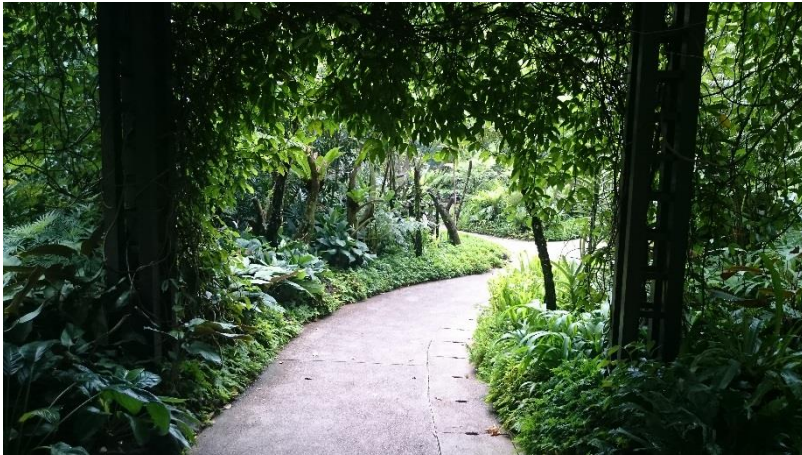




DATA STANDARDS DECISIONS

Insight → Interpretation → Implementation



FDA Submission Requirements

– How to interpret the FDA Data Standards Catalogue for nonclinical data

Gitte Frausing

Principal Consultant

Data Standards Decisions

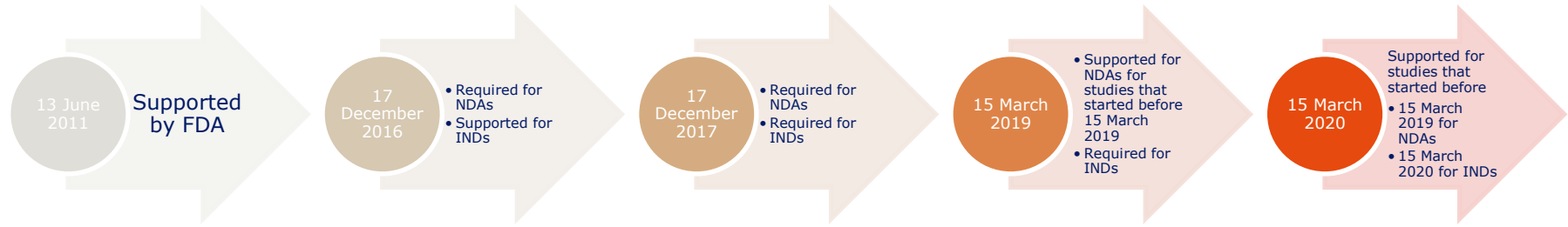
FDA Data Standards Catalog v4.7 (09-01-2017) - Supported and Required Standards

This table contains a listing of the data exchange, file formats and terminology standards supported at FDA. These standards have gone through all the steps necessary to make this part of the regulatory review process, including posting of regulatory guidance documents and associated implementation guidelines and technical specifications. The submission of standardized data using any standard not listed, or to an FDA Center not listed, should be discussed with the Agency in advance. This catalog is incorporated by reference in the guidance to industry, *Providing Regulatory Submissions in Electronic format-Standardized Study Data* (<http://www.fda.gov/downloads/Drugs/Guidances/UCM292334.pdf>).

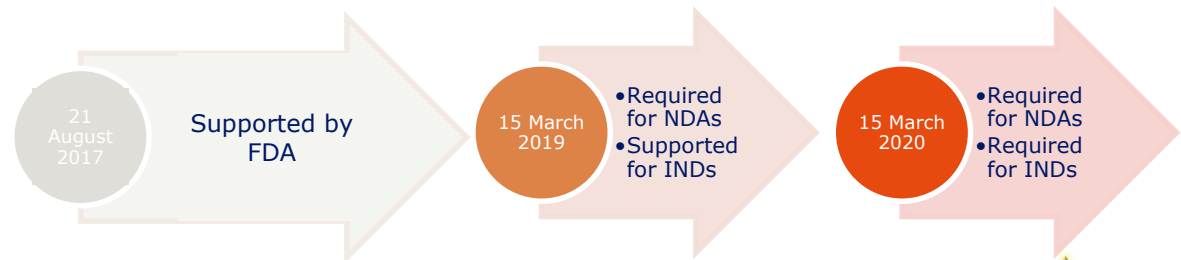
Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends	Regulatory Reference and Information Sources
Clinical study datasets	SDTM	XPT	CDISC	1,3	3.1.3	CDER, CBER	12-01-2012		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
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]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1,2	3.1.2	CDER, CBER	30-10-2009	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1,1	3.1.1	CDER, CBER	Ongoing	01-28-2015			CDISC.org - SDTM
Clinical study datasets	Analysis Data Model (ADaM)	XPT	CDISC	2,1	1,0	CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - ADaM
Animal study datasets	Standard for Exchange of Nonclinical Data (SEND)	XPT	CDISC	1,2	3,0	CDER	06-13-2011	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]	CDISC.org - SEND
Animal study datasets	SEND	XPT	CDISC	1,5	3,1	CDER	08-21-2017		3/15/2019 [1] 3/15/2020 [2]		CDISC.org - SEND
Study data definition	Define	XML	CDISC	1,0	N/A	CDER, CBER, CDRH	Ongoing	03-15-2018	12/17/2016 [1] 12/17/2017 [2]		CDISC.org - Define-XML
Study data definition	Define	XML	CDISC	2,0	N/A	CDER, CBER, CDRH	08-07-2013		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - Define-XML

SEND Requirements at FDA

SEND 3.0



SEND 3.1



- The requirements are based on the Study Start date for studies included in submissions to FDA.
- The Study Start date for nonclinical studies is the date the study plan is signed.

