



State of the CDISC Standards

Presented by Bess LeRoy
Head of Standards Development, CDISC

10 June 2021



Meet the Speaker

Bess LeRoy

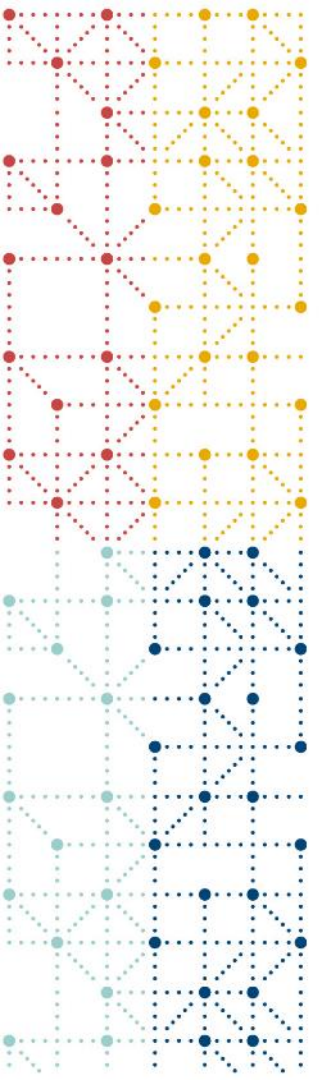
Title: Head of Standards Development

Organization: CDISC



Bess LeRoy is the **Head of Standards Development at CDISC**. Bess has been a **CDISC team member since 2011**. She is a **member of the CDISC Technical Leadership Team and leads the Global Governance Group**. Bess has **over 15 years' experience** working in public health research and has held positions at the Framingham Heart Study, the Rotterdam Study, the Arizona Cancer Center, and the Critical Path Institute.

Bess has a BS from the University of Michigan, an MPH from Boston University School of Public Health, and is currently pursuing a DrPh from Johns Hopkins Bloomberg School of Public Health.



Agenda

1. What happened over the last year?
2. What are we working on now?



**What
Happened
Over the
Last Year?**



Standards and TAUGs Published in the Last Year

Foundational Standards

- SENDIG v3.1.1
- SEND Conformance Rules v3.0
- Conformance Rules for Define-XML v2.1

Therapeutic Area User Guides

- Heart Failure Therapeutic Area User Guide v1.0
- Diabetes Type 1 Therapeutic Area User Guide v1.0 - Pediatrics and Devices Modules
- Psoriasis Therapeutic Area User Guide v1.0
- Acute Kidney Injury Therapeutic Area User Guide v1.0

Other Documents Published in the Last Year

COVID-19 Resources

- Interim Guide
- Ongoing Studies
- Resources for Public Health Researchers

Example Documents

- LOINC LB Mapping Spreadsheet
- SDTM Metadata Submission Guidelines v2.0

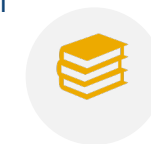
Development of ADaM QRS Supplements

- First Questionnaire Supplement to the Analysis Data Model Implementation Guide - Geriatric Depression Scale Short Form (GDS SHORT FORM)



FOLLOWS
STANDARD
DEVELOPMENT
PROCESS
OUTLINED IN
COP-001

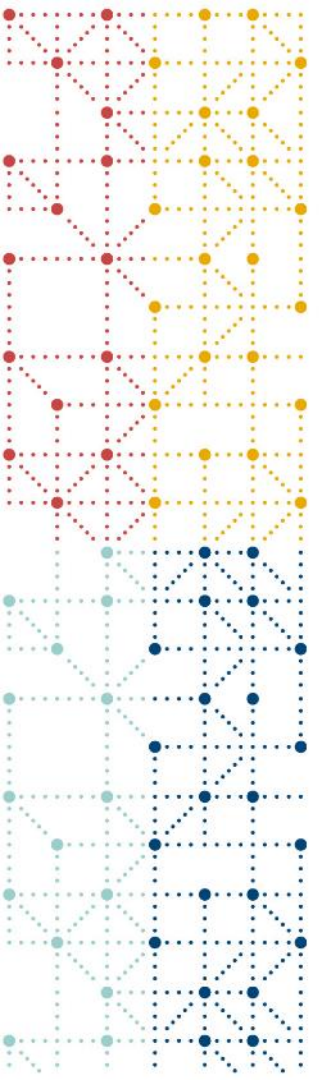
POSTED FOR
30-DAY PUBLIC
REVIEW



PUBLISHED IN
BATCHES
MULTIPLE
TIMES A YEAR

New QRS Supplements				
	Short Name (--CAT)	SDTM Domain/ADaM Dataset	Permission	Version Release Date
Kurtzke Functional Systems Scores	KFSS	RS	Public Domain	Version: 2.0 3 Apr 2021
Abnormal Involuntary Movement Scale	AIMS	RS	Public Domain	Version: 2.0 3 Apr 2021
Eastern Cooperative Oncology Group Performance Status	ECOG	RS	Public Domain	Version: 2.0 3 Apr 2021
Karnofsky Performance Scale	KPS SCALE	RS	Public Domain	Version: 2.0 3 Apr 2021
Inflammatory Bowel Disease Questionnaire	IBDQ	QS	Granted	Version: 1.0 3 Apr 2021
Disability Rating Scale	DRS	RS	Public Domain	Version: 2.0 3 Apr 2021

<https://www.cdisc.org/standards/foundational/grs>



CDISC Conformance Rules

Conformance Rules Operational Group



Operational group representing all CDISC Foundational teams



Harmonize as much as is reasonable



Help define and support a clearly defined structure for management within the CDISC Library



Boost knowledge and expertise across teams that develop rules

Development of Rules Catalog for Each Standard



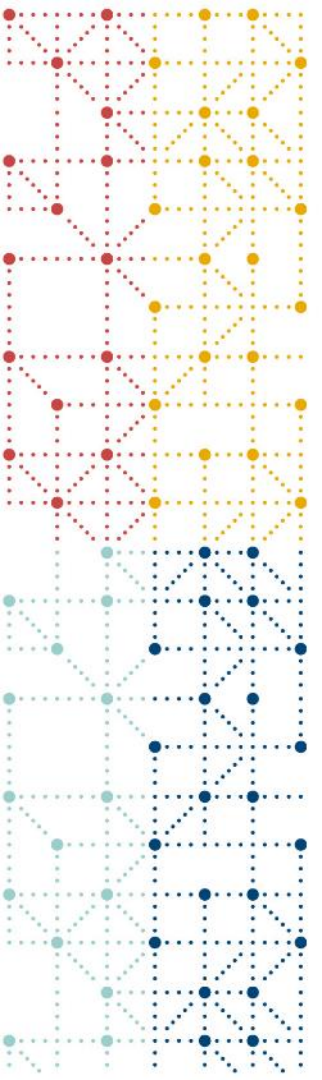
The published rules catalog is cumulative (e.g., SDTMIG v3.3, SDTMIG v3.4)



When the current catalog is published, the previous catalog will be archived but accessible from the CDISC website for that standard



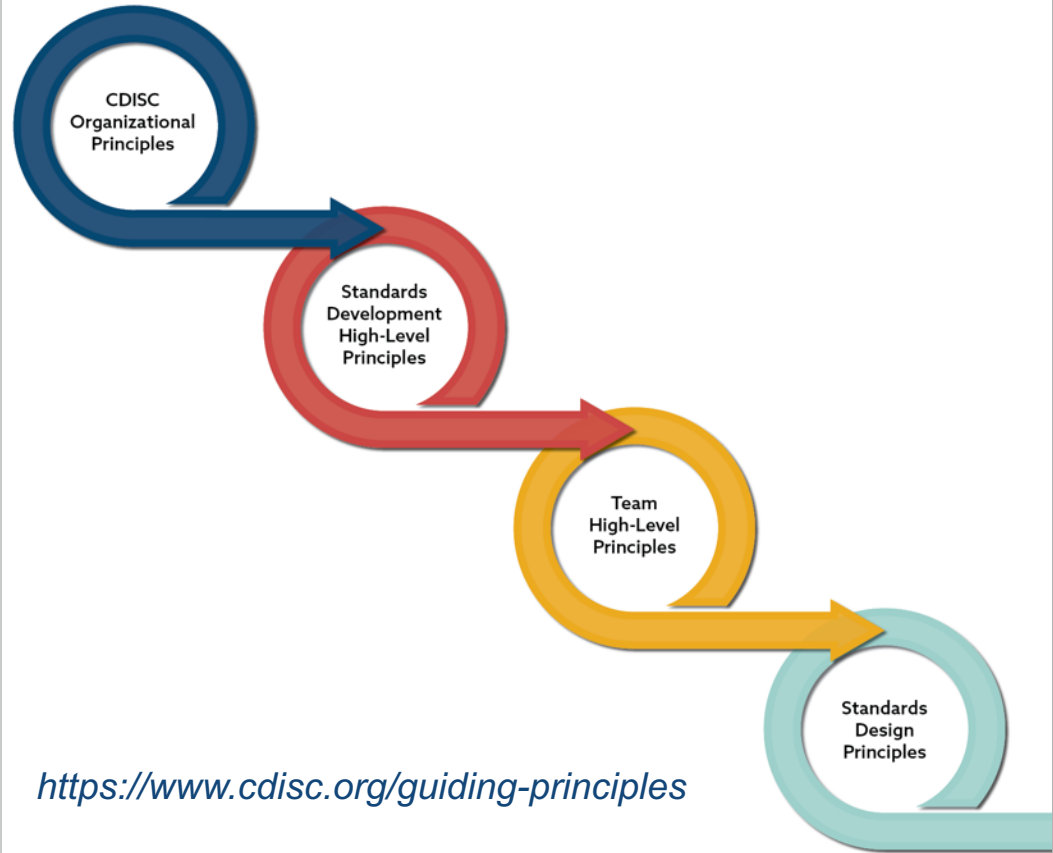
Teams may also publish a supplemental “read me” document with additional information about rules (e.g., development approach)



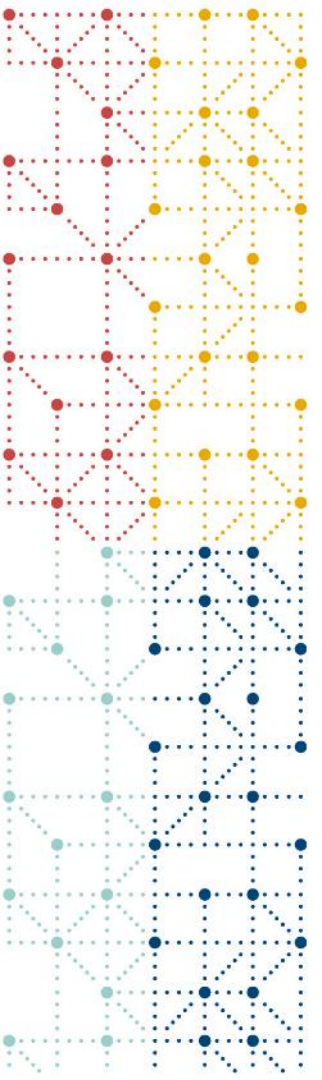
CDISC Guiding Principles

CDISC Guiding Principles

PRINCIPLES HIERARCHY



<https://www.cdisc.org/guiding-principles>



CDISC Implementation Primer

CDISC Primer

- Content to introduce new users to CDISC
- Topics covered:
 - How to get started with CDISC
 - Links among CDISC standards
 - Traceability

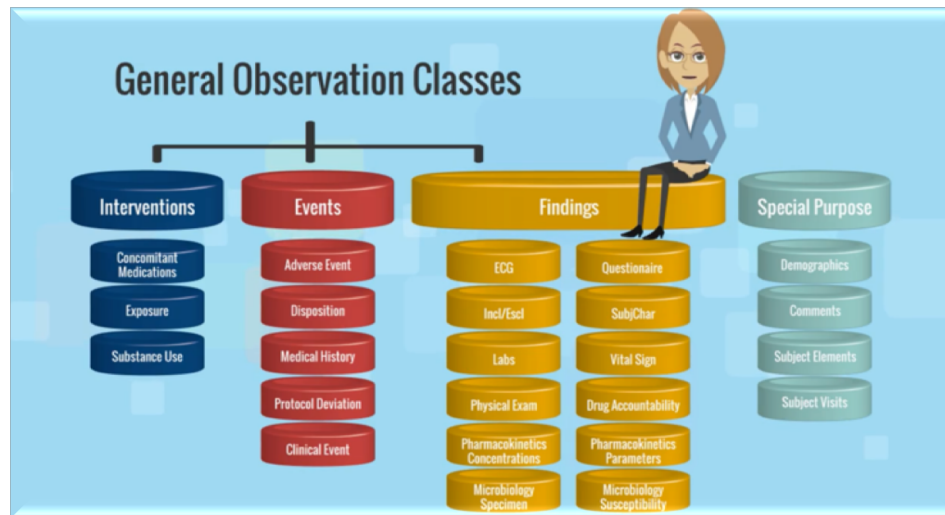
<https://www.cdisc.org/primer>



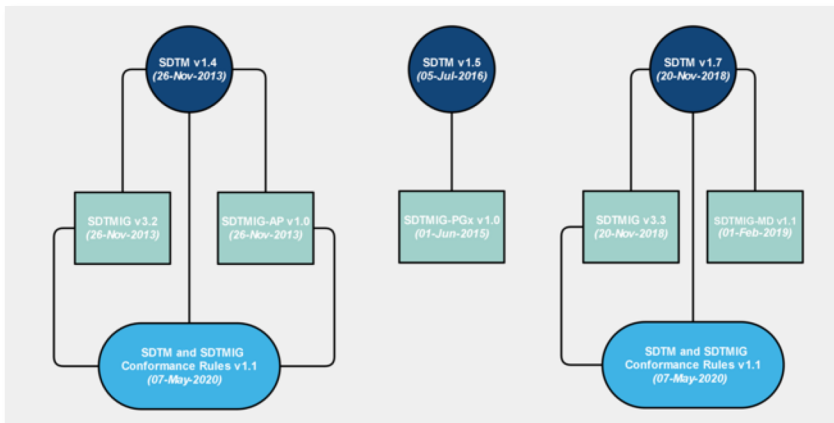
Getting Started with CDISC

3-Minute Videos Covering

- CDISC Foundational Standards
- Controlled Terminology
- Therapeutic Area User Guides
- Regulatory Requirements



Links Among Standards

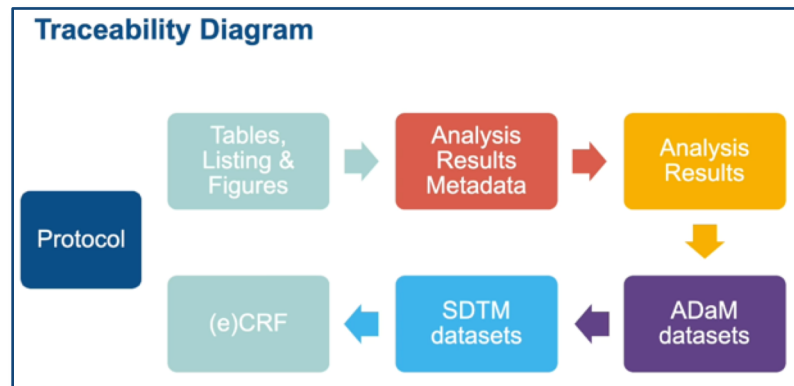
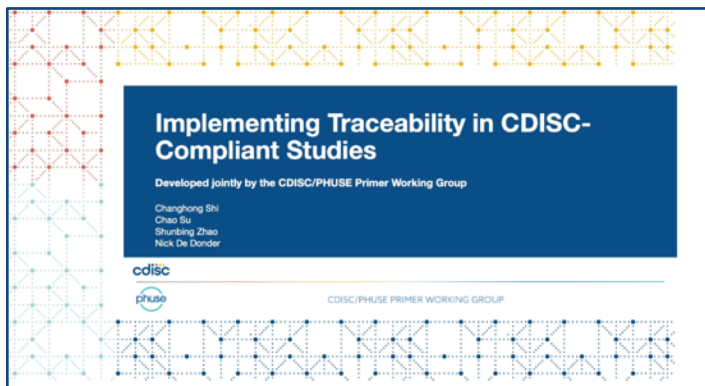


A Study Data Tabulation Model Implementation Guide (SDTMIG) is developed in reference to a specific SDTM model. However, the SDTM is cumulative – each new release builds on the previous model. Therefore, the models are backward compatible. For example, SDTMIG-AP v1.0 was developed in reference to SDTM v1.4, but it may be used in a submission that uses SDTM v1.7.

Implementers should be aware that if they are referencing a model for which the IG was not originally developed, variables may have been added or deprecated from the model. In addition to models and implementation guides, conformance rules have been developed, which help to ensure that generated data structures conform to the standards. These rules aim to identify all conformance rules and case logic from the SDTM and SDTMIG, classifying and codifying them in a form that supports quality processes and tool development.

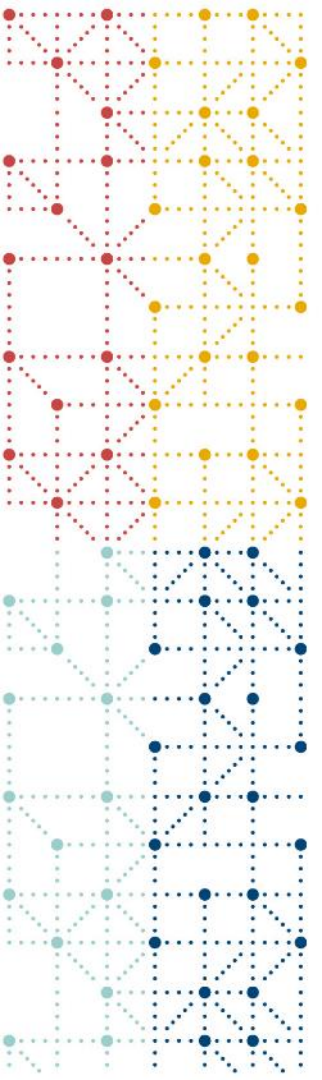
Version	Related
SDTMIG v3.3 20 November 2018	SDTM v1.7 SDTMIG for Medical Devices v1.1 SDTMIG-PGx v1.0 SDTMIG-AP v1.0 Conformance Rules v1.1 for SDTMIG v3.2 and v3.3
SDTMIG v3.2 26 November 2013	SDTM v1.4 SDTMIG for Medical Devices v1.0 SDTMIG-AP v1.0 Conformance Rules v1.1 for SDTMIG v3.2 and v3.3
SDTMIG for Medical Devices v1.1 1 February 2019	SDTM v1.7
SDTMIG for Medical Devices v1.0 23 January 2012	SDTM v1.4
SDTMIG-PGx v1.0 1 June 2015	SDTM v1.5
SDTMIG-AP v1.0 12 December 2013	SDTM v1.4 Conformance Rules v1.1 for SDTMIG v3.2 and v3.3

Traceability



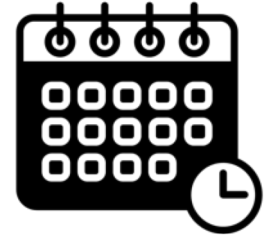
What Are We Working On Now?





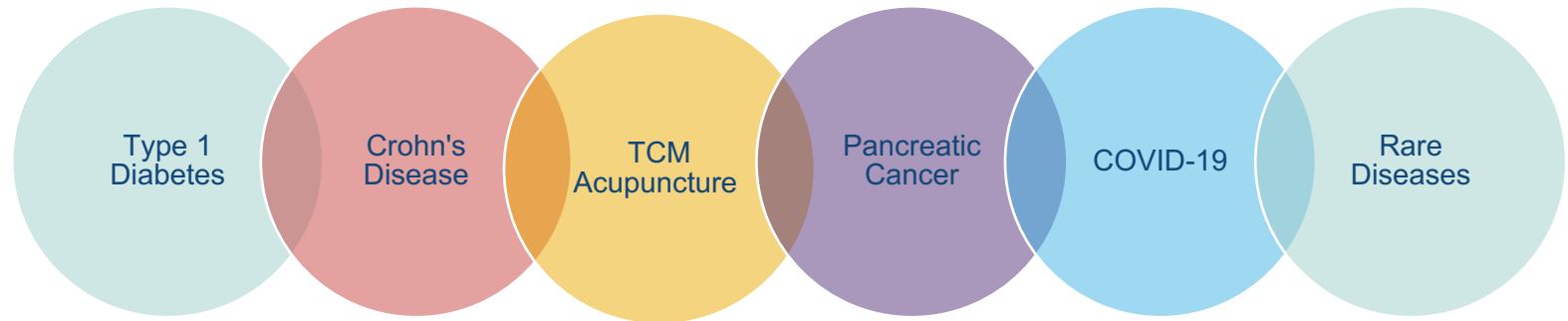
Foundational Standards and Therapeutic Area User Guides

Updated Standards Release Schedule



- Moving away from the November release schedule
- Informative content and Normative Standards released once completed COP-001
 - Normative content is released with conformance rules
 - Relevant CDISC Library content released at time of publication
- CT and QRS released quarterly
- To provide predictability and transparency, a specific foundational standard will be released no more than once every other year, with a preferred cadence of 3-5 years

Therapeutic Area User Guides Currently In Development



<https://www.cdisc.org/standards/in-development>

2021 Anticipated Foundational Standards Publications

ADaMIG v1.3 and Conformance Rules

ADaMIG OCCDS v1.1 and Conformance Rules

ADaMIG Medical Devices v1.0 and Conformance Rules

ADaMIG Non-compartmental Analysis v1.0 and Conformance Rules

CDASH v1.2

CDASHIG v2.2

SDTM v2.0

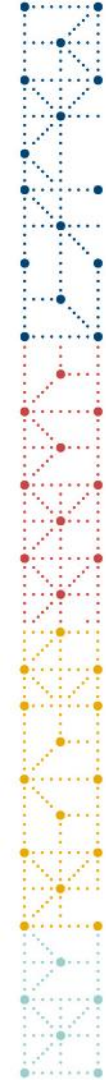
SDTMIG v3.4

**SEND Conformance
Rules v4.0**

SDTMIG-PGx v1.0 Deprecation

- CDISC will be deprecating SDTMIG-PGx v1.0 and much of its content will be subsumed into the upcoming release of SDTMIG v3.4
- Why is this change being made?
 - All PGx Domains are applicable to other SDTMIG laboratory domains (LB, MB, MS, MI, etc.)
- Certain domains will be deprecated and others will be incorporated into SDTMIG v3.4
 - The provisional PF domain will be deprecated and superseded by the GF domain
 - The BE, BS, and RELSPEC domains will be incorporated into the SDTMIGv3.4 as is and may be updated in a future version of the SDTMIG
 - The provisional PG, PB, SB domains will be deprecated. Re-instantiation of this content may be considered in the future if valid use cases are presented to CDISC





2021 Anticipated Example Documents Publications

ADaM Traceability
Examples

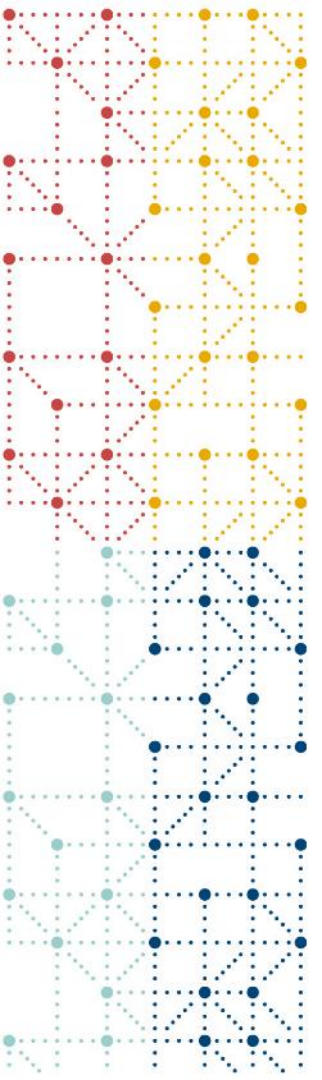
ADaM Guidance for
Ongoing Studies Disrupted
by COVID-19 Pandemic

HL7 FHIR to CDISC
Mapping

HL7 FHIR to CDISC Mapping

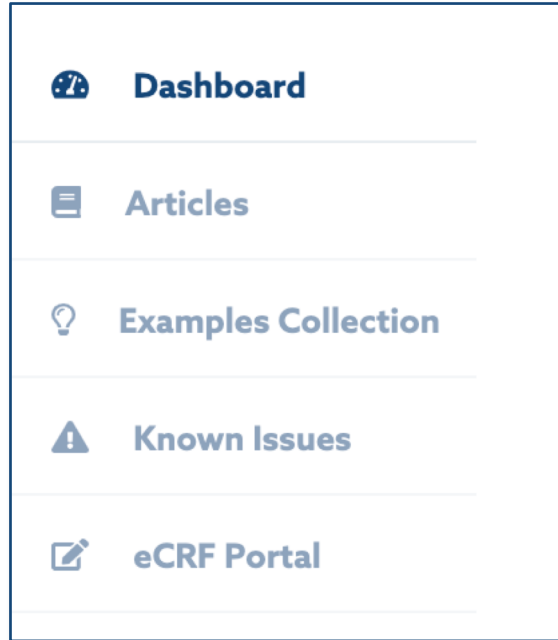
- Fast Healthcare Interoperability Resources (FHIR) is a new standard published by HL7 for exchanging healthcare information electronically
- Goal of mapping is to achieve greater interoperability and exchange of data from Electronic Health Records (EHRs) to clinical research submission-ready datasets
- Scope: Adverse Events, Adverse Events, Medications, Concomitant Medications, Demographics, Medical History, Procedures, Vital Signs, Laboratory Test Results
- Mappings jointly balloted by CDISC and HL7 using their respective governance processes





Knowledge Base

CDISC Knowledge Base



- An open, assessible, searchable and user-friendly interface on the CDISC Website to host new and existing website content for CDISC implementers
- Contains articles, known issues, eCRF portal, and examples collection

Articles

Search Knowledge Base



Standard



Proficiency



Apply

Clear

Articles



UCUM and CDISC Codelists

Unified Code for Units of Measure (UCUM) was developed by Regenstrief Institute and the UCUM Organization as an unambiguous system of units and their combinations. UCUM is intended to include all units of measure currently used internationally in science, engineering and business and has been adopted internationally by IEEE, DICOM, LOINC, and HL7, and is also in the ISO 11240:2012 standard.

[Read More >](#)

Standard(s):

Controlled Terminology, SDTMIG

Intermediate

LOINC and the SDTM

LOINC is a pre-coordinated laboratory coding system used in healthcare IT systems. It includes lab tests, clinical measures, HIPAA documents and standardized survey instruments. It also contains terms for human clinical research but its scope goes beyond research use. LOINC is used in over 170 countries and is mandated in 30.

[Read More >](#)

Standard(s):

Controlled Terminology, SDTM, SDTMIG

Intermediate

SDTM Structure Diagrams

SDTM describes several types of datasets. This diagram illustrates hierarchical view of these types of datasets. Findings may be findings about a study subject or about an associated person. A finding record can be linked to supplemental qualifiers, to comments, or to other records via relationships represented in RELREC.

[Read More >](#)

Standard(s):

SDTM

Novice

Examples Collection

- Examples exist across many Implementation and User Guides in PDFs
- Goal is to make examples easily accessible for implementors through the CDISC Knowledge Base
- Users will be able to select examples by biomedical concept, therapeutic area, observation class, domain, etc.
- Curation to ensure examples remain consistent with one another
- Initial scope: Diabetes v1.0, Diabetic Kidney Disease v1.0, Type 1 Diabetes v1.0
- First round of content is now available



Search Knowledge Base



Standard



Proficiency



Apply

× Clear

Examples Collection

Self-Monitoring Blood Glucose aCRF

This is a sandbox area for exploring what could or might go into an example. It is not a proper example, but a test page.

[Read More >](#)

Standard(s):

CDASH

Urine Protein 1

This example shows 24-hour urine protein results for two subjects.

[Read More >](#)

Standard(s):

SDTMIG, SDTM

Diabetes Complications aCRF

This example shows data collection for diabetes complications and their dates of diagnosis.

[Read More >](#)

Standard(s):

CDASH

Urine Protein 2

This example shows albumin excretion rate result values for the same subject at different visits.

[Read More >](#)

Standard(s):

SDTMIG, SDTM



Urine Protein 1

This example shows 24-hour urine protein results for two subjects.

[Read More >](#)

Standard(s):

SDTMIG, SDTM

Known Issues

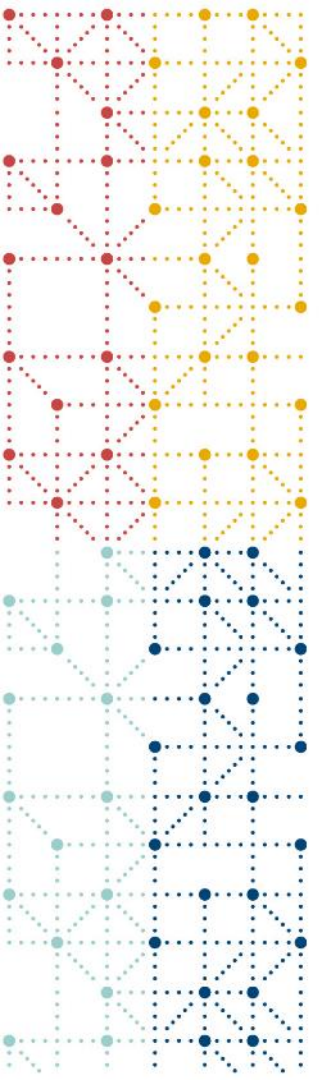
- A known issue is a problem or concern with a CDISC standard that CDISC is aware of and may be working actively to mitigate or resolve.
- Unlike errors or errors that affect conformance, known issues have no obvious solution when they are first identified; and some known issues may prove to be irresolvable.



Known Issue Example

Variable Labels more than 40 characters

Short Name	Variable Labels more than 40 characters
Affected Standard	SDTMIG v3.2
Description of Error	Variable labels listed below are more than 40 characters, but 40 characters is the maximum length of a label in the SAS v5 transport format required by regulators
Efforts to Correct Error	Variable labels no more than 40 characters in length are included in SDTMIG v3.3.



CDASH eCRF Portal



CDASH eCRF Portal

- The eCRF Portal adds functionality to the CDASH model.
 - Visual representation of CRF layout with CDASH annotations
 - Machine-readable ODM format
- Will include:
 - CRFs from the CDASH Implementation Guide
 - CRFs from Questionnaires, Ratings and Scales (QRS instruments)
 - CRFs from Therapeutic Area User Guides
- Formedix offered the CDISC community MDR use at no cost to help deliver the eCRF Portal.

CDASH eCRF Portal Benefits

- “Out-of-the-box” solution for new users
- Meets the basic needs for many users, but also customizable
- Increase use of CDASH
- Align with CDISC 360’s vision for end-to-end automation



CDASH eCRF Portal – Project Status

- 22 eCRF Packages posted on the CDISC website - publicly available
- New CRFs to be added incrementally



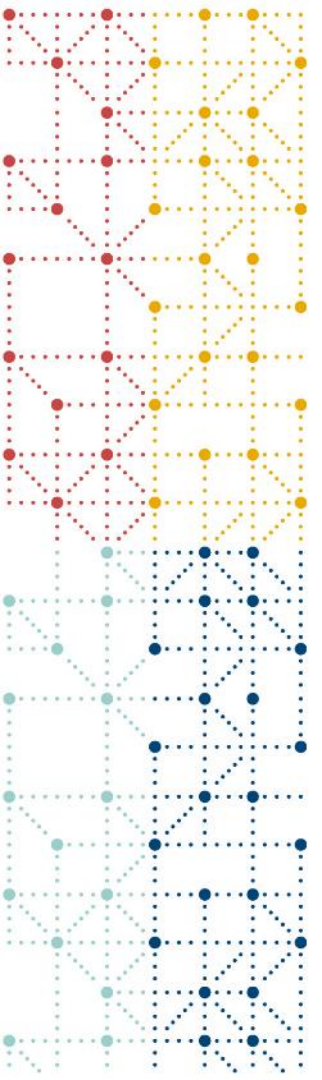
Learn More!

Session 4C: CDISC Foundational, Part I

15:30 - 16:00

Introduction to the CDASH eCRF Project

Alana St. Clair, CDISC



Analysis Results Standard

Enhancing ADaM standards



Add features that support automation of analysis results by extending Analysis Results Metadata (ARM) for Define-XML



Create a standardized structure for analysis results to support reuse and dynamic data display generation



Decrease implementation variability by tightening the standardization of ADaM metadata for generally accepted analyses

Extending Analysis Results Metadata (ARM) for Define-XML

Study - CDISC 360

Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN (N=XX)	HUMAN INSULIN (N=XX)
Age (years)		
n	XX	XX
Mean	XX.X	XX.X
SD	XX.XX	XX.XX
Min	XX	XX
Q25	XX.X	XX.X
Median	XX.X	XX.X
Q75	XX.X	XX.X
Max	XX	XX
Age Group - n (%)		
15 - <30 years	XX (XX.X)	XX (XX.X)
30 - <45 years	XX (XX.X)	XX (XX.X)
>=45 years	XX (XX.X)	XX (XX.X)
Gender - n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)

Max = Maximum. Min = Minimum. N = Number of subjects in treatment group. n = Number of subjects included in analysis. SD = Standard deviation.
 Datasets used - adsl
 Executed by <Username> on DDMMYYYY:HH:MM

Study	Analysis	Group	Order	DisplayID	DisplayVersion	Filename	Type	StyleID
CDISC	CDISC 360	Safety	1	T14111_SAF_DEMOG	1	t-demog_saf	rtf	table_rtf
CDISC	CDISC 360	Safety	2	T14131_SAF_AE2TIER	1	tae_soc_pt_saf	rtf	table_rtf
CDISC	CDISC 360	Efficacy	3	T1421_EFF	1	tmace_edpt_fas	rtf	table_rtf

DisplayID	DisplayName	DisplayTitle	Title1	Title2	Title3
T14111_SAF_DEMOG	Table 14.1.1.1	Demographic characteristics (SAF)	Study - CDISC 360	Table 14.1.1.1	Demographic characteristics (Safety Population)

ResultDisplayOID	AnalysisResultOID	Version	ResultDescription	DisplayPattern
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	n	xxx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Mean	xx.x
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	SD	xx.xx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Min	xx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Q25	xx.x
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Median	xx.x
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Q75	xx.x

WhereClauseOID	Dataset	Variable	Comparator	Value
T14111_02_SAF_DEMOG_01	ADSL	AGEGR1	EQ	15 <= to <30 years
T14111_02_SAF_DEMOG_02	ADSL	AGEGR1	EQ	30 <= to <45 years
T14111_02_SAF_DEMOG_03	ADSL	AGEGR1	EQ	>=45 years
T14111_03_SAF_DEMOG_01	ADSL	SEX	EQ	M
T14111_03_SAF_DEMOG_02	ADSL	SEX	EQ	F

Analysis Results Dataset

qb:Observation	qb:Table	dim.population	dim.treatment	dim.parameter	dim.sex	dim.agecat	dim.statistic	analysisResult
1001	dm.summary	enrolled	Treatment.A	param.subjects	sex.ALL	agecat.ALL	stat.freq	100
1002	dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.freq	60
1003	dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.percent	60
1004	dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.freq	40
1005	dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.percent	40
1006	dm.summary	enrolled	Treatment.B	param.subjects	sex.ALL	agecat.ALL	stat.freq	50
1007	dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.freq	30
1008	dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.percent	60
1009	dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.freq	20
1010	dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.percent	40
1011	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.ALL	agecat.ALL	stat.freq	150
1012	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.freq	90
1013	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.percent	60
1014	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.freq	60
1015	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.percent	40
1016	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.freq	100
1017	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.mean	40.7
1018	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.stdev	10.7
1019	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.median	37.0
1020	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.min	21.0
1021	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.max	66.0
1022	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.freq	50
1023	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.mean	41.2
1024	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.stdev	10.3
1025	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.median	36.0
1026	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.min	23.0
1027	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.max	67.0
1028	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.freq	150
1029	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.mean	40.9
1030	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.stdev	10.4
1031	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.median	37.0
1032	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.min	21.0
1033	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.max	67.0

Standardized Analysis Results Support Dynamic Data Display Generation and Reuse

qb:Observation	qb:Table	dim.population	dim.treatment	dim.parameter	dim.sex	dim.agecat	dim.statistic	analysisResult
1001	dm.summary	enrolled	Treatment.A	param.subjects	sex.ALL	agecat.ALL	stat.freq	100
1002	dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.freq	60
1003	dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.percent	60
1004	dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.freq	40
1005	dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.percent	40
1006	dm.summary	enrolled	Treatment.B	param.subjects	sex.ALL	agecat.ALL	stat.freq	50
1007	dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.freq	30
1008	dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.percent	60
1009	dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.freq	20
1010	dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.percent	40
1011	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.ALL	agecat.ALL	stat.freq	150
1012	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.freq	90
1013	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.percent	60
1014	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.freq	60
1015	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.percent	40
1016	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.freq	100
1017	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.mean	40.7
1018	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.stdev	10.7
1019	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.median	37.0
1020	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.min	21.0
1021	dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.max	66.0
1022	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.freq	60
1023	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.mean	41.2
1024	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.stdev	10.3
1025	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.median	36.0
1028	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.min	23.0
1027	dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.max	67.0
1028	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.freq	150
1029	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.mean	40.9
1030	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.stdev	10.4
1031	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.median	37.0
1032	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.min	21.0
1033	dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.max	67.0

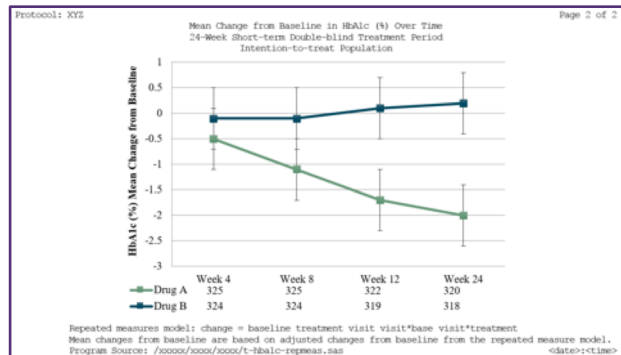
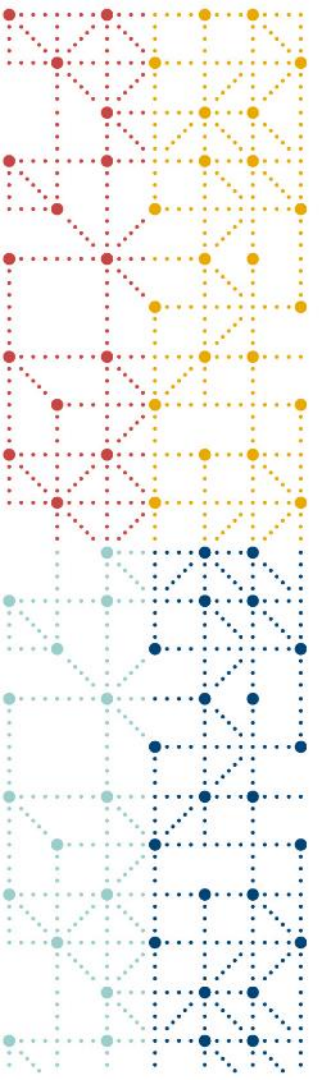


Table 4.2.1: HbA1c Longitudinal Repeated Measures Analysis - Table Shell
Protocol: XYZ Page 1 of 2

HbA1c (%) Longitudinal Repeated Measures Analysis
24-Week Short-term Double-blind Treatment Period
Intention-to-treat Population

BASELINE	N#	Drug A		Drug B	
		Mean (SD)	SE	Mean (SD)	SE
			125		125
			X.XX (X.XXX)		X.XX (X.XXX)
WEEK 4	N#		XXX		XXX
		Change from baseline: Mean (SD)	X.XX (X.XXX)		X.XX (X.XXX)
		Adjusted change from baseline: Mean (SE)	X.XX (X.XXX)		X.XX (X.XXX)
		95% Confidence interval for adjusted mean	(XX.XX, XX.X)		(XX.XX, XX.X)
		Difference vs. Drug B (SE)	(XX.XX, XX.X)		XX.XX (X.XXXX)
		95% Confidence interval for difference	(XX.XX, XX.X)		(XX.XX, XX.X)
		P-value vs. Drug B			X.XXXX
...					
WEEK 12	N#		X.XX(X.XXX)		X.XX (X.XXX)
		Change from baseline: Mean (SD)	XXX		XXX
		Adjusted change from baseline: Mean (SE)	X.XX (X.XXX)		X.XX (X.XXX)
		95% Confidence interval for adjusted mean	X.XX (X.XXX)		(XX.XX, XX.X)
		Difference vs. Drug B (SE)	(XX.XX, XX.X)		XX.XX (X.XXXX)
		95% Confidence interval for difference	(XX.XX, XX.X)		(XX.XX, XX.X)
		P-value vs. Drug B			X.XXXX

N# the number of subjects in the Intention-to-treat (ITT) population.
N# the number of subjects in the ITT population with non-missing baseline and non-missing Week t value.
Repeated measure model: change = baseline treatment visit visit*treatment
Program Source: /sxxxx/xxxx/xxxx/t-hba1c-rptmean.sas <date>=ctime>

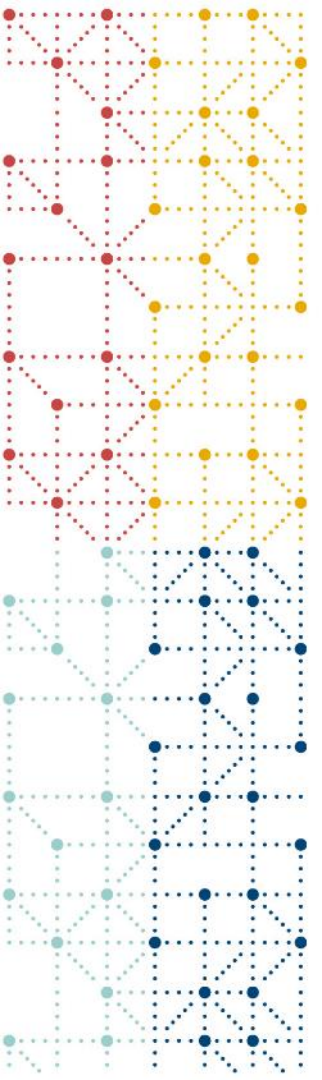


Safety User Guide

Safety User Guide

- Currently there is lack of a unified CDISC Safety User Guide that spans from data collection through analysis results
 - Each CDISC Foundational Standard has information on Safety Data that is commonly collected across studies of a wide-variety of indications
 - The TAUGs also often collect disease-specific safety information and examples
- Safety User Guide is aiming to align collection, tabulation, analysis and display of the most common safety data collected in research





Non-Standard Variable (NSV) Registry



Purpose and Goals


- NSVs and Supplemental Qualifiers appear in Therapeutic Area User Guides and Implementation Guides but are not always used consistently
- Ensure the development teams use the NSVs consistently
- Help identify NSVs for promotion to the model/IG
- Allow CDISC users to access the NSV information so they can use them within their organizations

NSV Registry Landing Page

Non-standard Variable Registry Home
Created by John Owen, last modified on Feb 23, 2021


For more information on the CDISC NSV Registry please contact Rebecca Baker (rbaker@cdisc.org) or John Owen (jowen.external@cdisc.org)

💡 Have an idea or improvement we can make for the NSV Registry - Use this [link](#) to enter a JIRA issue and we will take a look 😊




NSV Registry

- [NSV Registry Overview](#)
- [Search/Request NSVs](#)
- [Register New Source Document](#)
- [Request a Change to an NSV](#)




Fragment Database

- [Fragment Database Overview](#)
- [Search/Request Fragments](#)
- [Request a Change to a Fragment](#)



NSV Team

- [SDTM NSV Sub-Team Meeting Notes](#)
- [SDTM NSV Ongoing Projects with NSVs](#)
- [SDTM NSV Curation Process](#)
- [SDTM NSV Suggestions](#)


Clear Data. Clear Impact.
www.cdisc.org

<https://wiki.cdisc.org/display/NSVREG/Non-standard+Variable+Registry+Home>

NSV Registry Search

Search


To perform a word or phrase search, surround it by asterisks. For example, to look for records with the word source, you'd enter *source* in an applicable field.

Tab out of the field for the auto-filter to take effect


Variable Name:


Label:

Description:

Source(s): 

Limited to:

Status of t: 

Status of t: 

- TAUG-Asthma v1.1
- TAUG-Alzheimers v2.0
- TAUG-CDAD v1.0
- TAUG-CrCa v1.0
- TAUG-Diabetes v1.1
- TAUG-DMD v1.0
- TAUG-Ebola v1.0

NSV Example

Search

To perform a word or phrase search, surround it by asterisks. For example, to look for records with the word source, you'd enter *source* in an applicable field.

Tab out of the field for the auto-filter to take effect

Variable Name:

Label:

Description:

Source(s):

Limited to Domain(s):

Status of the Source Document:

Status of the NSV Review:

Reset

NSV Registry Results

Status of the Source Document	Status of the NSV Review	Variable Name	Label	Simple Datatype	XML Datatype	Define-XML Datatype	Codelist	External Dictionary	Notes	Description	Role	Qualifying Variable(s)	Status of the Source Document	Limited to Class(es)
	In Review	CLMTH	Specimen Collection Method	Char	string	text			Examples: INCISIONAL BIOPSY, NEEDLE BIOPSY	The method or process by which the specimen was collected	Non-Standard Variable Qualifier			Findings

[Export](#) Records: 1 Size: 1.5 KB

Fragment Database

Search

FRAGMENT KEYWORD

6 Character Fragment:

5 Character Fragment:

4 Character Fragment:

3 Character Fragment:

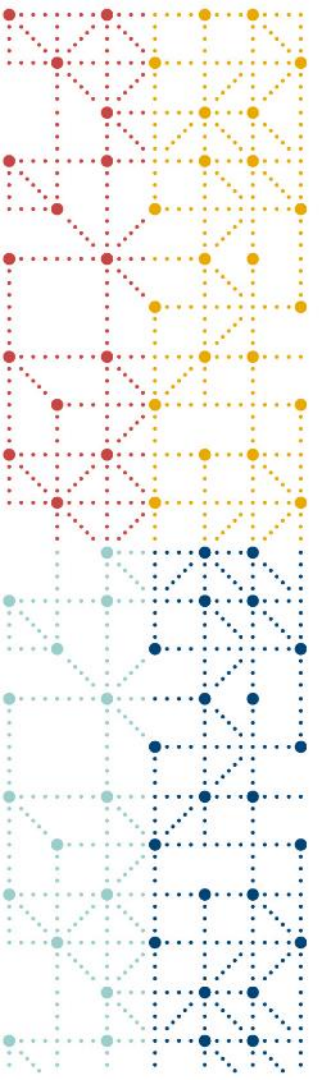
2 Character Fragment:

1 Character Fragment:

Filter Reset

Fragment Database Results

Status	Fragment Keyword	6 Character Fragment	5 Character Fragment	4 Character Fragment	3 Character Fragment	2 Character Fragment	1 Character Fragment
APPROVED	ACTION	ACTION	ACTON	ACTN	ACN	AC	A
APPROVED	ADJUSTMENT	ADJUST	ADJUST	ADJT	ADJ	AJ	A
APPROVED	ANCHOR	ANCHOR	ANCHR	ANCR	ANR	AN	A
APPROVED	ASSAY		ASSAY	ASAY	ASY	AS	A
APPROVED	BASELINE	BASLNE	BASLN	BSLN	BLN	BL	B
IN-REVIEW	BIRTH		BIRTH	BRTH	BTH	BT	B
IN-REVIEW	BODY			BODY	BOD	BD	B
APPROVED	CANCER	CANCER	CANCR	CANC	CAN	CA	C
APPROVED	CATEGORY	CATGRY	CATGY	CATG	CAT	CT	C
APPROVED	CHARACTER	CHARCT	CHARC	CHAR	CHR	CR	C
IN-REVIEW	CLASS		CLASS	CLAS	CLS	CS	C
APPROVED	CLINICAL	CLINCL	CLINC	CLIN	CLN	CL	C
APPROVED	CODE			CODE	COD	CD	C
APPROVED	COMMENT	COMMNT	COMNT	COMT	COM	CO	C
IN-REVIEW	CONCOMITANT				CON	CM	C
APPROVED	CONDITION	CONDTN	CNDTN	COND	CND	CN	C
IN-REVIEW	CONGENITAL			CONG			
APPROVED	COUNTRY	CONTRY	CNTRY	CTRY	CNR	CR	C
APPROVED	CRITERIA	CRITRA	CRITR	CRIT	CRT	CR	C
IN-REVIEW	DAY				DAY	DY	
IN-REVIEW	DEATH				DTH		
IN-REVIEW	DECODE		DECOD				
IN-REVIEW	DERIVED				DRV		
IN-REVIEW	DESCRIPTION			DESC			
APPROVED	DETAILS	DETAIL	DETAL	DETL	DTL	DE	D
IN-REVIEW	DISABILITY		DISAB				
IN-REVIEW	DOSAGE			DOSE	DOS		
IN-REVIEW	DOSES		DOSES	DOSE	DOS	DS	D



CDISC Certification



Certification Program Highlights

Tabulate
Certification Pilot

- NOV 2020 – APR 2021

Tabulate
Certification
Analysis

- MAY – JUN 2021

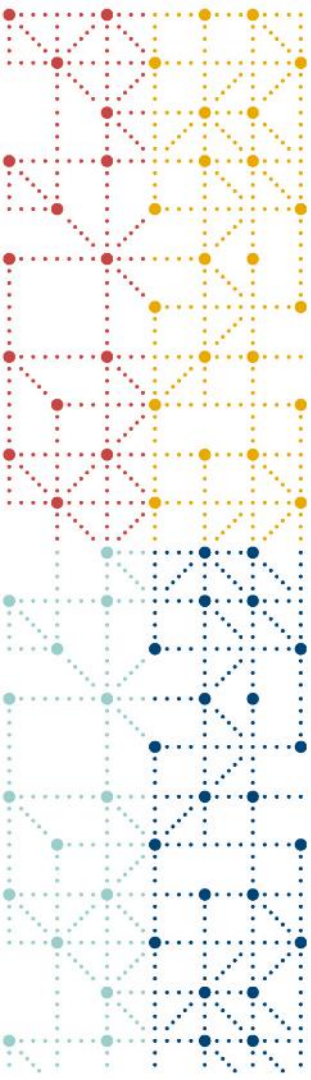
Final Tabulate
Exam Available

- JUL 2021

2nd Certification
Exam
Development

- Q4 2021

Contact certification@cdisc.org or visit the CDISC website for more information



Thank You!

cdisc