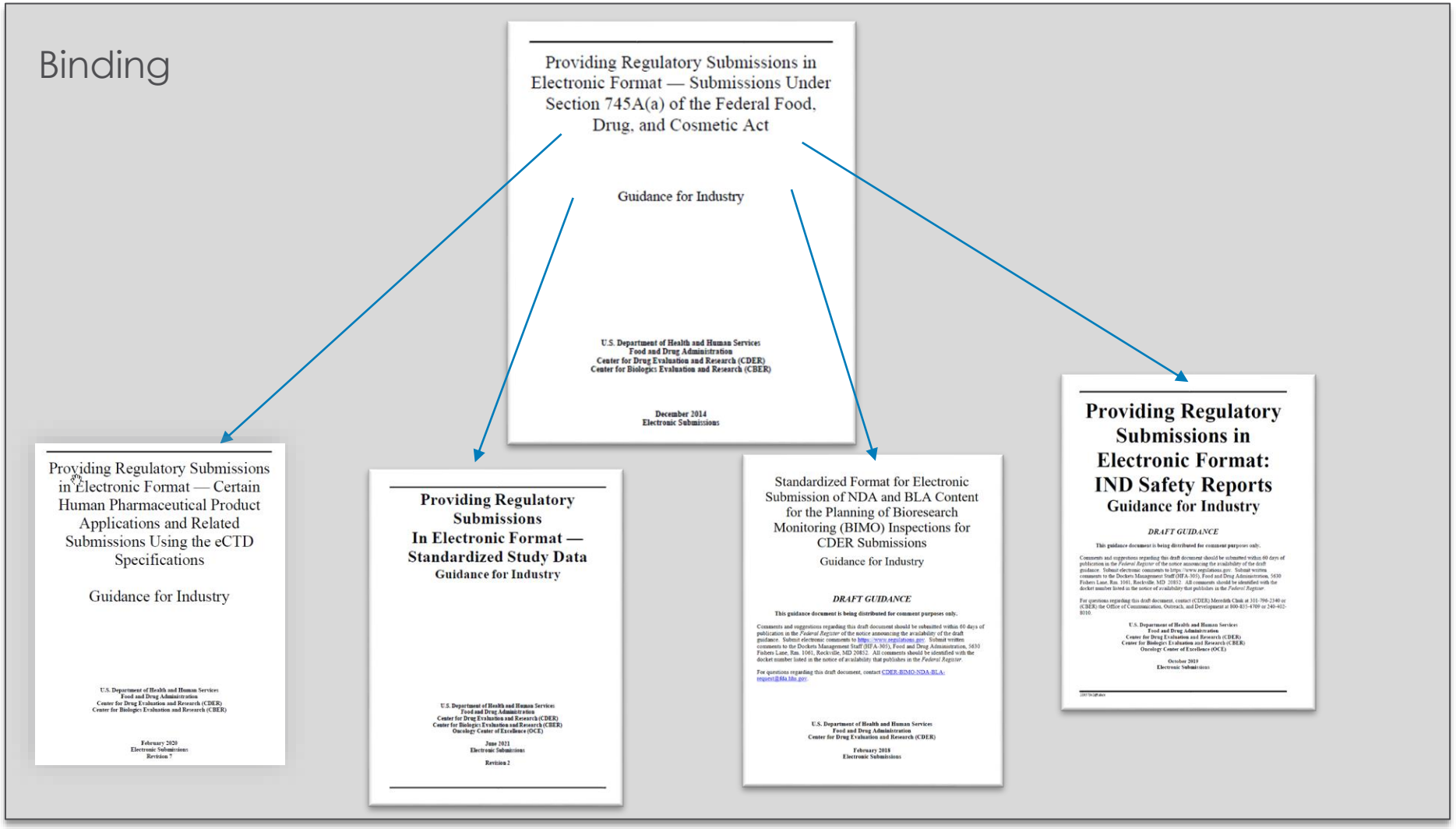
FDA's Study Data Policy Framework
Recent Updates

Helena Sviglin, Office of Strategic Programs, CDER, USFDA

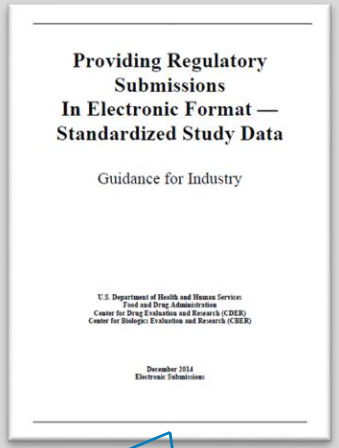
July 2022

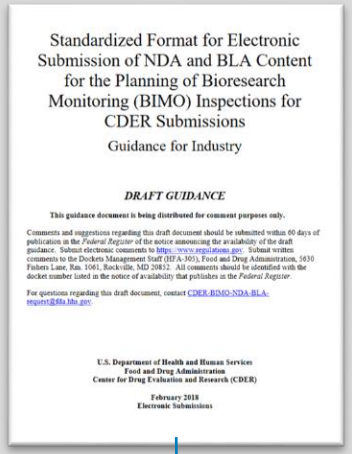
How the FDA communicates technical requirements for submitting study data

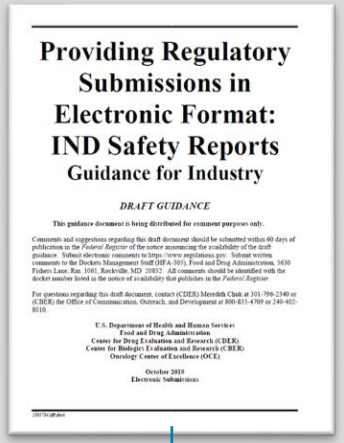


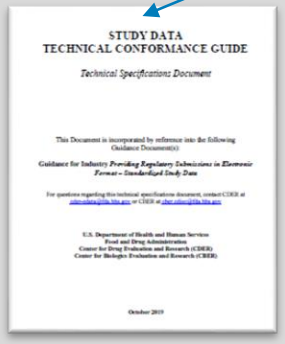
How the FDA communicates technical requirements for submitting study data

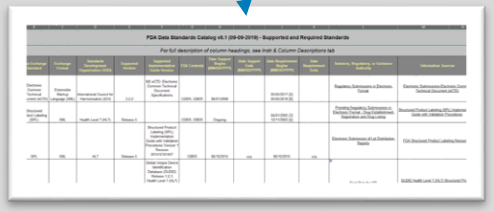
Binding – Level I



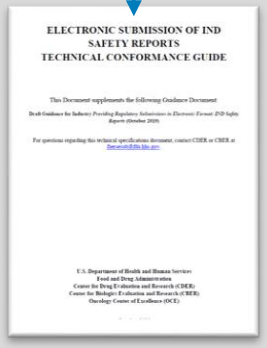








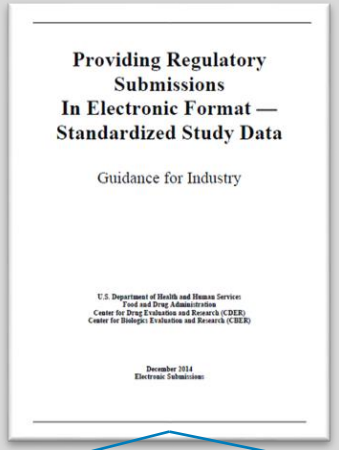
BIMO
TCG

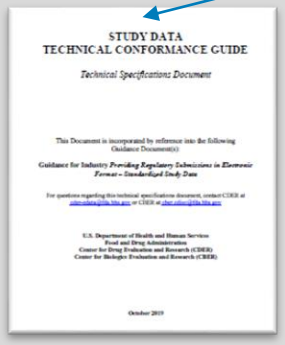


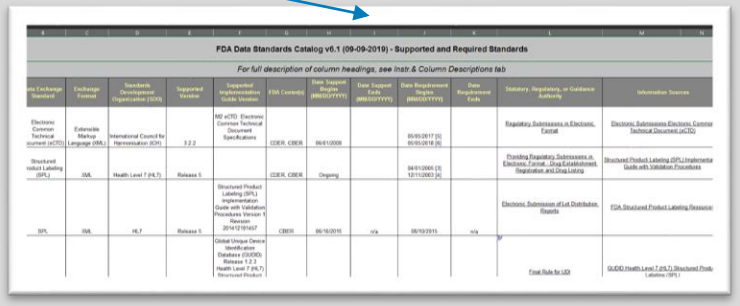
Non-Binding – Level II – but these sit under a binding guidance

Focus on study data

Binding – Level I







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

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

Additional CDISC Propertied in sdTCG v4.9

Appendix D: Additional Documents Evaluated By FDA

The Agency recognizes that there are 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

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

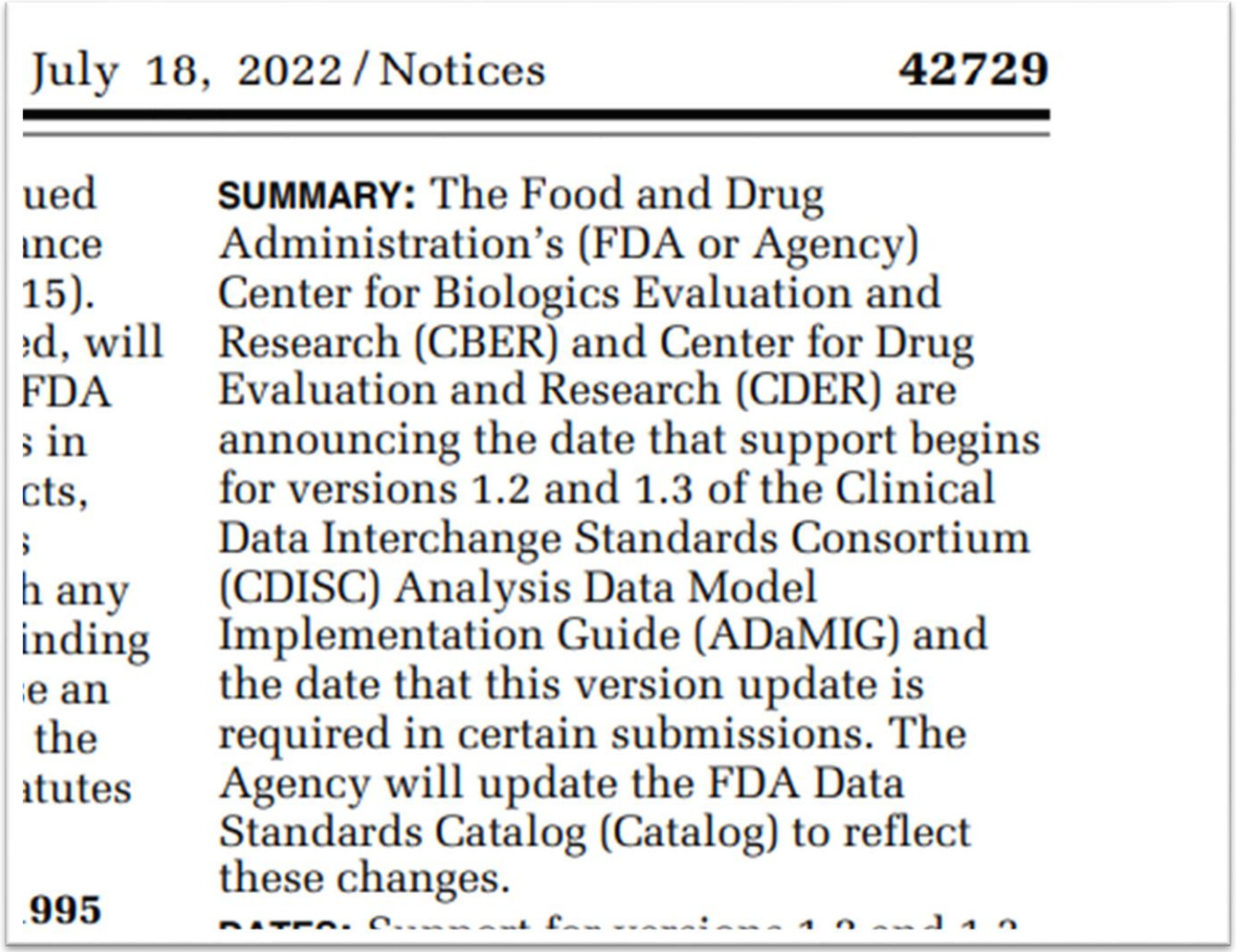
FDA Data Standards Catalog Recent Updates

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



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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.

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

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?