FDA's Study Data Policy Framework and Recent Activities

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Data Standards Staff

December 2023

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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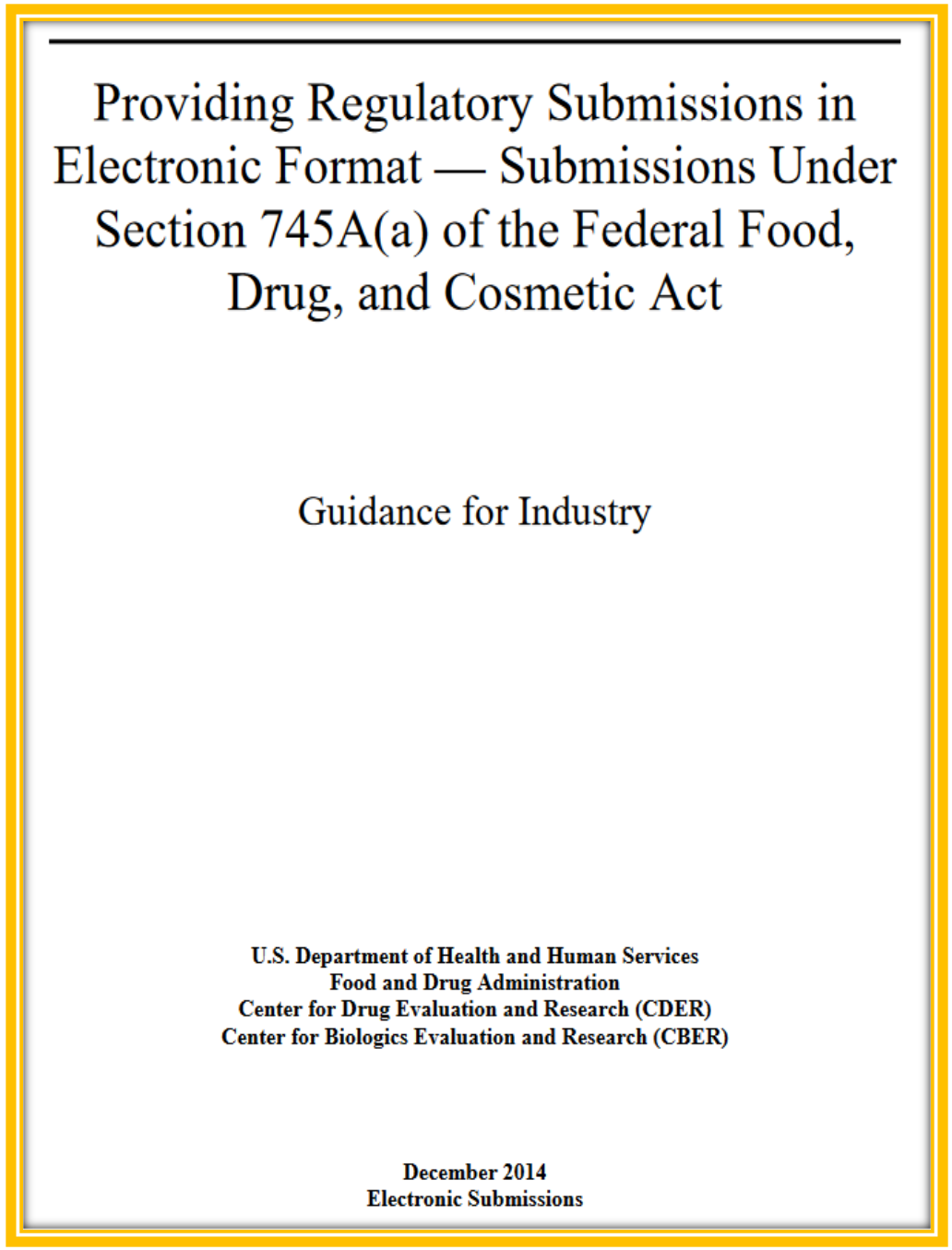
FDA CDER Office of Strategic Programs

Disclaimer:

These topics discussed here are to help Industry prepare study data for submission to Regulators and can not be generalized to topics specific to Inspections.

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)

Study Data Standards Resources | FDA (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

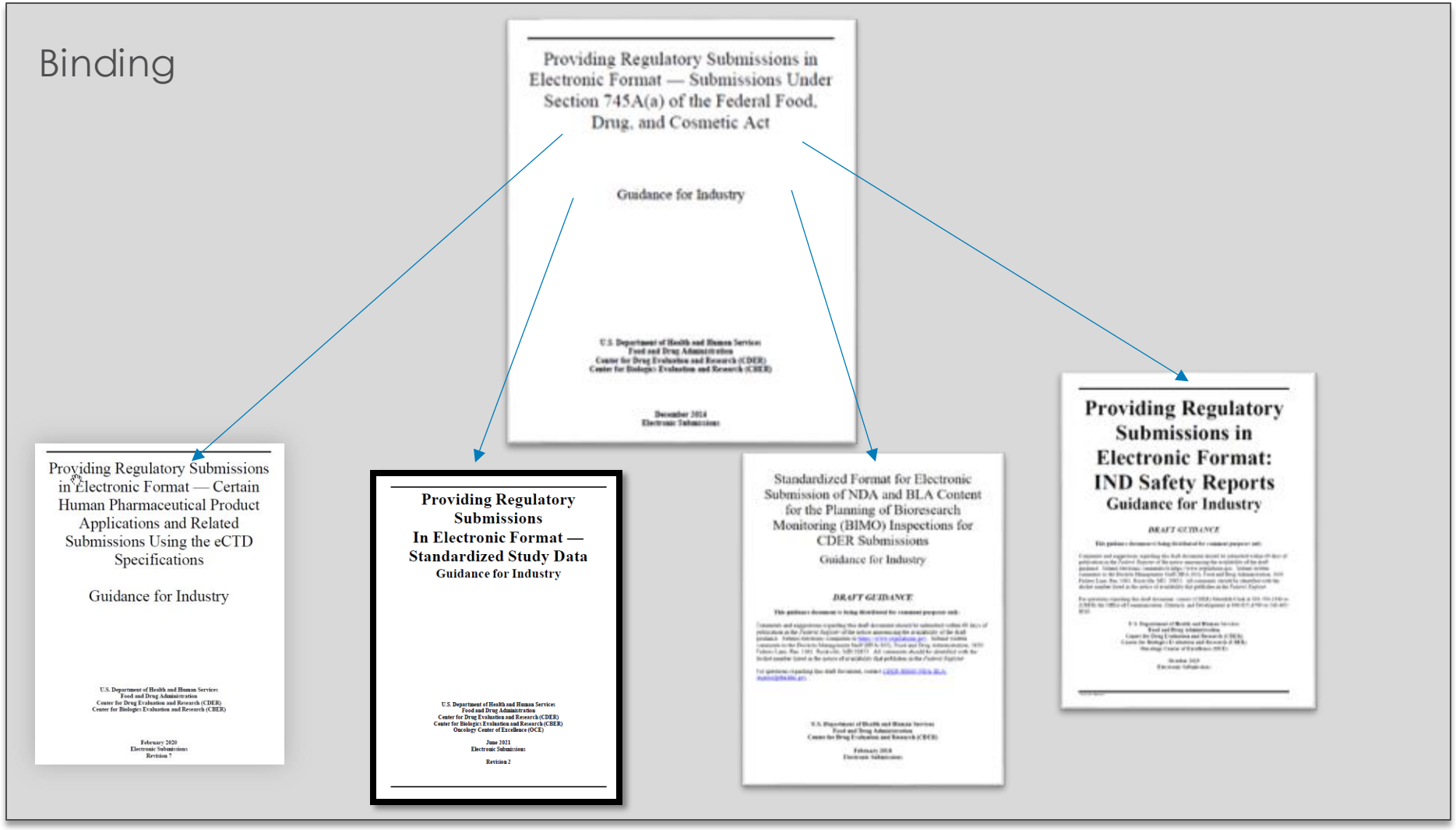
- Technical Conformance Guides (TCGs)
- FDA Data Standards Catalog (Catalog)
- Certain Technical Specifications (Tech Specs)

Search for FDA Guidance Documents | FDA (fda.gov/regulatory-information/search-fda-guidance-documents)

Study Data Standards Resources | FDA (fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources)

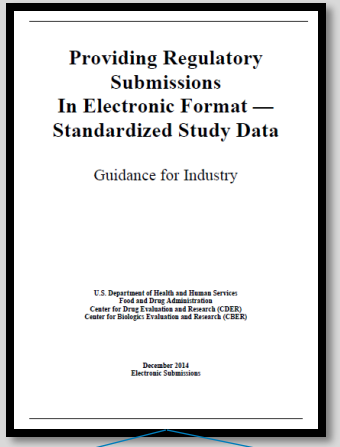
How FDA communicates technical requirements for submitting study data

Binding



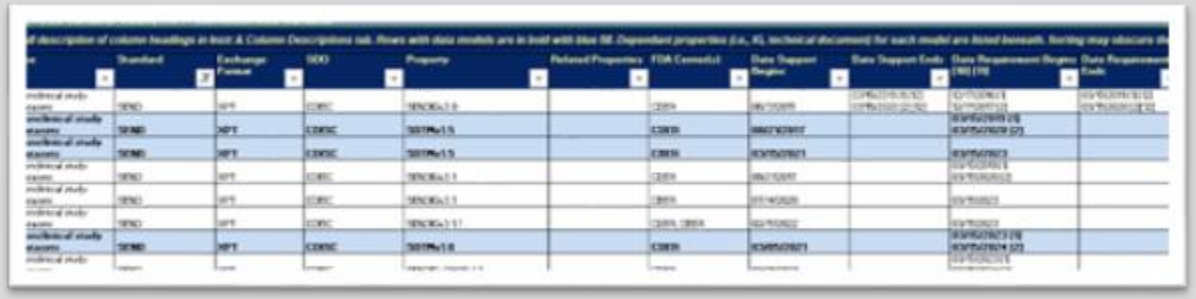
Focus on study data

Binding



eStudy

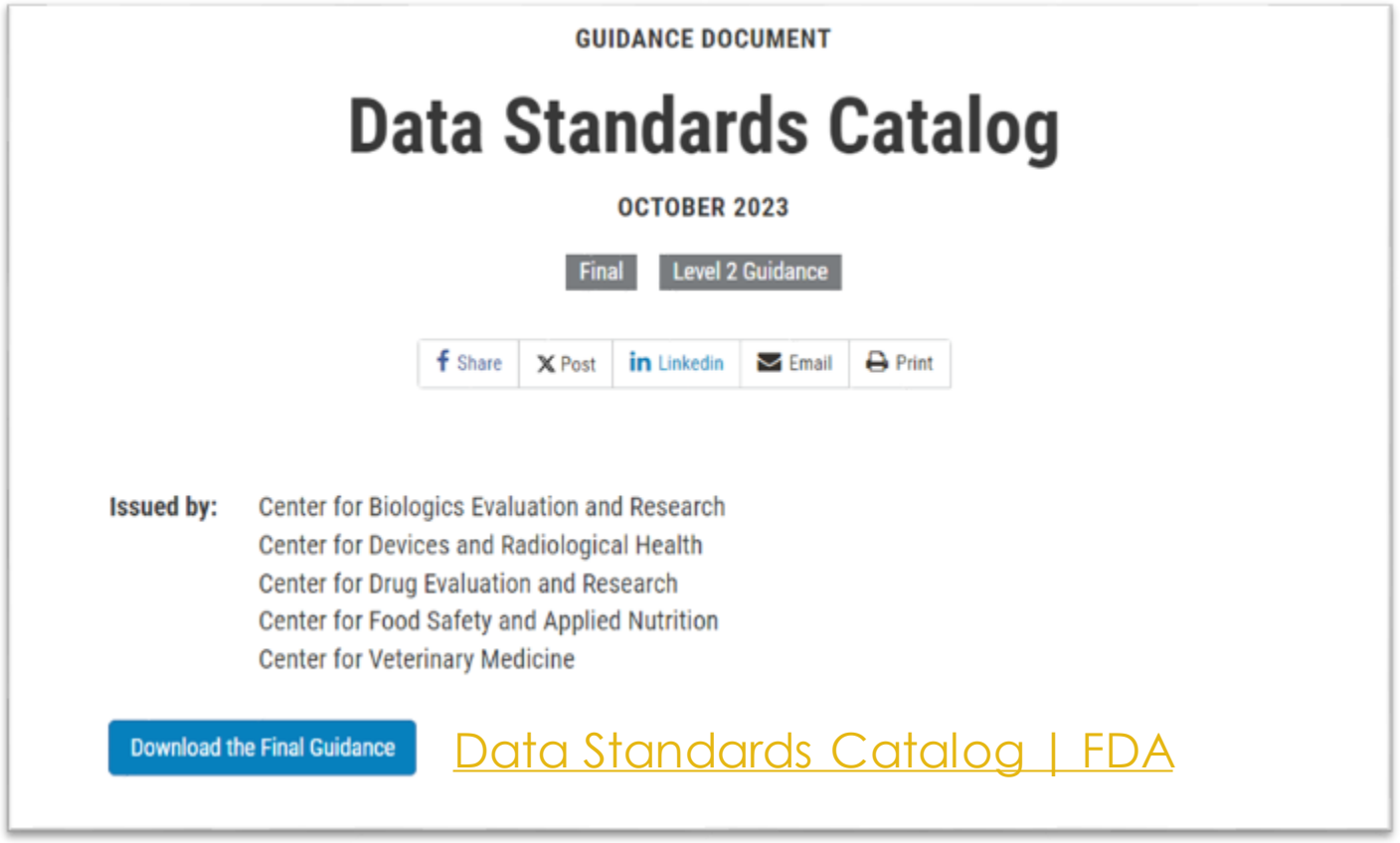
Catalog



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

Data Standards Catalog | FDA

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)).

Data Standards Catalog | FDA

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)
ADaM	XPT	CDISC	ADaM 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 ber

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

For NDAs, ANDAs, and certain BLAs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document

Data Standards Catalog | FDA

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	033/15/2021 [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]	

Study Data Technical Conformance Guide (sdTCG) Updates

FDA sdTCG Recent Updates

GUIDANCE DOCUMENT

Study Data Technical Conformance Guide - Technical Specifications Document

OCTOBER 2023

Download the Final Guidance Document | Read the Federal Register Notice

Final

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Docket Number: FDA-2014-D-0092

Issued by: Center for Drug Evaluation and Research

This technical specifications document represents the Food and Drug

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

Revision History		
Date	**Version**	**Summary of Revisions**
October 2023	5.5	Footnotes – Added links to the FDA Data Standards Catalog and SAS Help Center Section 3.3.2 (Dataset Size) – Updated for clarity Section 3.3.3 (Dataset Column Length) – Updated for clarity Section 4.1.1.3 (SDTM Domain Specifications) – Added PC Domain (Pharmacokinetic Concentration) and PP Domain (Pharmacokinetic Parameters) Section 4.1.1.3 (SDTM Domain Specifications) – Added SV Domain (Subject Visits) Section 4.1.3.2 (General Considerations) – Updated for clarity Section 4.1.3.3 (SEND Domain Specifications) – PC Domain (Pharmacokinetic Concentration) updated for clarity Section 4.1.3.3 (SEND Domain Specifications) – Updated Custom Domains to include SENDIG v3.1.1 Section 4.1.3.4.1 (Scope of SEND for SENDIGs v3.0, v3.1 and v3.1.1) – Updated to include mentions of SENDIG v3.1.1 Section 4.1.3.4.1 (Scope of SEND for SENDIGs v3.0, v3.1 and v3.1.1) – Section C updated for clarity. Section 4.1.3.4.3 (Scope of SEND for SENDIG-DART v1.1 for CDER) – Sections H, I, J, and K, updated for clarity Section 4.1.4.1 (Variables in SDTM and SEND: CDISC Required, Expected, and Permissible) – Updated to address baselines Section 4.1.4.7.1 (SEND Requirements During the COVID-19 Public Health Emergency) – Language added to address the end of the 180-day wind-down period for the modification to the SEND requirement Section 6.1.3 (Maintenance of Controlled Terminologies) – Updated for clarity Section 6.5.1.1 (General Considerations) – Language added to reflect CDER preferences Appendix C – Added the following TSPARMCDs: PPTCNAM, PPTEGID, PPTEGSYM, PPTMDA Appendix D – Updated list of SDO properties that align or do not align with current CBER and CDER business needs Appendix G – Updated for clarity Appendix H – Language added to address the end of the 180-day wind-down period for the modification to the SEND requirement Glossary – Addition of PHE and SDO

Questions

1. When will SDTMIGv3.4 go on the FDA Data Standards Catalog?

- The Agency always announces support and initiates requirements through a Federal Register Notice (FRN) and cannot share this information prior

Questions

U.S. FOOD & DRUG ADMINISTRATION

2. How often does FDA update the sdTCG?

- *At a minimum, Every March and October*

Questions

U.S. FOOD & DRUG ADMINISTRATION

3. How long does it take the FDA to evaluate a CDISC property?

- *It depends on the size and complexity of the CDISC property. It can often take as long to evaluate as it did to develop.*