



News from CDISC and Other News

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February 20, 2020



Pfizer
La Jolla, CA

CDISC: Current Public Reviews

CURRENT PUBLIC REVIEWS

Psoriasis Therapeutic Area User Guide v1.0

Comments Due by: 17 Mar 2020

ADaM OCCDS v1.1

Comments Due by: 20 Mar 2020

Chinese Translations of SDTMIG v3.2, ADaMIG v1.1, ADaM OCCDS v1.0, ADaM v2.1

Comments Due by: 20 Mar 2020

LOINC to LB Mapping File

Comments Due by: 11 Apr 2020

CDISC: Standards In Development

Foundational

For current versions of the standards, please visit the [Standards Home Page](#).

Standard	Development	Public Review	Release Notes	Projected Publication Date
ADaM Data Structures for Integration	Completed	Completed	Resolving Public Comments.	2020
ADaM Geriatric Depression Scale (GDS) Short Form Questionnaire Supplement	Completed	Completed	Resolving Public Comments.	2020
ADaM Medical Devices v1.0	In Progress		In Development.	2020
ADaM Non-compartmental Analysis IG v1.0	In Progress		In Development.	2021
ADaM OCCDS v1.1	Completed	Comments Due 20 Mar 2020	Public Review runs through 20 Mar.	2021
ADaM Oncology	In Progress		In Development.	2020
ADaM Traceability Examples	In Progress		In Development.	2020
CDASH SAE v2.0 Supplement	In Progress		In Development.	2021
Conformance Rules v1.0 for SENDIG v3.0	Completed		Resolving Public Comments.	2020
Conformance Rules v1.0 for SENDIG v3.1	In Progress			2020
Conformance Rules v1.1 for SDTMIG v3.2 & v3.3	Completed		Resolving Public Comments.	2020
SDTM Metadata Submission Guidelines v2.0	In Progress		In Development.	2020
SDTM v2.0	Completed			2020
SDTM Variable Definitions	Completed	Completed	Resolving Public Comments.	2020
SDTMIG v3.4	Completed			2020
SENDIG v3.1.1 PP, PC Updates	Completed	Completed	Preparing for Publication.	2020
SENDIG-Genotoxicity v1.0	In Progress		In Development.	2020

CDISC: Standards in Development (Cont'd)

Data Exchange

For current versions of the Data Exchange standards, please visit the [Data Exchange page](#).

Standard	Development	Public Review	Release Notes	Projected Publication Date
Define-XML v2.1 Conformance Rules	In Progress		In Development.	2020
ODM v2.0	In Progress		In Development.	2020

Therapeutic Areas

For current versions of the Therapeutic Area (TA) standards, please visit the [TA Home Page](#).

Therapeutic Area	Development	Public Review	Release Notes	Projected Publication Date
Acute Kidney Injury Therapeutic Area User Guide v1.0	Completed		Preparing for Public Review.	2020
Crohn's Disease Therapeutic Area User Guide v1.0	In Progress		In Development.	2021
Diabetes - Type 1 Therapeutic Area User Guide v1.0	Completed	Completed	Resolving Public Comments.	2020
Heart Failure Therapeutic Area User Guide v1.0	Completed		Preparing for Public Review.	2020
Pancreatic Cancer Therapeutic Area User Guide v1.0	In Progress		In Development.	2021
Psoriasis Therapeutic Area User Guide v1.0	Completed	Comments Due 16 Mar 2020	Public Review runs through 16 Mar.	2020
Traditional Chinese Medicine - Acupuncture	In Progress		In Development.	2020

Newly Added FDA Guidance Documents

- Adaptive Design Clinical Trials for Drugs and Biologics Guidance for Industry – Final November 2019
- Electronic Submission of IND Safety Reports Technical Conformance Guide – Final October 2019

FDA Guidance Agenda 2020

CATEGORY – Biostatistics

- Adjustment for Covariates in Randomized Clinical Trials for Drugs and Biologics Using Nonlinear Models
- Multiple Endpoints in Clinical Trials
- Statistical Aspects of the Design, Analysis and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals

Technical Rejection Criteria For Study Data

- Technical rejection criteria are being added to the existing electronic common technical document (eCTD) validation criteria to enforce deadlines. The FDA will give the industry **90 days'** notice on the eCTD web page prior to the criteria described in the technical rejection criteria becoming effective.
 - As of 10/9/2019 there were updates related to TS.xpt and STUDYID.

Upcoming Events

- Users Network
 - Bay Area CDISC Network Meeting – Date TBD/Spring
- CDISC Interchanges
- PhUSE CSS/PhUSE US Connect

PHUSE US Connect 2020

8 Mar 2020 to 11 Mar 2020

Orlando, Florida, United States

PHUSE 2020 Computational Science Symposium



PHUSE 2020 Computational Science Symposium

June 7th–9th 2020
Silver Spring, Maryland

2020



2020 CDISC Europe Interchange

Berlin, Germany
30 March - 03 April 2020



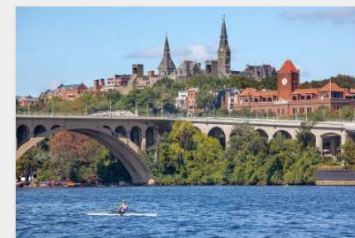
2020 CDISC Japan Interchange

Tokyo, Japan
20 - 22 May 2020



2020 CDISC China Interchange

Beijing, China
7 - 8 August 2020



2020 CDISC US Interchange

Bethesda, MD USA
05 - 09 October 2020



Thank You



Keep in touch and say involved!

- e-mail
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- San Diego CDISC Users Network on LinkedIn
<https://www.linkedin.com/groups/4055118/>
- SDCUN Wiki
<https://wiki.cdisc.org/display/SDUN/San+Diego+User+Network+Home>