifier	Exp
Results Variables	RV-3	--STRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Exp
Results Variables	RV-3	--STRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Exp
Result Variables	Mandatory	--STAT	Completion Status	Char	(ND)	Record Qualifier	Perm
Result Variables	Mandatory	--REASND	Reason Not Done	Char		Record Qualifier	Perm
Object Identifier	OI-3	--SPEC	Specimen Material Type	Char	(SPEC)	Record Qualifier	Exp
Object Identifier	OI-3	--ANTREG	Anatomical Region of Specimen	Char		Variable Qualifier	Exp
Object Identifier	OI-3	--SPCCND	Specimen Condition	Char		Variable Qualifier	Perm
Object Identifier	OI-3	--SPCUEL	Specimen Usability for the Test	Char	(NY)	Variable Qualifier	Perm
Object Identifier	OI-3	--LAT	Specimen Laterality within Subject	Char	(LAT)	Variable Qualifier	Perm
Object Identifier	OI-3	--DIR	Specimen Directionality within Subject	Char	(DIR)	Variable Qualifier	Perm
Object Identifier	OI-3	--PORTOT	Portion or Totality	Char	(PORTOT)	Variable Qualifier	Perm
Result Variables	RV-3	--BLFL	Baseline Flag	Char	(NY)	Record Qualifier	Exp
Results Variables	Mandatory	--EXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Perm
Results Variable	Mandatory	--REASEX	Reason for Exclusion	Char		Record Qualifier	Perm
Timing Variables	Mandatory	VISITDY	Planned Study Day	Num		Timing	Exp
Timing Variables	TM-1	--DTC	Date/Time of Test	Char	ISO 8601	Timing	Exp
Timing Variables	TM-1	--DY	Study Day of Test	Num		Timing	Exp
Timing Variables	TM-2	--TPT	Planned Time Point Name	Char		Timing	Exp
Timing Variables	TM-2	--TPTNUM	Planned Time Point Number	Num		Timing	Exp
Timing Variables	TM-2	--ELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Exp
Timing Variables	TM-2	--TPTREF	Time Point Reference	Char		Timing	Exp
Timing Variables	TM-2	--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Exp



<http://goo.gl/QOCw3n>

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