WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

2022 US INTERCHANGE

26-27 OCTOBER | AUSTIN

Meet the Speaker

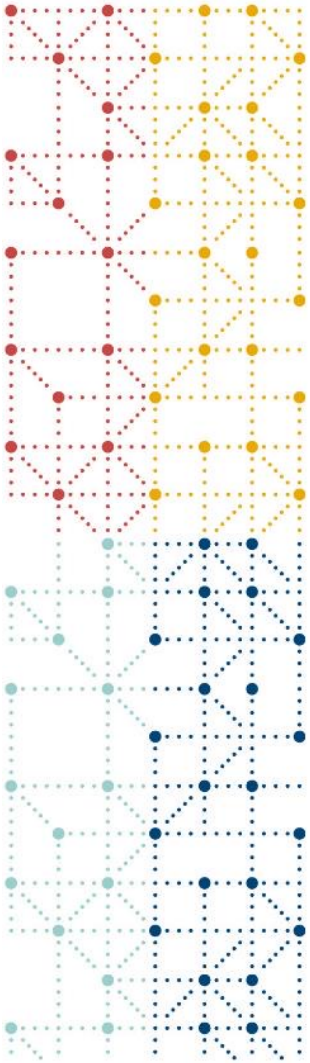
Amy Palmer

Title: Head of Standards Development Operations

Organization: CDISC

Amy Palmer is the Head of Standards Development Operations at CDISC. Amy has been with CDISC since 2013. She is a member of the CDISC Technical Leadership Team and leads the Global Governance Group. Amy has over 28 years' experience working in clinical research. She has been involved in the development of multiple therapeutic area user guides as well the foundational standards and has been working with CDISC standards since 2010.

Amy has a BS from Mary Washington College and an MPH from the University of Montana.



Agenda

1. CDISC Standards Development Publications
2. New and Ongoing Standards Development Activities

CDISC Standards Development Publications

Foundational Standards Publications

SDTM v2.0 and Conformance Rules

SDTMIG v3.4 and Conformance Rules

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

All documents simultaneously published 29 November 2021 on CDISC Website and in CDISC Library

TAUGs and Other Publications

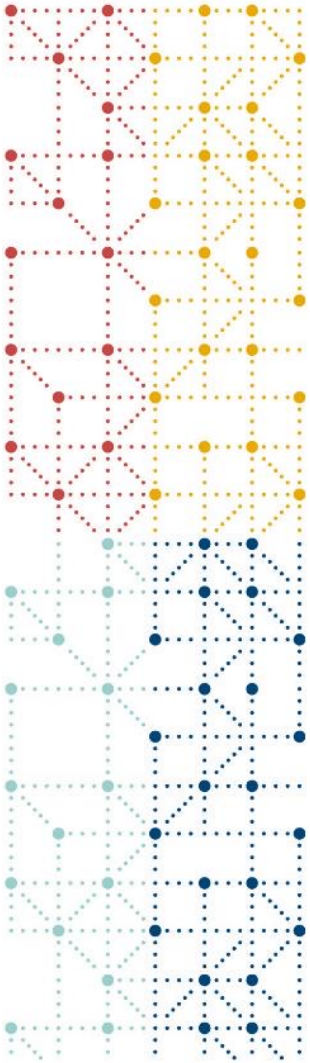
Type 1 Diabetes – Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes

ADaM Examples of Traceability

Quarterly Controlled Terminology Releases

QRS Supplements

CDISC Glossary v16.0



New and Ongoing Standards Development Activities

Standards and Therapeutic Area User Guides in Development

ADaM Oncology Examples	ADaM Metadata Submission Guidelines	ADaM popPK Implementation Guide	ODM v2.0	SENDIG – DART v1.2
SEND Tumor Combinations	SENDIG - Dermal Ocular v1.0	SENDIG – GeneTox v1.0	SDTMIG-Medical Devices Conformance Rules	Tobacco Implementation Guide v1.0
Safety User Guide v1.0	Pediatrics User Guide v1.0	Rare Diseases TAUG v1.0	COVID TAUG v2.0	TCM – Acupuncture TAUG v1.0

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

Foundational Standards Development Highlights

- ADaM – Planning for a consolidated ADaMIG
- SDS – Multiple Subject Participations – DM and DC domains
- CDASH – Aligning with SDTMIG v3.4 including GF and CP domains
- SEND – Implementing new domains including IS, CP, PI, OE, and SX
- Medical Devices – Addressing how to represent multiple device components

Domain Scope Changes Across SDTMIG v3.2 through SDTMIG v3.4

IGv3.2

- **IS** domain scoped for study therapy-induced subject immune response.
- **LB** domain scoped to include other non-host microorg and subject immune response assessments.
- **MB** domain scoped to include some non-host microorg identification tests only.

IGv3.3

- **IS** domain scoped for study therapy-induced subject immune response.
- **LB** domain scoped to include other subject immune response assessments but no non-host microorg tests.
- **MB** domain scope broadened to include all detection, identification, quantification, and other characteristics assessments of non-host microorg, via direct detection methods and indirect, induced-host/subject immune response.

IGv3.4

- **IS** domain scoped for any antigen (incl. therapy and microorg) induced subject immune response.
- **LB** domain no longer contains non-host microorg or subject immune response assessments.
- **MB** domain contains "direct" detection, identification, quantification, and other characteristics assessments of non-host microorg. It no longer contains microorg induced-subject/host immune assessments.

Domain Scope Changes Affect CDISC CT

- The change in the LB, MB, and IS domain scope will result in the deprecation of approximately 400 antibody TEST and TESTCD values from both the LB and MB domains, and instead,
- These terms will be remodeled in the IS domain, using IS domain standard variables including but not limited to: ISTESTCD, ISBDAGNT (Binding Agent), and ISTSTDTL (Test Detail)

- Changes announced at the CT Webinar on 2022-10-04
  - https://www.cdisc.org/events/webinars
- Announcements/presentations at public meetings
- Topic integration into CDISC education courses

Note: There is no plan to immediately deprecate the affected antibody LBTEST-CD/MBTEST-CD terms. Deprecation will happen in December 2023.

Collaboration with National Organization for Rare Disorders (NORD)

Document scope includes cross-cutting concepts, endpoints, questionnaires, terminology

Public Review anticipated Q1 2023

Topics of interest: Diagnosis – Genetic Testing; Family History; in vivo and ex vivo gene therapies

Pediatrics User Guide

Publication planned December 2022

conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

imi innovative medicines initiative

efpia

Areas of Focus

- Information about the subject (e.g., demography, vital signs, diet and nutrition, body system assessments)
- Information about the subject's family (e.g., medical conditions, medications, substance use)
- Pregnancy and Birth
- Study Conduct
- QRS

DRAGON: An IMI-Funded Project

Develop AI-enhanced tools for evaluating COVID patients' *CT scans* and *clinical data* to provide accurate diagnoses and predict patient outcome.

cdisc's Role

- EHR data harmonization design and mapping support to feed data to AI
- COVID-19 User Guide v2.0 Imaging Guide
- Considerations for using CDISC standards for observational research
- CDISC Basic: abridged CDASH & SDTM for non-submission research

CDISC eCRF PORTAL

- The eCRF Portal provides machine readable eCRFs
  - Visual representation of CRF layout with CDASH annotations
  - Machine-readable ODM format

- Includes CRFs from:
  - CDASH Implementation Guide v2.1
  - Crohn's Disease Therapeutic Area User Guide
  - Upcoming – COVID-19 Therapeutic Area User Guide
  - 54 eCRFs to date (Oct 2022)

- Formedix offers the Ryze platform at no cost

- Used as a base to create OpenClinica and REDCap CRFs

Tobacco Implementation Guide (TIG) v1.0

- Proactively designed to reflect use cases unique to tobacco studies
- A single, comprehensive implementation guide for tobacco studies

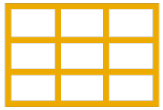
An overview of standards and general implementation

With guidance by topics and use cases; e.g.

- Product Description
- Nonclinical
- Clinical Studies

Key scientific concepts and maps

Data Collection (*CDASH eCRFs*, *ODM-XML*)



Data Tabulation (*SEND*, *SDTM Human Clinical*, *Define-XML*)

Analysis (*ADaM*, *Define-XML*)

Common Language (*Controlled Terminology*)

Measures of Adherence (*Conformance Rules*)

Accessible in platforms which optimize use (including *CDISC website*, *CDISC Library*)

Education and Outreach (including *webinars*, *formal training*)

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Learn More About the Tobacco Implementation Guide

Session 8: Closing Plenary, Global Regulatory Presentations and Panel Discussion

Thursday, 15:30 – 17:30

Ballroom A

FDA-CTP and CDISC Project to Develop Tobacco Related Standards to Achieve Efficiencies for All Stakeholders

16:00 – 16:30

Christine Connolly, CDISC; and Amy Malla, FDA-CTP

Digital Data Flow Phase 2 Overview

- Enhancements/bug fixes from DDF Phase 1
- Updates to accommodate Biomedical Concepts to facilitate EDC Automation
- Updates to add additional structured elements enabling export and population of the TransCelerate Common Protocol Template
- Updates to the model in order to cater for more complex study designs
- Updates from Connectathon feedback (still being collated)

Deliverable	Development Format(s)	Final Format(s)	Official CDISC Standard
1. User Stories	WIKI	Integrated into Implementation Guide as user narratives	No
2. Visual Diagram: Relationships Among Standards	.cmap, .pdf	.pdf	No
3. Unified Study Definition Model (USDM) Class Diagram	.png, .eapx. .xmi	.png, .eapx. .xmi	Yes
4. CDISC Controlled Terminology	.xls	NCI EVS vocabulary formats (.OWL, .html, .pdf, .txt, .xls)	Yes
5. Application Programming Interface (API) Specification	.json, .yaml	.json, .yaml	Yes
6. USDM Implementation Guide	WIKI	.pdf	Yes

Digital Data Flow Phase 2

Session 5: Track B - Trial Design

Thursday, 8:30 – 10:30

Ballroom B

TransCelerate Digital Data Flow: An Update on DDF Phase 2

8:30 – 9:00

Mikkel Traun, Novo Nordisk A/S and Vijay Reddi, Roche Products Ltd

COSMoS
Conceptual & Operational Standards Metadata Services

Pragmatic Implementation of Biomedical Concepts

- Reduce variability by extending foundational standards
  - explicit variable relationships
  - improved semantics
  - operational metadata
- Light-weight curation and governance process
- Biomedical Concepts available via CDISC Library APIs
- End goal is to reduce variability in standards implementations, increase metadata-driven automation

Biomedical Concepts and COSMoS Presentations

Session 2: Second Opening Plenary - CDISC Looking Ahead
Wednesday, 11:00 - 12:30
Ballroom A

Biomedical Concepts Vision and Value for the Community
Bess Leroy and Jon Neville, CDISC

Session 6, Track B - Business Optimization & Technical Topics
Thursday, 11:00 – 13:00
Ballroom B

COSMoS Technical Implementation, API Layer and Use Cases
Lex Jansen & Linda Lander, CDISC

CORE To Date

2021 – APR

EU Interchange
- First notice

2021 - JUL

Kick-off
- Kick-off meeting
- Start Microsoft engagement
- Sprint 0

2022 - JUL

Next Phase
- Virtual Private Cloud Evaluation Deployment
- End Microsoft engagement

2022 - SEP

Transition to Open-Source
- Start of CORE Roadmap Board
- CORE in GitHub
- Initiation of SDTMIG 3.2, 3.3, SENDIG, ADaMIG

5 sprints

19 sprints

2022 - APR

EU Interchange
- CDISC-Provided Cloud Evaluation Deployment
- Rules Authoring Tool
- 210 of 336 executable rules in SDTMIG 3.4

Learn More About CORE

Session 2: Second Opening Plenary - CDISC Looking Ahead

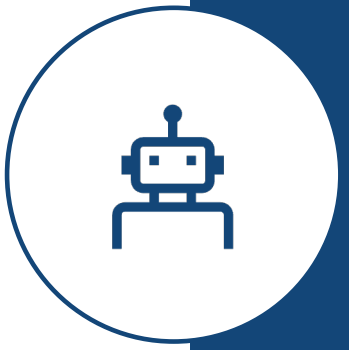
Wednesday, 11:00 - 12:30

Ballroom A

CDISC Conformance Rules and the CORE Engine

Progress and Roadmap

Peter Van Reusel, CDISC Chief Standards Officer



Analysis Results Standards

Unnecessary variation in analysis results reporting

Limited CDISC standards to support analysis results and associated metadata

CDISC has been working towards creating standards to support, consistency, traceability, and reuse of results data

We anticipate that the CDISC work will support sponsor submissions of analysis results in a standard format that aligns with the FDA effort to standardize safety tables and figures

Analysis Results Standards Presentations

Session 5: Track C - CDISC Fundamentals

Thursday, 8:30 – 10:30

Bluebonnet

CDISC Analysis Results Standards - Approach and Development Update

Bhavin Busa, Independent; and Andrew Miskell, Eli Lilly and Company

Session 7: CDISC Special Topics

Thursday, 14:00 - 15:00

Ballroom A

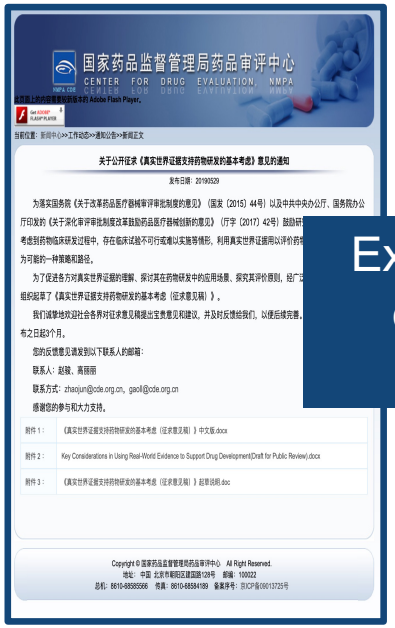
Advancing Pre-Market Safety Analytics

14:30 – 15:00

Dr. Vaishali Popat, FDA-CDER; and Bess LeRoy, CDISC

RWD and the Regulatory Environment

China's NMPA



http://www.cde.org.cn/news.do?method=largeInfo&id=23a2b4cbe0807fe2

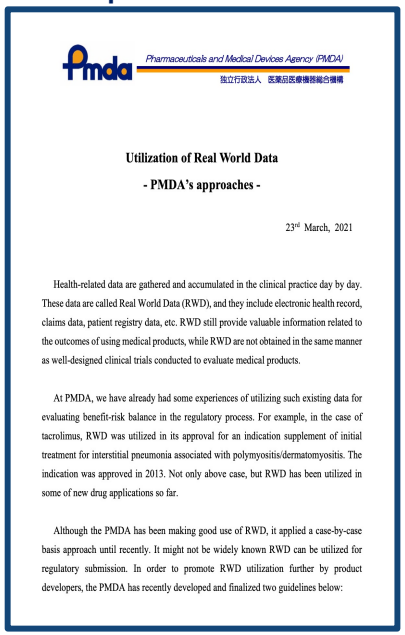
US FDA

https://www.fda.gov/media/120060/download

EU EMA

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

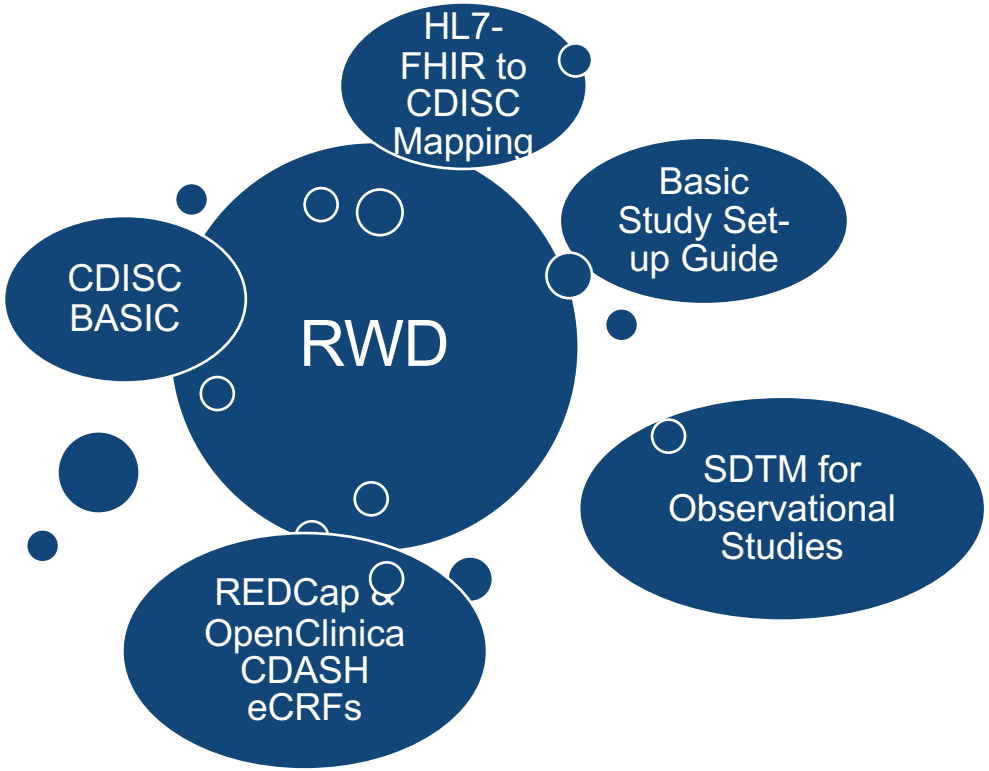
Japan's PMDA



https://www.pmda.go.jp/english/about-pmda/0004.pdf

Exploring and promoting the use of high-quality RWD in decision-making as a strategic goal

CDISC Real World Data Resources



Why CDISC BASIC?

Shared data is hard to use if it is not in standard format

CDISC Standards were developed specifically for clinical research

Barriers to adopting CDISC standards

- Overwhelming (sheer volume)
- Siloed (separate standards for collection, tabulation, analysis, metadata)
- Originally written for those who worked with data in the pharmaceutical industry full time

Aim of CDISC BASIC: Lower Barriers to Using CDISC

Reduce volume by concentrating on most common data

Present collection and tabulation in an integrated manner

Write for an audience new to CDISC and less immersed in data handling

Link to other resources

REDCap and OpenClinica CRFs

CDISC resources such as

- eCRF Portal
- Knowledge Base
- Free educational courses and webinars

Specific CDISC Standards for more detail, when needed

Learn More About CDISC Basic

Session 4: Track B - Real World Data

Wednesday, 16:00 – 17:30

Ballroom B

CDISC BASIC Introduction

17:00 - 17:30

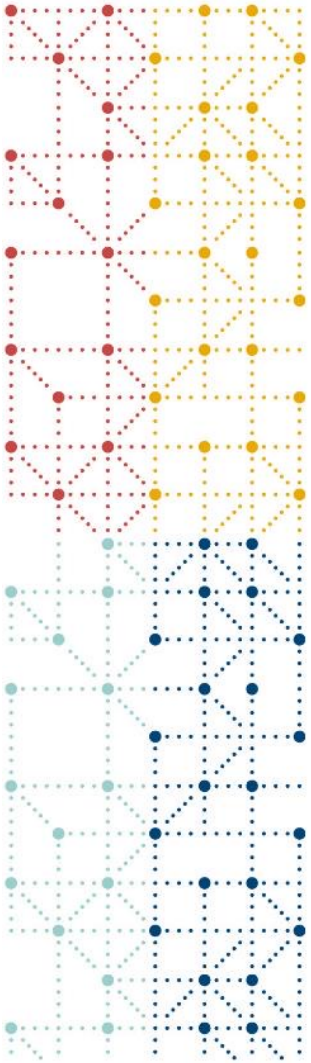
Diane Wold and Gary Walker, CDISC

CDISC Volunteer Spotlight

CDISC's strength derives from the diverse perspectives of our community of volunteers

- Interviewed by CDISC Communications
  - Why volunteer?
  - Tips for those using CDISC Standards
  - What did you want to be when you grew up?
- Published monthly

https://www.cdisc.org/volunteer/spotlight



Thank You!

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