

Mapping Data to SDTM

Making Use of CDASH And ODM Metadata

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My Mapping Tool – the Tabulator

Tabulator - AC-058-111/tabulatorAEMHCM.tbt - Eclipse

File Edit Navigate Search Project Run Window Help

Validate on Save Transform

Navigator

- Tabulator Fehlermeldungen 20110
- Tabulator Fehlermeldungen 20110
- Tabulator Fehlermeldungen.docx
- tabulatorAEMHCM.tbt
- tabulatorCO.tbt

Input ODM

- (Subject Protocol)
- e.screening
 - f.visitdate
 - ig.visit
 - i.sv_visdat
 - f.consents
 - f.demos
 - f.medhist
 - f.ecg
 - f.vitalsigns
 - f.labsampling
 - f.hematology
 - f.chemistry
 - f.inclxcl
 - f.randomization
 - e.a1b1_day-1
 - f.visitdate
 - f.labsampling
 - f.hematology
 - f.chemistry
 - e.a1b1_day1
 - f.visitdate
 - f.ccbbadmin

Tabulator Overview

File

File OID: AC-058-111.Mapping.AEMHCM

Originator: Kurt Hellstern, Hands-on GmbH

Study

Study OID: AC-058-111

Study Name: AC-058-111

Study Description: Single center, open-label, randomized, two-part, two-way crossover study to i

Protocol Name: AC-058-111

MDV

Meta Data Version (MDV) relating to the tabulator.xml/define.xml file (not to be confused with the M)

MDV OID: MDV.SDTM.1

MDV Name: Version at study start

MDV Description: Mapping from AC-058-111 ODM MDV.1 to SDTM

Data Standard name: CDISC SDTM

Data Standard version: 3.1.2

Setup

Overview Domains Mappings Source

CRT Variable

OID	Name	DataTy.
AEACN	AEACN	text
AEBODSYS	AEBODSYS	text
AEDECOD	AEDECOD	text
AEENDTC	AEENDTC	text
AEENDY	AEENDY	float
AEENRF	AEENRF	text
AEHLGT	AEHLGT	text
AEHLGTCD	AEHLGTCD	text
AEHLT	AEHLT	text
AEHLTCD	AEHLTCD	text
AELLT	AELLT	text
AELLTCD	AELLTCD	text
AEOUT	AEOUT	text
AEPTCD	AEPTCD	text
AEREL	AEREL	text
AESQ	AESQ	integer
AESER	AESER	text
AESV	AESV	text
AESOCDD	AESOCDD	text
AESPID	AESPID	text
AESTDTC	AESTDTC	text
AESTDY	AESTDY	float
AETERM	AETERM	text
CMCAT	CMCAT	text
CMDECOD	CMDECOD	text
CMDOSE	CMDOSE	float
CMDOSFRQ	CMDOSFRQ	text
CMDOSTXT	CMDOSTXT	text
CMDOSU	CMDOSU	text

Tabulating

- **Define tables and variables (target structure)**
- **Map (tabulate) items from the eCRF into the variables in the tables**

Define Tables and Variables

The screenshot displays the Tabulator - Eclipse interface with the following components:

- Domains Panel:**
 - Domain: SDTM_DM (Selected)
 - Properties:
 - Domain OID: SDTM_DM
 - Domain Name: DM
 - Label: Demographics
 - Class: Special Purpose
 - Structure: One record per subject
 - Repeating: No
 - Domain Columns:

OID	Mandatory	Role
STUDYID	Yes	Identifier
DOMAIN	Yes	Identifier
USUBJID	Yes	Identifier
SUBJID	Yes	Topic
RFSTDTC	No	Timing
RFENDTC	No	Timing
SITEID	No	Record Qualifier
INVNAM	No	Synonym Qualifier
AGE	No	Result Qualifier
AGEU	No	Result Qualifier
SEX	No	Result Qualifier
RACE	No	Result Qualifier
ARM	No	Synonym Qualifier
- Variable Definition Table (CRT Variables):**

OID	Name	Data...	Length	Label
AGE	AGE			RFSTDTC
AGEU	AGEU			
ARM	ARM			Description of Element
ARMCD	ARMCD	text	50	Arm Code
COUNTRY	COUNTRY	text	5	Country
DMDTC	DMDTC	text	10	Date/Time of Collection
DMDY	DMDY	integ...	4	Study Day of Collection
DOMAIN	DOMAIN	text	10	Domain Abbreviation
INVNAM	INVNAM	text	200	Investigator Name
RACE	RACE	text	200	Race
RFENDTC	RFENDTC	text	20	Subj. Reference End Date
RFSTDTC	RFSTDTC	text	20	Subj. Reference Start Date
SEX	SEX	text	10	Sex
SITEID	SITEID	text	20	Study Site Identifier
STUDYID	STUDYID	text	40	Study Identifier
SUBJID	SUBJID	text	20	Subj. Identifier for Study
SUPPRACE...	SUPPRACE...	text	200	Other Race
USUBJID	USUBJID	text	40	Unique Subj. Identifier
ELEMENT	ELEMENT	text	200	Description of Element
EPOCH	EPOCH	text	50	Epoch
ETCD	ETCD	text	8	Element Code
INVID	INVID	text	20	Investigator Identifier
TABRANCH	TABRANCH	text	200	Branch
TAETORD	TAETORD	integ...	3	Order of Element within A
TEENRL	TEENRL	text	200	Rule for End of Element
TESTRL	TESTRL	text	200	Rule for Start of Element
TSPARM	TSPARM	text	200	Trial Summary Parameter
TSPARMCD	TSPARMCD	text	8	Trial Summary Parameter
TSVAL	TSVAL	text	200	Parameter Value
TSVAL1	TSVAL1	text	200	Parameter Value
TVSTRL	TVSTRL	text	200	Visit Start Rule
VISIT	VISIT	text	50	Visit Name
VISITNUM	VISITNUM	float	8	Visit Number

Map eCRF Items into Tables

- **Click, drag and drop**
- **Derive items: transform, concatenate, ...**
- **Map under conditions**
- **Include external data**
- **etc.**

Mapping: the Writers

Writers:

STUDYID	C	AC-058-111
DOMAIN	C	AE
USUBJID	E	concat ("AC-058-111-", toString(\$randomnr))
AESEQ	S	AE.seq1
AESPID	P	../ItemData[@OID="i.ae_aespid"]
AETERM	E	\$contextNode
AELLT	P	../ItemData[@OID="i.ae_aellt"]
AELLTCD	P	../ItemData[@OID="i.ae_aelltcd"]
AEDECOD	P	../ItemData[@OID="i.ae_aedecod"]
AEPTCD	P	../ItemData[@OID="i.ae_aeptcd"]
AEHLT	P	../ItemData[@OID="i.ae_aehlt"]
AEHLTCD	P	../ItemData[@OID="i.ae_aehltcd"]
AEHLGT	P	../ItemData[@OID="i.ae_aehlgt"]
AEHLGTCD	P	../ItemData[@OID="i.ae_aehlgtcd"]
AEBODSYS	P	../ItemData[@OID="i.ae_aebodsys"]
AESOCCD	P	../ItemData[@OID="i.ae_aesoccd"]
AESEV	E	transcode(1, "Mild", 2, "Moderate", 3, "Severe", 4, "not applicabl
AESER	E	transcode(1, "Y", 2, "N", source := \$aeser)
AEACN	E	transcode(1, "None", 2, "Dose reduced", 3, "Dose increased", 4, "Te
AEREL	E	transcode(1, "Y", 2, "N", source := \$aerel)
AEOUT	E	transcode(1, "Resolved without sequelae", 2, "Resolved with sequela
AESTDTC	E	choose (when isValue(\$aesttim) && isValue(\$aestdat) then concat(toS
AEENDTC	E	choose (when isValue(\$aeentim) && isValue(\$aeendat) then concat(toS
AESTDY	E	choose (when in(1,3,element:=\$strsequence) then round(daysDiff(\$aest

Legend:

- C = constant value
- S = SEQ number generator
- P = Path (1:1 mapping)
- E = Expression (various functions)

OID	Name
AEACN	AEACN
AEBODSYS	AEBODSYS
AEDECOD	AEDECOD
AEENDTC	AEENDTC
AEENDY	AEENDY
AEENRF	AEENRF
AEREL	AEREL
AESEQ	AESEQ
AESER	AESER
AESEV	AESEV
AESOCCD	AESOCCD
AESPID	AESPID
AESTDTC	AESTDTC
AESTDY	AESTDY
AETERM	AETERM
CMCAT	CMCAT
CMDECOD	CMDECOD
CMDOSE	CMDOSE
CMDOSFRQ	CMDOSFRQ
CMDOSTXT	CMDOSTXT
CMDOSU	CMDOSU
CMENDTC	CMENDTC
CMENRF	CMENRF
CMINDC	CMINDC
CMROUTE	CMROUTE
CMSE0	CMSE0

CDASH for Mappings into Finding Domains

Marvin - AC-057-115 Demo Stud - Mozilla Firefox

File Edit View Chronik Lesezeichen Extras Hilfe

https://actelion.xclinical.net/marvin/studydata/action.do?requestId=4&requestId=X

Meistbesuchte Seiten Spotfire maps Google Actelion Cor-03 Cor-03T Lhon Lhon-T Falken WM wetter cecina

Marvin - AC-057-115 Dem...

Nummer: 30 -- Alter: 26 -- Datum Tag 1: 17.11.2008

Screening (Tag -21 bis Tag -3) 11.11.2008 Studientag 1 17.11.2008 Studientag 2 18.11.2008 Studientag 3 19.11.2008 Studientag 4 20.11.2008

VSDDAT

Studientag 1 ?

Visit Datum Vital Signs Blood Sampling ECG Lab specimen information Labs: hematology Labs: clinical chemistry Almorexant administration Vital Signs Blood Sampling ECG ECG

Please add item groups for the timepoints: 90 min / 4 h / 12 h

Vital Signs						
Row number	Geplanter Zeitpunkt	Zeit	Systolic Blood Pressure	Diastolic Blood Pressure	Heart rate	
1	90 min	08:49	111 mmHg	74 mmHg	57 Schläge pro Minute	<input type="checkbox"/>
2	4 h	10:03	103 mmHg	66 mmHg	59 Schläge pro Minute	<input type="checkbox"/>
3	12 h	19:18	115 mmHg	71 mmHg	57 Schläge pro Minute	<input type="checkbox"/>

VSDTIM

Weiter Verlassen SDV speichern Formular löschen Event löschen

VSDTC	VSTESTCD	VSORRES
2008-11-17T08:49	SYSBP	111
2008-11-17T08:49	DIABP	74
2008-11-17T08:49	HR	57

TEST INSTANCE

MARVIN

Fertig

CDASH plus: Use of Metadata

The screenshot displays the Eclipse IDE interface for a CDASH project. The main window shows the 'Data Definition' for the element 'i.vs_diabp'. The configuration is as follows:

OID:	i.vs_diabp
Name:	Diastolic blood pressure
Binary:	No
Data Type:	integer
Length:	3
SASFieldName:	DIABP
SDSVarName:	DIABP
en:	Diastolic blood pressure

The 'Questions' section is currently empty. The 'Element Paths' section is also empty.

In the ODM Tree on the left, the element 'i.vs_diabp' is highlighted with a red box, indicating its selection.

A red box at the bottom of the screenshot contains the text: **Controlled terminology in ODM elements**.

Use of Metadata from Item i.vs_diabp

W Writers:

aaa = tabulator functions

bbb = Kurt's wish for enhancements

STUDYID	C	AC-058-111
DOMAIN	C	VS
USUBJID	E	<code>concat ("AC-058-111-", \$randomnr)</code>
VSSEQ	S	VS.Seq1
VSSPID	N	[null]
VSTESTCD	E	sdsVarNameOF(\$contextNode)
VSTEST	E	nameOF(\$contextNode)
VSPOS	C	Supine
VSORRES	E	<code>withDefault (\$contextNode, default:= null)</code>
VSORRESU	E	measurementUnitValueOF(\$contextNode)
VSORNRLO	C	lowerRangeValueOF(\$contextNode)
VSORNRHI	C	upperRangeValueOF(\$contextNode)
VSSTRESC	E	<code>withDefault (\$contextNode, default:= null)</code>
VSSTRESN	E	<code>withDefault (\$contextNode, default:= null)</code>
VSSTRESU	C	measurementUnitValueOF(\$contextNode)
VSSTNRLO	E	: lowerRangeValueOF(\$contextNode)
VSSTNRHI	E	: upperRangeValueOF(\$contextNode)

Push your providers to

- **Develop mapping tools**
- **To increase the tool's features**