CDISC Requirements FDA – PMDA

14-Mar-2023

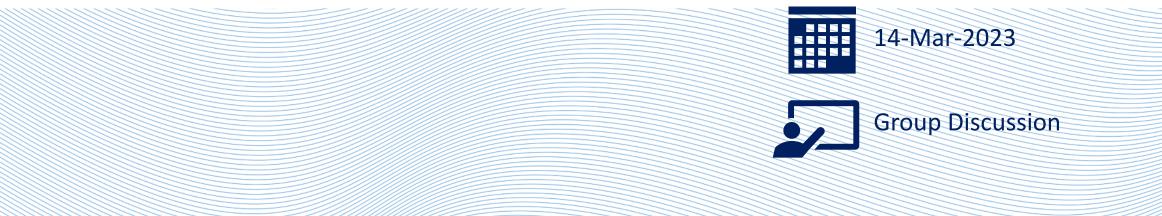Group Discussion

Recent CDISC Mailings

Date: 2023-03-07, Subject: FDA Mandate, Diff Reports v2

FDA Mandate of CDISC Standards

Effective 15 March 2023 all studies must use the following CDISC standards in submissions to US FDA:

- SDTMIG v3.3
- SENDIG v3.1.1
- SENDIG v3.1
- SENDIG-AR v1.0
- SENDIG-DART v1.1
- Define-XML v2.1

For more information: FDA Study Data Standards Resources

Date: 2023-03-08, Subject: CORRECTION: FDA Mandate, Diff Reports v2

FDA Requirement for Studies Starting On or After   March 15 2023

The FDA Data Standards Catalog states certain CDISC Standards will be required for submissions of studies that start on or after March 15 2023. The CDISC Library DIFF Report Generation Tool helps users assess changes when up-versioning standards.

FDA Study Data Standards Catalog v9.0

Sheet: Instr. & Column Descriptions

- *The FDA Data Standards Catalog (Catalog) lists the data standards and terminologies that FDA supports for use in regulatory submissions to better enable the evaluation of safety, effectiveness, and quality of FDA-regulated products. In addition, the FDA has the statutory and regulatory authority to require certain standards and terminologies and these are identified in the Catalog with the date the requirement begins and, as needed, the date the requirement ends, and information sources. The submission of data using standards or terminologies not listed in the Catalog should be discussed with the Agency in advance. Where the Catalog expresses support for more than one standard or terminology for a specific use, the sponsor or applicant may select one to use or can discuss, as appropriate, with their review division. Sponsors and applicants should review the Catalog terms below, as well as any references associated with specific standards or terminologies.*

Use	Data Standard	Exchange Format	Standards Development Organization (SDO)	Version(s)	Designated Implementation Guide Version(s)	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY) [10] [11]	Date Requirement Ends (MM/DD/YYYY)
Clinical study datasets	SDTM	XPT	CDISC	SDTM v 1.4	3.2	CDER, CBER	08/17/2015		03/15/2018 [1] 03/15/2019 [2]	
Clinical study datasets	SDTM	XPT	CDISC	SDTM v 1.7	3.3	CDER, CBER	03/15/2021		03/15/2023	
Study data definition	Define	XML	CDISC	2	N/A	CDER, CBER	08/07/2013		12/17/2016 [1] 12/17/2017 [2]	
Study data definition	Define	XML	CDISC	2.1	N/A	CDER, CBER	03/15/2021		03/15/2023	

PMDA Data Standards Catalog 2023-02-28

PMDA Data Standards Catalog (2023-02-28) - Data Exchange Standards							
Use	**Data Exchange Standard**	**Supported Version(s)**	**Implementation Guide Version**	**Exchange Format**	**Date Support Begins (YYYY-MM-DD)**	**Date Support Ends (YYYY-MM-DD)**	**Notes**
Clinical study datasets - Transport	SAS Transport (XPORT)	5	-	XPT	2016-10-01		
Clinical study datasets	SDTM	1.7	3.3	XPT	2023-04-01		
Clinical study datasets	SDTM	1.4	3.2	XPT	2016-10-01		
Clinical study datasets	SDTM	1.3	3.1.3	XPT	2016-10-01		
Clinical study datasets	SDTM	1.2	3.1.2 Amendment1	XPT	2016-10-01		
Clinical study datasets	SDTM	1.2	3.1.2	XPT	2016-10-01		
Clinical study datasets	ADaM	2.1	1.1	XPT	2022-01-01		
Clinical study datasets	ADaM	2.1	1.0	XPT	2016-10-01		
Clinical study data definition files	Define	2.0	-	XML	2016-10-01		
Clinical study data definition files	Define	1.0	-	XML	2016-10-01	2025-03-31	
Documents	PDF	1.4-1.7	-	PDF	2016-10-01		In principle, eCTD PDF specification should be referenced for details.