



CJUG SDTM LISaS Team

TERMINOLOGY MAPPING



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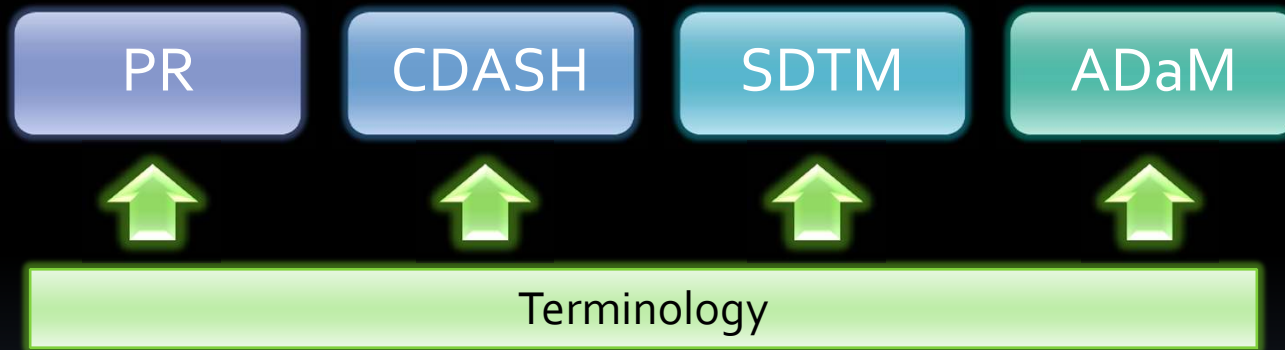


1. Basic of Terminology



Principles

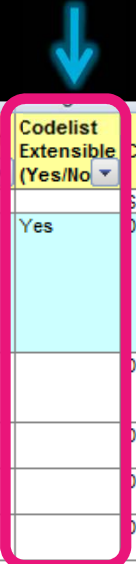
- **Key component** for interoperability.
- Cross-standards (CDASH, SDTM, ADaM and PR)



- SDTM datasets should be compliant to it.

How it looks?

- Found at NCI web site*
- Some can be extended, others cannot.



Code	Code Extensible (Yes/No)	Code Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C25376		Size	SMALL		Limited in number, quantity, magnitude or extent. (NCI)	Small
C66734	Yes	Domain Abbreviation	DOMAIN	Domain Abbreviation	A unique, 2-character domain code used in the regulatory submission process. The domain abbreviation is used consistently throughout the submission, i.e. in the dataset name, as the value of the domain variable within the dataset, and as a prefix for most variable names in the dataset. (CDISC Glossary)	CDISC SDTM Submission Domain Abbreviation Terminology
C49563		Domain Abbreviation	AD	Analysis Dataset	Datasets used for statistical analysis and reporting by the sponsor. These are submitted in addition to the data tabulation datasets.	Analysis Dataset Domain
C49562		Domain Abbreviation	AE	Adverse Events	Adverse events may be captured either as free text or a pre-specified list of terms.	Adverse Event Domain
C49565		Domain Abbreviation	AU	Autopsy	Additional data about deaths, specific to findings from autopsies.	Autopsy Domain
C49566		Domain Abbreviation	BM	Bone Measurements	Findings resulting from evaluations of bone mineral density.	Bone Measurements Domain

*<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>

In details

- Submission Value, NCI Code and Preferred Term are found.

OID	Name (CDISC Submission Value)	Data Type Extensible	NCI Code
	CDISC Submission Value [ODM:CodedValue]		
CL.C66767.ACN	Action Taken with Study Treatment (ACN)	text Extensible: No	C66767
	DOSE INCREASED		C49503
	DOSE NOT CHANGED		
	DOSE DECREASED		

CDISC Definition	Preferred Term
Action Taken with Study Treatment	CDISC SDTM Action Taken with Study Treatment Terminology
An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased

Define.XML

- All terminology in the submission datasets must be clearly described in Define.XML.

Controlled Terminology (Code Lists) Section	
Code Value	Code Text
EGTESTCD, Reference Name (EGTESTCD)	
HRMEAN	HRMEAN
PRMEAN	PRMEAN
QRSDUR	QRSDUR
QTCF	QTCF
QTMEAN	QTMEAN
RRMEAN	RRMEAN
EGSTRESC, Reference Name (EGSTRESC)	
ND	ND
VSTESTCD, Reference Name (VSTESTCD)	
BLDTYP	BLDTYP
DIABP	DIABP
HEIGHT	HEIGHT

Relation to variables

- SDTM IG guides which code list should apply

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	
AGE	Age	Num		Record Qualifier	Age expressed in years BIRTHDTM subject prior to study
AGEU	Age Units	Char	(AGEU)	Variable Qualifier	Units associated with AGE
SEX	Sex	Char	(SEX)	Record Qualifier	Sex of the subject
RACE	Race	Char	(RACE)	Record Qualifier	Race of the subject Ethnicity ICD-10 regarding the http://www.who.int/classifications/icd10/ethnicity/ regarding the subject
ETHNIC	Ethnicity	Char	(ETHNIC)	Record Qualifier	The ethnic and Ethnic guidance regarding http://www.who.int/classifications/icd10/ethnicity/ the subject
ARMCD	Planned Arm Code	Char	*	Record Qualifier	ARMCD is used to restrictions: "short" variables needed for period cross each treatment would be 1

Extensible, but...

- CDISC Controlled Terminology User guide

The third column 'Codelist Extensible (Yes/No)', defines if controlled terms may be added to the codelist. New terms may be added to existing codelist values as long as they are not duplicates or synonyms of existing terms.

- Extensible doesn't mean "Possibilities are infinite".



2. Ideal and Real



Paradiso

- Terminology is fully implemented in advance.
 - Protocol
 - CRF
 - Conversion Program etc.
- Updating is in place.
- No special measure is required



Inferno

- However, we sometimes see
 - No appropriate terminology
 - Terminology is added later
 - Legacy Data Conversion
 - Create SDTM, retrospectively
 - Miss operation (ex. CRF)
- As consequence, CRF entry doesn't match terminology
 - Have to address issues.
 - This is reality.





3. Possible choices



Our reality

- We see items terminology applied.

TERM	SEVERITY	ACTION TO DRUG	REL
Headache	Mild	DOSE CHANGED	NO
Common Cold	Moderate	NOT CHANGED	YES

- Mapped to SDTM terminology
- Mapping difficulty: Simple \leftrightarrow Tricky
- Some choices to map

Who are our stakeholders?



FDA

- SDTM spec compliant
- Study data representation
- Easy to review



Data Warehouse

- Enables analysis in future



Medical Writer

- Protocol fits to medical

Requirements differ among stakeholders!!



Programmer

- Easy to create



DM

- Easy to use
- Data Cleaning Friendly
- Complete reflection of CRF
- Best for storage



STAT

- Easy to analyze

Rule of the game


- Our goal is to provide SDTM with maximum satisfaction of stakeholders.
 - Stakeholders are not always the same.*
 - Conflict of interests.
 - Constraints of SDTM specification.

*) No submission is planned.
Data transfer to sponsor.
SDTM is operational DB. etc.





Let's see the examples!!

- Put these prerequisites in mind, we see some ideas to map terminology.
 - 6 solutions (simple \leftrightarrow tricky) with points to consider.
- 

Solution 1

- SDTM Terminology applies


TERM	SEVERITY
Headache	Mild
Common Cold	Moderate



AETERM	AESEV	AEACN	AEREL
Headache	MILD
Common Cold	MODERATE




Solution 1: Consideration

- Best scenario.
 - But applicable only when CRF data is compliant to SDTM requirements.
 - Definition must be compliant to SDTM terminology.
- 

Solution 1: Consideration

- Submission value does not fit to CRF.
 - “Yes/No” , rather than “Y/N” as CRF.
 - Character case might be adjusted.
 - Conversion needs to be documented??
 - Preferred term helps?

No Yes Response	NY	CDISC SDTM Yes No Unknown or Not Applicable Response Terminology
No Yes Response	N	No
No Yes Response	NA	Not Applicable
No Yes Response	U	Unknown
No Yes Response	Y	Yes



Solution 2

- Create SDTM Terminology

Variable Name	Variable Label	Type	Controlled Terms Code list or Form	Role	
AEREL	Causality	Char	*	Record Qualifier	Records the treatment. UNLIKELY Terminology authority:

TERM	SEVERITY	RELATIONSHIP
Headache	Mild	YES
Common Cold	Moderate	NO

AETERM	AESEV	AEACN	AEREL
Headache	MILD	...	Y
Common Cold	MODERATE	...	N

Solution 2: Consideration

- Applicable when no terminology is specified.
- Less data conversion.
- Creation of code list
 - New
 - Recycle
 - NY(C66742) applies in example.
- Clearly described in define.XML

Solution 3

- Expand terminology

3	C74456		Yes	Anatomical Location	LOC	Anatomical Location
4	C12220	C74456		Anatomical Location	LIP	Lip
5	C12230	C74456		Anatomical Location	HARD PALATE	Hard Palate
6						

+ LEFT EAR

TERM	SEVERITY	LOCATION	RELATIONSHIP
Ear haemorrhage	Mild	Left ear	No

AETERM	AESEV	AELOC	AEREL
Ear haemorrhage	MILD	LEFT EAR	N



Solution 3: Consideration

- Applicable when terminology is “extensible”.
- Less data conversion.
- Investigation is mandatory
 - No addition of existing terminology.
- Clearly described in define.xml

Solution 4

- Store into SUPP--

TERM	SEVERITY	ACTION TAKEN	REL.
Headache	Mild	DOSE CHANGED	NO
Common Cold	Moderate	NOT CHANGED	YES

AE

AETERM	AESEV	AEACN	AEREL
Headache	MILD	.	N
Common Cold	MODERATE	.	Y

SUPPAE

RDOMAIN	QLABEL	QVAL
AE	Action Taken due to AE	DOSE CHANGED
AE	Action Taken due to AE	NOT CHANGED

Please note

Codelist Extensible (Yes/No) ▼	Codelist Name ▼	CDISC Submission Value ▼	NCI Preferred Term ▼
No	Action Taken with Study Treatment	ACN	CDISC SDTM Action Taken with Study Treatment Terminology
	Action Taken with Study Treatment	DOSE INCREASED	Dose Increased
	Action Taken with Study Treatment	DOSE NOT CHANGED	Dose Not Changed
	Action Taken with Study Treatment	DOSE REDUCED	Dose Reduced
	Action Taken with Study Treatment	DRUG INTERRUPTED	Drug Interrupted
	Action Taken with Study Treatment	DRUG WITHDRAWN	Drug Withdrawn
	Action Taken with Study Treatment	NOT APPLICABLE	Not Applicable
	Action Taken with Study Treatment	UNKNOWN	Unknown

Solution 4: Consideration

- Can store original data as it is.
 - No terminology limitations
- Important information must not be sent to SUPP domain.
- Complicated the data structure.
 - Who gets satisfied?
- PKD (draft) standard describes this solution

Solution 5

- Replace/Conversion

TERM	SEVERITY	ACTION TAKEN	REL.
Headache	Mild	DOSE CHANGED	NO
Common Cold	Moderate	NOT CHANGED	YES




AE

AETERM	AESEV	AEACN	AEREL
Headache	MILD	.	N
Common Cold	MODERATE	DOSE NOT CHANGED	Y

DOSE CHANGED cannot be converted!!



Solution 5: Consideration

- Data is stored as SDTM designs.
 - Conversion sometimes eliminates original information.
 - Not always converted.
 - Conversion needs to be documented. (for traceability)
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Solution 4+5

- Combination 4+5

TERM	SEVERITY	ACTION TAKEN	REL.
Headache	Mild	DOSE CHANGED	NO
Common Cold	Moderate	NOT CHANGED	YES

AE


AETERM	AESEV	AEACN	AEREL
Headache	MILD	.	N
Common Cold	MODERATE	DOSE NOT CHANGED	Y

SUPPAE

RDOMAIN	QLABEL	QVAL
AE	Action Taken due to AE	DOSE CHANGED
AE	Action Taken due to AE	NOT CHANGED



Solution 4+5: Consideration

- Original data is kept and important data is stored in the SDTM domain.
 - Complicated structure.
 - Resource consuming.
 - Conversion needs to be documented.
- 

Solution 6

- --ORRESU for original data
--STRESU for terminology compliant

[CRF]

Pulse ___ ___ bpm



USUBJID	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
HTT.1001	PULSE	60	bpm		60	BEATS/MIN



Solution 6: Consideration

- Only applicable for findings class domains.
- Agreement/explanation is required.
- Terminology must be registered (or can be added as appropriate)
 - Define.XML includes BEATS/MIN and bpm!

Summary

- Best practice
 - Straight forward mapping
 - Solution 1, 2 and 3
 - Good preparation is the **keystone**.
 - SDTM terminology doesn't always fit to CRF, though.
 - Y/N versus Yes/No
 - MILD versus Mild
 - --TEST, --TESTCD
 - EKG Mean PR Duration
 - Erythrocytes
 - BASO



Summary

- Special handling.
 - Needed for legacy data conversion.
 - SDTM spec provides possible answers.
 - Several ways to handle.
 - No “Silver Bullet”.
 - Strength accompanies weak points.
 - Decide based on business requirements.



Case Study



How do you handle?

- CRF : bpm for Pulse
 - No “bpm” entry in Terminology
 - BEATS/MIN is found
 - Extensible


[CRF]
Pulse ___ __ bpm



USUBJID	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
HTT.1001	PULSE	60	???		60	???




Assumption 1

- No FDA submission.
 - Data shall be stored in SDTM format.
 - How do you handle? What's your rationale?
- 



Assumption 2

- Will be submitted to FDA.
 - This is the last study.
 - All other studies choose to represent raw data on the CRF (hence “bpm” is found).
 - How do you handle? What’s your rationale?
- 




Assumption 3

- This is new compound.
- No preceding studies.
- CRF is still in construction.
- How do you handle? What's your rationale?



Assumption 4

- You work in CRO.
 - Sponsor doesn't clarify how to handle "bpm".
 - Probably submitted to FDA.
-
- How do you handle? What's your rationale?
- 



Appendix





Reference

- Guidance for Industry Providing Regulatory Submissions in Electronic Format — Standardized Study Data DRAFT GUIDANCE (Feb 2012)
- CDER Common Data Standards Issues Document (ver. 1.1/December 2011)
- CDISC Controlled Terminology User guide (ver. 1.0/11 Jul 2011)
- Study Data Tabulation Model (ver. 1.2)
- SDTM IG (ver. 3.1.2)

Connection LISaS-3&4

Terminology flows

Protocol

CRF

SDTM

ADaM

Listings

