

SDTM
Mapping Issues
Documentation of Mapping Issues

Monika Kawohl

Statistical Programming

Accovion GmbH, Marburg, Germany



Extension Studies

- ✓ USUBJID Retained from Parent Study
 - Study A, Subject 1 => STUDYID="A", USUBJID="A1"
 - Study Aext, Subject 1 => STUDYID="Aext", USUBJID="A1"
- ✓ Data from Parent Study with Relevance for Ext. Study
 - Baseline Values
 - Medical History, Ongoing Conmeds, AEs
- ✓ Included in DB for Ext. Study (N/Y)?
- ✓ To be included in SDTM for Ext. Study (N/Y)?
- ✓ Data Handling to be described in define.xml/reviewer'guide

Unscheduled Visits

- ✓ Repeated Measurements
 - e.g. to follow up on abnormal lab values
- ✓ Multiple records for the same visit?
- ✓ Repeated visit gets VISITNUM with Decimal?
 - VISITNUM=1, VISITNUM=1.01
 - Respective VISIT values?
- ✓ VISIT=UNSCHEDULED, VISITNUM=9999?
- ✓ Consistency with TV and SV to be considered
- ✓ Keys in define.xml should uniquely identify a record

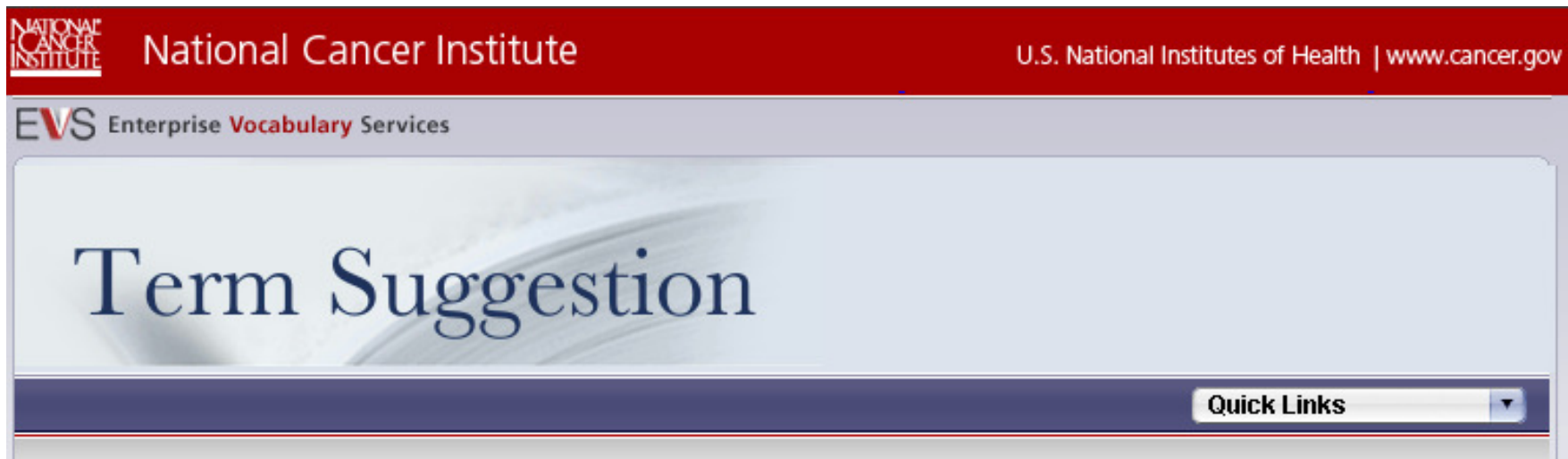
Controlled Terminology (CT)

- ✓ Handling of CDISC CT Updates in a Submission Project?
- ✓ Values that Do not Fit in Non-Extensible Codelists?
- ✓ Conventions from SDTM IG not included in CDISC CT
 - MULTIPLE
 - TESTCD=<Domain>ALL (e.g., LBTESTCD="LBALL")
 - Include in define.xml Codelists N/Y?
- ✓ Mapping to CDISC CT of reported --ORRESU values?

Controlled Terminology (CT)

- ✓ Use of New Term Request Functionality on NCI website?
- ✓ <http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>

The [CDISC New Term Request](#) web page handles suggestions for both new terminology and changes to existing terminology. The [CDISC Term Request Tracking](#) Excel spreadsheet helps members of the CDISC community review and comment on all submitted requests.



Standard Domain vs. Custom Domain

✓ Use of Standard Domains vs. Custom Domains?

- Non Study Drug Treatment of Special Interest
- Underlying Disease
- Surgical History

✓ General Strategy?

- Few rather Generic Domains
 - With Topic Distinction via -CAT
- More Specific Domains



Monitoring Questions/Trigger Questions

✓ Map N/Y?

- Did any AE occur?
- Did the subject take any concomitant medication?
- Were <Tests> performed?

✓ Comments linked with those monitoring/trigger questions

Exposure (EX)

- ✓ Documentation of Study Drug not Taken
- ✓ Rule per current SDTM IG
 - EX Records only for Study Drug Taken
- ✓ Issue:
 - Details on study drug not taken in the source data may be necessary to determine/calculate compliance
 - Generate EX records with missing dose
 - Document exception from SDTM IG and provide reason for it
 - Define.xml, reviewer's guide

Protocol Deviations

- ✓ Documented Deviations
- ✓ Derived Deviations
 - Inclusion discouraged by SDTM IG
- ✓ What's the Process regarding Protocol Deviations in your company?

Adding Variables to Standard Domains

- ✓ Timing variables
- ✓ Variables applicable for a certain observation class but not included in the SDTM IG domain table
 - Check IG for variables “generally not expected”
- ✓ TSVAL1-TSVALx
- ✓ COVAL1-COVALx
- ✓ Acceptable Variables per SDTM compliance check tools
- ✓ No extension of the standard domain tables at all
 - SUPPQUAL

Remaining Issues from Compliance Checks

- ✓ Checks for SDTM Compliance Highly Recommended
- ✓ Tools used at the FDA
 - CBER: OpenCDISC
 - CDER: WebSDM with Plans to Change to OpenCDISC (source: Draft CDER Data Standards Plan)
- ✓ Documentation of remaining issues
 - Draft SDTM Metadata Submission Guidelines
 - Sample on how to address those in reviewer's guide
 - CBER: Validation and Data Interpretation Report

Harmonization across Trials

- ✓ Values as Collected vs. Mapping to CT?
 - Mapping to CDISC CT
 - Sponsor Specific Terminology
 - For Codelist Extensions
 - For New Codelists
- ✓ Documentation of value mapping
annotations on blankcrf.pdf, comment in define.xml
- ✓ Process
- ✓ Tools to Analyze/Verify Harmonization across Trials

Handling of Free Text

✓ Non Result Qualifiers

Location of Injection	
Right Arm	Left Arm
Right Thigh	Left Thigh
Other, Specify: <u>Upper Abdomen</u>	

✓ Options for populating supplemental qualifiers

- EXLOC=OTHER, QNAM=EXLOCOTH, QVAL=UPPER ABDOMEN
- EXLOC=ABDOMEN, QNAM=EXLOCOTH, QVAL=UPPER ABDOMEN
- EXLOC=UPPER ABDOMEN; No SUPPEX

✓ Choice driven by analysis/sponsor requirements

- Categories/grouping of locations in analysis table

Handling of Free Text (continued)

✓ Result Qualifiers

Eye Color	
Brown	Black
Blue	Green
Other, specify: Blueish Gray	

✓ Options for representation in SDTM

- SCTEST= Eye Color, SCORRES=BLUEISH GRAY
 - SCSTRESC=OTHER
 - SCSTRESC=GRAY
 - SCSTRESC=BLUEISH GRAY

✓ Choice driven by analysis/sponsor requirements

- Categories/grouping of results in analysis table

Handling of "Check All that Apply"

AE Dataset

AETERM	AELOC
RASH	MULTIPLE

✓ Applicable for Non-Result Qualifiers

SUPPAE Dataset

QNAM	QLABEL	QVAL
AELOC1	Location of the Reaction 1	FACE
AELOC2	Location of the Reaction 2	NECK
AELOC3	Location of the Reaction 3	CHEST

✓ Options

- More specific naming and labeling
- Most relevant selection may be mapped to domain variable

Multiple Responses for Findings

✓ Multiple records per --TEST possible

✓ Sample EG:

EGTESTCD=RHYRATE, EGTEST=Rhythm and Rate, EGORRES=ATRIAL FIBRILLATION

EGTESTCD=RHYRATE, EGTEST=Rhythm and Rate, EGORRES=ATRIAL FLUTTER

✓ --SEQ or --SPID necessary to uniquely identify a record

Splitting of Domains

- ✓ Possible reason: size issue
- ✓ Split on --CAT level
- ✓ Allow for retrospective combination
 - Same DOMAIN value and prefix
 - Consistent variable lengths
 - --SEQ unique over all split domains
 - Separate SUPP---- datasets following the same concept
- ✓ Sample:
QS36, SUPPQS36 with DOMAIN and RDOMAIN = QS

RELREC Samples

✓ Relationships between single records

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
EFC1234	AE	123456	AESEQ	5		1
EFC1234	CM	123456	CMGRPID	COMBO1		1

✓ General relationships between domains

- Prerequisite: all concentrations used for derivation of parameters

RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
PC		PCGRPID		MANY	A
PP		PPGRPID		MANY	A

Findings About (FA)

- ✓ Findings about Events or Interventions
- ✓ Use Cases
 - Different timing than event/intervention
 - Details collected in Findings" structure (occurrence at a fixed date/visit)
 - Details on events/interventions which have qualifiers of their own
 - E.g., units, methods
 - Details on underlying disease when not collected as MH
 - FAOBJ=<underlying disease>
 - Related symptoms or therapies
 - Occurrence of pre-specified AEs
 - AEOCCUR='N' **not** allowed in AE domain
- ✓ Combination of FAOBJ and FATESTCD
 - FAOBJ: Name of clinical event or condition
 - FATESTCD: characteristic of event/condition

Findings About (FA) - Sample

Migraine Symptoms Diary	
Migraine Reference Number	xx
When did the migraine start	DD-MM-YY HH-MM
Answer the following 5 Minutes BEFORE Dosing	
Severity of Migraine	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
Associated Symptoms:	
Sensitivity to light	<input type="radio"/> No <input type="radio"/> Yes
Sensitivity to sound	<input type="radio"/> No <input type="radio"/> Yes
Nausea	<input type="radio"/> No <input type="radio"/> Yes
Aura	<input type="radio"/> No <input type="radio"/> Yes

CE

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

FACE

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

Row	FAORRES	FASTRES C	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

✓ Express relationship in RELREC

Clinical Events (CE)

- ✓ Use e.g. for efficacy criteria not to be reported as AEs
- ✓ Data collected in "Events" structure (start and end date)

Event	Yes	No	Date Started	Date Ended	Severity
Nausea	<input type="checkbox"/>	<input type="checkbox"/>			
Vomit	<input type="checkbox"/>	<input type="checkbox"/>			
Diarrhea	<input type="checkbox"/>	<input type="checkbox"/>			
Other, Specify					

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CEPRESP	CEOCCUR	CESTAT	CESEV	CESTDTC	CEENDTC
1	ABC123	CE	123	1	Nausea	Y	Y		MODERATE	2005-10-12	2005-10-15
2	ABC123	CE	123	2	Vomit	Y	N				
3	ABC123	CE	123	3	Diarrhea	Y		NOT DONE			
4	ABC123	CE	123	4	Severe head pain				SEVERE	2005-10-09	2005-10-11