FDA Study Data Policy Framework for Submitting Study Data to the U.S. Food and Drug Administration (FDA)

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Data Standards Staff

November 2024

Current Contributions:

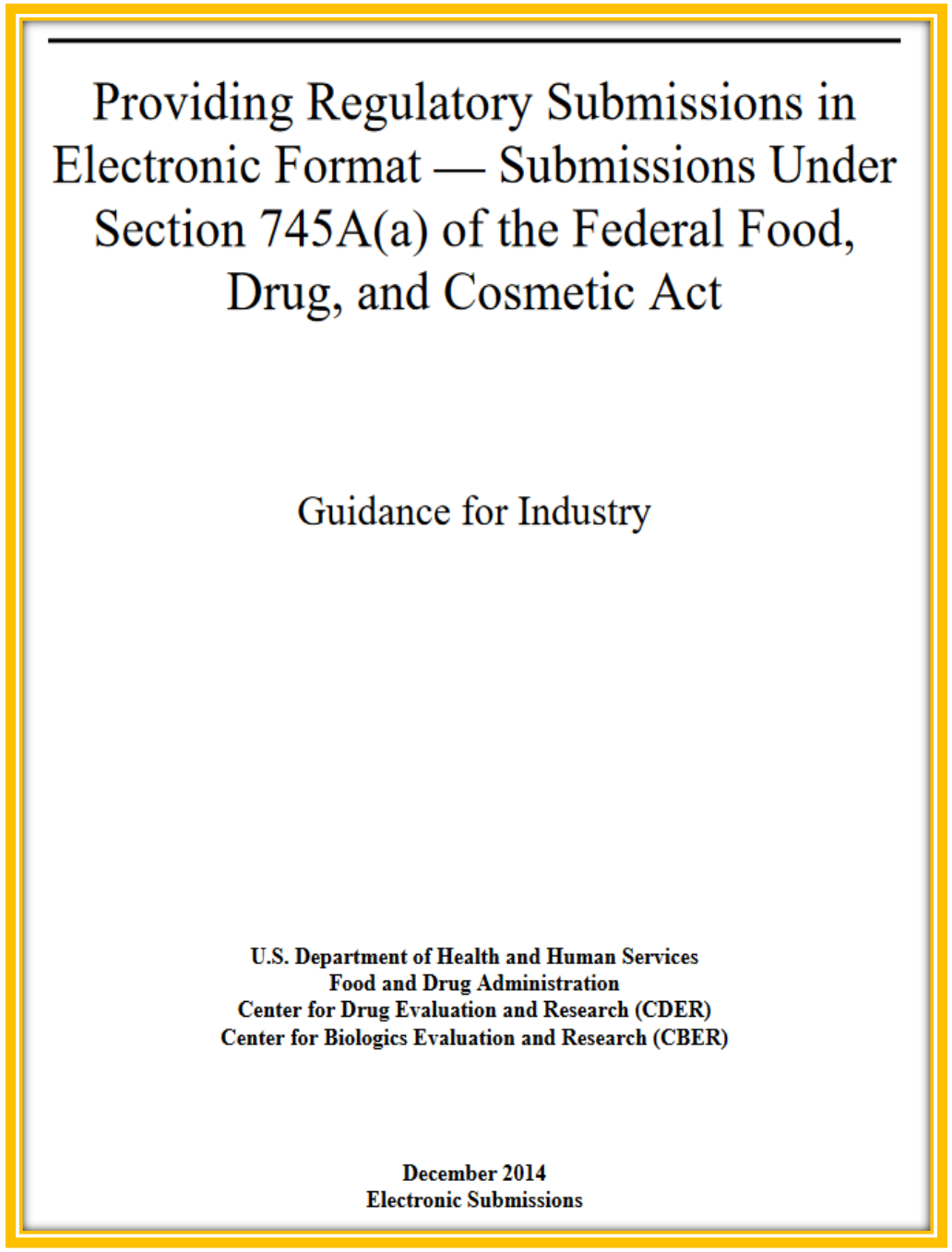
- Internal policy development and study data governance, CDER
- Chair, FDA Study Data Technical Conformance Guide (sdTCG)
- Chair, FDA Data Standards Catalog
- eData responses for standards related questions
- *I AM NOT A LAWYER*

Helena Sviglin (she/her),
US FDA CDER OSP

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 (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

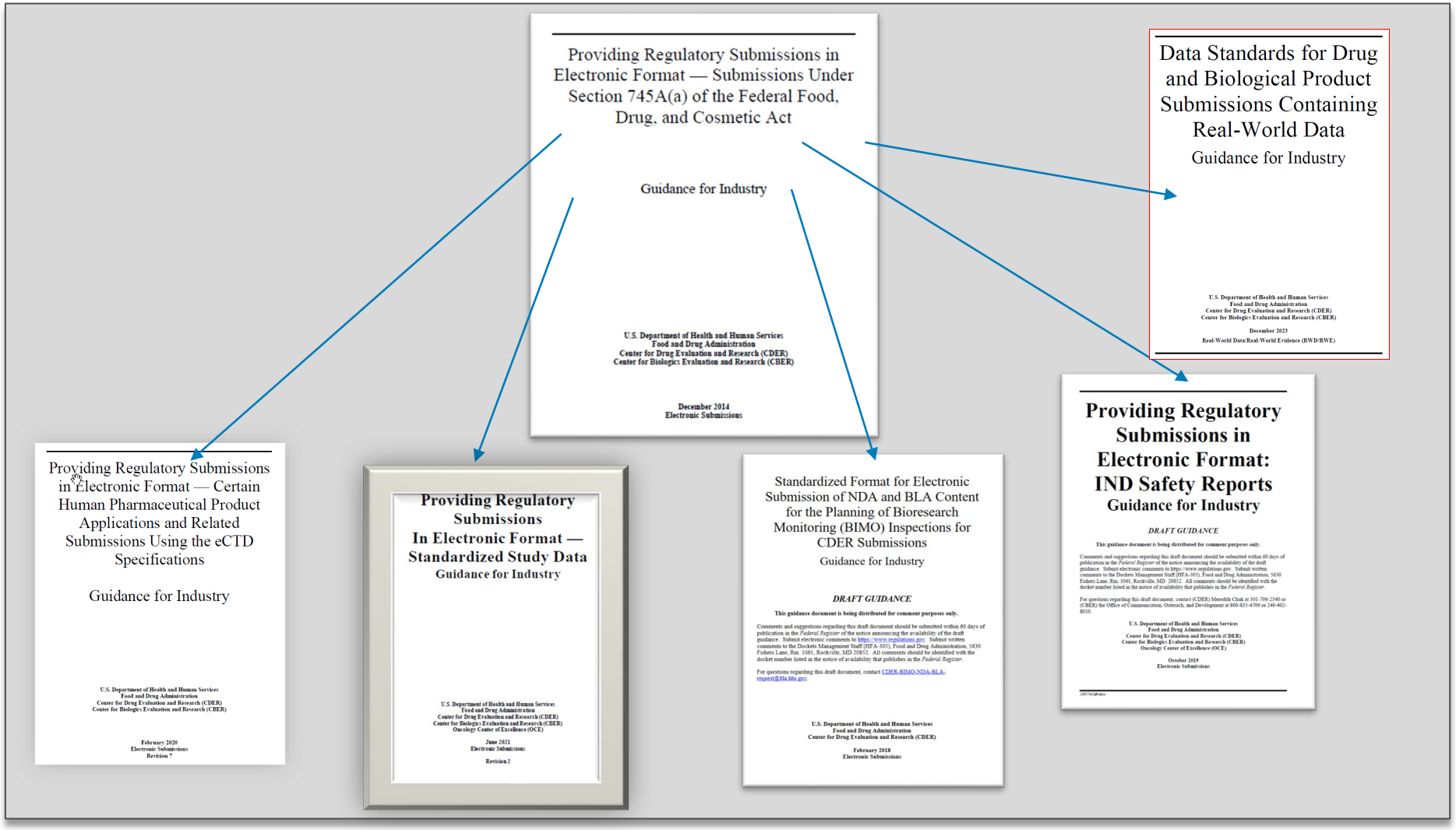
Primary Statute – 745A(a)

This gives FDA the authority from our Congress to set forth the requirements for study data

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

Website for references:
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 through the Framework



FDA Study Data Policy Framework

Binding Guidance sitting under 745A(a)

- eStudy Data
- eCTD
- Real World Data

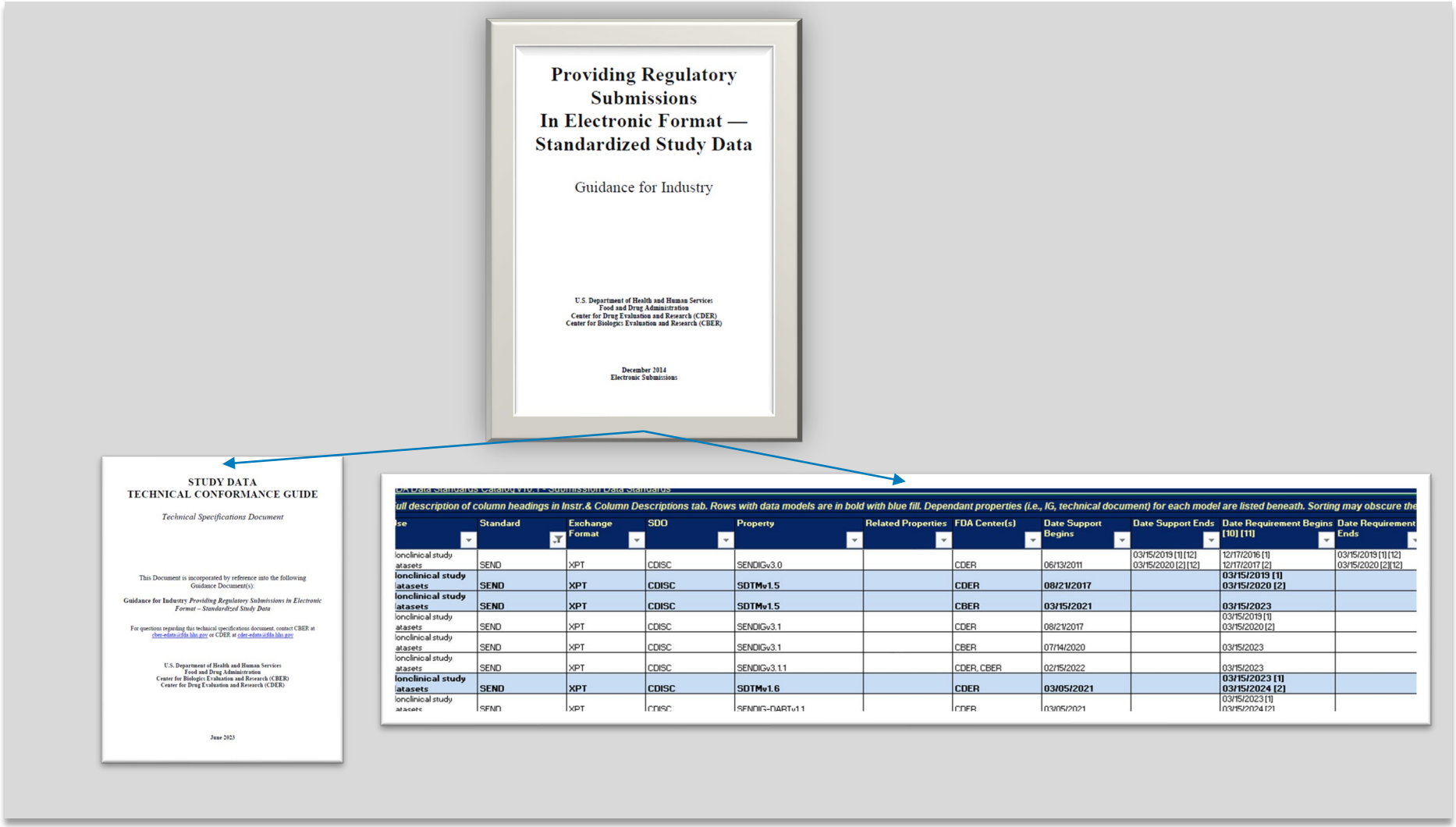
Incorporated by reference into Binding Guidance

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

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

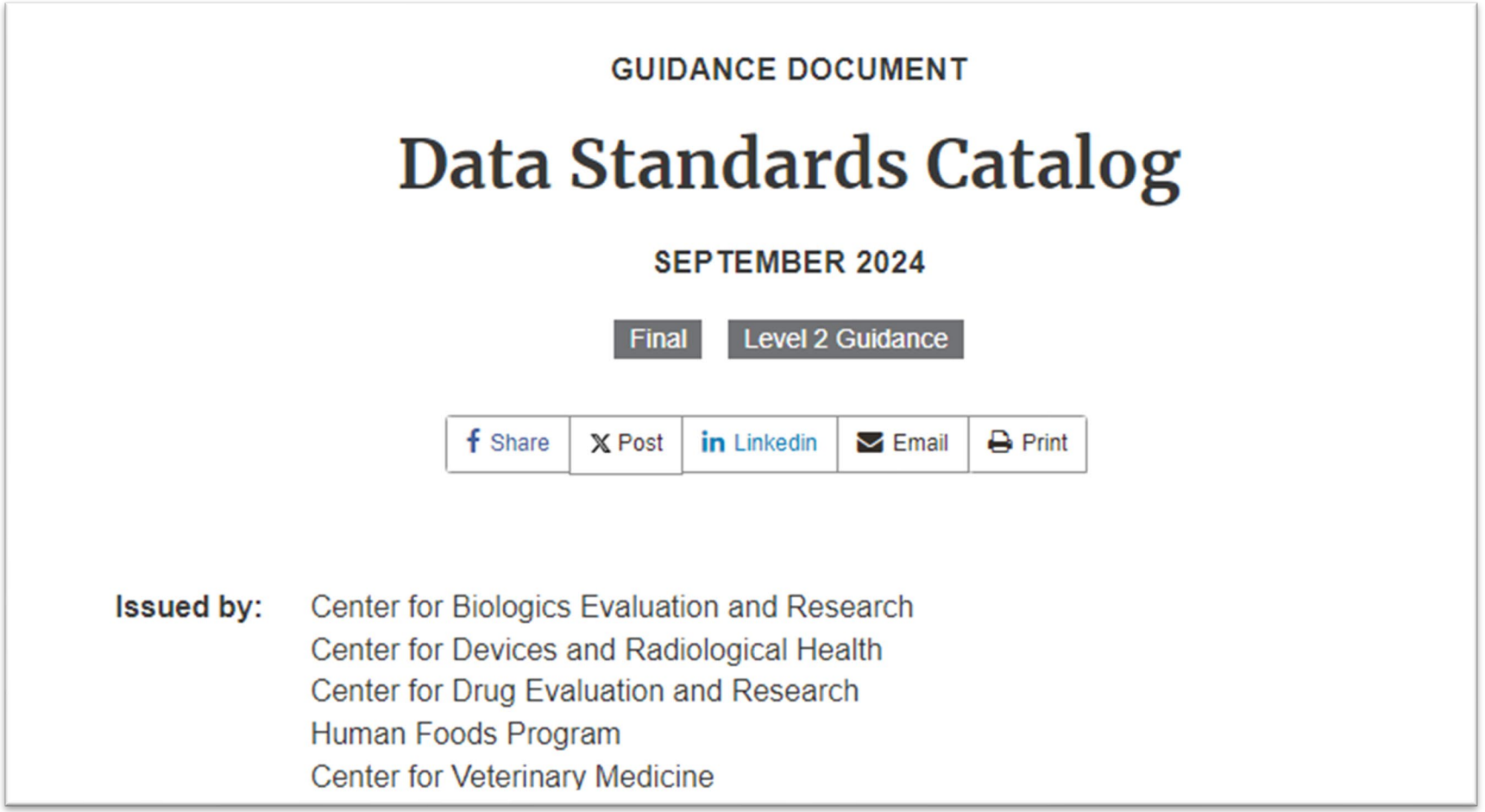
Study Data Standards Resources | FDA (fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources)

Guidance documents that focus on standardized study data



FDA Data Standards Catalog (Catalog) Updates

The FDA Data Standards Catalog in the Guidance Database



GUIDANCE DOCUMENT

Data Standards Catalog

SEPTEMBER 2024

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
Human Foods Program
Center for Veterinary Medicine

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog

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

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog

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]	

Let's take a look at a screenshot of the Catalog

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog

Here are the terminology versions for SDTM, ADaM, and SEND

FDA Data Standards Catalog v10.2 - Submission Data Terminologies

For full description of column headings, see Instr. & Column Descriptions tab

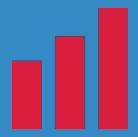
Use	Terminolo	Organization(s	Accepte Version	FDA Cent	Date Supp Begins	Date Supp Ends	Date Requirem Begins [10] [11]	Date Requirem Ends	Examples of Use
General Clinical Data	CDISC	EVS	2011-06-10 or later	CBER, CDER	06/13/2011		12/17/2016 [1] 12/17/2017 [2]		Use CDISC Submission values
General Clinical Data	CDISC	EVS	All Previous Versions	CBER, CDER	Ongoing				Use CDISC Submission Values. Do not use for studies initiated after 2011-06-13.
Non Clinical Data	CDISC	EVS	All Previous Versions	CDER					SEND Data

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog

Let’s take a look at the Catalog

(Navigate to the site)

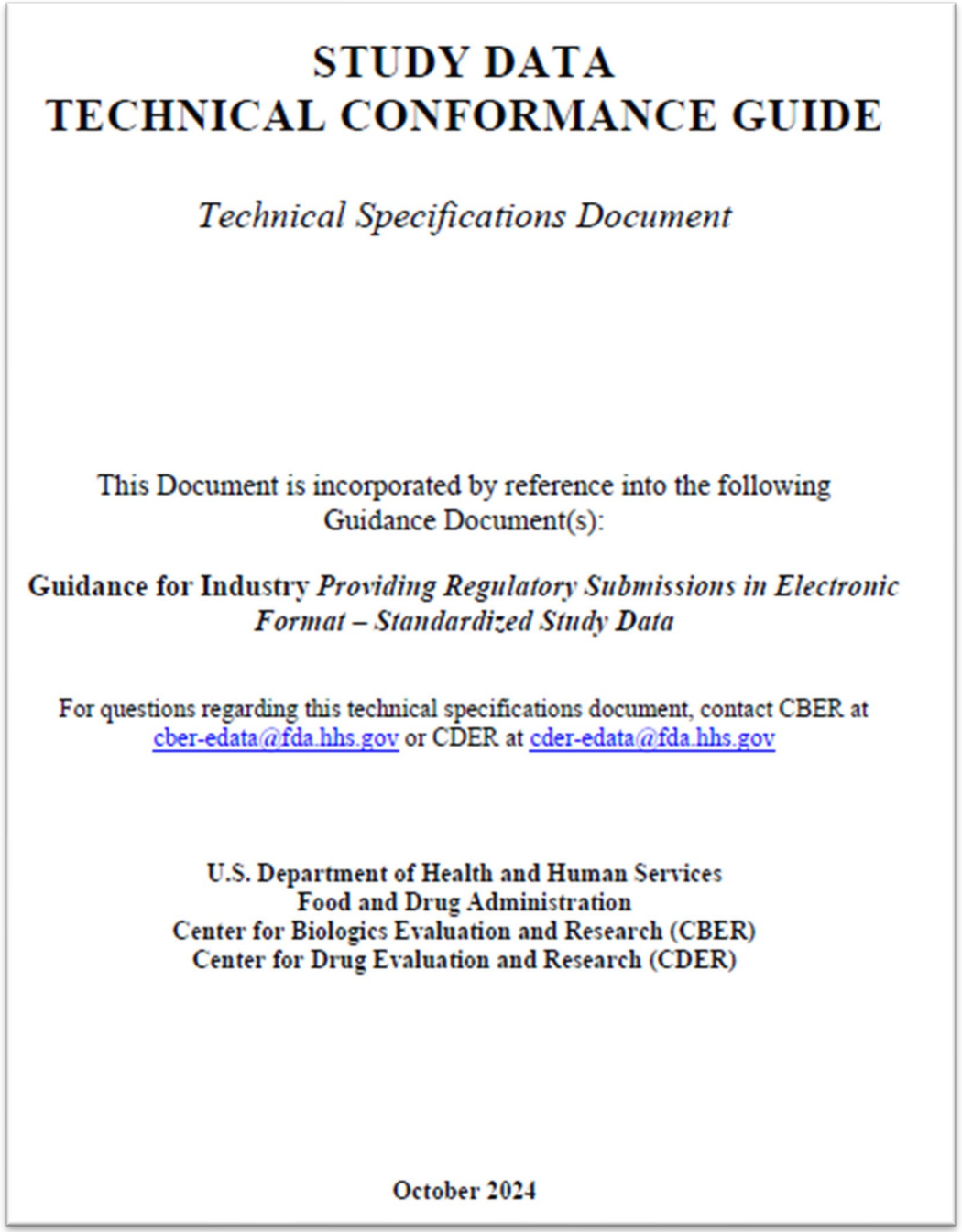
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog



Study Data Technical Conformance Guide (sdTCG)

FDA sdTCG in the Guidance Database

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document



STUDY DATA
TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following Guidance Document(s):

Guidance for Industry *Providing Regulatory Submissions in Electronic Format – Standardized Study Data*

For questions regarding this technical specifications document, contact CBER at cber-edata@fda.hhs.gov or CDER at cder-edata@fda.hhs.gov

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

October 2024

FDA sdTCG

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document

FDA sdTCG Recent Updates

Revision History		
Date	**Version**	**Summary of Revisions**
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
September 2024	5.8	Section 2 (Planning and Providing Standardized Study Data) – Addressed submissions in eCTDv4.0 Section 2.1.2 (SDRG for Nonclinical Data) – Addressed submissions in eCTDv4.0 Section 4.1.1.2 (SDTM General Considerations) – Added reference to Section 7.1 Section 4.1.3.2 (General Considerations) – Added referecnces to Section 7.1, addressed submissions in eCTDv4.0 Section 4.1.4.5 (Data Definition Files for SDTM, SEND, and ADaM) – Addressed submissions in eCTDv4.0 Section 7.1 (eCTD Specifications) – New Section, clarifying language Section 7.1.2 (eCTDv4.0 Specifications) – New Section, addressed submissions in eCTDv4.0 Section 7.1.3 (Weight of Evidence) – New Section Section 8.1.2.1 (eCTD Technical Rejection Criteria for Study Data) – Addressed submissions in eCTDv4.0 Section 8.1.2.2 (Technical Rejection Criteria and Use of a Simplified ts.xpt for Clinical Studies) – Addressed submissions in eCTDv4.0 Section 8.1.2.3 (Technical Rejection Criteria and Use of a Simplified ts.xpt for Nonclinical Studies) – Addressed submissions in eCTDv4.0 Appendix F – Addressed submissions in eCTDv4.0 Appendix G – New STUDYID examples added to address submissions in eCTDv4.0
October 2024	5.9	Section 4.1.1.3 (SDTM Domain Specifications) – Updated the LB Domain and added the MB Domain Section 4.1.3.4.4 (Scope of SEND for SENDIG-Genetox-v1.0) – New Section, SENDIG-Genetox v1.0 Section 6.1.2 (Use of Controlled Terminologies) – Language updated Section 6.1.2.1 (Use of the Specific Controlled Term 'OTHER') – Language updated Section 6.1.4.1 (General Considerations) – Language updated Appendix B – Updated the FDA Notes for TSPARMCDs Appendix D – Updated lists of SDO properties

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document

Technical Conformance Guide (TCG) Recent Updates

- Study Data TCG (sdTCG) updated October 2024
- Biomedical Monitoring (BIMO) TCG updated September 2024
- IND Safety Reports TCG updated April 2022

https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources

Study Data Technical Specifications (Tech Specs)

FDA Study Data Technical Specifications (Tech Spec)

- Tech Spec - Submitting Clinical Trial Datasets and Documentation for Clinical Outcome Assessments Using Item Response Theory
- Tech Spec - Bioanalytical Methods Templates
- Tech Spec - Clinical Endpoint BE Studies
- Tech Spec - HIV
- Tech Spec - QT Studies
- Tech Spec - Next Gen Sequencing
- Tech Spec - Rodent Carcinogenicity Studies
- Tech Spec - Vaccines
- Tech Spec - Noncirrhotic Nonalcoholic Steatohepatitits (NASH)
- Tech Spec - M11
- Tech Spec - Submitting Patient-Reported Outcome Data in Cancer Clinical
- Data Standards and Terminology Standards for Information Submitted to C
- Electronic Source Data in Clinical Investigations
- Tech Spec - Submitting Clinical Trial Datasets and Documentation for Clinical Outcome Assessments Using Item Response Theory
- Tech Spec - Submitting Patient-Reported Outcome Data in Cancer Clinical Trials

References

For Study Data:

https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources

For eCTD:
https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber

How Industry can submit questions to the agency

For questions to CDER:

cder-edata@fda.hhs.gov

For questions to CBER:

cber-edata@fda.hhs.gov

Questions

U.S. FOOD & DRUG ADMINISTRATION

1. When does a new CDISC standard 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 before this notice

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.*

Questions

U.S. FOOD & DRUG ADMINISTRATION

2. How often does FDA update the sdTCG?

- *At a minimum, Every March and October*

U.S. FOOD & DRUG ADMINISTRATION

Questions?

1. How long does it take the FDA to evaluate a new version of supported CDISC Property?
2. Does FDA evaluate everything CDISC develops?
3. Does FDA participate in CDISC Public Comment Periods?
4. Do FDA and CDISC have regular meetings?

Thank you 감사합니다