FDA's Study Data Policy Framework and Recent Activities

Helena Sviglin, CDER Office of Strategic Policy

Data Standards Staff

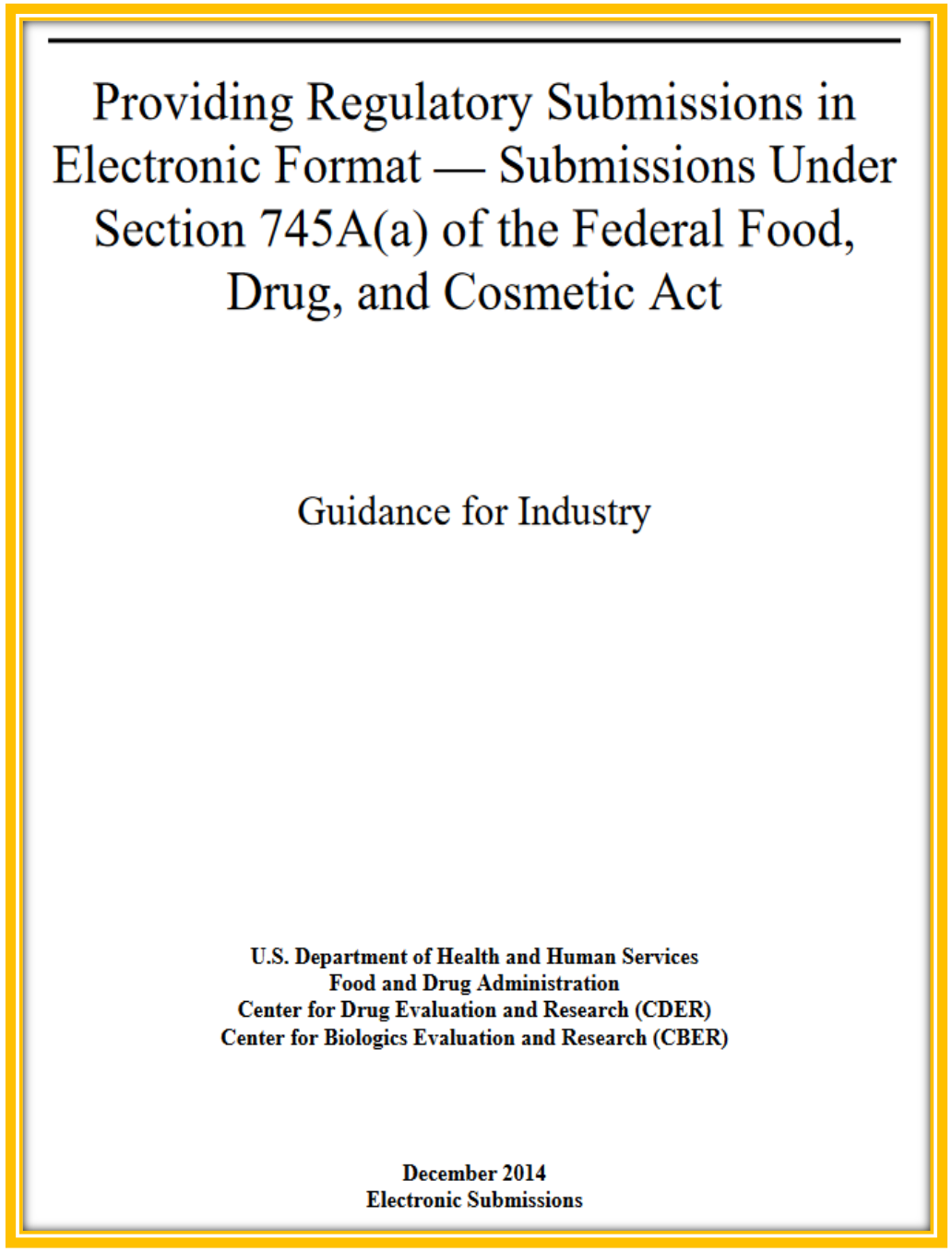
April 2023

Current Contributions:

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

Helena Sviglin, 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)

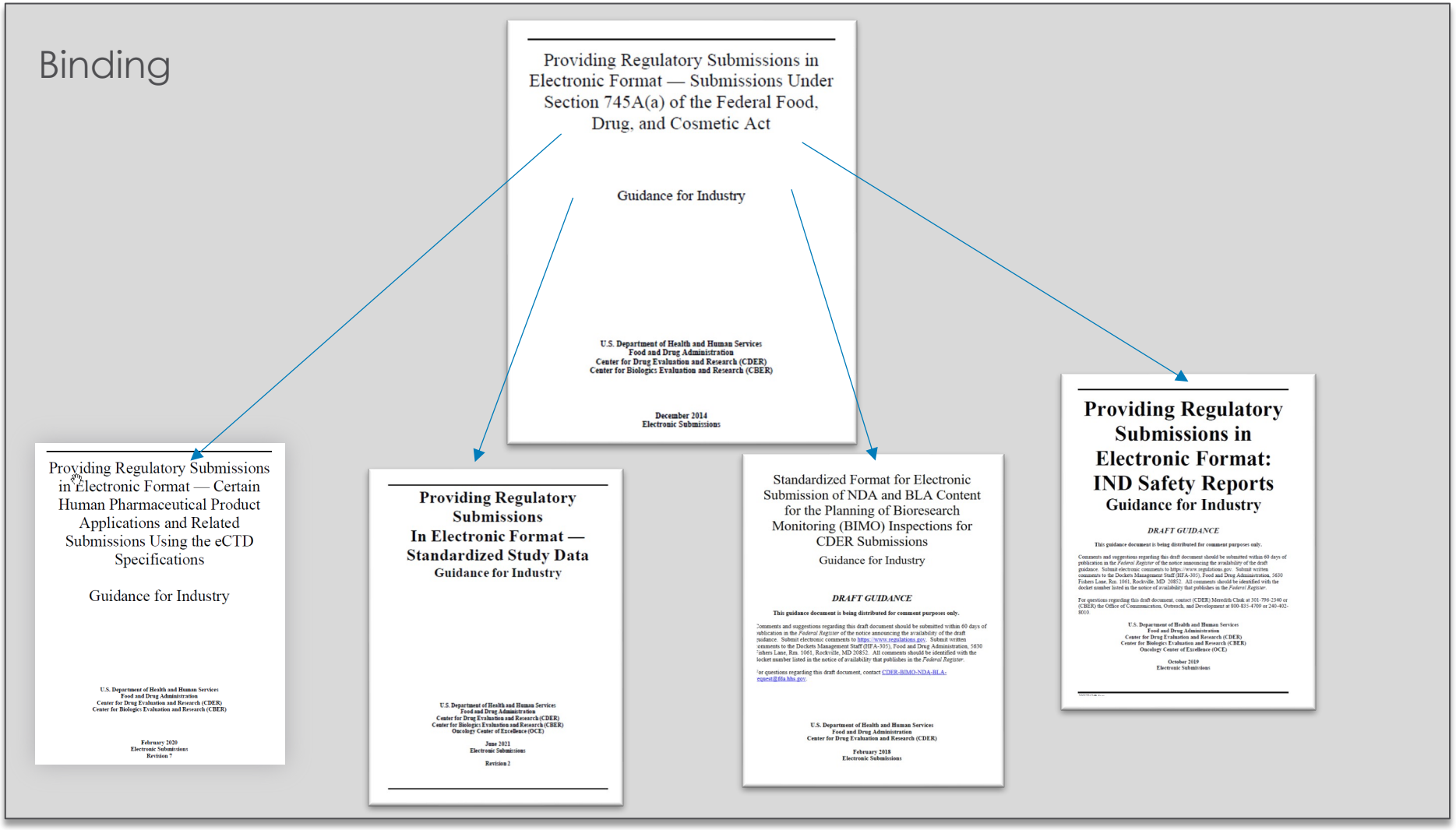
December 2014
Electronic Submissions

Primary Statute

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

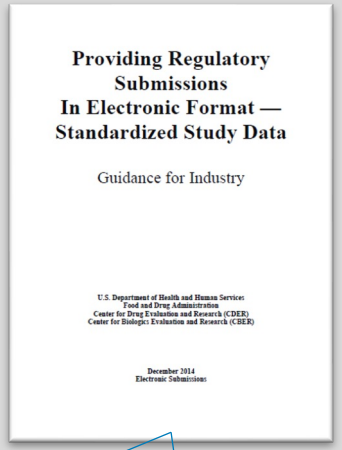
Study Data Standards Resources | FDA (fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources)

How FDA communicates technical requirements for submitting study data



How FDA communicates technical requirements for submitting study data

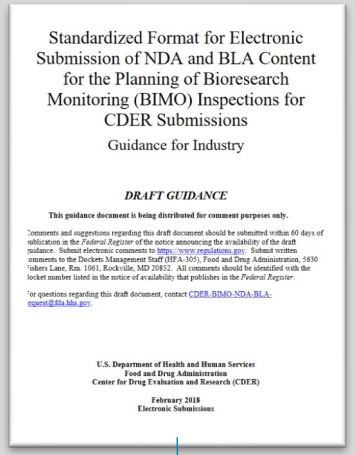
Binding – Level I


Providing Regulatory Submissions In Electronic Format — Standardized Study Data

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


Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions

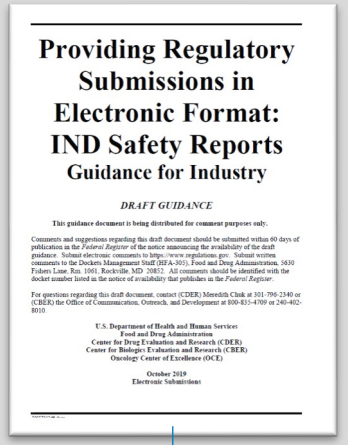
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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

February 2018
Electronic Submissions


Providing Regulatory Submissions in Electronic Format: IND Safety Reports

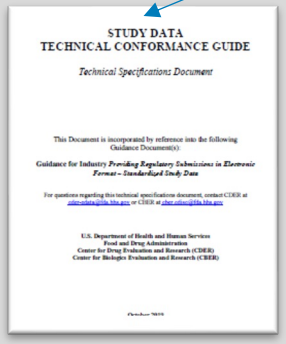
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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)
Oncology Center of Excellence (OCE)

October 2019
Electronic Submissions

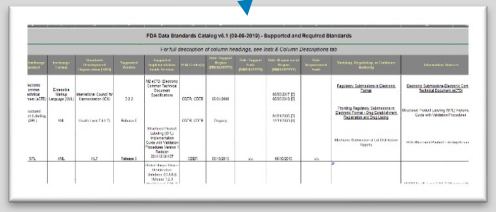

STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

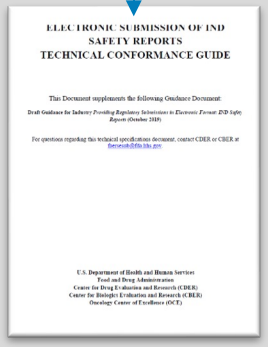
This Document is incorporated by reference into the following Guidance Document(s):

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

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)



BIMO TCG


ELECTRONIC SUBMISSION OF IND SAFETY REPORTS TECHNICAL CONFORMANCE GUIDE

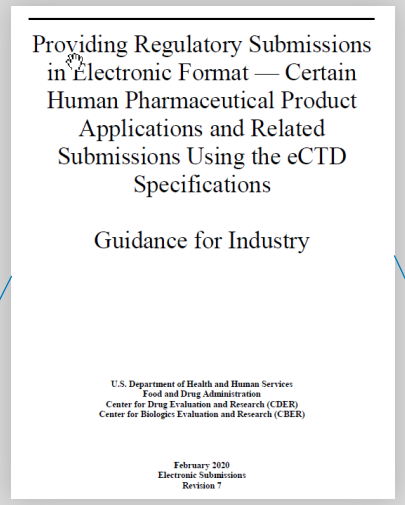
This Document supplements the following Guidance Document:

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)
Oncology Center of Excellence (OCE)

Technically non-binding – Level II – but sit under a binding guidance and are incorporated by reference

Related guidance: eCTD – requires electronic data, eCTD format

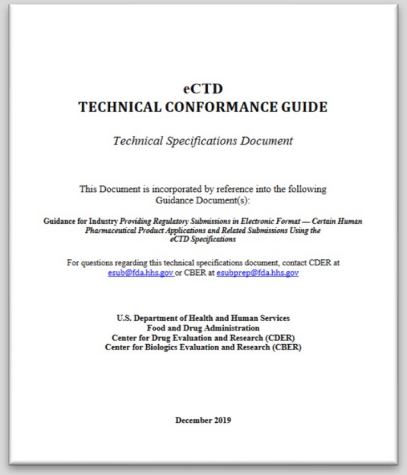
Binding – Level I


Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications

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)

February 2020
Electronic Submissions
Revision 7


eCTD
TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

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

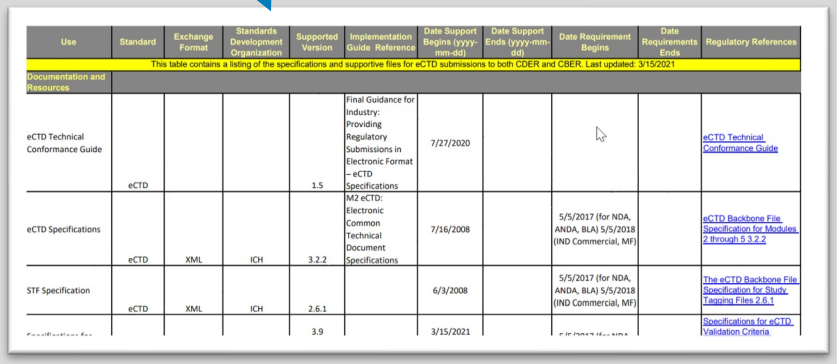
Guidance for Industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*

For questions regarding this technical specifications document, contact CDER at esub@fda.hhs.gov or CBER at esubprep@fda.hhs.gov

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 2019

Technically non-binding but Level II guidances sit under a binding guidance and are incorporated by reference

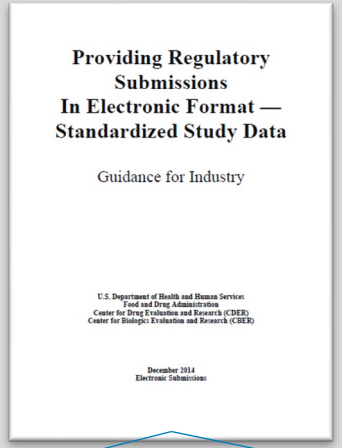


Use	Standard	Exchange Format	Standards Development Organization	Supported Version	Implementation Guide Reference	Date Support Begins (yyyy-mm-dd)	Date Support Ends (yyyy-mm-dd)	Date Requirement Begins	Date Requirements Ends	Regulatory References
This table contains a listing of the specifications and supportive files for eCTD submissions to both CDER and CBER. Last updated: 3/15/2021										
Documentation and Resources										
eCTD Technical Conformance Guide	eCTD			1.5	Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format – eCTD Specifications	7/27/2020				eCTD Technical Conformance Guide
eCTD Specifications	eCTD	XML	ICH	3.2.2	M2 eCTD: Electronic Common Technical Document Specifications	7/16/2008		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		eCTD Backbone File Specification for Modules 2 through 5 3.2.2
STF Specification	eCTD	XML	ICH	2.6.1		6/3/2008		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		The eCTD Backbone File Specification for Study Tagging Files 2.6.1
				3.9		3/15/2021				Specifications for eCTD Validation Criteria

eCTD Data Standards 031521 (fda.gov)

Focus on study data

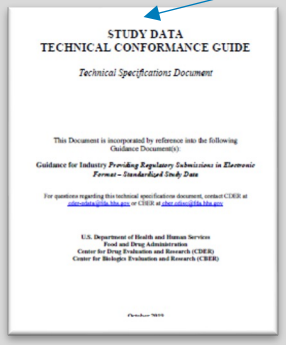
Binding – Level I


Providing Regulatory Submissions In Electronic Format — Standardized Study Data

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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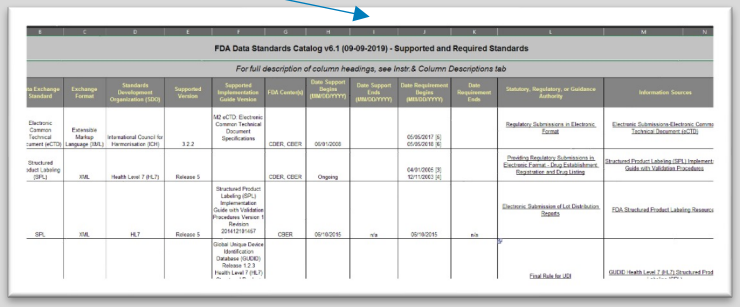
FDA Data Standards Catalog v6.1 (09-09-2019) - Supported and Required Standards

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

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Level I vs. Level II Guidance

Level 1 guidances set forth the agency's initial interpretations of new significant regulatory requirements; describe substantial changes in FDA's earlier interpretation or policy; and deal with complex scientific or highly controversial issues.

Level 2 guidances usually address existing practices or minor changes in FDA's interpretation or policy.

Fact Sheet: FDA Good Guidance Practices | FDA

(fda.gov/about-fda/transparency-initiative/fact-sheet-fda-good-guidance-practices#:~:text=In%20general%3A,scientific%20or%20highly%20controversial%20issues.)

Level I vs. Level II Updates to Guidance

Level 1 ***updates*** to guidances describe substantial changes in FDA's earlier interpretation or policy; and deal with complex scientific or highly controversial issues.

Level 2 guidance ***updates*** usually address changes to existing practices or minor changes in FDA's interpretation or policy.

Fact Sheet: FDA Good Guidance Practices | FDA

(fda.gov/about-fda/transparency-initiative/fact-sheet-fda-good-guidance-practices#:~:text=In%20general%3A,scientific%20or%20highly%20controversial%20issues.)

FDA's Study Data Policy Framework

Level I Guidance (sitting under 745A(a))

- eStudy Data Guidance (eStudy)
- Real World Data (RWD) (currently in Draft)
- *eCTD Guidance*

Level II 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)

eStudy Data Guidance Updates

Two Level II Updates were made since 2020

1. Technical Rejection Criteria (TRC) considerations, 2020
2. Scope of SEND, 2021

Providing Regulatory Submissions in Electronic Format -- Standardized Study Data | FDA

RWD Guidance Update

- Establishes that RWD is considered study data at the point of submission and falls under 745A(a)
- Draft Published late 2021
- Review of public comments completed
- This review will inform the final guidance

Providing Regulatory Submissions in Electronic Format -- Standardized Study Data | FDA (fda.gov/regulatory-information/search-fda-guidance-documents)

Technical Conformance Guide (TCG) Recent Updates

- Study Data TCG (sdTCG) updated March 2023
- Biomedical Monitoring (BIMO) TCG updated April 2022
- IND Safety Reports TCG updated April 2022
- FDA Data Standards Catalog updated January 2023

Study Data Standards Resources | FDA

FDA Data Standards Catalog Recent Updates

Catalog continues to be updated to address the current state of requirements for study data at other Centers:

- Annotated ECG (aECG) standard
- Open docket added
- Added CVM as an involved center for UNII Add USCDI+ to the catalog
- S-CAP for CDRH
- ISCR R2 for CDRH
- CDISC Standards ADaM IG v1.2 and 1.3

FDA Data Stds Catalog_8.01.2022 (v8.2).xlsx (live.com)

Let’s take a look at the Catalog

FDA_Data Stds Catalog_01.25.2023 (v9.0).xlsx

(Navigate to the site)

FDA Study Data Technical Specifications (Tech Spec) Recent Updates

1. Submitting Nonclinical Datasets for Evaluation of Rodent Carcinogenicity Studies of Pharmaceuticals, Guidance for Industry, Technical Specifications Document v. 1.0 (May 2021)
2. Submitting Next Generation Sequencing Data to the Division of Antiviral Products v. 1.0 (July 2019)
3. QT Studies Technical Specification Document v. 1.0
4. Bioanalytical Methods Validation (BMV) Tech. Spec. v1.0
5. HIV Technical Specifications Guidance v. 1.0 (March 2018)
6. Vaccines Technical Specification Guidance v2.1
7. Clinical Endpoint BE Studies v1.0
8. Technical Specifications for Submitting Clinical Trial Data Sets for Treatment of Noncirrhotic Nonalcoholic Steatohepatitis (NASH) (Jan 2022)

U.S. FOOD & DRUG ADMINISTRATION

Questions?