

US FDA's Study Data Policy Framework and Recent Activities

Helena Sviglin, US FDA CDER

Office of Strategic Policy

Data Standards Staff

April 2024

Current Contributions:

- Internal policy development and study data governance
- Chair, FDA Study Data Technical Conformance Guide (sdTCG)
- Chair, FDA Data Standards Catalog
- Chair, FDA Business Rules
- eData responses
- I AM NOT A LAWYER



Helena Sviglin (she/her),
FDA CDER Office of
Strategic Programs



FDA Study Data Policy Framework Overview

Providing Regulatory Submissions in
Electronic Format — Submissions Under
Section 745A(a) of the Federal Food,
Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2014
Electronic Submissions

Primary Statute



[Search for FDA Guidance Documents | FDA
\(fda.gov/regulatory-information/search-fda-
guidance-documents\)](https://www.fda.gov/regulatory-information/search-fda-guidance-documents)

[Study Data Standards Resources | FDA
\(fda.gov/industry/fda-data-standards-advisory-
board/study-data-standards-resources\)](https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources)

FDA's Study Data Policy Framework



Binding Guidance (sitting under 745A(a))

- eStudy Data
- Real World Data
- eCTD

Incorporated by reference into Binding Guidance

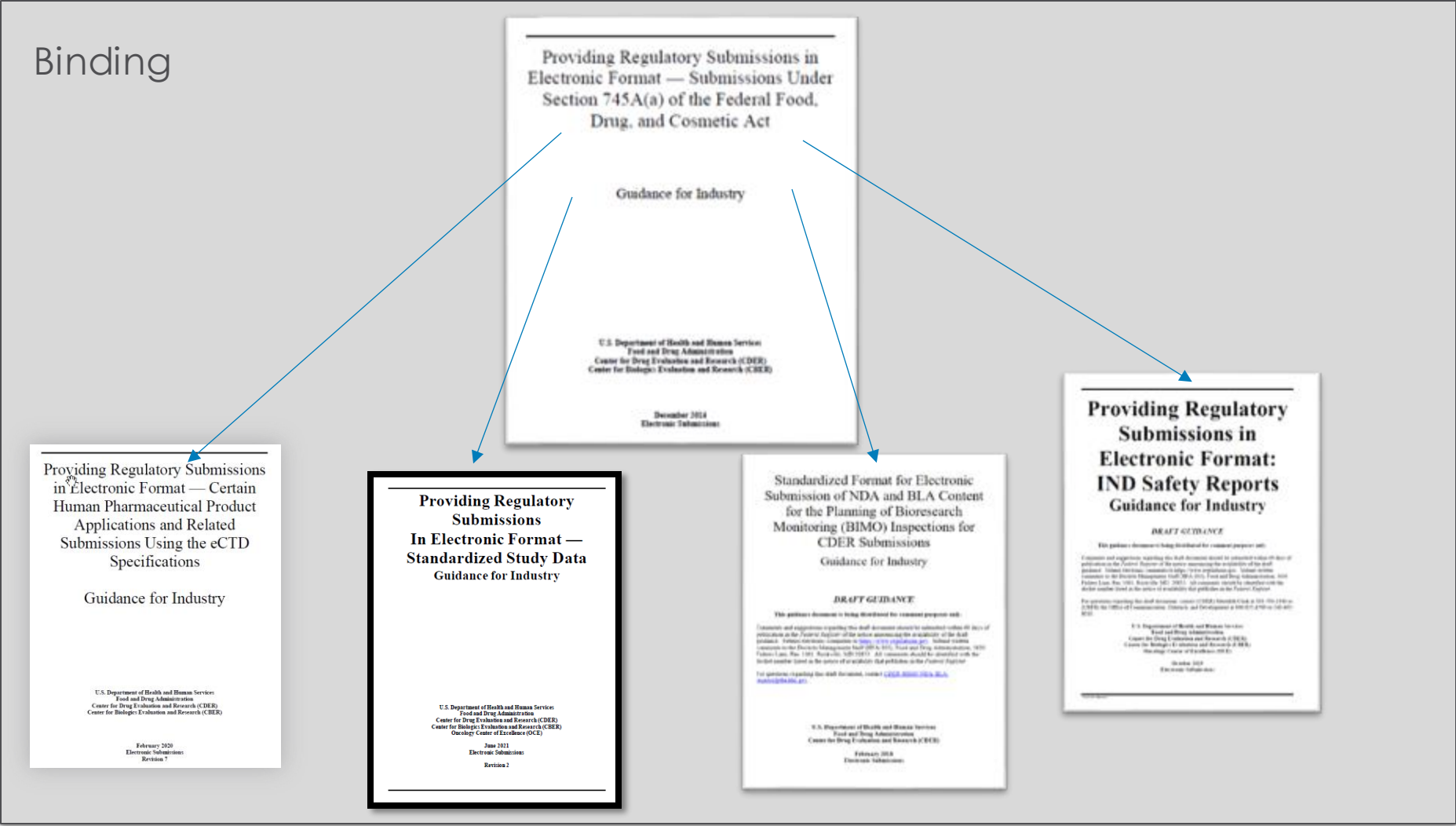
- Technical Conformance Guides (TCGs)
- FDA Data Standards Catalog (Catalog)
- Certain Technical Specifications (Tech Specs)

[Search for FDA Guidance Documents | FDA \(fda.gov/regulatory-information/search-fda-guidance-documents\)](https://www.fda.gov/regulatory-information/search-fda-guidance-documents)

[Study Data Standards Resources | FDA \(fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources\)](https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources)

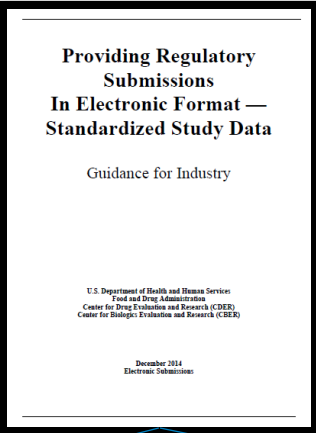
How FDA communicates technical requirements for submitting study data

Binding



Focus on study data

Binding



of description of column headings in table 4. Column Descriptions tab. Items with data models are in bold with blue SF. Dependent properties (i.e., R), neither of document for each model are listed below. Sorting may obscure the

	Standard	Exchange Format	SDO	Property	Referenced Properties	FDA Element(s)	Data Support Region	Data Support Ends	Data Requirement Region (M/F)	Data Requirement Ends
medical study	SDMO	SDTE	SDMO	SDMO.S1.0		CDER	SDMO.S1.0	SDMO.S1.0	CDER	SDMO.S1.0
medical study	SDMO	SDTE	SDMO	SDMO.S1.1		CDER	SDMO.S1.1	SDMO.S1.1	CDER	SDMO.S1.1
medical study	SDMO	SDTE	SDMO	SDMO.S1.2		CDER	SDMO.S1.2	SDMO.S1.2	CDER	SDMO.S1.2
medical study	SDMO	SDTE	SDMO	SDMO.S1.3		CDER	SDMO.S1.3	SDMO.S1.3	CDER	SDMO.S1.3
medical study	SDMO	SDTE	SDMO	SDMO.S1.4		CDER	SDMO.S1.4	SDMO.S1.4	CDER	SDMO.S1.4
medical study	SDMO	SDTE	SDMO	SDMO.S1.5		CDER	SDMO.S1.5	SDMO.S1.5	CDER	SDMO.S1.5
medical study	SDMO	SDTE	SDMO	SDMO.S1.6		CDER	SDMO.S1.6	SDMO.S1.6	CDER	SDMO.S1.6
medical study	SDMO	SDTE	SDMO	SDMO.S1.7		CDER	SDMO.S1.7	SDMO.S1.7	CDER	SDMO.S1.7
medical study	SDMO	SDTE	SDMO	SDMO.S1.8		CDER	SDMO.S1.8	SDMO.S1.8	CDER	SDMO.S1.8

Incorporated by reference into Binding Guidance



FDA Data Standards Catalog (Catalog) Updates

FDA Data Standards Catalog Recent Updates



GUIDANCE DOCUMENT

Data Standards Catalog

OCTOBER 2023

Final Level 2 Guidance

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Issued by: Center for Biologics Evaluation and Research
Center for Devices and Radiological Health
Center for Drug Evaluation and Research
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

[Download the Final Guidance](#) [Data Standards Catalog | FDA](#)

The FDA Data Standards Catalog Structure



The contents of the Catalog are housed in a spreadsheet with multiple tabs:

- Instructions
- Column Descriptions
- Submission Data Standards
- Submission Data Terminologies
- Abbreviations
- Change History

New with Catalog version 10.3 (last reported on 10.0)



FDA Data Standards Catalog v10.3- Change History		
Date	Version	Notes
4/12/2024	10.3	Submission Data Standards tab - Added SENDIG-ARv1.0 with Date Support Begins and Date Requirement Begins for CBER
12/13/2023	10.2	Submission Data Standards tab - Added SDTMIGv3.4 with Date Support Begins and Date Requirement Begins - Added SDTMv2.0 with Date Support Begins and Date Requirement Begins - Added SENDIG-Genetoxv1.0 with Date Support Begins and Date Requirement Begins - Updated Date Requirements Ends for SDTMIGv3.2
10/17/2023	10.1	Submission Data Standards tab ~correction of Date Requirement Ends for ADaMv2.1 ~correction of Date Support Ends for ADaMv2.1
		Submission Data Standards tab

Full description of column headings in Instr.& Column Descriptions tab. Rows with data models are in bold with blue fill. D

Use	Standard	Exchange Format	SDO	Property	Related Properties	FDA Center(s)	Date
Clinical study datasets	ADaM	XPT	CDISC	ADaMv2.1		CDER, CBER	06/2017
Clinical study datasets	ADaM	XPT	CDISC	ADaMIGv1.0		CDER, CBER	06/2017
Clinical study datasets	ADaM	XPT	CDISC	ADaMIGv1.1		CDER, CBER	10/2017
Clinical study datasets	ADaM	XPT	CDISC	ADaMIGv1.2		CDER, CBER	07/2018
Clinical study datasets	ADaM	XPT	CDISC	ADaMIGv1.3		CDER, CBER	07/2018
Clinical study datasets	SDTM	XPT	CDISC	SDTMv1.1		CDER, CBER	06/2017
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.1.1		CDER, CBER	06/2017
Clinical and Nonclinical study datasets	SDTM, SEND	XPT	CDISC	SDTMv1.2		CDER, CBER	10/2017
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.1.2		CDER, CBER	10/2017
Clinical study datasets	SDTM	XPT	CDISC	SDTMIG Version 3.1.2 Amendment 1		CDER, CBER	08/2018
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.0		CDER	06/2017
Clinical study datasets	SDTM	XPT	CDISC	SDTMv1.3		CDER, CBER	12/2017
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.1.3		CDER, CBER	12/2017
Clinical study datasets	SDTM	XPT	CDISC	SDTMv1.4		CDER, CBER	08/2018
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.2		CDER, CBER	08/2018
Nonclinical study datasets	SEND	XPT	CDISC	SDTMv1.5		CDER	08/2018
Nonclinical study datasets	SEND	XPT	CDISC	SDTMv1.5		CBER	03/2018
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1		CDER	08/2018
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1		CBER	07/2018
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1.1		CDER, CBER	02/2019
Nonclinical study datasets	SEND	XPT	CDISC	SENDIG-Genotaxv1.0		CDER, CBER	12/2018
Nonclinical study datasets	SEND	XPT	CDISC	SDTMv1.6		CDER	03/2019
Nonclinical study datasets	SEND	XPT	CDISC	SENDIG-DARTv1.1		CDER	03/2019
Clinical study datasets	SDTM	XPT	CDISC	SDTMv1.7		CDER, CBER	07/2019
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.3		CDER, CBER	07/2019
Nonclinical study datasets	SDTM	XPT	CDISC	SDTMv1.8		CDER	03/2019
Nonclinical study datasets	SDTM	XPT	CDISC	SENDIG-ARv1.0		CDER	03/2019
Nonclinical study datasets	SDTM	XPT	CDISC	SENDIG-ARv1.0		CBER	03/2019
Study data definition	Define	XML	CDISC	Define.xmlv1.0		CDER, CBER	06/2017
Study data definition	Define	XML	CDISC	Define.xmlv2.0		CDER, CBER	08/2018
Study data definition	Define	XML	CDISC	Define.xmlv2.1		CDER, CBER	07/2019
Clinical study datasets	SDTM	XPT	CDISC	SDTMv2.0		CDER, CBER	12/2019
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.4		CDER, CBER	12/2019



Let's take a look at the Catalog

[Data Standards Catalog | FDA](#)

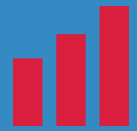
Problem: Please share thoughts.
How best to display Properties that don't follow the model and IG outline?

FDA Data Standards Catalog v10.3

Full description of column headings in Instr.& Column Descriptions tab. Rows with data models are in bold with blue fill. Dependant properties (i.e., IG, technical document) for each model are in bold with blue fill.

Use	Standard	Exchange Format	SDO	Property	Related Properties	FDA Center(s)	Date Support Begins	Date Support Ends	D
Nonclinical study datasets	SDTM	XPT	CDISC	SENDIG-ARv1.0		CDER	03/11/2020		0:
Nonclinical study datasets	SDTM	XPT	CDISC	SENDIG-ARv1.0		CDER	03/11/2020		0:
Nonclinical study datasets	SDTM	XPT	CDISC	SENDIG-ARv1.0		CDER	03/11/2020		0:
Nonclinical study datasets	SDTM	XPT	CDISC	SENDIG-ARv1.0		CDER	03/11/2020		0:
Study data definition	Define	XML	CDISC	Define.xmlv1.0		CDER, CBER	Ongoing	03/15/2018 (12)	12
Study data definition	Define	XML	CDISC	Define.xmlv2.0		CDER, CBER	08/07/2013		12
Study data definition	Define	XML	CDISC	Define.xmlv2.1		CDER, CBER	07/07/2020		0:

[Data Standards Catalog | FDA](#)



Study Data Technical Conformance Guide (sdTCG) Updates

GUIDANCE DOCUMENT

Study Data Technical Conformance Guide - Technical Specifications Document

MARCH 2024

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Final

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Docket Number: [FDA-2014-D-0092](#)

Issued by: Center for Drug Evaluation and Research

[Study Data Technical Conformance Guide -
Technical Specifications Document | FDA](#)

FDA sdTCG Recent Updates



		Glossary – Addition of T1E and SDC
December 2023	5.6	Section 4.1.1.3 (SDTM Domain Specifications) – Updated to address LOINC Section 4.1.3.4.2 (Scope of SEND for SENDIG-Animal Rule v1.0) – Updated for clarity Section 5.3 (List of FDA Technical Specification Documents) – Section updated Section 6.7 (Laboratory Tests) – Updated for clarity
March 2024	5.7	Section 4.1.1.3 (SDTM Domain Specifications) – Updates for LB and LC Domain Section 4.1.3.2 (General Considerations) – Addressed ELTM and DOSDUR Section 4.1.3.3 (SEND Domain Specifications) – Updates for LB Domain Section 4.1.4.3 (Naming Conventions in SDTM and SEND) – Addressed naming for drugs and metabolites Section 8.2.2.3 (Technical Rejection Criteria and Use of a Simplified ts.xpt for Nonclinical Studies) – Language updated Appendix B – Added new TSPARMCD Appendix C – Added reference to Section 4.1.3.2 for the DOSDUR TSPARMCD Appendix D – Updated lists

[Study Data Technical Conformance Guide -
Technical Specifications Document | FDA](#)

Questions?