CDISC Italian User Network TC

https://wiki.cdisc.org/display/ITAUG/Italian+User+Network+Home

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22.09.2021

Agenda

1. New Standards or for Public Review and Regulatory Update
   Focus on SDTM Metadata Submission Guidelines v2.0
2. CDISC Certification Program
3. CDISC Event 2021/2022
4. CDISC Open Rules Engine (CORE)
5. Other Topics

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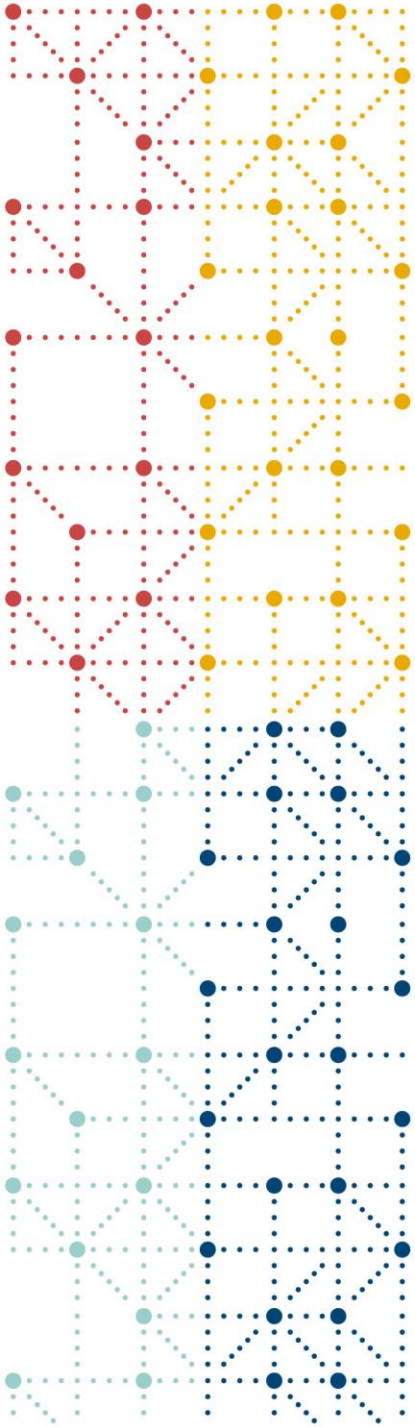

New Standards or for Public Review

Focus on SDTM Metadata Submission Guidelines v2.0

Regulatory Update

New Standards Released (from March-2021)

- **FHIR to CDISC Joint Mapping Implementation Guide v1.0 (Sep-2021)**

https://www.cdisc.org/standards/publications

- New TAUGs
  - **COVID-19 Therapeutic Area User Guide v1.0 (Jul-2021)**
  - **Crohn's Disease Therapeutic Area User Guide v1.0 (Jul-2021)**
  - Diabetes Type 1 Therapeutic Area User Guide v1.0 - Exercise and Nutrition Modules (Jun-2021)
  - Controlled Terminology Relationships v1.0 for SDTM v1.4 and SDTMIG v3.2 (Jun-2021)
  - Diabetes Type 1 Therapeutic Area User Guide v2.0 - Pediatrics and Devices Modules (May-2021)
  - CDASH SAE Supplement v2.0 (Apr-2021)
  - Conformance Rules for Define-XML v2.1 (Mar-2021)
  - SEND IG 3.1.1 (Mar-2021)
  - SEND Conformance Rules v4.0 (Jul-2021)

Next to be Released

Standard	Release Notes	Projected Publication
ADaM Examples of Traceability	Resolving Public Comments.	Q4 2021
ADaM OCCDS v1.1 and Conformance Rules	Preparing for Publication.	Q4 2021
ADaM Oncology Examples	In Development.	2022
ADaMIG Medical Devices v1.0 and Conformance Rules	Preparing for Publication.	Q4 2021
ADaMIG Non-compartmental Analysis v1.0 and Conformance Rules	Preparing for Publication.	Q4 2021
ADaMIG v1.3 and Conformance Rules	Preparing for Publication.	Q4 2021
Analysis Results Standard v1.0	In Development.	2022
CDASH v1.2	Preparing for Publication.	Q3 2021
CDASHIG v2.2	Preparing for Publication.	Q3 2021
Conformance Rules v2.0 for SDTM v2.0 and SDTMIG v3.4	Preparing for Publication.	Q4 2021
Medical Devices Conformance Rules	In Development.	2022
Safety User Guide v1.0	In Development.	2022
SDTM v2.0	Preparing for Publication.	Q4 2021
SDTMIG v3.4	Preparing for Publication.	Q4 2021

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

Regulatory Update

FDA Study Data Technical Conformance Guide v.4.8 September 2021

https://www.fda.gov/media/152175/download

FDA Data Standards Catalogs v7.4 September 2021

https://www.fda.gov/media/85137/download

Regulatory Update
FDA Study Data Technical Conformance Guide v.4.8

March-2021 – Section 4.1.1.3 SDTM Domain Specifications

FDA may require laboratory data using conventional units for reviewing submissions and labeling. ***Sponsors should discuss with the review divisions what laboratory data should utilize conventional units prior to submission***

August 2021 – Section 8.2.2 Support on Data Validation Rules

When a xpt formatted dataset is submitted, the STF for the study is then checked for the presence of a trial summary (TS) file (full or simplified). ***A full ts.xpt file would be expected when the study type and study initiation date meet the criteria for requiring SDTM and ADaM datasets as described in the current FDA Data Standards Catalog****.*

*There are cases in which a xpt formatted dataset submitted to TRC applicable sections within eCTD Module 5 using one of the STFs (see section 7.1) is not required to include accompanying SDTM and ADaM datasets****. In such cases, a simplified ts.xpt file should be included with the xpt formatted dataset. A simplified ts.xpt file serves to provide limited machine-readable information such that any submitted xpt formatted dataset not requiring SDTM and ADaM datasets will be appropriately identified by the Center's processing system***

PhUSE - **Optimizing the Use of Data Standards**

https://phuse.global/Deliverables/1

- Testing Simplified TS Examples Against FDA Technical Rejection Criteria https://phuse.s3.eu-central-1.amazonaws.com/Deliverables/Nonclinical+Topics/Testing+Simplified+TS+Examples.zip
- Simplified TS datasets required for non-standard datasets (SDTM) submission

STUDYID	TSPARMCD	TSVAL	TSVALNF
StudyN	STSTDTC	2001-03-13	

- The FDA "Simplified ts.xpt creation Guide" https://www.fda.gov/media/132457/download

New Standards or for Public Review
Focus on SDTM Metadata Submission Guidelines v2.0

https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v2-0

- Version 2.0 after 10 years from version 1.0 (2011-12-30)
- It includes updated «Sample Submission Package»
- Focus is on SDTM package
  - Standard for aCRF annotations and bookmarking

New Standards or for Public Review
Focus on SDTM Metadata Submission Guidelines v2.0

https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v2-0

- Suggested color schema

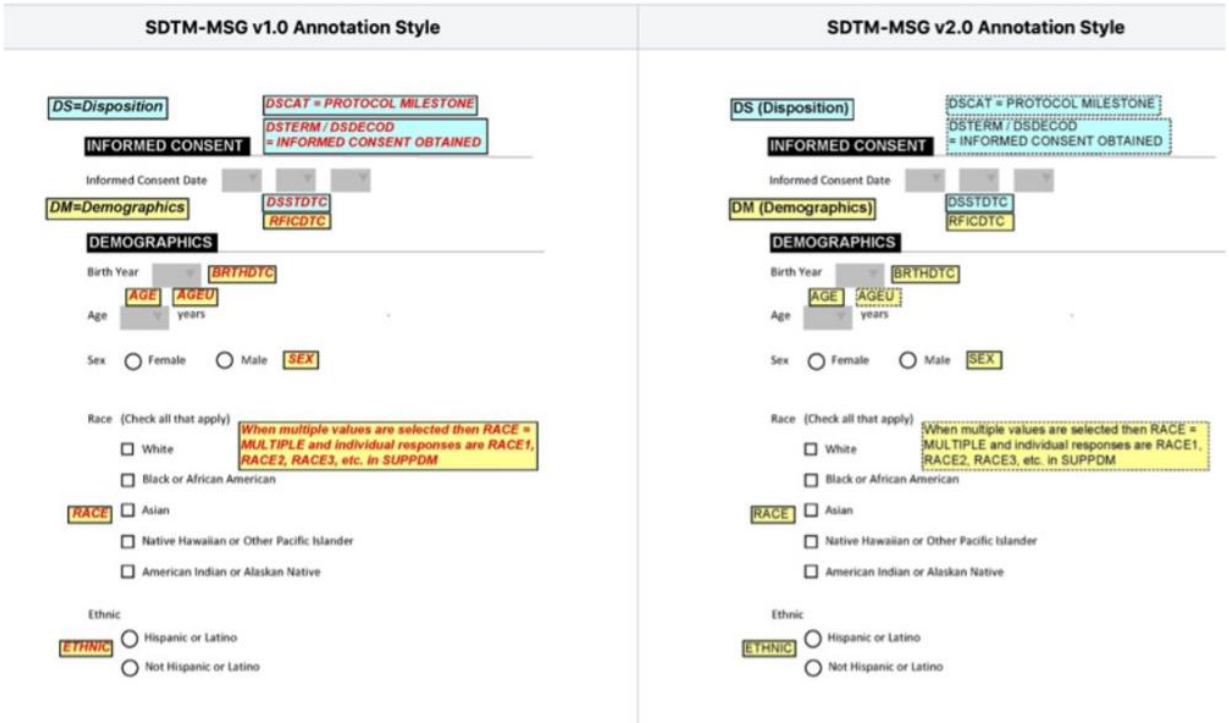
BLUE	DM (Demographics)	191, 255, 255
YELLOW	DS (Disposition)	255, 255, 150
GREEN	SC (Subject Characteristics)	150, 255, 150
ORANGE	VS (Vital Signs)	255, 190, 155

SDTM-MSG v1.0 Annotation Style	SDTM-MSG v2.0 Annotation Style
11=First Color	11 (First Color)
22=Second Color Center	22 (Second Color)
Third Color	Third Color
Fourth Color	Fourth Color

New Standards or for Public Review
Focus on SDTM Metadata Submission Guidelines v2.0

https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v2-0

- Suggested Style



- Domains:
  - Arial
  - Bold
  - Not italic
  - Black
- Normal Annotations:
  - Arial
  - 12pt
  - Not bold
  - Not italic
  - Black

New Standards or for Public Review
Focus on SDTM Metadata Submission Guidelines v2.0

https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v2-0

- Appearance of annotations

Domains

SV (Subject Visit) See Page 22

IBM Clinical Development -- Generated on 08-JUL-21 08:5

- Abbreviations
- Full name in brackets

Quotations

DSDECOD=INFORMED CONSENT OBTAINED

- No Quotation marks

Variables by value

- Use arrows to address

The MSG team has not identified a use case that would require an annotation format to “<variable> = <value> when <variable> = ...”

Collected but not mapped Data

[NOT SUBMITTED]

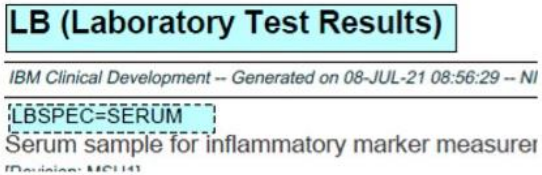
- Normal text style
- Text box with dotted borders

New Standards or for Public Review
Focus on SDTM Metadata Submission Guidelines v2.0

https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v2-0

- Appearance of annotations (by specific type of data)

Assigned Data

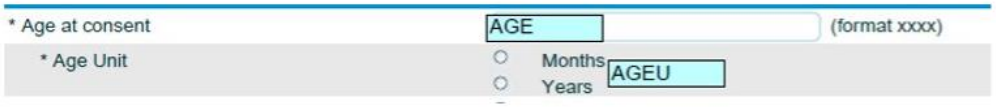


- Textbox with dotted borders

e. g. --SPEC or --CAT, not collected / not entered

Precaution

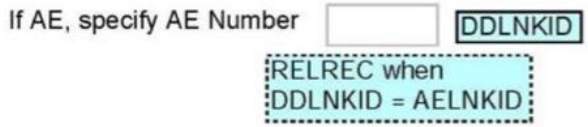
- AGEU is assigned



- AGEU is collected

RELREC

Example 1: Annotations for RELREC



When a form indicates a relationship between collected data, the annotations should indicate the collection as well as the RELREC relationship.

CDISC Certification Program

CDISC Certification Program

Officially launched End of August 2021

https://www.cdisc.org/education/cdisc-standards-certification

Cost: 500$

Duration: 3 years

Delivered by Prometric

200 Questions

CDISC recommend at least three years of experience with CDISC standards prior to take the certification

CDISC Certification Program

No specific version, but it includes questions related to most recent version e.g. IG 3.3

200 questions

- General Concepts, Terms and Assumptions, and Conformant Dataset Structure
- General Observation Classes
- Domain-Specific Knowledge
- Findings About, Custom Domains, Associated Persons, and Study References
- Special Purpose Domains
- Controlled Terminology
- The Trial Design Model
- Relationships Among Datasets and Record

CDISC Events 2021/2022

CDISC Events 2021/2022

- **US CDISC Interchange 20-21 October 2021 – Online**
  - CDISC updates and CDISC looking ahead (CDISC 360, CDISC Open Rules Engine - CORE), Open Source Projects (CDISC Open Source Alliance - COSA)
  - 2 ADaM sessions + Analysis Results Standards
  - QRS, Covid-19, RWD, MDR, CDISC foundational
  - 2 Global Regulatory sessions (FDA, EMA, PMDA) including FDA roundtable

- **EU CDISC Interchange 27-28 April 2022 – Copenhagen**
  - Call for abstract will be launched soon
  - Topic required similar to last year

Upcoming Webinars and Partner Events

https://www.cdisc.org/events/webinar

- 2021 Virtual US Interchange Sneak Peek - 23SEP21
- Controlled Terminology Updates for Q3 2021 - 30SEP21
- Digital Data Flow: Project Information and Call for Volunteers - 5OCT21 https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/
- Controlled Terminology Updates for Q4 2021 - 21DEC21

- SCDM Annual Conference 26-29 Sep 2021
- PHUSE EU Connect 15-20 Nov 2021

Recent Past Webinars

- CDASH Office Hours + eCRF Portal Update 6JUL21

  Ask panelists any questions regarding the development and implementation of CDASH, CDISC's standard for data collection. Presentation of the eCRF Portal, where you can download ready-to-use, CDASH-compliant, annotated case report forms in PDF, HTML and XML.

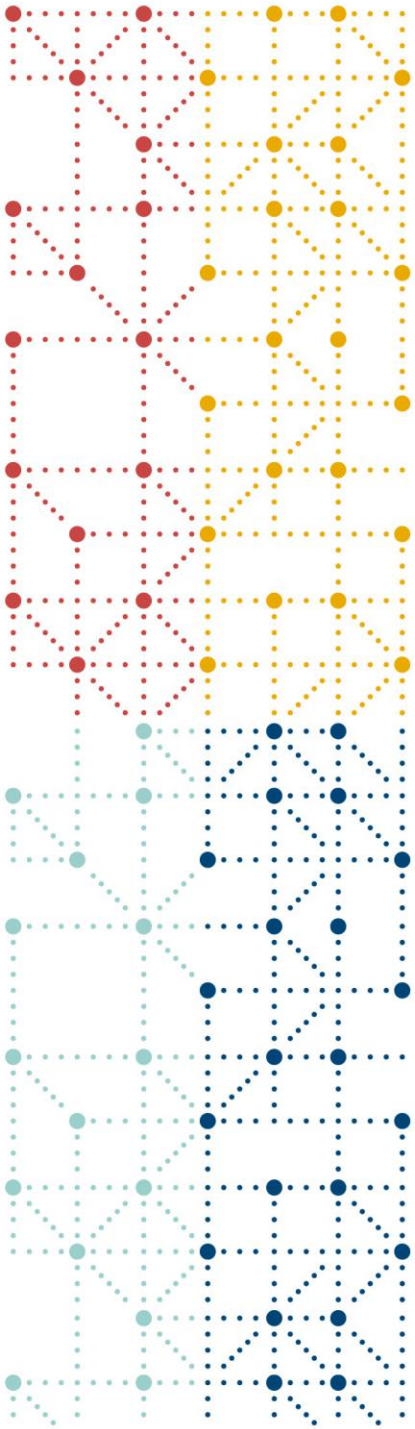
- CDISC Open Rules Engine (CORE) Call for Participation Webinar 20JUL21

  CDISC is partnering with Microsoft to develop the CDISC Open Rules Engine (CORE), open-source software that will deliver a governed set of unambiguous executable Conformance Rules for each Foundational Standard and an open-source execution engine for the Rules. CORE will be released as open source under the MIT license and not be offered by CDISC as a commercial product or service.

- CDISC Tabulate Certification Launch 7SEP21

Italian User Network 2021

- Friday 3 December 2021 (to be confirmed)
- Hosted by SIMEF/IBIG
- Half Day
- Virtual
- Agenda to be defined - Possible theme “traceability”



CDISC Open Rules Engine (CORE)

Why is CDISC doing CORE?

CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.

CDISC Data Standards Lifecycle

Why is CDISC doing CORE?

CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.

CDISC Data Standards Lifecycle

Automation requires:

- *Standard Machine-executable content for Useability*
- *Standard Technology Interfaces for Integration for Accessibility*
- *Standard Verification and Conformance Rules for Integrity*

CORE – Further Considerations

- CORE will be released as open source under the MIT license
  - Not offered by CDISC as a commercial product or service
- Executable rules - next step in the evolution of the conformance rules that CDISC publishes with every standard
- Executable rules published by CDISC should make it much easier for rule vendors to adapt these rules for use in their own software
- Existing rule vendors are free to contribute to or use the CORE engine software
- https://www.cdisc.org/core

Thank You!

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