Controlled Terminology (CT)
How to Implement?

May 29, 2018

Understand CT

CDISC CT

CT Pitfalls

Understand Controlled Terminology

Definition of Standardization

➢ *Mindset* that tends to create via a set of *processes* a collection of *reusable and maintainable* components

➢ **Overview**: mindset
➢ **Approach**: process oriented
➢ **Purpose**: reusable and maintainable components

Controlled Terminology Overview

➢ Standardization starts with CT

➢ Most important part of CDISC standards implementation

➢ *SDTM classes* are defined in CT

➢ *SDTM domains* are represented in CT

➢ Concepts collected in *normalized structure* must be in CT

What is Controlled Terminology?

1. **Language**
2. **Define concepts** separately from recorded values
3. Assign preferred value(s) to represented concepts
4. Submit consistently same concepts regardless of the study

Controlled Terminology is a **language of concepts**

Real-life Example

➢ *Concept:* Table
➢ Recorded value in tabular structure: TABLE, TBL, TLB, Table
➢ Additional details needed: shape, type or something else …

How to **handle additional details** associated with the *concept of **Table?***

CDISC Controlled Terminology

CDISC Controlled Terminology

➢ *Foundational language* for building sponsor defined controlled terminology
➢ Versioning system
➢ 2 types of concepts
➢ Concepts defined to be used as elements of collection
➢ Concepts defined to be used as a collection (codelist)
➢ Concepts are track via unique code

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66742		No	No Yes Response	NY	No Yes Response	A term that is used to indicate a question with permissible values of yes/no/unknown/not applicable.	CDISC SDTM Yes No Unknown or Not Applicable Response Terminology
C49487	C66742		No Yes Response	N	No	The non-affirmative response to a question. (NCI)	No
C48660	C66742		No Yes Response	NA	NA; Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	C66742		No Yes Response	U	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C49488	C66742		No Yes Response	Y	Yes	The affirmative response to a question. (NCI)	Yes

Submission/Recorded Value

➤ Data recorded in tabular structure

➤ Not unique within controlled terminology

➤ Reusable across studies

➤ Determine synonyms of recorded value

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C48660	C85495		Microbiology Susceptibility Testing Result Category	NOT APPLICABLE	NA; Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C48660	C66742		No Yes Response	NA	NA; Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C48660	C66737		Trial Phase Response	NOT APPLICABLE	NA; Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable

Linked Codelist

➢ SDTM model is about structure

➢ Data collected in normalized structure (e.g. *Findings* class, *SUPPQUAL*) have linked codelist

➢ 1 concept has 2 submission values based on codelist

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C51948	C65047		Laboratory Test Code	WBC	Leukocytes; White Blood Cells	A measurement of the leukocytes in a biological	Leukocyte Count
C51948	C67154		Laboratory Test Name	Leukocytes	Leukocytes; White Blood Cells	A measurement of the leukocytes in a biological	Leukocyte Count

Controlled Terminology Pitfalls

Synonym Concepts

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C94189	C96784		Tumor or Lesion Identification Test Code	LESIDENT	Lesion Identification	An indication that a lesion has been located and characterized.	Lesion Identification
C94523	C96784		Tumor or Lesion Identification Test Code	TUMIDENT	Tumor Identification	A classification of malignant disease manifestation as part of the response assessment.	Tumor Identification

➢ Which one should be used?

➢ Both concepts will be mapped to TU

➢ End-user should be trained to make the distinction

➢ Same data will be submitted differently across studies

The **more generic** concept should be implemented

Mel Consulting

Combining Concepts within One

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C119567	C96784		Tumor or Lesion Identification Test Code	GRLIDENT	Graft Lesion Identification	An indication that a graft with a lesion has been located and characterized.	Graft Lesion Identification
C94189	C96784		Tumor or Lesion Identification Test Code	LESIDENT	Lesion Identification	An indication that a lesion has been located and characterized.	Lesion Identification
C119568	C96784		Tumor or Lesion Identification Test Code	LMLIDENT	Limb Lesion Identification	An indication that a limb containing a lesion has been selected and characterized.	Limb Associated Lesion Identification
C119569	C96784		Tumor or Lesion Identification Test Code	VSLIDENT	Vessel Lesion Identification	An indication that a vessel with a lesion has been located and characterized.	Vessel Lesion Identification

- ➤ It is all about *Lesion Identification*
- ➤ Created concept are made of *Lesion Identification* and *Anatomical Location* concepts
- ➤ Number of concepts within *Tumor or Lesion Identification Test Code/Name* will increase quickly
- ➤ Metadata maintenance is challenging

> Collect data **separately** in each concept

Concepts tied to Particular Domain

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C85495		No	Microbiology Susceptibility Testing Result Category	MSRESCAT	Microbiology Susceptibility Testing Result Category	Used to categorize the result of a finding in a standard format.	CDISC SDTM Microbiology Susceptibility Testing Result Category Terminology

➤ Why the concept of *Result Category* is tied to MS domain?

➤ Any findings domain may have a result category (LB, MB ...)

➤ Concepts collected (codelist elements) will be applicable to several domain

➤ Metadata maintenance is challenging

> Define concepts **without any domain** in mind

Concepts tied to a Therapeutic Area

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C132313		Yes	Asthma Findings About Test Code	ASFATSCD	Asthma Findings About Test Code	Terminology relevant to the test codes that describe findings about an asthma event or intervention.	CDISC SDTM Asthma Findings About Test Code Terminology
C119015		No	Cardiovascular Findings About Test Code	CVFATSCD	Cardiovascular Findings About Test Code	Terminology relevant to the test codes that describe findings about a cardiovascular event or intervention.	CDISC SDTM Cardiovascular Findings About Test Code Terminology
C122007		Yes	COPD Findings About Test Code	CPFATSCD	COPD Findings About Test Code	Terminology relevant to the test codes that describe findings about a COPD event or intervention.	CDISC SDTM COPD Findings About Test Code Terminology
C129940		Yes	Diabetic Kidney Disease Findings About Test Code	DKFATSCD	Diabetic Kidney Disease Findings About Test Code	Terminology relevant to the test codes that describe findings about a diabetic kidney disease event or	CDISC SDTM Diabetic Kidney Findings About Test Code Terminology
C139018		Yes	Duchenne Muscular Dystrophy Findings About Test Code	DMFATSCD	Duchenne Muscular Dystrophy Findings About Test Code	Terminology relevant to the test codes that describe findings about a Duchenne muscular dystrophy event or intervention.	CDISC SDTM Duchenne Muscular Dystrophy Findings About Test Code Terminology
C132316		Yes	Ebola Virus Findings About Test Code	EBFATSCD	Ebola Virus Findings About Test Code	Terminology relevant to the test codes that describe findings about an Ebola virus infection event or	CDISC SDTM Ebola Virus Findings About Test Code Terminology
C132320		Yes	Malaria Findings About Test Code	MRFATSCD	Malaria Findings About Test Code	Terminology relevant to the test codes that describe findings about a malaria event or intervention.	CDISC SDTM Malaria Findings About Test Code Terminology
C117741		Yes	Multiple Sclerosis Findings About Test Code	MSFATSCD	Multiple Sclerosis Findings About Test Code	Terminology relevant to the test codes that describe multiple sclerosis findings.	CDISC SDTM Multiple Sclerosis Findings About Test Code Terminology
C124302		Yes	Schizophrenia Findings About Test Code	SZFATSCD	Schizophrenia Findings About Test Code	Terminology relevant to the test codes that describe findings about a schizophrenia event or intervention.	CDISC SDTM Schizophrenia Findings About Test Code Terminology
C127266		Yes	Tuberculosis Findings About Test Code	TBFATSCD	Tuberculosis Findings About Test Code	Terminology relevant to the test codes that describe findings about a tuberculosis event or intervention.	CDISC SDTM Tuberculosis Findings About Test Code Terminology
C142187		Yes	Vaccines Findings About Test Code	VNFATSCD	Vaccines Findings About Test Code	Terminology relevant to the test codes that describe findings about a vaccines event or intervention.	CDISC SDTM Vaccines Findings About Test Code Terminology

➤ Findings About are not tied to any therapeutic area

➤ End-user will have a mindset narrowed to their disease area

➤ Metadata maintenance is challenging

Do not include therapeutic area while implementing controlled terminology concepts

Conclusions

- Implement controlled terminology on top of CDISC CT
- Build your own language
- Take time to define reusable concepts across studies
- Make it your own!
- Use metadata repository (MDR) for driving controlled terminology

Change your mind!

Thanks for your attention ☺