

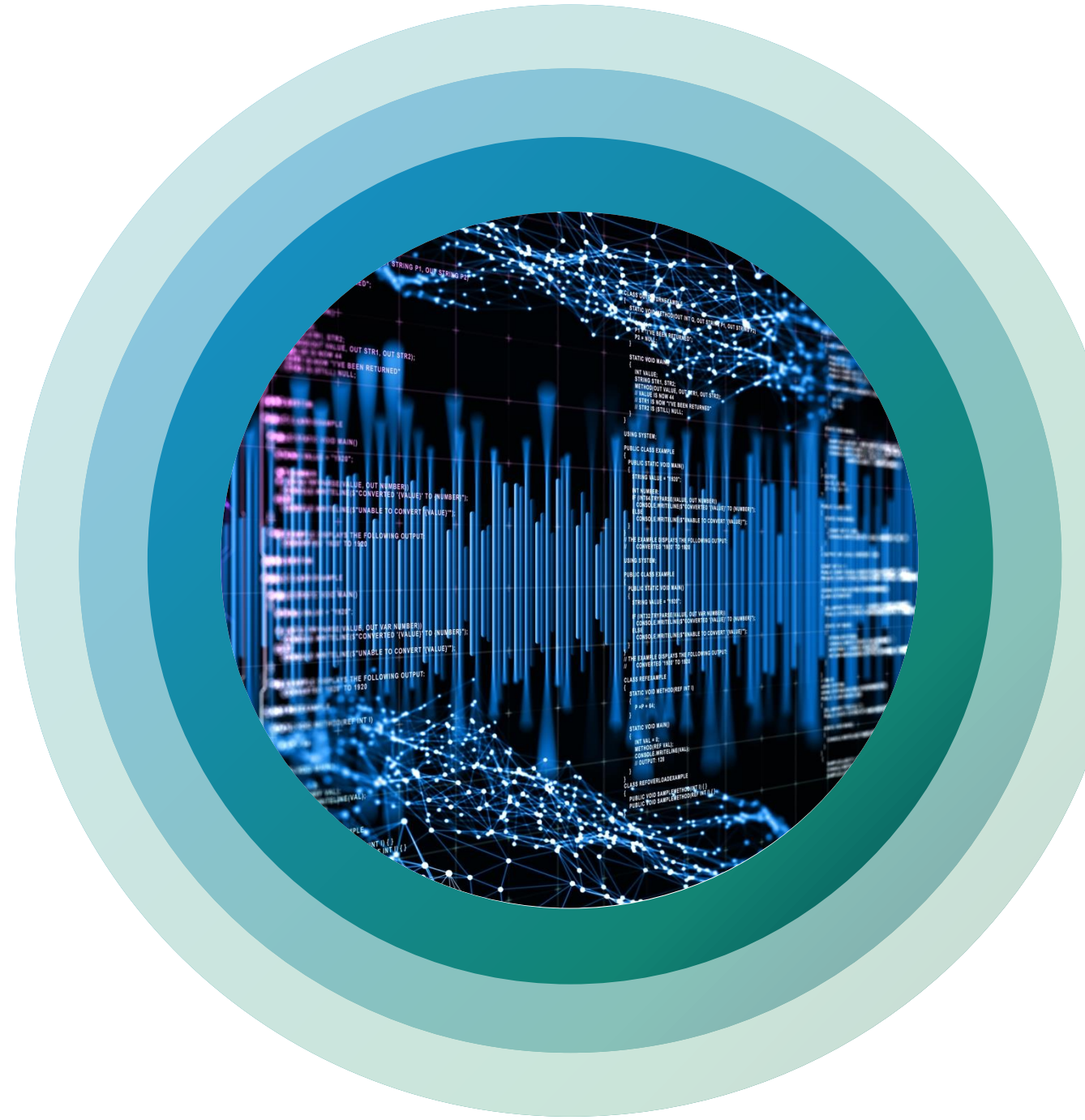


Not Another Other

David Fielding and Susana Jimenez

ICON Global Data Standards

PHUSE 2026



CDISC and Controlled Terminology

CDISC Goal (Source: cdisc.org)

- *Expand and enable standards-driven automation across end-to-end study information lifecycle from study design through results*

Key Component for Data Sources: Controlled Terminology

- *Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets*
- *Controlled Terminology does not tell you WHAT to collect; it tells you IF you collected a particular data item, how you should submit it in your electronic dataset*
- *Currently includes more than 45,000 submission values and over 78,000 synonyms*

CDISC and Controlled Terminology



Common data collection domains include fields like Frequency, Route, and Unit

All included in Controlled Terminology
Often implemented with partial lists combined with free-text fields



Free-Text fields undermine the goal and requirement

Fields like “Other, Specify” become a challenge to ensure alignment with Controlled Terminology

Must-Do(s)



Improve data quality and streamline workflows



Leverage the full breadth of controlled terminology and minimize reliance on free-text fields



Challenge “what-if” justification to have free-text fields



Accommodate synonyms while adhering to submission values

The Solution



INCLUDE the entire list from CDISC CT to leverage EDC capabilities to search codelists



Data collection is set up in a way that satisfies data entry and passes through to SDTM



Use the CDISC Submission Value as the code



CDISC Submission Value, CDISC Synonym(s), and NCI Preferred Term in the label (as needed)



Can be implemented for many long lists: UNIT, ROUTE, LOC, METHOD

CDISC CT > EDC Codelist > EDC Data Entry > Define-XML

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	NCI Preferred Term
Unit	10^6/L	/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L	Thousand per Milliliter



Codelist Name	Coded Value	Code Value Text (Investigator Visual)
UNIT	10^6/L	10^6/L [/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L]
UNIT	10^10/L	10^10/L [10^4/mm3; 10^4/uL; 10^7/mL]
UNIT	10^11/L	10^11/L [10^5/mm3; 10^5/uL; 10^8/mL]
UNIT	10^12 IU/L	10^12 IU/L [Tera International Unit per Liter; TIU/L]
UNIT	10^12/L	10^12/L [/pL; 1/pL; 10^6/mm3; 10^6/uL; M/uL; Mill/mcL; T/L; Tera/L; TI/L]
UNIT	10^3 CFU	10^3 CFU [Thousand CFU; Thousand Colony Forming Units]
UNIT	10^3 CFU/g	10^3 CFU/g [Thousand CFU/g; Thousand Colony Forming Units per Gram]



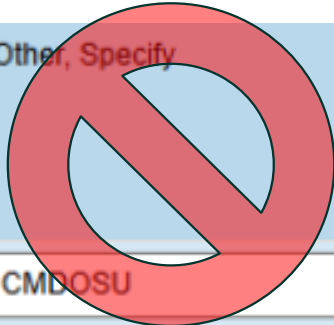
Unit [C71620] [CDISC/NCI SDTM 2025-03-28]

Permitted Value (Code)	Display Value (Decode)
10^10/L [C105517]	10^10/L [10^4/mm3; 10^4/uL; 10^7/mL]
10^11/L [C105488]	10^11/L [10^5/mm3; 10^5/uL; 10^8/mL]
10^12 IU/L [C105518]	10^12 IU/L [Tera International Unit per Liter; TIU/L]
10^12/L [C67308]	10^12/L [/pL; 1/pL; 10^6/mm3; 10^6/uL; M/uL; Mill/mcL; T/L; Tera/L; TI/L]
10^3 CFU [C68895]	10^3 CFU [Thousand CFU; Thousand Colony Forming Units]
10^3 CFU/g [C68899]	10^3 CFU/g [Thousand CFU/g; Thousand Colony Forming Units per Gram]
10^6/L [C67452]	10^6/L [/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L]

Uses: UNIT - Example with Concomitant Medication/Treatment/Therapy

- Extensive list of submission values with multiple synonyms (contains close to 2100 values and synonyms)
- A free text field ends up including the dose, frequency, dosage form, route, and other information that is not needed or should be stored in a more appropriate field

Uses: UNIT - Example with Concomitant Medication/Treatment/Therapy

What was the (concomitant) [medication/treatment/therapy] (name/term)?	For what indication was the (concomitant) [medication/treatment/therapy] taken?	What was the individual dose of the (concomitant) [medication/treatment/therapy]?	What is the unit (for the dose of concomitant [medication/treatment/therapy])?	Other, Specify
CMTRT	CMINDC	CMDOSE	Choose	 CMDOSU

Codelist Name	CDISC Submission Value	CDISC Synonym(s)
Unit	10^6/L	/mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L

/mm3

10^10/L [10^4/mm3; 10^4/uL; 10^7/mL]

10^11/L [10^5/mm3; 10^5/uL; 10^8/mL]

10^12/L [pL; 1/pL; 10^6/mm3; 10^6/uL; M/uL; Mill/mcL; T/L; Tera/L; TI/L]

10^6/L [mm3; /uL; 1/mm3; 1/uL; 10^3/mL; M/L; Mega/L]

10^8/L [10^2/mm3; 10^2/uL; 10^5/mL]

10^9/L [nL; 1/nL; 10^3/mm3; 10^3/uL;

Uses: ROUTE (Route of Administration Response)

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	NCI Preferred Term
Route of Administration Response	ORAL GAVAGE		Oral Gavage Route of Administration
Route of Administration Response	ORAL	Intraoral Route of Administration; PO	Oral Route of Administration
Route of Administration Response	OROMUCOSAL		Oromucosal Route of Administration

Codelist Name	Coded Value	Code Value Text (Investigator Visual)
ROUTE	ORAL	Oral [Intraoral; PO]
ROUTE	ORAL GAVAGE	Oral Gavage
ROUTE	OROMUCOSAL	Oromucosal

Uses: LOC (Anatomical Location)

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	NCI Preferred Term
Anatomical Location	ACROMION	Acromion	Acromion
Anatomical Location	ACUTE MARGINAL ARTERY	ACUTE MARGINAL ARTERY SEGMENT(S); AMARG	Acute Marginal Artery

Codelist Name	Coded Value	Code Value Text (Investigator Visual)
LOC	ACROMION	Acromion
LOC	ACUTE MARGINAL ARTERY	Acute Marginal Artery [Acute Marginal Artery Segment(s); AMARG]

Challenges: Setup

Initial setup

EDC system may have restrictions on the number of values allowed in a codelist

Maintenance for each release

Challenges: Technical Restrictions

- ❖ EDC system may have restrictions on the number of values allowed in a codelist
- ❖ Some values are case sensitive and there are EDC systems that do not have the ability to distinguish between cases in coded values so there may need to be some mapping required

Codelist Name	Coded Value	Coded Value Text
UNIT	PA	PA [/Year; Every Year; Per Annum; Per Year]
UNIT	Pa	Pa [Pascal]

Challenges: Annotation

- Define-XML allows for the reference of an external data dictionary (MedDRA or WHODrug) and not the codelist within that dictionary

Dose	CMDOSE	CMDOSTXT	
Dose Unit	CMDOSU		[CDISC/NCI SDTM UNIT C71620]
Dose Form	CMDOSFRM		[CDISC/NCI SDTM FRM C66726]
Frequency	CMDOSFRQ		[CDISC/NCI SDTM FREQ C77113]
Route	CMROUTE		[CDISC/NCI SDTM ROUTE C66729]

- Future Define-XML should consider referencing CDISC codelists in the same manner

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
CMDOSU	Dose Units	text	Variable Qualifier	200	<u>Unit</u>	Collected (Source: Investigator)

Reference Name	Dictionary	Dictionary Version	Codelist
Unit	CDISC/NCI SDTM 2025-03-28	2025-03-28	Unit [C71620]

CDISC 360i Initiative and Biomedical Concepts

- ❖ Leveraged connected standards and end-to-end automation
- ❖ Biomedical concepts linked to USDM > eCRF specifications, ODM.xml, SDTM annotated CRFs (aCRFs), SDTM dataset specializations, SDTM trial design domains, define.xml, and SDTM shell data sets
- ❖ Example:
 - Value list has ms and s, so we could have a subset codelist UNIT_PRAG that could always be used for this test
 - C42574 is a ‘Unit of Time’ codelist which in itself is a subset of the UNIT codelist for measurements of time

vlm_group_id	short_name	sdm_variable	dec_id	codelist	codelist_submission_value	subset_codelist	value_list
PRAG	PR Interval Aggregate	EGORRESU	C42574	C71620	UNIT		ms;s

Final Thoughts



Relying on free-text “Other, specify” fields is no longer necessary nor desirable



By fully exposing CDISC Controlled Terminology to site users through intelligent search and filtering, we can capture structured data at the point of entry



Reduce downstream coding burden, SDTM programming, and enhance SDTM compatibility



Although challenges remain, especially around large lists and system limitations, thoughtful design and automation can mitigate these issues



Thank you!
Any Questions?

David.Fielding@iconplc.com

Susana.Jimenez@iconplc.com