

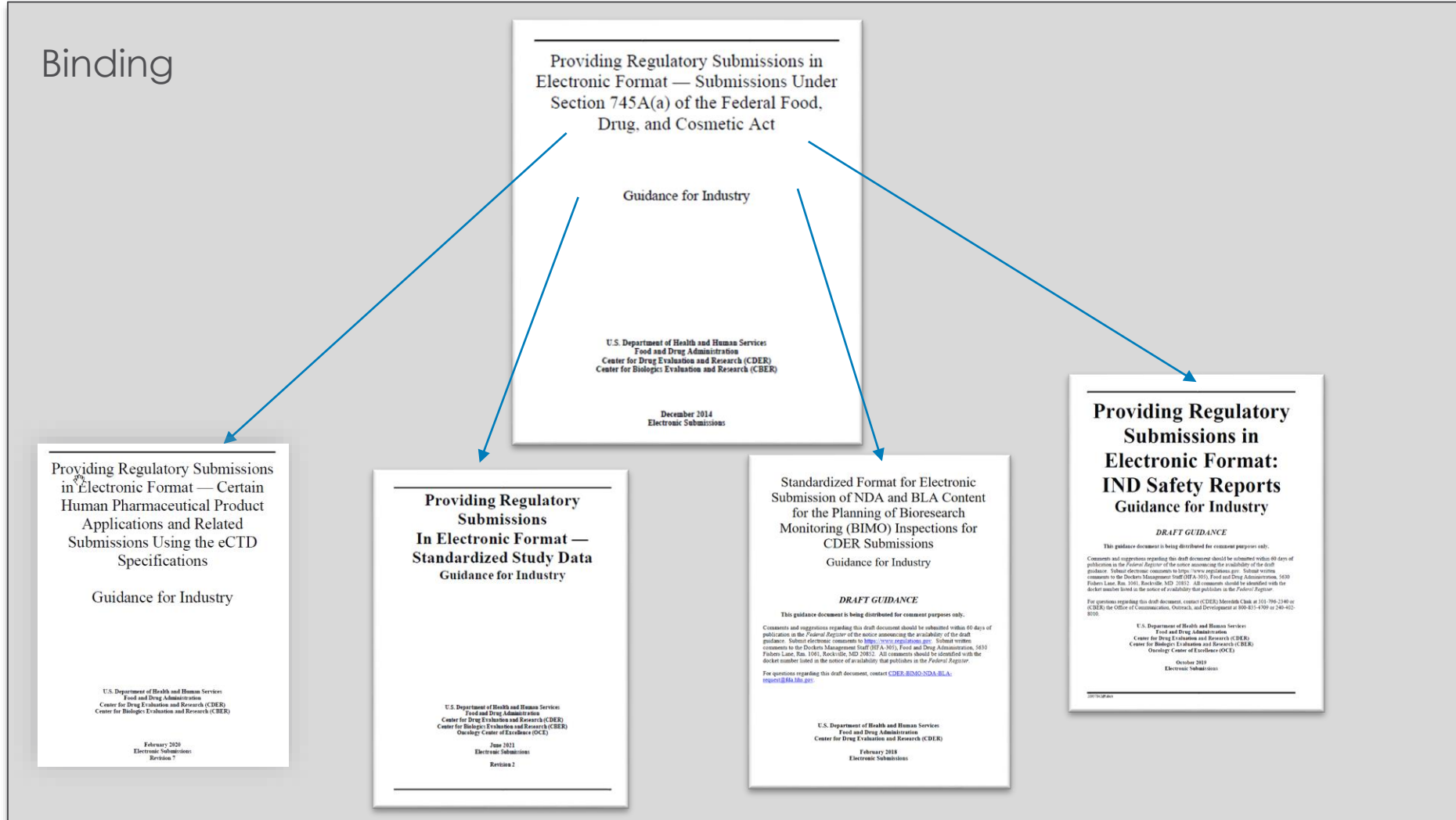
FDA's Study Data Policy Framework

Recent Updates

Helena Sviglin, Office of Strategic Programs, CDER, USFDA

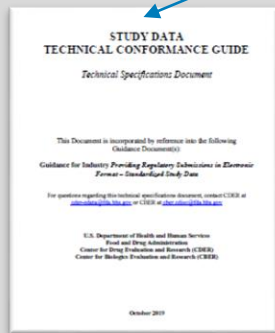
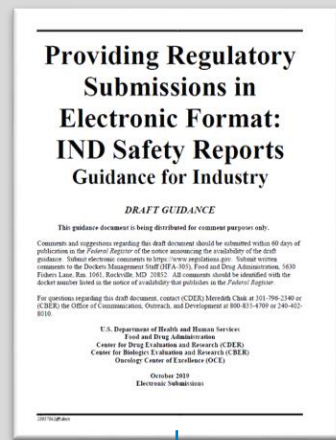
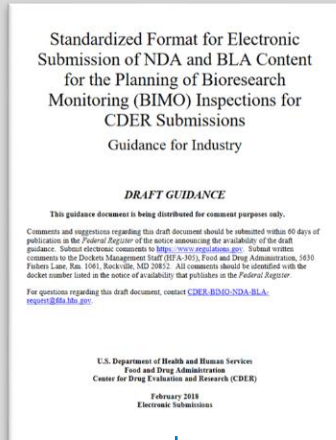
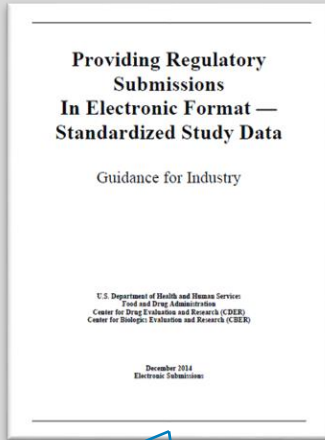
July 2022

How the FDA communicates technical requirements for submitting study data



How the FDA communicates technical requirements for submitting study data

Binding –
Level I



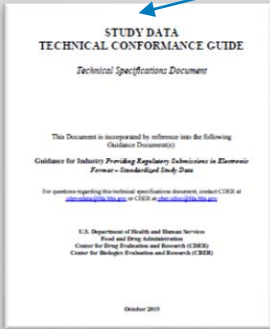
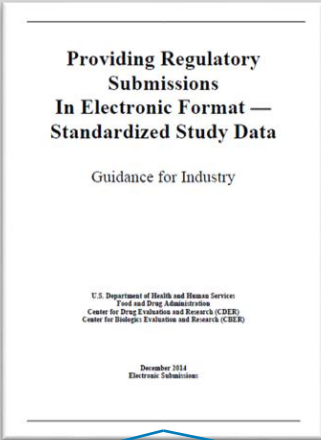
Standard ID	Standard Name	Standard Description	Standard Status	Standard Version	Standard Effective Date	Standard Expiration Date	Standard Author	Standard Maintainer	Standard Reviewer	Standard Approver
...



Non-Binding – Level II – but these sit under a binding guidance

Focus on study data

Binding –
Level I



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

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

Language Standard	Language Format	Standards Organization / Organization (ISO)	Supersedes	Terminated Organization / Code Version	USA Country	Date Supported (YYYYMMDD)	Date Supported (YYYYMMDD)	Date Requirement (YYYYMMDD)	Date Requirement (YYYYMMDD)	Issued by Regulatory or Guidance Authority	Information Sources
Electronic Common Technical Document (eCTD)	Electronic Markup Language (XML)	International Council for Harmonization (ICH)	3.2.2	MD aCTD Electronic Common Technical Document Specifications	CDER, CBER	06/15/2008		06/05/2017 (I) 06/05/2018 (II)		Regulatory Submissions in Electronic Format	Electronic Submissions Electronic Common Technical Document (eCTD)
Structured Product Labeling (SPL)	XML	Health Level 7 (HL7)	Release 5	Structured Product Labeling (SPL) Implementation Guide with Validation Procedures Version 1.0 - Release 5	CDER, CBER	Ongoing		04/15/2016 (I) 12/11/2017 (II)		Providing Regulatory Submissions in Electronic Format - Drug Labeling, Specifications and Data Tables	Structured Product Labeling (SPL) Implementation Guide with Validation Procedures
SPL	XML	HL7	Release 5	2014 USPLS07 Structured Product Labeling (SPL) Implementation Guide with Validation Procedures Version 1.0 - Release 5	CBER	06/16/2016	09/01/2016	06/15/2016	09/01/2016	Electronic Submissions of a Distributor Report	FDA Structured Product Labeling Database
										Total Rows in CD	HL7 Health Level 7 (HL7) Structured Product Labeling (SPL)

Non-Binding – Level II – but sits under Level I

FDA's Study Data Policy Framework Overview



- Level I Guidance
 - eStudy
 - Real World Data (RWD) (*currently in DRAFT*)
- Level II Guidance
 - Technical Guides
 - [FDA Data Standards Catalog](#)
 - [Certain Technical Specifications](#)
(*see number three (3) at this link*)

[Search for FDA Guidance Documents | FDA](#)

eStudy Data Guidance Update



Two Level II updates were made since 2020

1. Technical Rejection Criteria (TRC) considerations, 2020
2. Scope of SEND content, 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)
- Published late 2021
- Public comment period is closed

[Providing Regulatory Submissions in Electronic Format
-- Standardized Study Data | FDA](#)

Technical Conformance Guide (TCG) Updates



- Study Data Technical Conformance Guide (sdTCG) updated March 2022
- BIMO TCG updated April 2022
- IND Safety Reports TCG updated April 2022

[Study Data Standards Resources | FDA](#)

24 CDISC TAUGS in Section 5 of sdTCG v4.9



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<https://www.fda.gov/media/153632/download>

Additional CDISC Properties in sdTCG v4.9



Appendix D: Additional Documents Evaluated By FDA

The Agency recognizes that there may be additional documents beyond Therapeutic Area User Guides (TAUGs), Implementation Guides (IGs), and Models that provide technical information about how to implement a CDISC standard and that these documents fall outside the scope of the FDA Data Standards Catalog. Use of the documents listed here is encouraged. For documents not yet listed here, please consult with your division.

1. CDISC Document: Interim User Guide for COVID-19

2. CDISC Document: Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic

It is the current preference of the Agency that for all clinical studies, not limited to those impacted by COVID-19, subject visit data for scheduled (whether or not they occurred), and unscheduled visits be submitted in one single dataset structured as the current CDISC Subject Visits (SV) domain. It is also Agency preference that three non-standard variables (NSVs) for missed visits, --REASOC (Reason for Occur Value), --EPCHGI (Epi/Pandemic Related Change Indicator), and --CNTMOD (Contact Mode), outlined in the CDISC document "Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic" be included within the SV domain and not within the supplemental SUPPSV domain or in other SDTM datasets. Submitting subject visits information in one single structured dataset allows both the human and technology consumer of this information to operate efficiently and with confidence that all visit data are considered during regulatory review.

As always, consult with the relevant FDA review division for the best approach in a specific application. Further updates to Agency thinking regarding how to submit data for studies that may have been impacted by the COVID-19 pandemic will be posted in updates to the Study Data Technical Conformance Guide.

3. Occurrence Dataset Structure (OCCDS) v1.0

[https://www.fda.gov/
media/153632/download](https://www.fda.gov/media/153632/download)

FDA Study Data Technical Specifications 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)

[Study Data Standards Resources | FDA](#)

FDA Data Standards Catalog Recent Updates



Change History

Date	Version	
2021-09-14	7.3	Terminology Standards: - Footnote 11 added
2022-02-15	8.0	Data Exchange Standards: - Added SENDIG v3.1.1 with the Date Support begins and the Date Requirement begins
2022-06-23	8.1	Added link to open docket in instructions for use Data Exchange Standards: - Updated links and references Terminology Standards: - Updated links and references

<https://www.fda.gov/media/159970/download>

Recent FRN adding new ADaMIGs to the Catalog



July 18, 2022 / Notices

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SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are announcing the date that support begins for versions 1.2 and 1.3 of the Clinical Data Interchange Standards Consortium (CDISC) Analysis Data Model Implementation Guide (ADaMIG) and the date that this version update is required in certain submissions. The Agency will update the FDA Data Standards Catalog (Catalog) to reflect these changes.

995

<https://www.regulations.gov/document/FDA-2022-N-1366-0001>

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?