

FDA's Study Data Policy Framework and Recent Activities

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Data Standards Staff

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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



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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

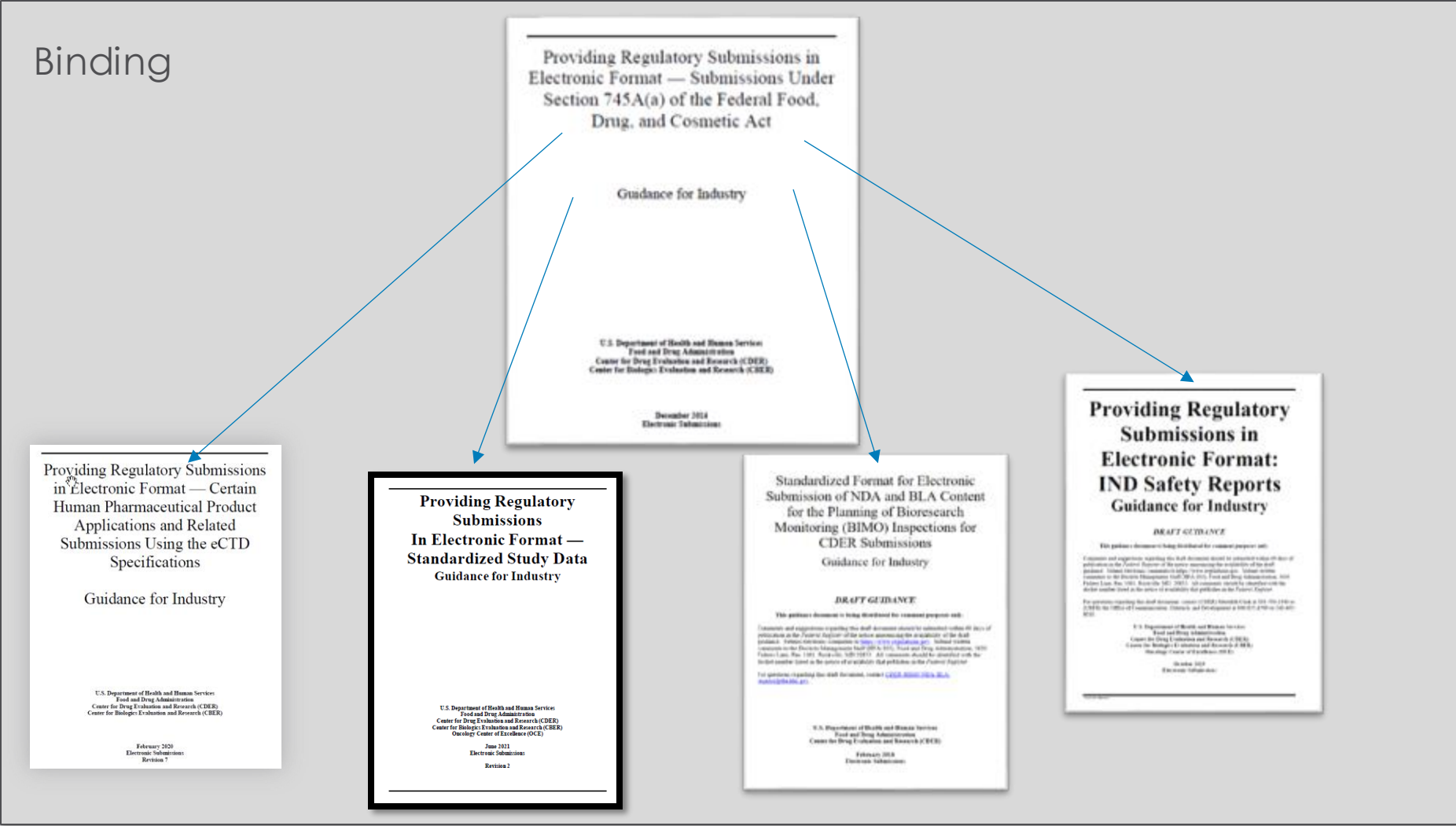
- Technical Conformance Guides (TCGs)
- FDA Data Standards Catalog (Catalog)
- Certain Technical Specifications (Tech Specs)

[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)

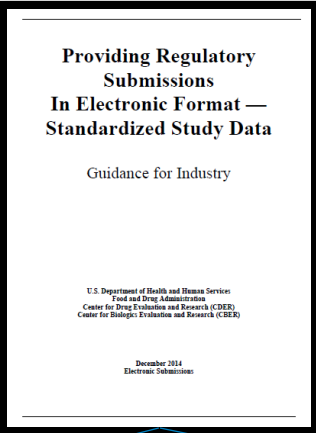
How FDA communicates technical requirements for submitting study data

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 ID	Data Support Design	Data Support Ends	Data Requirement Design	Data Requirement ID
medical study	SDMO	SDTE	SDMO	SDMO1.0		CDER	SDMO1.0	SDMO1.0	CDER	SDMO1.0
medical study	SDMO	SDTE	SDMO	SDMO1.1		CDER	SDMO1.1	SDMO1.1	CDER	SDMO1.1
medical study	SDMO	SDTE	SDMO	SDMO1.2		CDER	SDMO1.2	SDMO1.2	CDER	SDMO1.2
medical study	SDMO	SDTE	SDMO	SDMO1.3		CDER	SDMO1.3	SDMO1.3	CDER	SDMO1.3
medical study	SDMO	SDTE	SDMO	SDMO1.4		CDER	SDMO1.4	SDMO1.4	CDER	SDMO1.4
medical study	SDMO	SDTE	SDMO	SDMO1.5		CDER	SDMO1.5	SDMO1.5	CDER	SDMO1.5
medical study	SDMO	SDTE	SDMO	SDMO1.6		CDER	SDMO1.6	SDMO1.6	CDER	SDMO1.6
medical study	SDMO	SDTE	SDMO	SDMO1.7		CDER	SDMO1.7	SDMO1.7	CDER	SDMO1.7
medical study	SDMO	SDTE	SDMO	SDMO1.8		CDER	SDMO1.8	SDMO1.8	CDER	SDMO1.8

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 10.0



The 'Submission Data Standards' tab has been updated to clarify and differentiate the support and requirements for data models and separate technical documents (i.e., Implementation Guides (IGs)).

Catalog version 9.1, Submissions Data Standards tab



FDA Data Standards Catalog v9.1 (04/19/2023) - Submission Data Standards									
For full description of column headings, see Instr. & Column Descriptions tab									
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)
ADsM	XPT	CDISC	ADsM v 2.1	1	CDER, CBER	Ongoing	03/15/2019 [1] 03/15/2020 [2] [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2] [12]

New with Catalog version 10.1



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 listed below.

Standard	Exchange Format	SDO	Property	Related Properties	FDA Center(s)	Date Support Begins	Date Support Ends	Date Requirement Begins [10] [11]	Date Requirement Ends
ADaM	XPT	CDISC	ADaMv2.1		CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]	
ADaM	XPT	CDISC	ADaMIGv1.0		CDER, CBER	Ongoing	03/15/2019 [1] [12] 03/15/2020 [2] [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] [12] 03/15/2020 [2] [12]
ADaM	XPT	CDISC	ADaMIGv1.1		CDER, CBER	10/2/2017		03/15/2019 [1] 03/15/2020 [2]	
ADaM	XPT	CDISC	ADaMIGv1.2 ADaMIGv1.3		CDER, CBER	07/18/2022		03/15/2024	

For NDAs, ANDAs, and certain BLAs, see section II.A of the [Providing Regulatory Submissions In Electronic Format — Standardized Study Data](#) guidance document.

Let's take a look at the Catalog [Data Standards Catalog](#) | FDA



Property	Related Properties	FDA Center(s)	Date Support Begins	Date Support Ends	Date Requirement Begins [10] [11]	Date Requirement Ends
ADaMv2.1		CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]	
ADaMIGv1.0		CDER, CBER	Ongoing	03/15/2019 [1] [12] 03/15/2020 [2] [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] [12] 03/15/2020 [2] [12]
ADaMIGv1.1		CDER, CBER	10/2/2017		03/15/2019 [1] 03/15/2020 [2]	
ADaMIGv1.2						
ADaMIGv1.3		CDER, CBER	07/18/2022		03/15/2024	
SDTMv1.1		CDER, CBER	Ongoing	01/28/2015 [12]		
SDTMIGv3.1.1		CDER, CBER	Ongoing	01/28/2015 [12]		
SDTMv1.2		CDER, CBER	10/30/2009	03/15/2019 [1] [12] 03/15/2020 [2] [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] [12] 03/15/2020 [2] [12]
SDTMIGv3.1.2		CDER, CBER	10/30/2009	03/15/2019 [1] [12] 03/15/2020 [2] [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] [12] 03/15/2020 [2] [12]
SDTMIG Version 3.1.2 Amendment 1		CDER, CBER	08/07/2013	03/15/2019 [1] [12] 03/15/2020 [2] [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] [12] 03/15/2020 [2] [12]
SENDIGv3.0		CDER	06/13/2011	03/15/2019 [1] [12] 03/15/2020 [2] [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] [12] 03/15/2020 [2] [12]
SDTMv1.3		CDER, CBER	12/01/2012	03/15/2021 [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2021 [12]
SDTMIGv3.1.3		CDER, CBER	12/01/2012	03/15/2021 [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2021 [12]
SDTMv1.4		CDER, CBER	08/17/2015		03/15/2018 [1] 03/15/2019 [2]	
SDTMIGv3.2		CDER, CBER	08/17/2015		03/15/2018 [1] 03/15/2019 [2]	
SDTMv1.5		CDER	08/21/2017		03/15/2019 [1] 03/15/2020 [2]	
SDTMv1.5		CBER	03/15/2021		03/15/2023	
SENDIGv3.1		CDER	08/21/2017		03/15/2019 [1] 03/15/2020 [2]	
SENDIGv3.1		CBER	07/14/2020		03/15/2023	
SENDIGv3.1.1		CDER, CBER	02/15/2022		03/15/2023	
SDTMv1.6		CDER	03/05/2021		03/15/2023 [1] 03/15/2024 [2]	
SENDIG-DARTv1.1		CDER	03/05/2021		03/15/2023 [1] 03/15/2024 [2]	
SDTMv1.7		CDER, CBER	07/07/2020		03/15/2023	
SDTMIGv3.3		CDER, CBER	07/07/2020		03/15/2023	
SDTMv1.8		CDER	03/15/2020		03/15/2022 [1] 03/15/2023 [2]	
SENDIG-ARv1.0		CDER	03/11/2020		03/15/2022 [1] 03/15/2023 [2]	

Questions?