FDA's Study Data Policy Framework and relationship to CDEs

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Current Contributions:

Works at FDA CDER Office of Strategic Programs as an epidemiologist. She joined FDA in 2010

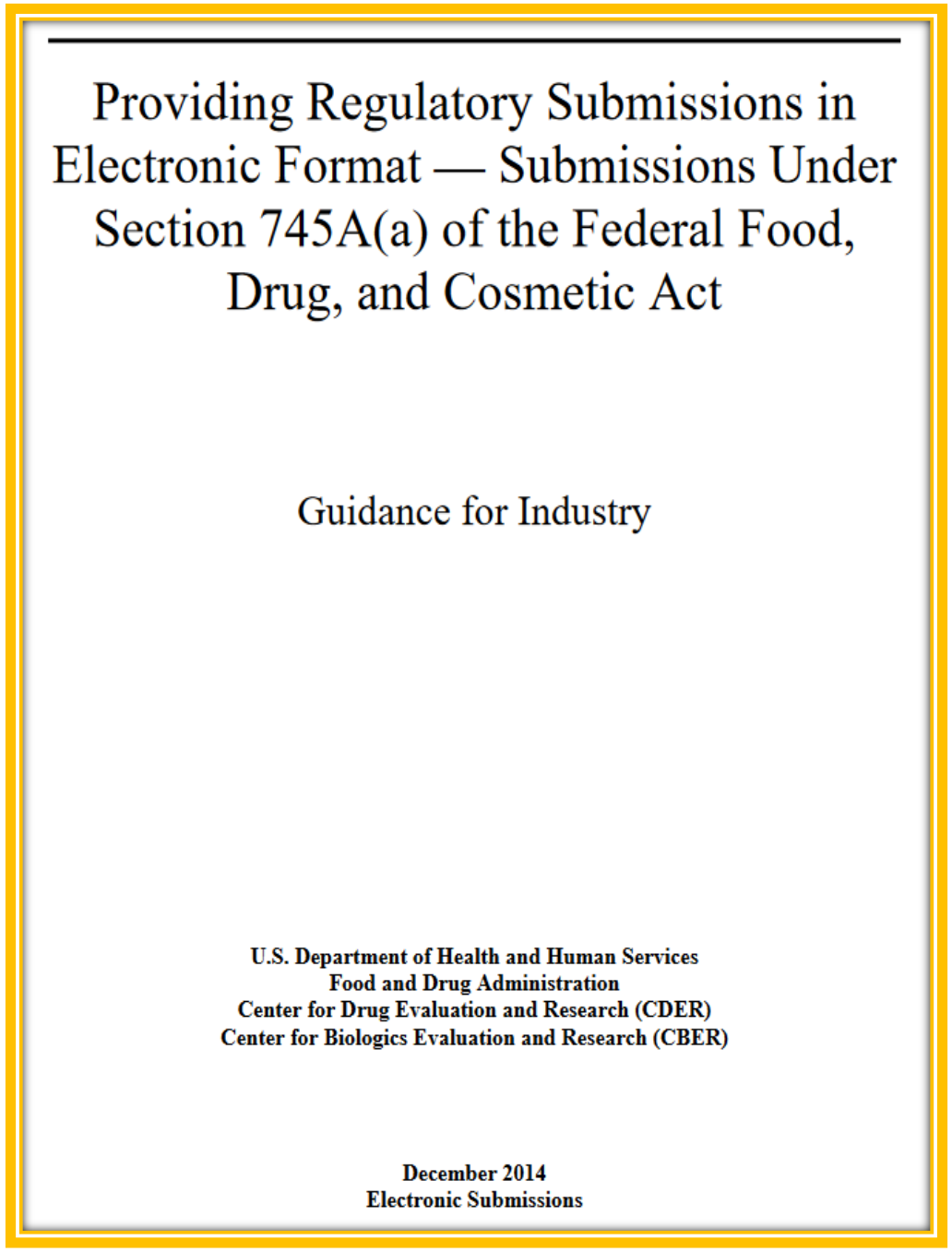
Her current contributions include leadership in maintaining of some of the guidance documents in the FDA CDER/CBER Study Data Policy Framework (which she will be discussing today).

She is a data scientist with a strong background in statistics and has made substantial contributions to the vision and current structure of the Framework.

- I AM NOT A LAWYER

Helena Sviglin (she/her), FDA CDER Office of Strategic Programs

FDA CDER and CBER 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)

"Parent" Guidance

FDA CBER and CDER's Study Data Policy Framework

Binding Guidance (sitting under 745A(a))

- eStudy Data
- Real World Data
- eCTD

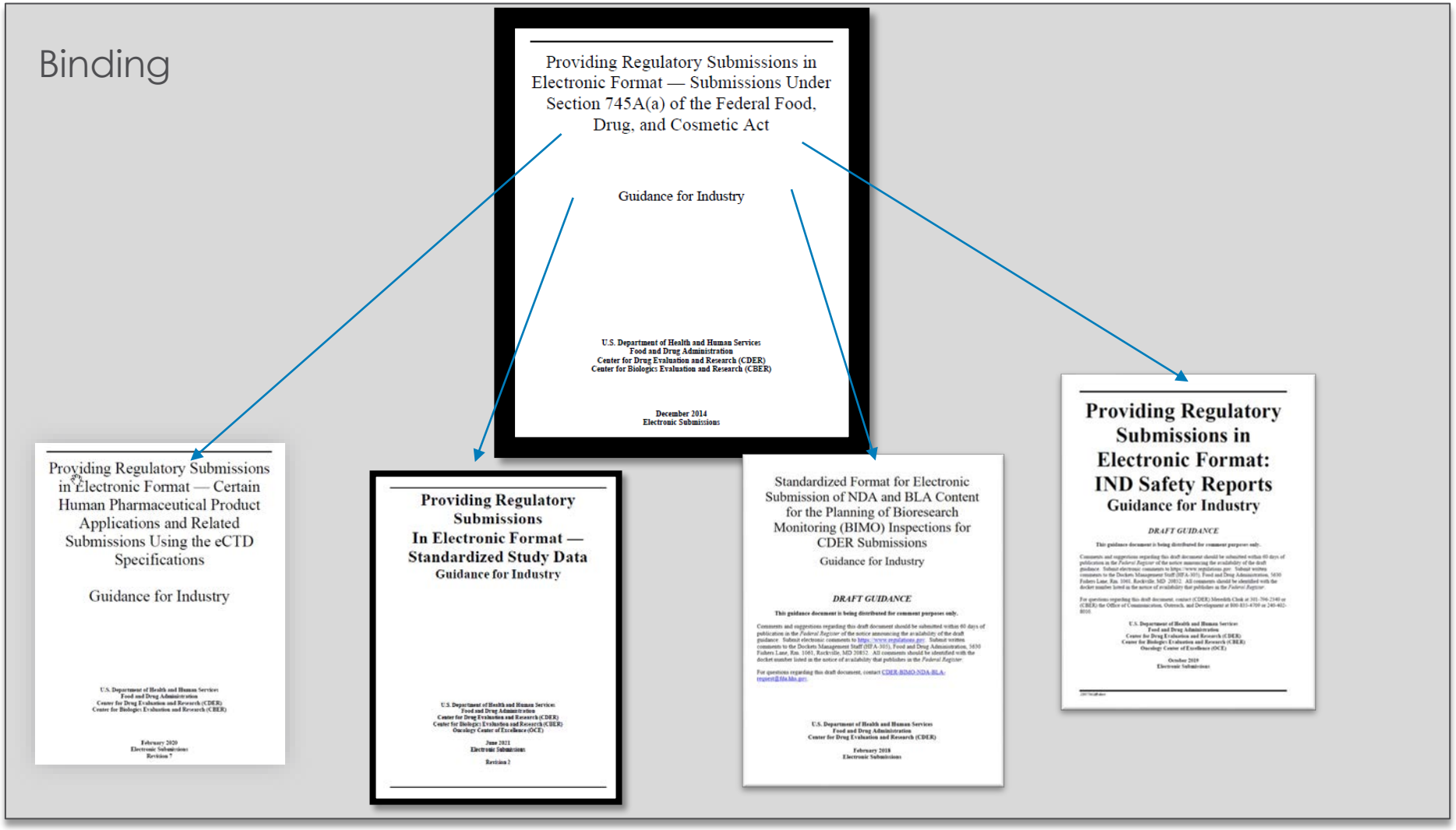
Incorporated by reference into Binding Guidance

- 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)

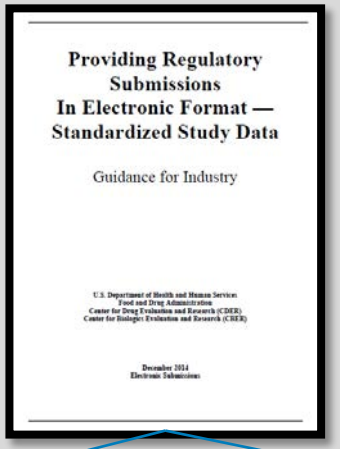
Study Data Standards Resources | FDA (fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources)

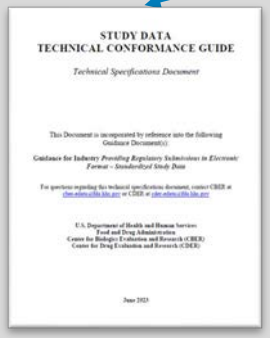
How FDA communicates technical requirements for submitting study data

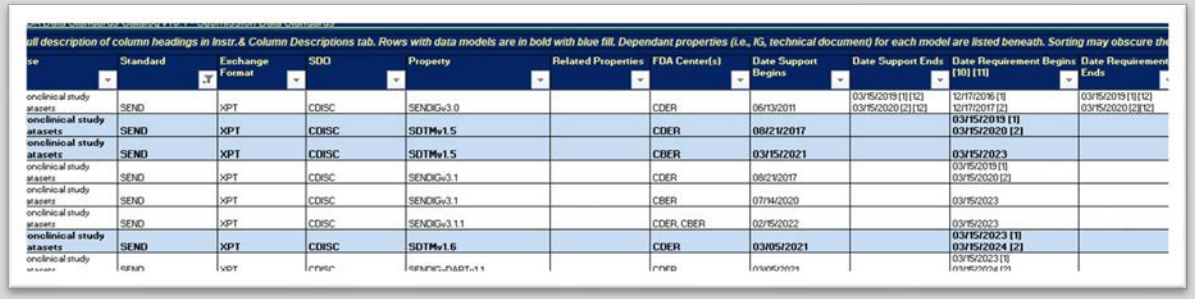


Focus on study data

Binding

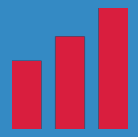






se	Standard	Exchange Format	SDO	Property	Related Properties	FDA Center(s)	Date Support Begins	Date Support Ends	Date Requirement Begins [10] [11]	Date Requirement Ends
onclinical study atasets	SEND	XPT	CDISC	SENDIGv3.0		CDER	06/13/2011	03/15/2019 [1] [12] 03/15/2020 [2] [12]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] [12] 03/15/2020 [2] [12]
onclinical study atasets	**SEND**	**XPT**	**CDISC**	**SDTMv1.5**		**CDER**	**08/21/2017**		**03/15/2019 [1] 03/15/2020 [2]**	
onclinical study atasets	**SEND**	**XPT**	**CDISC**	**SDTMv1.5**		**CBER**	**03/15/2021**		**03/15/2023**	
onclinical study atasets	SEND	XPT	CDISC	SENDIGv3.1		CDER	08/21/2017		03/15/2019 [1] 03/15/2020 [2]	
onclinical study atasets	SEND	XPT	CDISC	SENDIGv3.1		CBER	07/14/2020		03/15/2023	
onclinical study atasets	SEND	XPT	CDISC	SENDIGv3.1.1		CDER, CBER	02/15/2022		03/15/2023	
onclinical study atasets	**SEND**	**XPT**	**CDISC**	**SDTMv1.6**		**CDER**	**03/05/2021**		**03/15/2023 [1] 03/15/2024 [2]**	
onclinical study									03/15/2023 [1]	

Incorporated by reference into Binding Guidance



FDA Data Standards Catalog (Catalog)

GUIDANCE DOCUMENT

Data Standards Catalog

DECEMBER 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

Submit Comments

Submit comments on this guidance document electronically via docket ID: FDA-2013-S-0610 - Specific Electronic Submissions Intended For FDA's Dockets Management Staff (i.e., Citizen Petitions, Draft Proposed Guidance Documents, Variances, and other administrative record submissions)

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

The FDA Data Standards Catalog History

- Debuted in 2013 with version 1.0
- Currently in version 10.2 (Dec 2023)
- It debuted in 2013 but is not limited 745A(a)

Data Standards Catalog | FDA

Let's take a look at the Catalog

FDA Data Standards Catalog v10.2

Full description of column headings in Instr.& Column Descriptions tab. Rows with data models are in bold with blue fill. Dependant properties (i.e., IG,

Use	Standard	Exchange Format	SDO	Property	Related Properti	FDA Center(s)
Clinical study datasets	ADaM	XPT	CDISC	ADaMv2.1		CDER, CBER
Clinical study datasets	ADaM	XPT	CDISC	ADaMIGv1.0		CDER, CBER
Clinical study datasets	ADaM	XPT	CDISC	ADaMIGv1.1		CDER, CBER
Clinical study datasets	ADaM	XPT	CDISC	ADaMIGv1.2 ADaMIGv1.3		CDER, CBER
Clinical study datasets	SDTM	XPT	CDISC	SDTMv1.1		CDER, CBER
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.1.1		CDER, CBER
Clinical and Nonclinical study datasets	SDTM, SEND	XPT	CDISC	SDTMv1.2		CDER, CBER
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.1.2		CDER, CBER
Clinical study datasets	SDTM	XPT	CDISC	SDTMIG Version 3.1.2 Amendment 1		CDER, CBER
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.0		CDER
Clinical study datasets	SDTM	XPT	CDISC	SDTMv1.3		CDER, CBER
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.1.3		CDER, CBER
Clinical study datasets	SDTM	XPT	CDISC	SDTMv1.4		CDER, CBER
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.2		CDER, CBER
Nonclinical study datasets	SEND	XPT	CDISC	SDTMv1.5		CDER
Nonclinical study datasets	SEND	XPT	CDISC	SDTMv1.5		CBER
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1		CDER
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1		CBER
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1.1		CDER, CBER
Nonclinical study datasets	SEND	XPT	CDISC	SENDIG-Genetoxv1.0		CDER, CBER
Nonclinical study datasets	SEND	XPT	CDISC	SDTMv1.6		CDER
Nonclinical study datasets	SEND	XPT	CDISC	SENDIG-DARTv1.1		CDER
Clinical study datasets	SDTM	XPT	CDISC	SDTMv1.7		CDER, CBER

[Data Standards Catalog | FDA]

Here are all SDTM data models currently on the Catalog

FDA Data Standards Catalog v10.2

Full description of column headings in Instr.& Column Descriptions tab. Rows with data models are in bold with blue fill. Dependant properties (i.e., IG,

Use	Standard	Exchange Format	SDO	Property	Related Properti	FDA Center(s)
Clinical study datasets	**SDTM**	**XPT**	**CDISC**	**SDTMv1.1**		**CDER, CBER**
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.1.1		CDER, CBER
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.1.2		CDER, CBER
Clinical study datasets	SDTM	XPT	CDISC	SDTMIG Version 3.1.2 Amendment 1		CDER, CBER
Clinical study datasets	**SDTM**	**XPT**	**CDISC**	**SDTMv1.3**		**CDER, CBER**
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.1.3		CDER, CBER
Clinical study datasets	**SDTM**	**XPT**	**CDISC**	**SDTMv1.4**		**CDER, CBER**
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.2		CDER, CBER
Clinical study datasets	**SDTM**	**XPT**	**CDISC**	**SDTMv1.7**		**CDER, CBER**
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.3		CDER, CBER
Nonclinical study datasets	**SDTM**	**XPT**	**CDISC**	**SDTMv1.8**		**CDER**
Nonclinical study datasets	SDTM	XPT	CDISC	SENDIG-ARv1.0		CDER
Clinical study datasets	**SDTM**	**XPT**	**CDISC**	**SDTMv2.0**		**CDER, CBER**
Clinical study datasets	SDTM	XPT	CDISC	SDTMIGv3.4		CDER, CBER

Data Standards Catalog | FDA

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]	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

Data Standards Catalog | FDA

Relationship to CDEs and data models/terminologies

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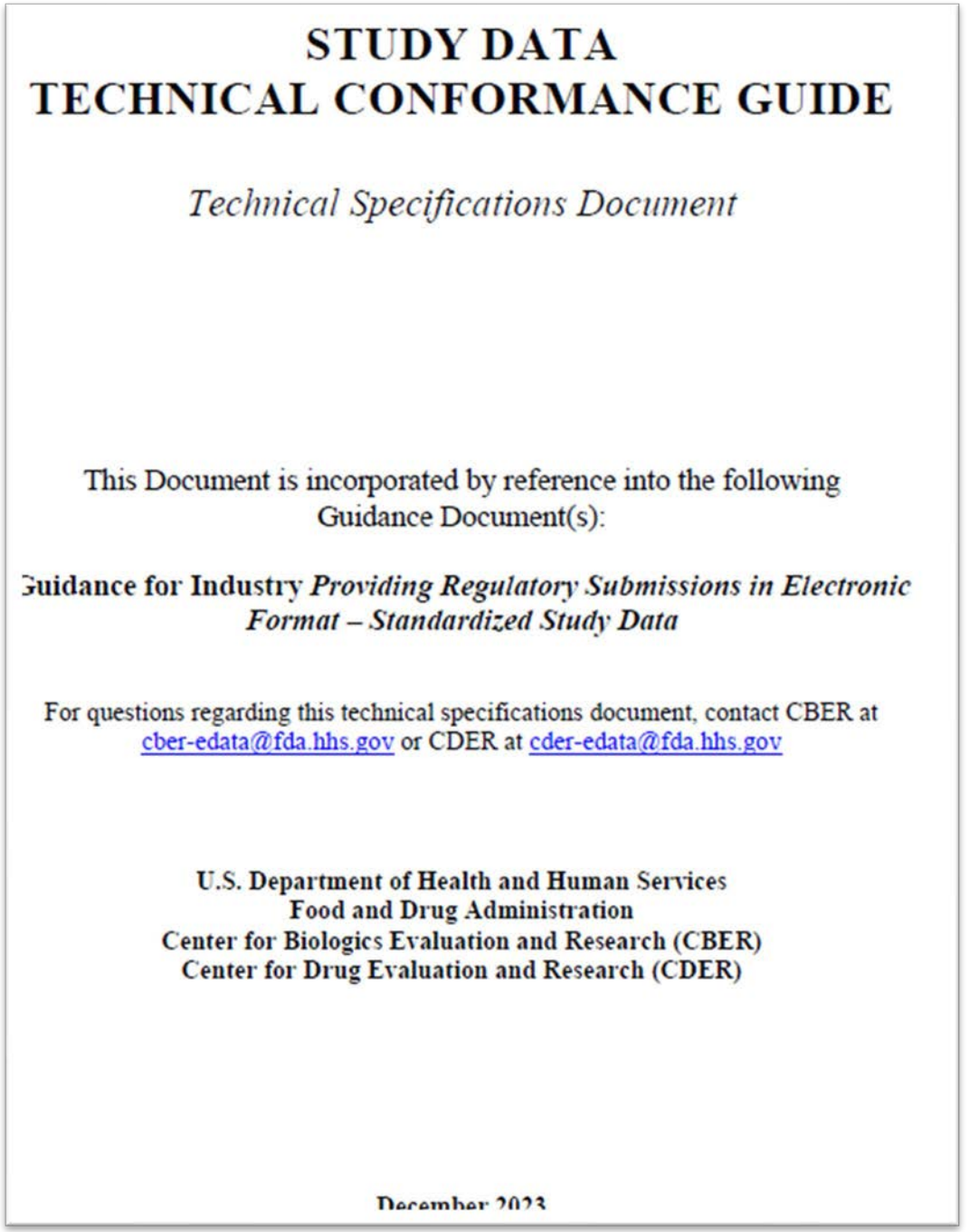
Study Data Technical Conformance Guide (sdTCG)

FDA CDER and CBER sdTCG

Study Data Technical Conformance Guide - Technical Specifications Document | FDA



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)

December 2023

FDA CDER and CBER sdTCG

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

Table of Contents

FDA CDER and CBER sdTCG

Study Data Technical Conformance Guide - Technical Specifications Document | FDA

DM Domain (Demographics)

In the DM domain, each subject should have only one single record per study.

Screen failures, when provided, should be included as a record in DM with the ARM, ARMCD, ACTARM, and ACTARMCD field left blank. For subjects who are randomized in treatment group but not treated, the planned arm variables (ARM and ARMCD) should be populated, but actual treatment arm variables (ACTARM and ACTARMCD) should be left blank.[27]

For subjects with multiple enrollments within a single study, the primary enrollment should be submitted in DM. Additional enrollments should be included in a custom domain with a similar structure to DM. Clarifying statements in the RG would be helpful.

For subjects with multiple screenings and no subsequent enrollment, include the primary screening in DM with additional screenings in a custom domain with a structure similar to DM.

For subjects with multiple screenings and subsequent enrollment, include the enrollment in DM with screenings in a custom domain with a structure similar to DM.

FDA CDER and CBER sdTCG

Study Data Technical Conformance Guide - Technical Specifications Document | FDA

LB Domain (Laboratory)

The size of the LB domain dataset submitted by sponsors is often too large to process (See section 3.3.2). This issue can be addressed by splitting a large LB dataset into smaller datasets according to LBCAT and LBSCAT, using LBCAT for initial splitting. If the size is still too large, then use LBSCAT for further splitting. For example, use the dataset name lb1 (file name 'lb1.xpt') for chemistry, dataset name lb2 (file name 'lb2.xpt') for hematology, and dataset name lb3 (file name 'lb3.xpt') for urinalysis. Splitting the dataset in other ways (e.g., by subject or file size) makes the data less useable. Sponsors should submit these smaller files in addition to the larger non-split standard LB domain file. Sponsors should submit the split files in a separate sub-directory/split that is clearly documented in addition to the non-split standard LB domain file in the SDTM datasets directory (See section 7).

For clinical studies, please submit two separate domains for lab results. The LB domain should contain SI units in LBSTRESU for the SI results in the LBSTRESC and LBSTRESN fields. An additional custom domain called LC structured identically to LB should contain conventional units in --STRESU for the results in conventional units in the --STRESC and --STRESN variables. It is ideal if both conventional and SI units come directly from the lab vendor.

There is no expectation to submit the new LB variables found in SDTMv2.0 and SDTMIGv3.4, which may support individual parts of a LOINC. These new variables should only be submitted in LB datasets when it is medically or scientifically appropriate to do so.

Relationship to CDEs and dataset structures?

?

U.S. FOOD & DRUG ADMINISTRATION

Questions?