

CDISC Italian User Network TC

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



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Agenda

1. Mapping COVID-19 related data into SDTM
2. ADaM Implementation Guide - Medical Devices v1.0
3. Other New Standards or for Public Review and Regulatory Update
4. CDISC Event 2021
5. Other Topics

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CDISC ITA UN October 2020

[Slides Available]

<https://wiki.cdisc.org/pages/viewpage.action?pageId=113577697>



Mapping COVID-19 related data into SDTM

Stefania Mirandola

→ Slide Da IBIG Forum 2020



ADaM Implementation Guide Medical Devices v1.0

<https://www.cdisc.org/public-review/adam-implementation-guide-medical-devices-and-conformance-rules>

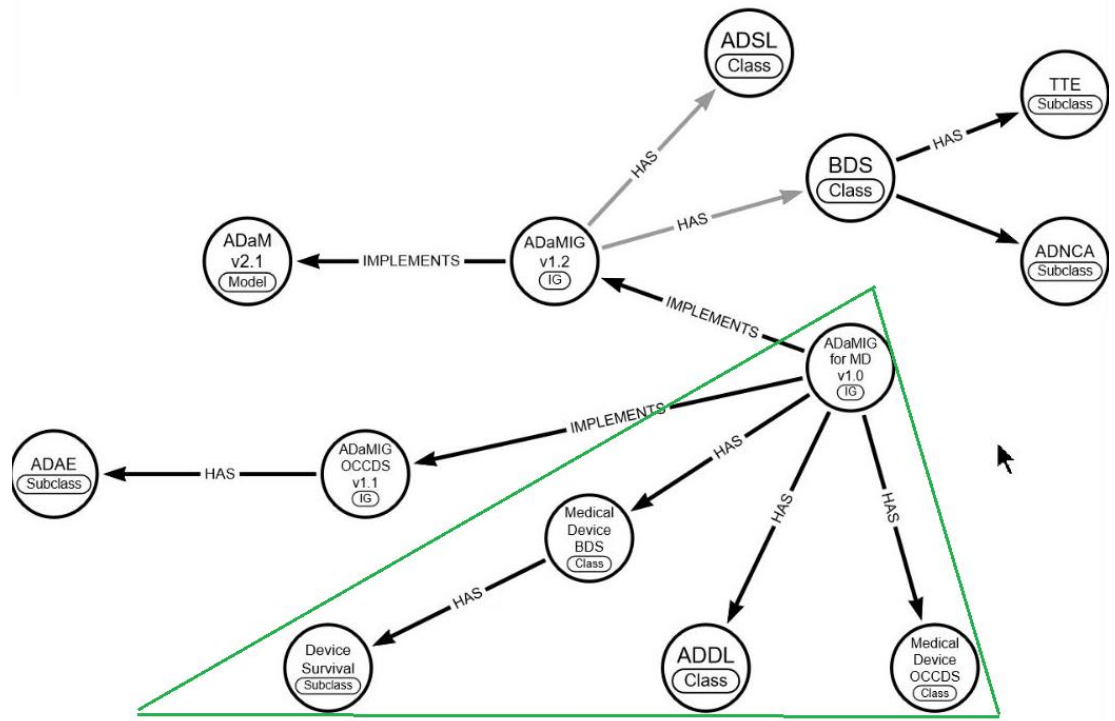
Comments due by 2 April 2021



ADaM Implementation Guide for Medical Devices v1.0

- Addresses typical needs for clinical trials using and analyzing medical device data.
- The guide introduces three new classes of data structures
 - ADDL → ADaM Device Level Analysis dataset
 - MDOCCDS → Medical Devices Occurrence Data Structure
 - MDBDS → Medical Devices Basic Data Structure
- One new subclass data structure under MDBDS for device survival analysis
 - Medical Device time-to-event MDTTE

ADaM Implementation Guide for Medical Devices v1.0





**Other New Standards or for Public
Review**

Regulatory Update

eCRF Portal

<https://www.cdisc.org/kb/ecrf>

The eCRF Portal consists of ready-to-use, CDASH-compliant, annotated eCRFs, available in PDF, HTML and XML, to use as is or import to an EDC system for customization.

To facilitate broad use, these eCRFs were developed based upon data management best practices, rather than features or limitations of any specific EDC system. The following guiding principles were followed:

- The Controlled Terminology publication from December 2019 was used.
- The layout shows one field per row on the eCRF. If the EDC system being used can accommodate more than one field per line, the layout may be adjusted accordingly
- Some fields (study ID, site ID, subject ID) were not included on the eCRFs because most EDC systems capture these as standard fields.
- For single check boxes, the text is shown, rather than the coded value
- Some codelists are subsetted. Users should create codelists based on their study parameters.
- Codelist order may be updated depending on user preference.
- In the Metadata Specification Excel files, the OID column format is IT.Name of the variable. The IT is a prefix appended during the creation of the Metadata Specification files and can be removed or amended once imported into the EDC system.

Adverse Events	Comments	Concomitant Medications
Demographics	Disposition	ECG Test Results - Central Reading
ECG Test Results - Central Reading with Investigator Assessment	Exposure	Exposure as Collected
Laboratory Test Results - Central Processing	Medical History	Physical Examination
Procedures	Subject Characteristics	Vital Signs



Next to be (soon) Released

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

In particular

- SDTMIG v3.4 / Version 2.0 November 2021
- SDTM Metadata Submission Guidelines v2.0 Q2 2021

Other Standard in Public Review

Standard/Therapeutic Area	Comments Due
ADaMIG v1.3 and Associated Conformance Rules	16 April 2021
COVID-19 Therapeutic Area User Guide v1.0	2 April 2021
ADaM Implementation Guide for Medical Devices and Conformance Rules	2 April 2021
CDASH Model v1.2 and CDASH Implementation Guide v2.2	22 March 2021
Type 1 Diabetes Pediatrics and Devices: ADaM Examples Module	11 March 2021
QRS Supplements	5 March 2021

Other Standard in Public Review - TAUGs

Therapeutic Area [▲]	Release Notes	Projecte d Publicati on
COVID-19 Therapeutic Area User Guide v1.0	<p>Public Review runs through 2 Apr 2021.*</p> <p>*CDISC expedited our standards development process to release an Interim User Guide for COVID-19 in early April 2020. We are now developing a Therapeutic Area User Guide for COVID-19 following our standards development process outlined in COP-001.</p>	Q2 2021
Crohn's Disease Therapeutic Area User Guide v1.0	Resolving Public Comments for Work Packages 1 and 2.	Q2 2021
Diabetes Type 1 Pediatrics and Devices: ADaM Examples Module	Public Review runs through 11 Mar 2021.	Q2 2021
Diabetes Type 1 Therapeutic Area User Guide - Prevention	Preparing for Public Review.	Q2 2021
Diabetes Type 1 Therapeutic Area User Guide v1.0 - Exercise and Nutrition Modules	Resolving Public Comments.	Q2 2021
Pancreatic Cancer Therapeutic Area User Guide v1.0	Preparing for Public Review.	Q3 2021
Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0	Preparing for Public Review.	Q3 2021

TAUGs Available or Under Development

<https://www.cdisc.org/standards/therapeutic-areas>

Acute Kidney Injury	Diabetes	Kidney Transplant	QT Studies
Alzheimer's	Diabetes Type 1 - Exercise and Nutrition	Lung Cancer	Rheumatoid Arthritis
Asthma	Diabetes Type 1 - Pediatrics and Devices	Major Depressive Disorder	Schizophrenia
Breast Cancer	Diabetes Type 1 - Prevention	Malaria	Traditional Chinese Medicine - Acupuncture
Cardiovascular	Diabetic Kidney Disease	Multiple Sclerosis	Traditional Chinese Medicine - Coronary
CDAD	Duchenne Muscular Dystrophy	Nutrition	Artery Disease-Angina
Colorectal Cancer	Dyslipidemia	Pain	Traumatic Brain Injury
COPD	Ebola	Pancreatic Cancer	Tuberculosis
COVID-19	Heart Failure	Parkinson's Disease	Vaccines
Crohn's Disease	Hepatitis C	Polycystic Kidney Disease	Virology
	HIV	Post Traumatic Stress Disorder	
	Huntington's Disease	Prostate Cancer	
	Influenza	Psoriasis	

Other ADaM documents under finalization

Standard ▲	Release Notes	Projected Publication
ADaM Geriatric Depression Scale (GDS) Short Form Questionnaire Supplement	Preparing for Publication.	Q1 2021
ADaM OCCDS v1.1 and Conformance Rules	Resolving Public Comments.	November Release 2021
ADaM Oncology Examples	In Development.	Q4 2021
ADaM Traceability Examples	In Development.	Q4 2021
ADaMIG Medical Devices v1.0 and Conformance Rules	Public Review runs through 2 Apr 2021.	November Release 2021
ADaMIG Non-compartmental Analysis v1.0 and Conformance Rules	Resolving Public Comments.	November Release 2021
ADaMIG v1.3 and Conformance Rules	Public Review runs through 16 Apr 2021.	November Release 2021



Other ADaM documents under finalization

ADaM Traceability Examples

- Traceability with Parameters from Multiple Input Datasets
- Traceability When Multiple Datasets Are Merged
- Traceability When Adding a Row to a BDS Dataset
- Using an Intermediate Dataset for ADSL Traceability
- Complex Traceability Example
- Traceability When Using a Look-Up Table

ADaM Method Used in Oncology

- ADSL Oncology Specific Variables
- Cycle Derivation
- CTCAE Lab Derivation
- Exposure



Regulatory Update

FDA Study Data Technical Conformance Guide v.4.6 November 2020

<https://www.fda.gov/media/143550/download>

- No major Update

FDA Data Standards Catalogs v6.6 July 2020

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

Regulatory Update

FDA Data Standards Catalogs v6.6 July 2020

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

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Supported Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends (MM/DD/YYYY)
Clinical study datasets	SDTM	XPT	CDISC	1.2	3.1.2	CDER, CBER	10/30/2009	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]
Clinical study datasets	SDTM	XPT	CDISC	1.2	Version 3.1.2 Amendment 1	CDER, CBER	08/07/2013	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]
Clinical study datasets	SDTM	XPT	CDISC	1.3	3.1.3	CDER, CBER	12/01/2012	03/15/2021	12/17/2016 [1] 12/17/2017 [2]	03/15/2021
Clinical study datasets	SDTM	XPT	CDISC	1.4	3.2	CDER, CBER	08/17/2015		03/15/2018 [1] 03/15/2019 [2]	
Clinical study datasets	SDTM	XPT	CDISC	1.7	3.3	CDER, CBER	03/15/2021		03/15/2023	

- **Date Support Begins:** It means FDA is ready to accept SDTM IG 3.3 by 15th March 2021
- **Date Support Ends:** It means a study started after 15 March 2021 can be not submitted using SDTM IG 3.1.3
- **Date Requirement Begins:** it means a study started after 15th March 2023 should SDTM IG 3.3



PhUSE - Optimizing the Use of Data Standards

<https://phuse.global/Deliverables/1> --> NEW PHUSE WEBSITE

- FDA and PMDA Study Data Submission Distinctions (Dec-2020, Update Feb-2021)
- Data Standards for Non-interventional Studies (Sep-2020)
- Industry Experiences Submitting Standardised Study Data to Regulatory Authorities (Sep-2020)
- Integration Strategies in Support of ISS/ISE Submissions (Oct-2020)



CDISC Events 2021

CDISC Events 2021

- The Virtual 2021 CDISC Europe Interchange will be held over two and a half days, 28 - 30 April: **CDISC Europe Interchange + CDISC TechniCon**
- This year, the Europe Interchange and CDISC TechniCon will be combined into a single event, and attendees that register for the Europe Interchange will gain access to the TechniCon - get two conferences for the price of one!

	Discounted Fees by 26 MAR	Full Fees
Government Agency	\$180	\$200
CDISC Platinum Member	\$432	\$480
CDISC Gold Member	\$576	\$640
Non-Member	\$720	\$800



CDISC Events 2021

- **CDISC Europe Interchange 28-29 Apr 2021 9:00-17:30 CET**
 - Global Regulatory Updates → news NMPA + Roundtable with representatives from DKMA, PMDA, E3C and NMPA
 - CDISC Updates, CDISC 360 Update
 - ADaM, CDISC Foundational, Global Submissions
 - Real World Data
 - Tech-Enabled Standards
 - COVID-19 Topics
- **CDISC Europe Interchange 30 Apr 2021 9:00-13:00 CET**
 - Exhibitor and Attendee Virtual Meetups



CDISC Events 2021

- **CDISC TechniCon 30 Apr 2021 13:00-17:30 CET**
 - Mapping EHR Data to EDC - A Case Study
 - System Automation for CDISC Standards: SDTM-ETL
 - System Automation for CDISC Standards: A3 MDR
 - How to Comply with CDISC Standards in Clinical Trial Design and Build
 - CDISC Library Browser
 - System Automation for CDISC Standards: illuminate®
 - National Cancer Institute Enterprise Vocabulary Services (EVS) REST API

CDISC Events 2021

<https://www.cdisc.org/events/interchange/2021-europe-interchange/program>

A graphic with a blue background and a faint city skyline. The text is centered and reads: "Program", "Confirmed presenters from EMA, FDA, PMDA and the Danish Medicines Agency!", and a "View Here" button.

Program

Confirmed presenters from EMA,
FDA, PMDA and the Danish
Medicines Agency!

[View Here](#)



CDISC Events 2021

- Japan Interchange (Virtual Event) 10 - 11 June 9:00-17:30 Japan Time
- China Interchange (in-person in Beijing, China) 6 - 7 Aug 9:00-17:30 China Time
- US Interchange (in-person in Bethesda, Maryland), with education courses on 18, 19 and 22 October, and the Main Conference on 20 - 21 October



Upcoming webinars

- QRS Office Hours, 16 MAR 2021
- Public Review Webinar: Pancreatic Cancer Therapeutic Area User Guide, 25 MAR 2021
- CDISC Library: Ideas for using the CDISC Library and a Look at What's Coming Next, 8 APR 2021

<https://www.cdisc.org/education/webinars>

Education and Certification (SDTM Pilot)

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

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

Description	Exam Scope	Registration	FAQ
<h2>Register for CDISC Standards Certification</h2> <p>To participate in the pilot exam and benefit from a discounted rate of \$300, please click on the button below to Certification program.</p> <p>Certification Program Details:</p> <ul style="list-style-type: none">• Exam fee: \$500• NOV 2020-APR 2021 discounted pilot rate: \$300• Passing exam grade establishes certification for 3 years• Recertification required after 3 years• Recertification exam fee: \$500• No annual maintenance fees• Group discounts available• Three years' experience working with CDISC standards is recommended to successfully complete exam• Contact CDISC Certification for more information			



CDISC Events Italy - Virtual

- define-xml e CDISC Submission Ready Documents
 - 2 Edition – May to be Confirmed
- Italian UN
 - September – To be confirmed



Thank You!

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The logo for CDISC, featuring the word "cdisc" in a bold, blue, sans-serif font. Above the letters "i", "s", and "c" are three small colored dots: red, yellow, and light blue.