

CDISC Italian User Network TC



Presented by Silvia Faini (Cytel) Angelo Tinazzi (Cytel)

30.03.2022





Agenda

1. CDISC and Data Submission What's New
2. SDTM and ADaM Update
3. Other Topics and Q&A

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



CDISC e Data Submission What's New

Upcoming Webinars, Trainings, New Standards and Working Progress



Webinars MAR-APR 2022

- **Introduction to the SDTM Genomics Findings (GF) Domain – 24MAR2022**
- **SDTM Office Hours – 29MAR2022**
- **CDISC Open Source Alliance Spotlight – 31MAR2022**
+ workshop on 29APR2022
- **QRS Office Hours – 19APR2022**



COSA free Workshop

29-Apr-20200 9:00 - 13:00 CET

Free of charge and open to anyone interested - registration for the main conference is not required <https://lnkd.in/g5z8YKG4>

The OpenStudyBuilder is an open-source project for clinical study specification. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.

At this workshop we will briefly present: <https://lnkd.in/gFCASEzx>

- Why you should consider to use the OpenStudyBuilder solution
- Why we share OpenStudyBuilder as an open source project
- Why you should consider to contribute to the OpenStudyBuilder solution
- Breakout sessions with facilitator <https://lnkd.in/gHBmm94w>

Public Trainings

- Virtual Classroom Training at Next CDISC-Eu Interchange 25, 26, 29 April
<https://learnstore.cdisc.org/Course/featuredCourse>

The image displays three promotional cards for CDISC training. The first card, 'VIRTUAL CLASSROOM TRAINING', features an illustration of an instructor pointing at a screen in a virtual classroom. The second card, 'ON DEMAND ONLINE TRAINING', shows a person interacting with a digital screen and gears. The third card, 'WEBINARS', depicts a person standing next to a large smartphone displaying a webinar interface with a lightbulb icon. Each card includes a 'LEARN MORE»' button.

VIRTUAL CLASSROOM TRAINING

Instructor-led CDISC Standards training in a virtual classroom setting.

ON DEMAND ONLINE TRAINING

Self-directed training. Choose any time and place that fits your schedule.

WEBINARS

Industry hot topics, best practices and challenges around implementing CDISC standards, allowing attendees to learn from our community of experts.

- **Blended Training:** Developed by CDISC subject matter experts, Blended Learning combines the flexibility of online training with one-on-one interaction with a live CDISC-authorized instructor!



CDISC Events

- EU CDISC Interchange 27-28 April 2022 VIRTUAL

<https://www.cdisc.org/events/interchange/2022-europe-interchange>

- REGULATORY STREAM
- CDISC updates
- TECH ENABLED STANDARDS
- ADaM
- SUBMISSIONS REQUIREMENTS
- REAL WORLD DATA (including update on DARWIN EU® by EMA)
- USE CASES
- CDISC FOUNDATIONAL
- CDISC CORE (launch)
- OPEN SOURCE (COSA initiatives)

CDISC Events

- EU CDISC Interchange 27-28 April 2022 VIRTUAL

<https://www.cdisc.org/events/interchange/2022-europe-interchange>

Non-Member \$880.00 Refund policy	Platinum Member \$528.00 Refund policy	Gold Member \$704.00 Refund policy
Student Rate \$220.00 Refund policy	Speaker \$165.00 Refund policy	Government \$220.00 Refund policy

Discounted passes for 5 members of ITA CDISC UN who have not attended any CDISC Interchanges over the past 2 years: US\$300.

CDISC Update

- Prossime pubblicazioni:

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

Standard	Release Notes	Projected Publication
ADaM Examples of Traceability	Preparing for Publication.	Q1 2022
ADaM Oncology Examples	In Development.	2022
ADaM popPK Implementation Guide v1.0	In Development.	Q4 2022
Conformance Rules for SDTMIG-Medical Devices v1.1	In Development.	Q4 2022
ODM v2.0	In Development.	2022

+ others in 2023

CDISC Update

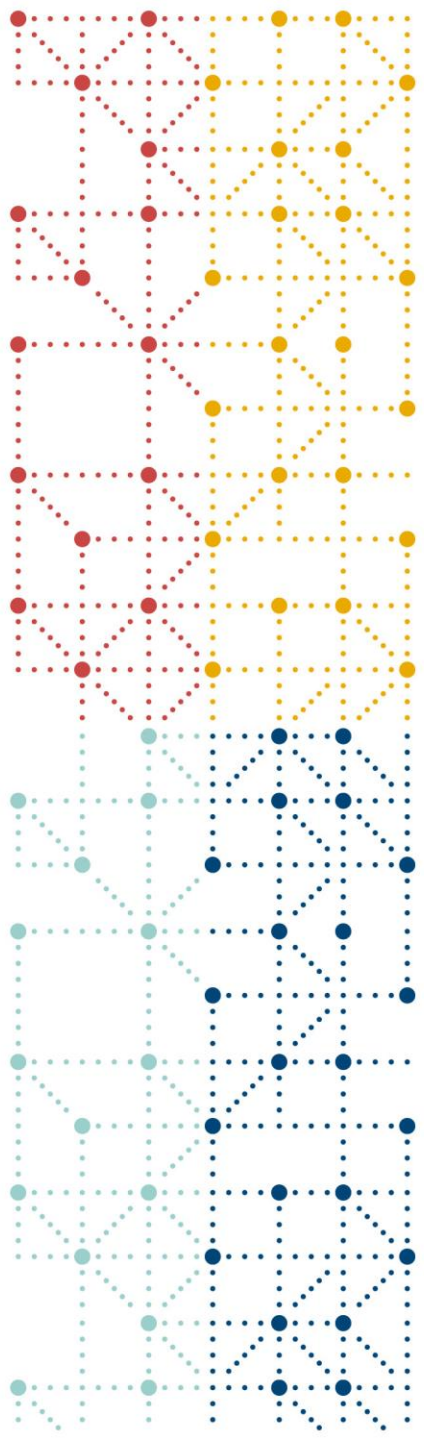
Therapeutic Area

Therapeutic Area	Release Notes	Projected Publication
Pediatrics User Guide v1.0	In Development.	Q4 2022
Rare Diseases Therapeutic Area User Guide	In Development.	Q4 2022
Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0	Preparing for Public Review.	Q4 2022



PHUSE WG for Data Standards

- PHUSE BIMO WG (Released draft **BIMO Reviewer Guide template**, public review closed)
- PHUSE **Clinical Integrated Study Data & Analysis Data Reviewer's Guide** (out for public review - feedback by 13 April)
- PHUSE ESTIMANDS WG (Launched March-2022)



SDTM and ADaM Update

SDTM and ADaM Update

New versions released last November

Standard	Updated Content
SDTM	<ul style="list-style-type: none">• SDTM Standard Version 2.0• SDTM Implementation Guidance Version 3.4
ADaM	<ul style="list-style-type: none">• ADaM Implementation Guidance Version 1.3• ADaM OCCDS Implementation Guidance Version 1.1• ADaM Implementation Guidance for Medical Device Version 1.0• ADaM Implementation Guidance for Non-Compartmental Analysis Version 1.0



SDTM and ADaM Update

SDTM

- SDTM v 2.0

- Some new standard variables added in the General Observational Classes e.g.,
 - EPCHGI (Epi/Pandemic Related Change Indicator) Any Class
 - REASOC (Reason for Occur Value) Events / Interventions
 - CLSIG (Clinically Significant, Collected) Findings
 - CNTMOD (Contact Mode) Any Class



SDTM and ADaM Update

SDTM – SDTM IG 3.4

- No new classes
- New Domains
 - From the SDTM PGx IG,
 - BE (Biospecimen Events), BS (Biospecimen Findings), GF (Genomics Findings) and RELSPEC (Related Specimens)
 - GF was previously named PF in the SDTM PGx IG
 - Most of the content of the SDTM PGx has been incorporated in the IG 3.4 and therefore now deprecated
 - CP (Cell Phenotype Findings)
 - The dataset MO (Morphology) has been deprecated replaced by separated specific morphology findings domains **organized by body systems** e.g., CV for Cardiovascular System physiological and morphological findings



SDTM and ADaM Update

SDTM – SDTM IG 3.4 (cont)

- SV now incorporates recommendation from “Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic” e.g., VE dataset
 - Actual and non-Occurred visit, with reason (SVREASOC)
 - Use of SVPRESP (Planned vs Unscheduled Visits) and SVOCCUR (to flag planned non-occurred / skipped visit)
 - Flag for Visit impacted by the Pandemic (SVEPCHGI)
 - Type of Visit (SVCNTMOD) with Standard CDISC CT e.g., TELEPHONE CALL, IN-PERSON

SDTM and ADaM Update

SDTM – SDTM IG 3.4 (cont)

VISITNUM	VISIT	SVPRESP	SVOCCUR	SVREASOC	SVCNTMOD	SVEPCHGI	VISITDY	SVSTDTC	SVE
8	FOLLOW-UP	Y	Y		IN PERSON			2020-02-27	2020-02-27
1	SCREEN	Y	Y		IN PERSON			2020-02-13	2020-02-18
2	DAY 1	Y	Y		IN PERSON		1	2020-02-19	2020-02-19
3	WEEK 1	Y	Y		IN PERSON		8	2020-02-25	2020-02-25
4	WEEK 2	Y	N	CLINIC CLOSED DUE TO BAD WEATHER			15		
4.1					REMOTE AUDIO VIDEO	Y		2020-03-07	2020-03-07
8	FOLLOW-UP	Y	Y		TELEPHONE CALL	Y		2020-03-16	2020-03-16



SDTM and ADaM Update

ADaM

- ADaM IG for Medical Device
 - Three standard ADaM classes (ADDL for ADSL, MDBDS for BDS and MDOCCDS for OCCDS)
 - See "ADaM Implementation Guide for Medical Devices" PharmaSUG 2021, Julia Yang, Karin LaPann, Silvia Faini
- ADaM IG for Non-Compartmental Analysis (NCA)
 - No new classes
 - Examples of BDS dataset
 - ADNCA (not a standard name)
 - specific flags to identify records not included in the analysis
 - additional dosing variables



SDTM and ADaM Update

ADaM – Updated IG

- ADaM Structure for Occurrence Data (OCCDS) 1.1
 - Three additional examples
 - Analysis of Adverse Events that Change over Time
 - Analysis of Adverse Events from Multiple Input Domains
 - Analysis of Protocol Deviations
 - New variables
 - TREMxxFL, where there are multiple periods analysis needs (example 4, Analysis of Treatment-emergent Adverse Events in a Cross-Over Interaction Study)
 - Concept of sub-class e.g., SubClass=ADVERSE EVENT (define 2.1)

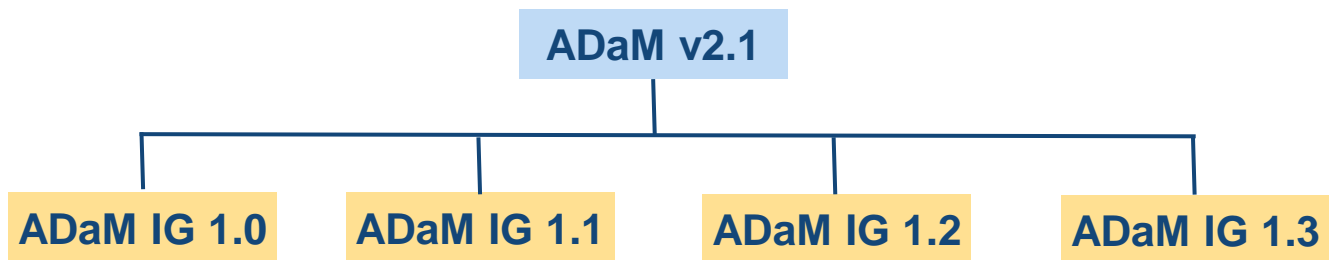
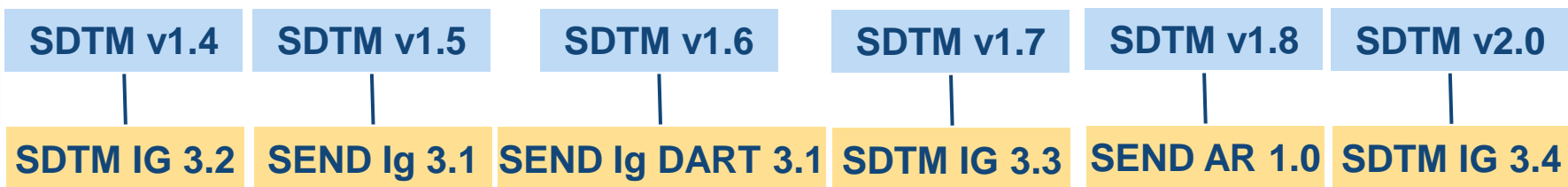
SDTM and ADaM Update

ADaM – Updated IG

Table 1.3.1.1 Other CDISC Documents and Their Applicability to ADaMIG Versions

Document	ADaMIG v1.0	ADaMIG v1.1	ADaMIG v1.2	ADaMIG v1.3
Analysis Data Model (ADaM) v2.1, December 2009	Foundational document for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaM Structure for Occurrence Data (OCCDS) Implementation Guide v1.1, November 2021	Not written for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaM Occurrence Data Structure (OCCDS) v1.0, February 2016	Not written for ADaMIG v1.0	Written for ADaMIG v1.1	Applicable	Applicable
ADaM Data Structure for Adverse Event Analysis v1.0, May 2012	Written for ADaMIG v1.0	Superseded by OCCDS v1.0	Superseded by OCCDS v1.0	Superseded by OCCDS v1.0
ADaM Implementation Guide for Non-compartmental Analysis Input Data (ADNCA), v1.0, November 2021	Not written for ADaMIG v2.0	Applicable	Applicable	Applicable
ADaM Implementation Guide for Medical Devices (ADaMIG-MD), v1.0, November 2021	Applicable	Applicable	Applicable	Applicable
ADaM Conformance Rules v4.0, November 2021	Applicable	Applicable	Applicable	Applicable
The ADaM Basic Data Structure for Time-to-Event Analyses v1.0, May 2012	Written for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaM Examples in Commonly Used Statistical Analysis Methods v1.0, December 2011	Written for ADaMIG v1.0	Applicable	Applicable	Applicable
Define-XML v2.0, March 2013	Applicable	Applicable	Applicable	Applicable
Analysis Results Metadata Specification for Define-XML Version 2 v1.0, January 2015	Applicable	Applicable	Applicable	Applicable

SDTM and ADaM Update



SDTM and ADaM Update

<https://wiki.cdisc.org/display/ITAUG/2022-03-30>

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2022-03-30

Created by Angelo Tinazzi, last modified just a moment ago

Agenda (copy of the slides

- CDISC and Data Submission What's New
- SDTM and ADaM Update
- Other Topics and Q&A

Additional Material:

- "ADaM Implementation Guide for Medical Devices" PharmaSUG 2021, Julia Yang, Karin LaPann, Silvia Faini ([PharmaSUG-2021-MD-035.pdf](#))
- "ADaM IG 1.3" ([ADaM IG 1.3](#))
- SDTM Ig 3.4 ([SDTM Ig 3.4](#))
- SDTM v2.0 ([SDTM v2.0](#))

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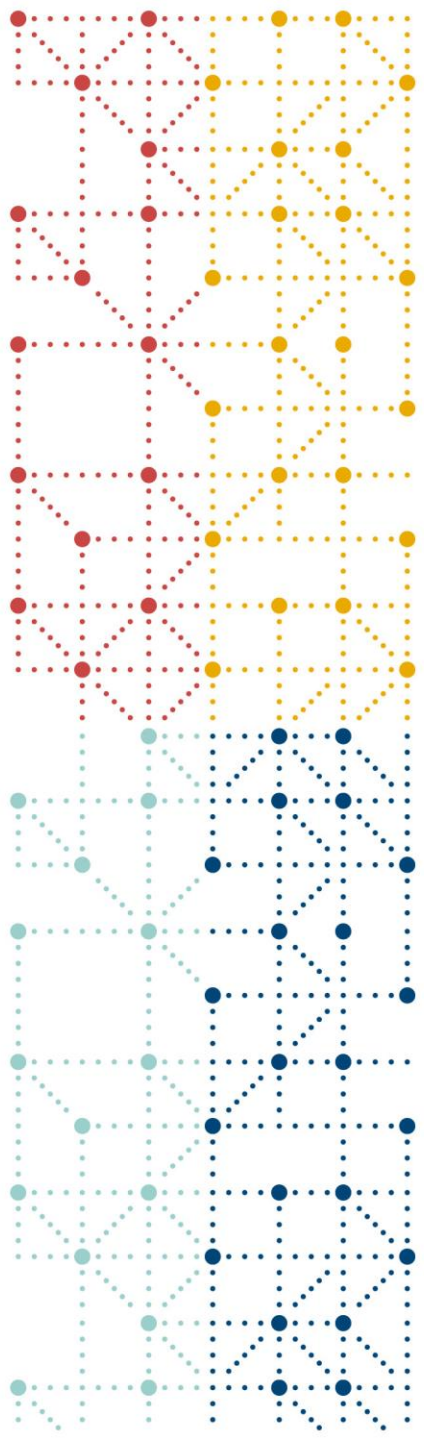
CDISC User Network Operational ...

PAGE TREE

Past Events

Regular Teleconferences

- 2015-2017
- 2018-02-07
- 2018-06-20
- 2018-11-28
- 2019-01-23
- 2020-07-01
- 2021-03-03
- 2021-09-22
- 2022-03-30



Other Topics and Q&A



Thank You!

Silvia Faini

silvia.Faini@cytel.com

Angelo Tinazzi

angelo.tinazzi@Cytel.com

The logo for CDISC, featuring the lowercase letters "cdisc" in a dark blue, sans-serif font. Above the letter "i" are three small colored dots: a red one, a yellow one, and a light blue one.