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A regulatory journey from PDUFA, FDASIA, and Guidances for standardized study data

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PHUSE CSS, September 13, 2021

Agenda



- PDUFA and 745A
- Data Standards Requirements
- Study Data Technical Rejection Criteria
- Tools to Help Industry



A Brief History

PDUFA and 745A

Looking back to 2012...

Problem to be Addressed

- The extreme variability and unpredictability of the format and content of submitted application data present a major obstacle to timely, consistent, and efficient review within current PDUFA timeframes
- Lack of standardized clinical data:
 - Limits ability to address in-depth questions and late-emerging issues in a timely manner
 - Impedes timely safety analysis to inform REMS decisions
 - Limits ability to transition to more standardized and quantitative approaches to benefit-risk assessment

Timeline of PDUFA & Guidances

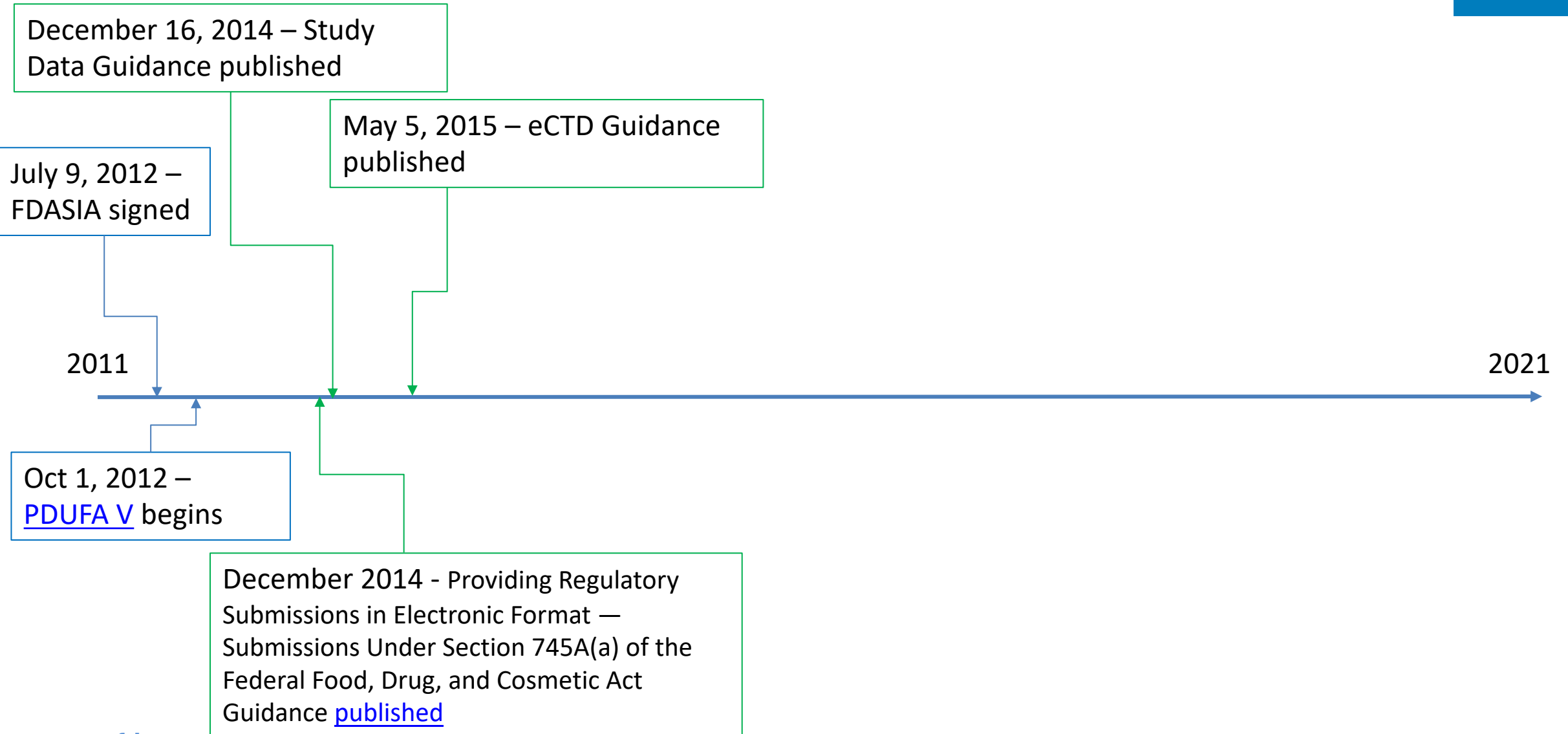


FDASIA/PDUFA V



- [PDUFA V goals](#) include a section “Improving the efficiency of human drug review through required electronic submissions and standardization of electronic drug application data”
- “Section 1136 of FDASIA amended the FD&C Act by adding section 745A, which addresses electronic submissions. ... Section 745A(a)(1) of the FD&C Act describes the general scope of section 745A(a) and provides that submissions under NDAs, ANDAs, BLAs, and INDs must be in electronic format specified in FDA guidance...” [Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A\(a\) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry, Section II](#)

Timeline of PDUFA & Guidances



745A(a) Guidances

- FDA issued “[Providing Regulatory Submissions in Electronic Format - Standardized Study Data: Guidance for Industry](#)” in December 2014 (updated in June 2021)
 - Sponsors must conform to standards in the FDA Data Standards Catalog:
 - NDA, certain BLA, ANDA studies that started after December 17th, 2016
 - Commercial IND studies started after December 17th, 2017
- FDA issued “[Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry](#)” in May 2015 (updated in February 2020)
 - Sponsors must submit in eCTD format:
 - NDA, certain BLA, ANDA applications starting May 5th, 2017
 - Commercial IND and certain MFs applications starting May 5th, 2018

eStudy Guidance

Binding Guidance— Requires that studies are compliant with the standards outlined in the FDA Data Standards



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

December
17
2014

24 Months*

December
17
2016

Compliance



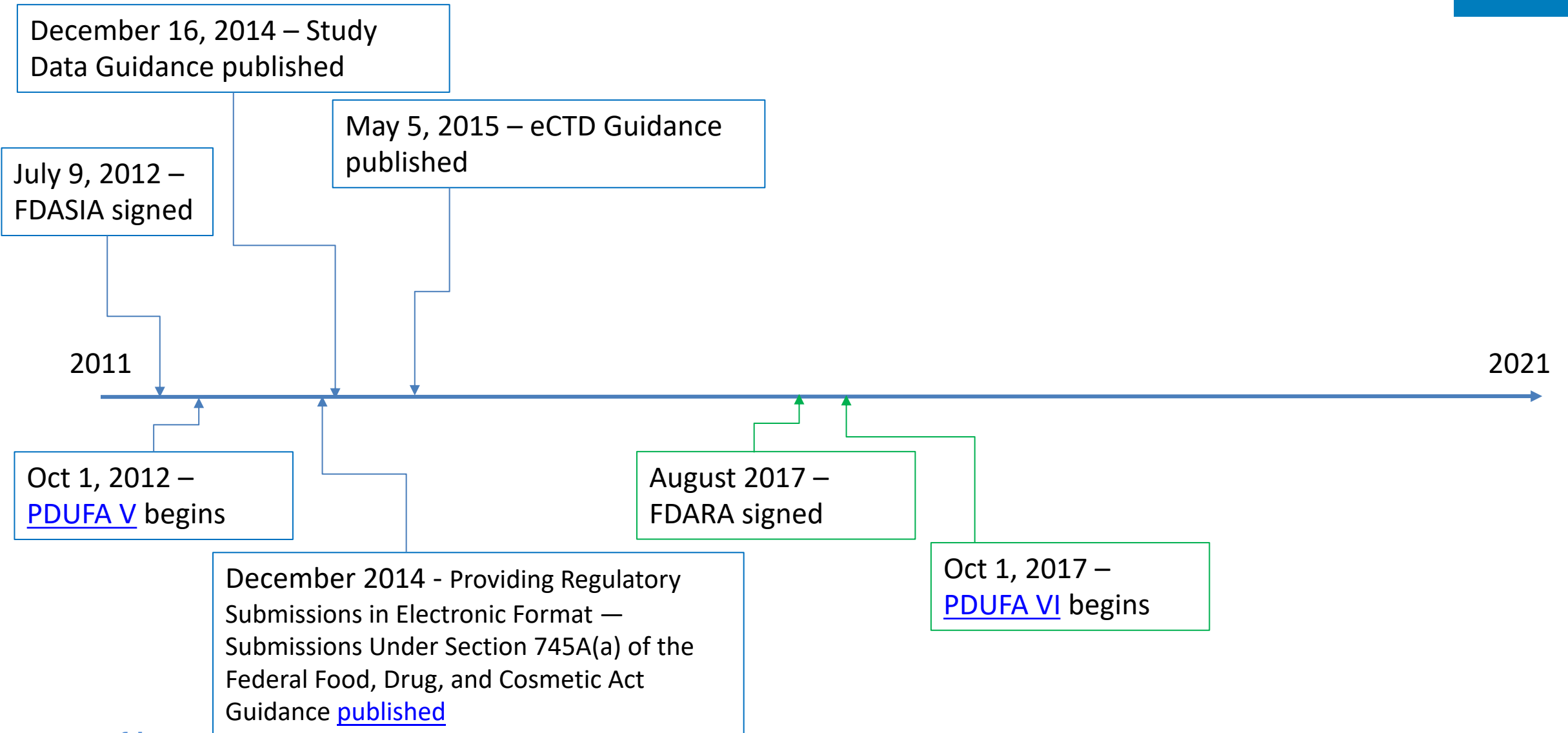
Studies starting**
after MUST use the
standards in the
Data Catalog (NDAs,
ANDAs, BLAs)

Final
Published
December, 2014

*36 months for INDs **Study Start Date in the SDTM Trial Summary Domain (TSPARMCD = SSTDTCT).

4

Timeline of PDUFA & Guidances



FDARA/PDUFA VI

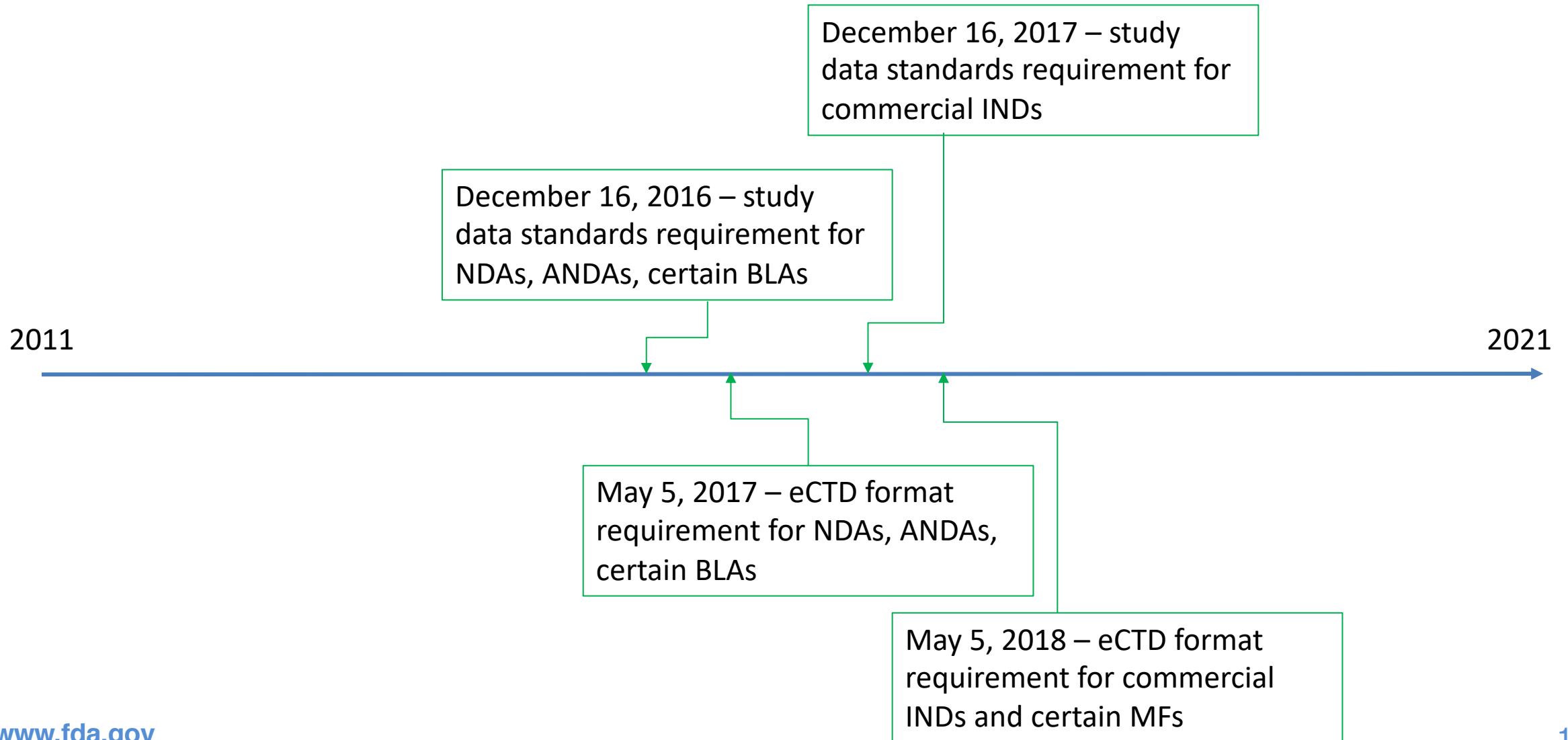


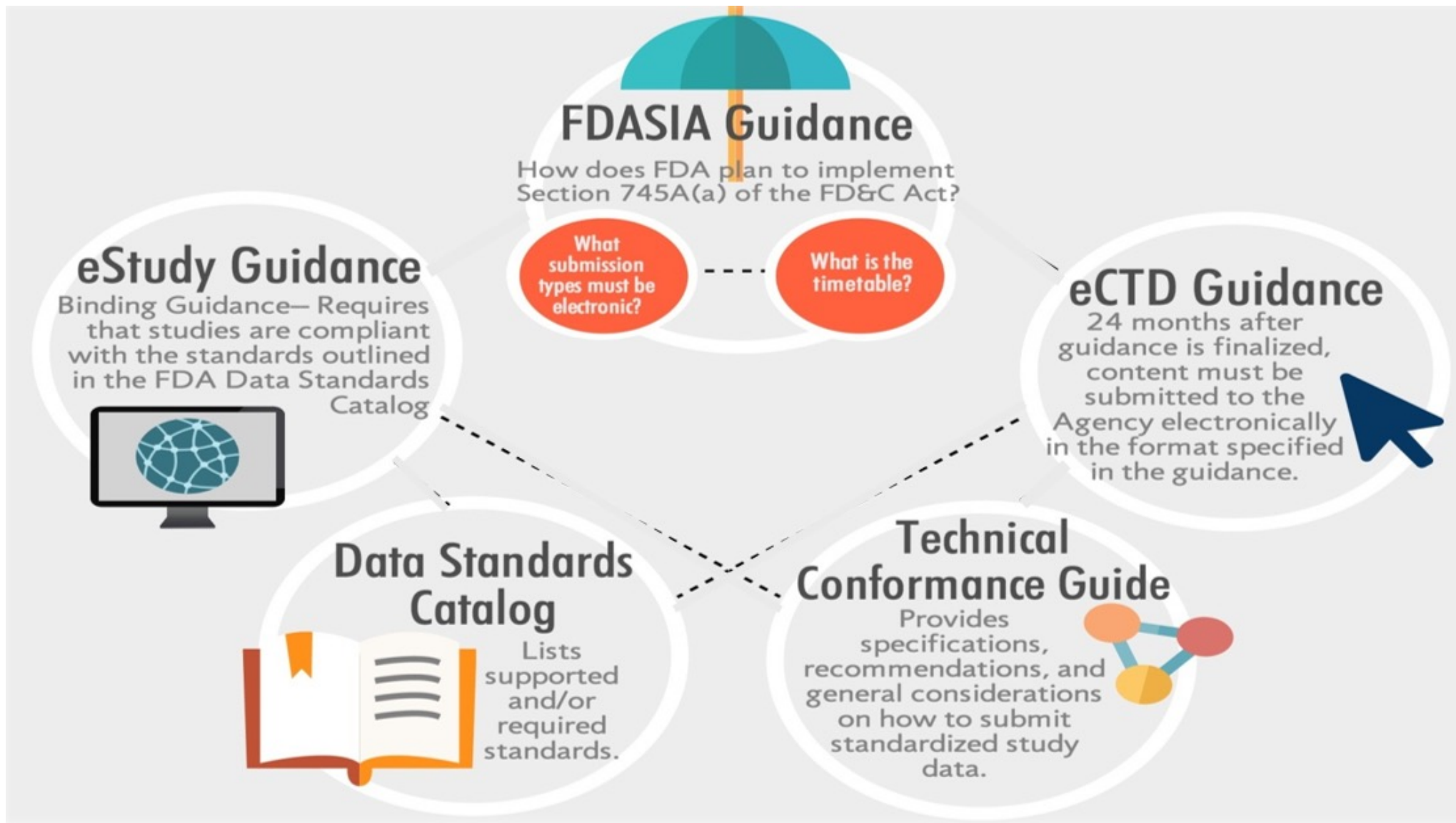
- [PDUFA VI goals](#) include a section “Enhance transparency and accountability of FDA electronic submission and data standards activities”
- [Deliverables](#) include:
 - Public Meetings for Electronic Submissions and Data Standards
 - CBER-CDER Data Standards Program Action Plan
 - FDA Data Standards Catalog
 - Joint Quarterly Meetings to Enhance Transparency and Accountability of FDA Electronic Submission and Data Standards Activities

How does it all connect?

Data Standards Requirements

Timeline of data standards



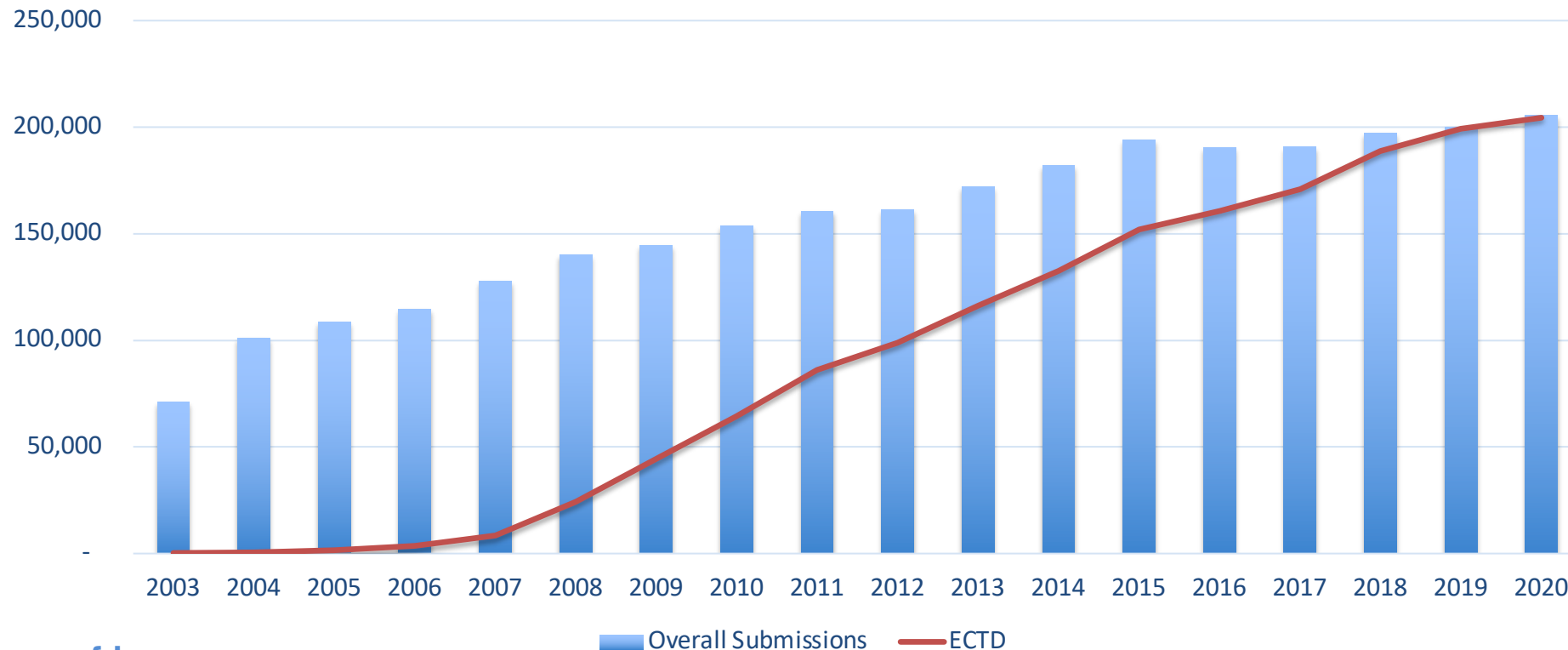


eCTD Submission Metrics 2003 - 2020



CDER received approximately 205,000* electronic submissions via ESG in FY 2020. Nearly all were in eCTD.

Comparison: Overall Submissions vs. eCTD Submissions

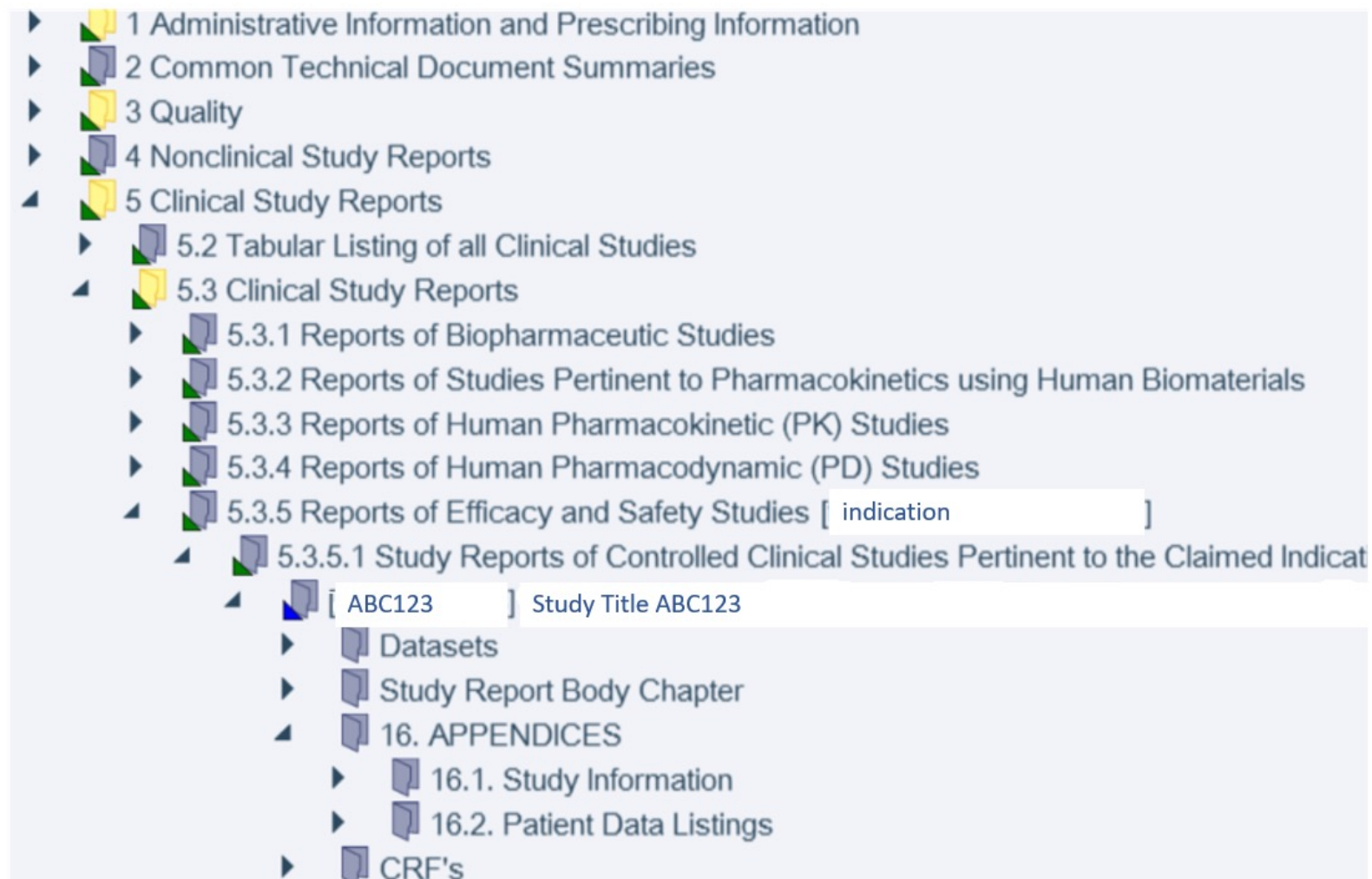


*excludes Non-Commercial IND and DMF Type III

Review of eCTD Submissions



FDA uses Lorenz docuBridge to support the review of eCTD formatted submissions



Study Data...SDTM, ADaM, SEND, Define.XML

FDA Data Standards Catalog (#4)(12-10-2014) - Supported and Required Standards											
Use	Data Exchange Standard	Exchange Format	Administrative Organization	Supporting Software Version(s)	Implementation Guide Revision	FDA Center(s)	Data Support Engine	SAS Support Code	SAS Requirement Engine	SAS Requirement Date	Regulatory Reference or Information Source
Clinical and Non-Clinical study data sets - High	SAS Transport (XPORT)	XPT	DAG	8	SAS Technical Support T-9446	CDER, CBER	Ongoing				FDA CDER and CBER website Technical Support Section
Clinical and Non-Clinical study data sets - Low / Temporary	SAS XPORT	XPT	DAG	8	SAS Technical Support T-9446	CDER, CFMRL, DVM	Ongoing				FDA CDER web site Regulatory Information for Medical Device Submissions
CDER, CBER, and CDRL internal unit											FDM, IBM, Technology
			WEC	1.0		CDER, CDER, CDRL	Ongoing				www.fda.gov
			ADP			CDER, CDER, CDRL	Ongoing				
	Clinical SAS Interchange Standards Consortium (CISC)	XPT		1.0	1.0.0	CDER, CBER	10/10/10				cisc.org - SMTN
	CISC	XPT		1.2	VERSIT 3.1.4 Amendment 1	CDER, CBER	8/7/13				cisc.org - SMTN
	CISC	XPT		1.2	1.1.2	CDER, CBER	10/3/09				cisc.org - SMTN
	CISC	XPT		1.1	1.1.1	CDER, CBER	Ongoing	UCB/2010			cisc.org - SMTN
	CISC	XPT		2.1	1.0	CDER, CBER	Ongoing				cisc.org - eSMTN
	PDOP	XPT		1.0	1.0.0	CDER	4/15/01				cisc.org - eSMTN

Lists supported and/or required standards.



December 2016

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
Electric Substations

eStudy Guidance
Binding Guidance— Requires that studies are compliant with the standards outlined in the FDA Data Standards



**Final
Published**

Data Standards Catalog



FDA Data Standards Catalog v7.2 (07-01-2021) - Supported and Required Standards

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

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Supported Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY) [1]	Date Requirement Ends (MM/DD/YYYY)	Statutory, Regulatory, or Guidance Authority	Information Sources
Clinical study datasets	SDTM	XPT	CDISC	1.2	3.1.2	CDER, CBER	10/30/2009	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]	Standardized Study Data	CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.2	Version 3.1.2 Amendment 1	CDER, CBER	08/07/2013	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]	Standardized Study Data	CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.3	3.1.3	CDER, CBER	12/01/2012	03/15/2021	12/17/2016 [1] 12/17/2017 [2]	03/15/2021	Standardized Study Data	CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.4	3.2	CDER, CBER	08/17/2015		03/15/2018 [1] 03/15/2019 [2]		Standardized Study Data	CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.7	3.3	CDER, CBER	03/15/2021		03/15/2023		Standardized Study Data	CDISC.org - SDTM
Animal Rule study datasets	SDTM	XPT	CDISC	1.8	SENDIG-AR v1.0	CDER	03/15/2020		3/15/2022 [1] 3/15/2023 [2]		Standardized Study Data	CDISC.org - SDTM
Clinical study datasets	Analysis Data Model (ADaM)	XPT	CDISC	2.1	1.0	CDER, CBER	Ongoing	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]	Standardized Study Data	CDISC.org - ADaM
Clinical study datasets	ADaM	XPT	CDISC	2.1	1.1	CDER, CBER	03/15/2018		03/15/2019 [1] 03/15/2020 [2]		Standardized Study Data	CDISC.org - ADaM
Animal study datasets	Standard for Exchange of Nonclinical Data (SEND)	XPT	CDISC	1.2	3.0	CDER	06/13/2011	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]	Standardized Study Data	CDISC.org - SEND
Animal study datasets	SEND	XPT	CDISC	1.5	3.1	CDER	08/21/2017		03/15/2019 [1] 03/15/2020 [2]		Standardized Study Data	CDISC.org - SEND
Animal study datasets	SEND	XPT	CDISC	1.5	3.1	CBER	03/15/2021		03/15/2023		Standardized Study Data	CDISC.org - SEND
Nonclinical study datasets									03/15/2023 [1]		Standardized Study Data	CDISC.org - SEND

Review of Study Data

FDA also utilizes multiple tools and systems to support analysis of standardized study data:

The screenshot displays the CDEROne Analytics dashboard. On the left, a sidebar contains various filters for clinical trials, including Application Type & Number, Product/Ingredient Name, Dosage Form, Approved ROA, SNOMED CT, Study ID, NCT ID, Trial Phase, Study Title, Trial Type, and Trial Disease/Condition Indication. The main area shows a table of clinical trials with columns for Application Type & Number, Product Name, Ingredient Name, Dosage Form, and Clinical Trial Details. A detailed view of a specific trial (Study ABC) is shown, including its title, phase, and type. On the right, there are sections for M5 Documents and M2 Documents, each with a table of documents and their associated data.

CDEROne

M5 Documents

Docu...	Document...	Submissi...	Submission	Seq Num	Module/S...
study report body	Study ABC Synopsis	1/1/2021	ORIGINAL-1	0001	m5-3-3-4-extrinsic-factor-pk-study-reports
study report body	Study ABC Study Report	1/1/2021	ORIGINAL-1	0001	m5-3-3-4-extrinsic-factor-pk-study-reports
study report body	Study ABC Protocol Amendment	1/1/2021	ORIGINAL-1	0001	m5-3-3-4-extrinsic-factor-pk-study-reports
study report body	Study ABC define.pdf	1/1/2021	ORIGINAL-1	0001	m5-3-3-4-extrinsic-factor-pk-study-reports

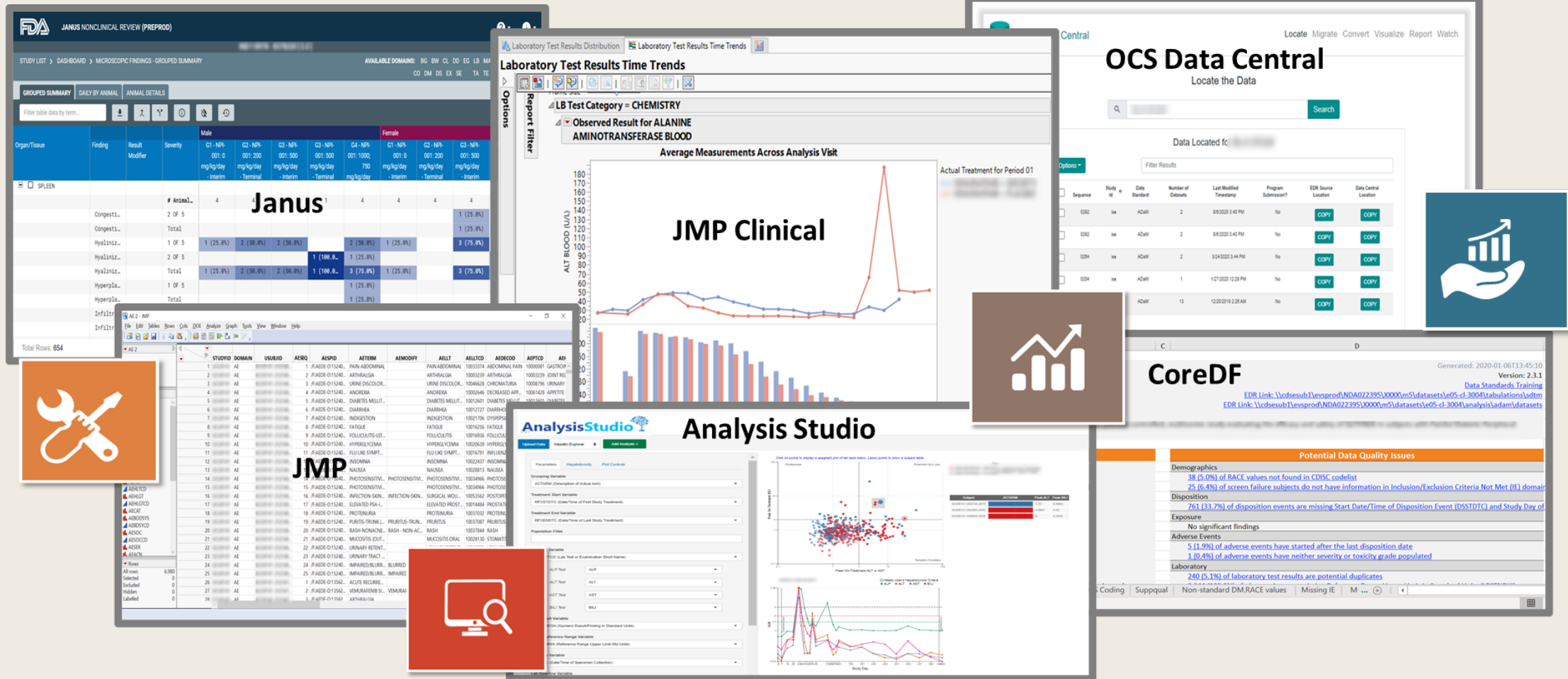
M2 Documents

Trial D...	Dataset N...	Submissi...	Submission	Seq Num	Module/S...
analysis dataset adam	AE	1/1/2021	ORIGINAL-1	0001	m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports
data tabulation dataset sdtem	DM	1/1/2021	ORIGINAL-1	0001	m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports
data tabulation dataset sdtem	TS	1/1/2021	ORIGINAL-1	0001	m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports
data tabulation dataset define	Define	1/1/2021	ORIGINAL-1	0001	m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports

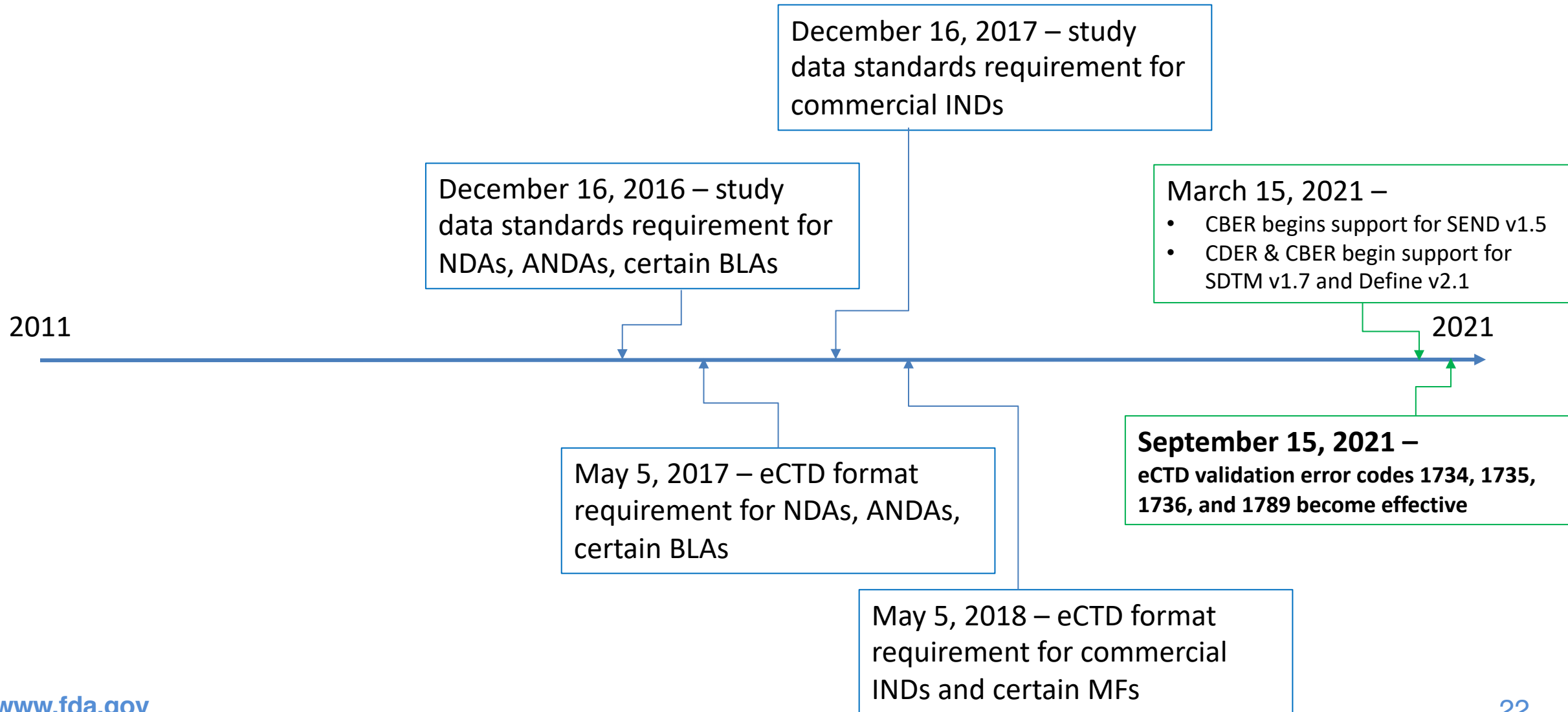
An unstandardized study cannot display with the same detailed information as a standardized study

Review of Study Data

FDA also utilizes multiple tools and systems to support analysis of standardized study data:



Timeline of data standards



How are we checking the Study Data Guidance requirements?

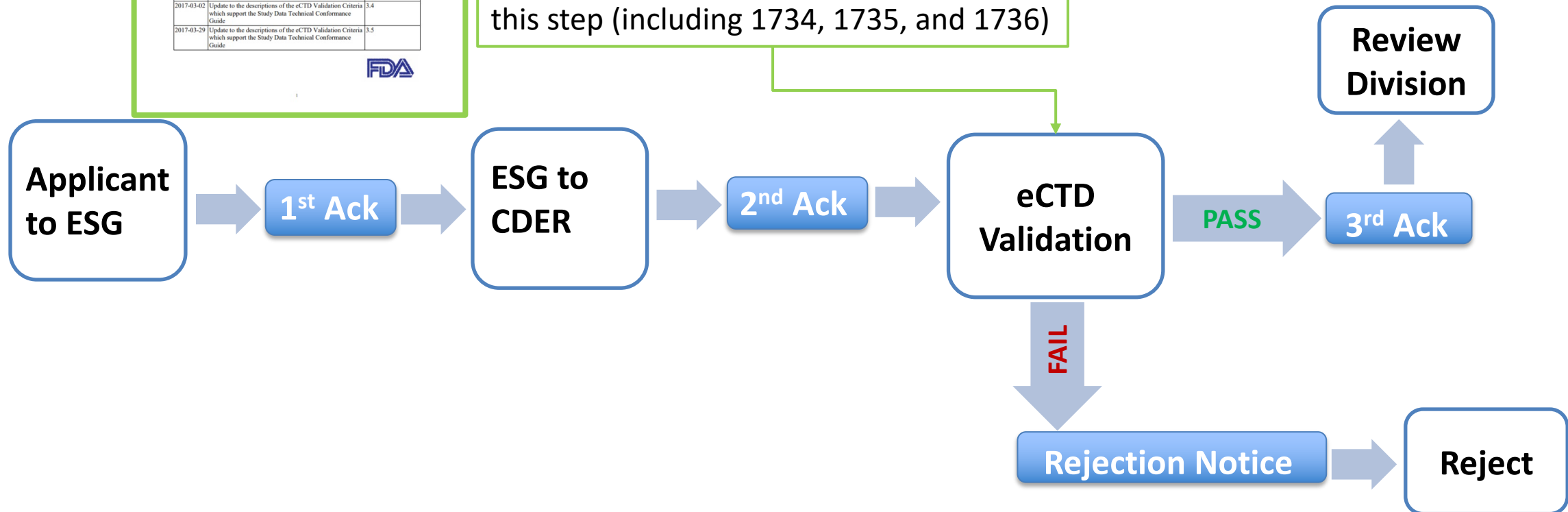
Specifications for eCTD Validation Criteria
US Food and Drug Administration

Specifications for eCTD Validation Criteria

Revision History

Date	Description	Version
2008-03-10	Initial Release of eCTD Validation Criteria	1.0
2010-12-10	eCTD Validation Criteria updated including additions and deletions of error codes - DRAFT	2.0
2011-12-20	eCTD Validation Criteria updated including clarifications and deletions of error codes - FINAL	2.1
2013-04-30	eCTD Validation Criteria effective dates updated - FINAL	2.2
2013-08-23	eCTD Validation Criteria added and existing criteria updated to incorporate changes for US eCTD Module 1 (using DTD version 3.2) - FINAL	3.0
2014-02-07	Updated DTD version 3.2 references to 3.3; DTD 2.01 added to the applicable DTD versions for error 2001; updated guidance sources where applicable - FINAL <small>Note: On 2014-03-07, corrections were made to a date and the descriptions in the last two rows of this Revision History.</small>	3.1
2016-09-21	eCTD Validation Criteria added to support Study Data Technical Conformance Guide	3.2
2016-11-07	Update to the descriptions of the eCTD Validation Criteria which support the Study Data Technical Conformance Guide	3.3
2017-03-02	Update to the descriptions of the eCTD Validation Criteria which support the Study Data Technical Conformance Guide	3.4
2017-03-29	Update to the descriptions of the eCTD Validation Criteria which support the Study Data Technical Conformance Guide	3.5

Validation, as listed in the [Specification for eCTD Validation Criteria](#), occurs during this step (including 1734, 1735, and 1736)





Are You Ready?

Study Data Technical Rejection Criteria

Overview of TRC Errors



- Technical Rejection Criteria for Study Data provides the conditions under which FDA will not accept submissions with study data

Error	Description (Reference to FDA Study Data Technical Rejection Criteria March 2021 version)	Severity Level	Effective Date
1734	A dataset named ts.xpt with information on study start date must be present for each study in required sections*	High	Sept. 15, 2021
1735	The correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections*	High	
1736	For Standard for Exchange of Nonclinical Data (SEND) data, a Demographic (DM) dataset and define.xml must be submitted in Module 4 required sections* For Study Data Tabulation Model (SDTM) data, a DM dataset and define.xml must be submitted in Module 5 required sections* For Analysis Data Model (ADaM) data, an ADaM Subject level analysis dataset (ADSL) dataset and define.xml must be submitted in Module 5 required sections*	High	
1789	A file has been submitted in a study section without providing an STF file. STFs are not required for 4.3 Literature references, 5.2 Tabular listings, 5.4 Literature references and 5.3.6 Postmarketing reports	High	

* Module 4 sections: 4.2.3.1, 4.2.3.2, 4.2.3.4

Module 5 sections: 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2

Relationship between the Technical Rejection Criteria for Study Data and the Specification for eCTD Validation Criteria

Technical Rejection Criteria for Study Data

Study data standards are required in clinical and nonclinical studies that start after December 17, 2016.¹ Technical rejection criteria have been added to the existing electronic common technical document (eCTD) validation criteria to enforce the deadlines below² and will become effective on September 15, 2021.

FDA will not accept an electronic submission that does not have study data in compliance with the required standards specified in the FDA Data Standards Catalog.³

The standards apply to the following types of submissions to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER):

- New drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and all subsequent submissions to these types of applications, including amendments, supplements, and reports, even if the original submission was filed before the requirements went into effect.
- Commercial investigational new drug applications (INDs) (for products that are intended to be distributed commercially).

Deadlines: Sponsors whose studies started after **December 17, 2016**, must use the data standards listed in the FDA Data Standards Catalog for NDAs, BLAs and ANDAs. For Commercial INDs, the requirement applies to studies started after **December 17, 2017**.

FDA implemented an approach to determine compliance with the requirement to submit electronic standardized study data. The technical rejection criteria are automated validations by the Center (CDER or CBER) inbound processing system using the FDA Specifications for eCTD Validation Criteria as described below.

This document focuses on the criteria used for the automated validation process. In order for the FDA automated eCTD validation process to determine the study start date (SSD) for the submitted study, FDA relies on the SSD value provided in the Trial Summary dataset (ts.xml) that is referenced in the Study Tagging File (STF).⁴ This validation confirms the submission of a valid STF (see validation code 1789) and a Trial Summary (TS) domain (see validation code 1734). For a study that contains a study report with file tags "pre-clinical-study-report," "agency-clinical-study-report," or "study-report-body," and/or an xml formatted dataset, the expectation for content in the TS domain (simplified or full) depends on whether the study is submitted in compliance with a Clinical Data Interchange Standards Consortium (CDISC) standard. FDA's Study Data Technical Conformance Guide provides the appropriate content.

¹ This requirement is discussed in the guidance for industry *Providing Regulatory Submissions in Electronic Format—Standardized Study Data*, available on the FDA guidance web page at <https://www.fda.gov/regulatory-information/submitting-efi> and on the FDA Study Data Standards Resources web page at <https://www.fda.gov/oc/industry-data-standards-resources>. We update guidance periodically. For the most recent version of a guidance, check the FDA guidance web page.

² See pp. 4-6.

³ Available on the FDA Study Data Standards Resources web page.

⁴ The Study Start Date (SSD) should follow the ISO 8601 standard that provides, at minimum, the year, month, and day for the study start date.

⁵ Please refer to Appendix 2 of this document for more information on the simplified TS file and the Study Data Technical Conformance Guide on the FDA Study Data Standards Resources web page for more information on the full TS file.

1

Revised 03/15/21



is a subset of

Specifications for eCTD Validation Criteria
US Food and Drug Administration

Revision History

Date	Description	Version
2008-03-10	Initial Release of eCTD Validation Criteria	1.0
2010-12-10	eCTD Validation Criteria updated including additions and deletions of error codes - DRAFT	2.0
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2017-03-29	Update to the descriptions of the eCTD Validation Criteria which support the Study Data Technical Conformance Guide	3.5

FDA

1

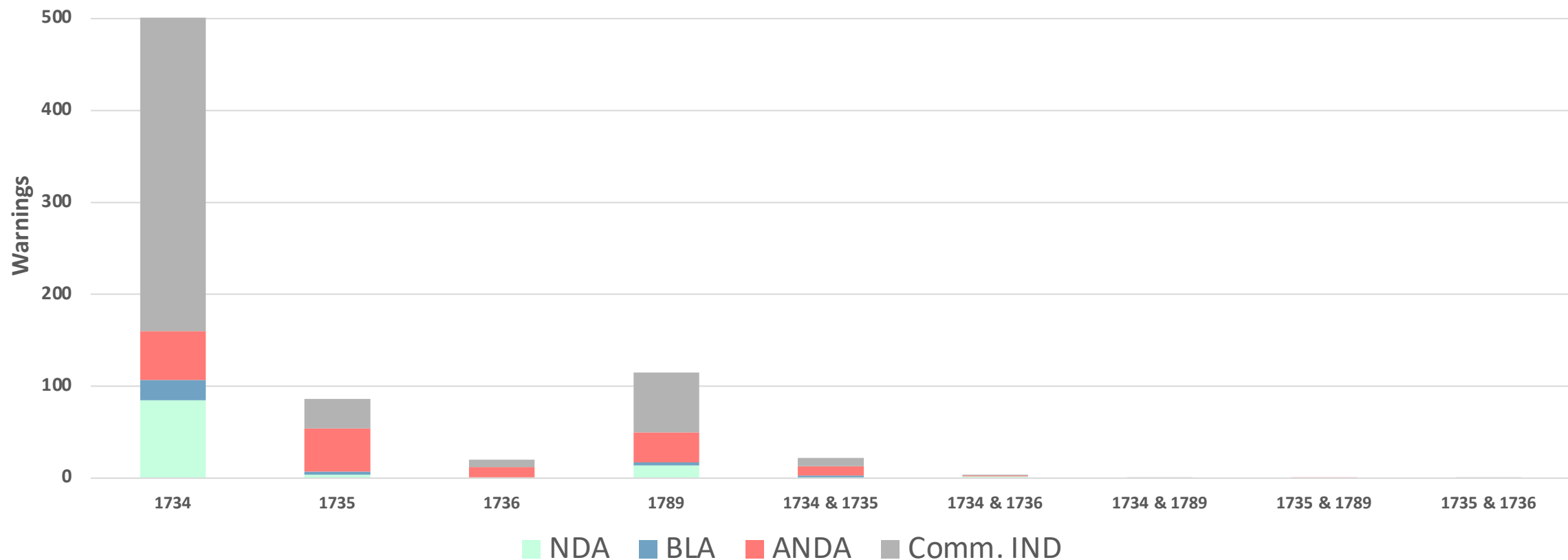
The Specification for eCTD Validation Criteria contains a **total of 161 validations**

46 are High severity, meaning failure of that validation leads to rejection

The **Technical Rejection Criteria for Study Data** provides **additional detail on 4 of these validations (1734, 1735, 1736, 1789)** to help industry understand under what conditions submission of study files will trigger them and criteria to pass

TRC Warning Notices (March 15 – August 15, 2021)

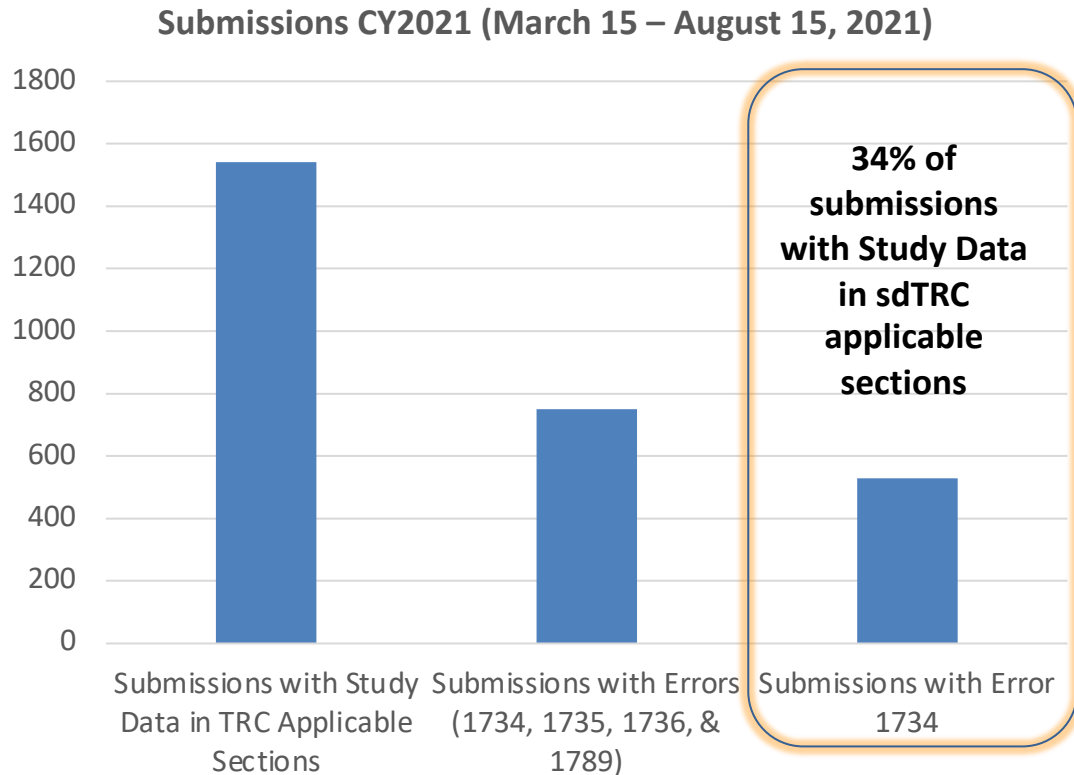
- 1734 is the most common failure reason, especially for Commercial IND submissions
- 1789 is the second largest failure reason and is particularly high for Commercial IND submissions



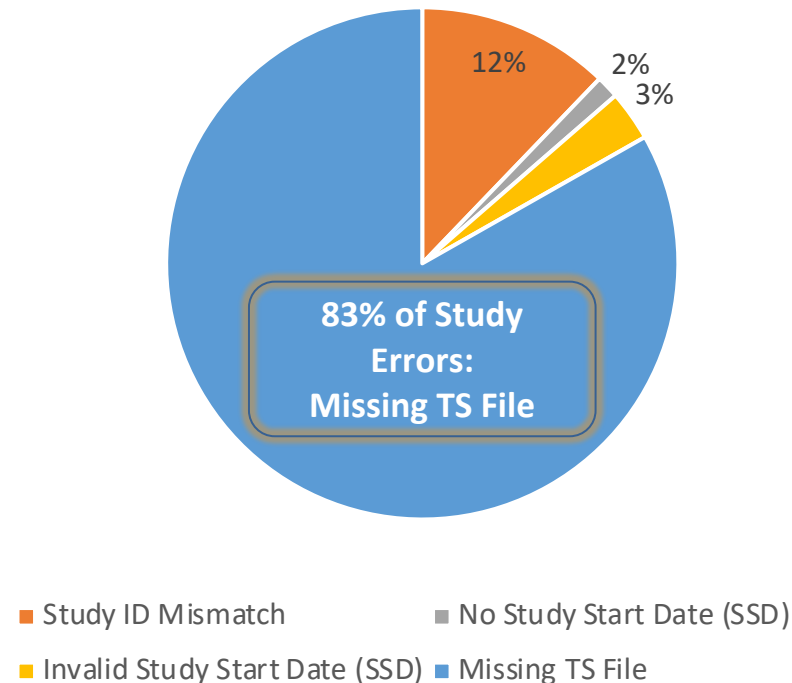
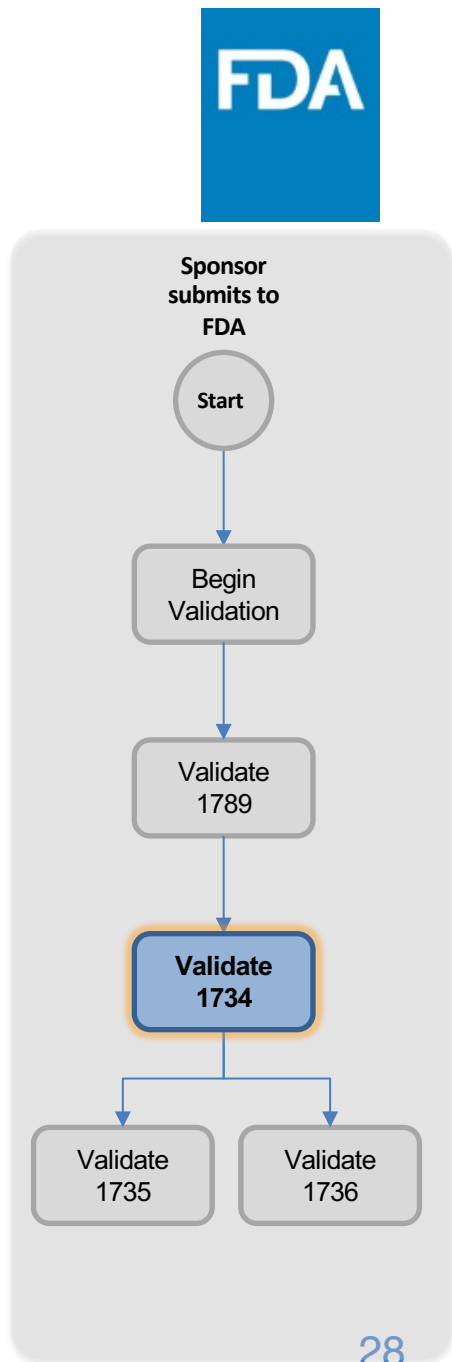
Validation Rule 1734

A dataset named ts.xpt with information on study start date must be present for each study in required sections*

- ✓ Trial Summary Dataset (ts.xpt) is present
- ✓ Study ID (or SPREFID) matches STF Study ID
- ✓ Study start date is provided (or TSVALNF = NA)
- ✓ Study start date is in a valid format



1734 Error Reasons**



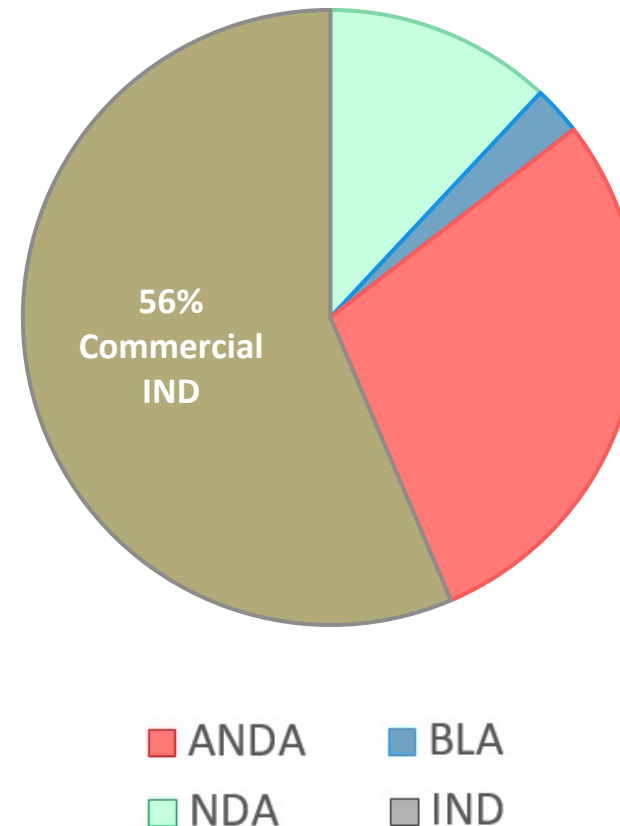
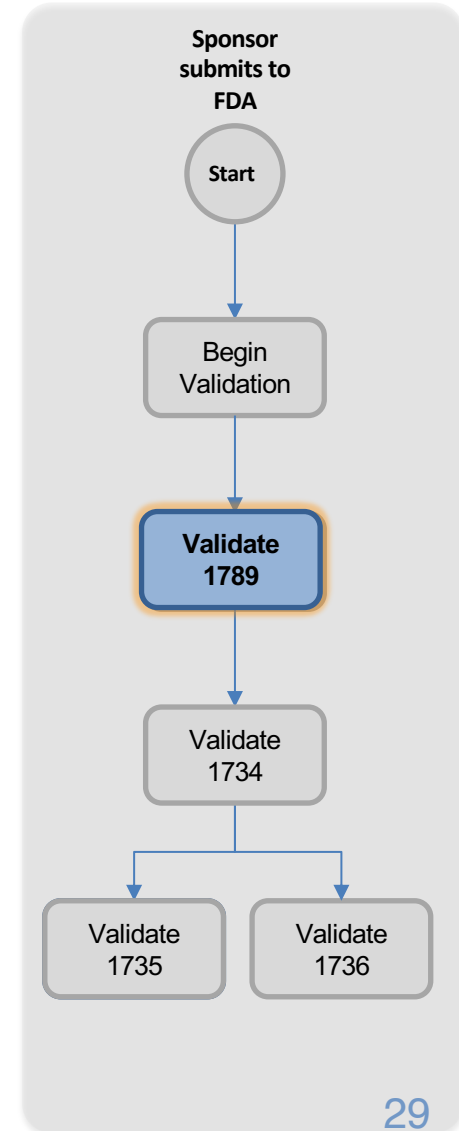
Validation Rule 1789

A file has been submitted in a study section without providing an STF file (STFs are not required for 4.3 Literature references, 5.2 Tabular listings, 5.4 Literature references and 5.3.6 Postmarketing reports).

✓ All study files are included in a Study Tagging File (STF)

1789 errors are the second largest source of sdTRC failures*

Submission Types for 1789 Errors*



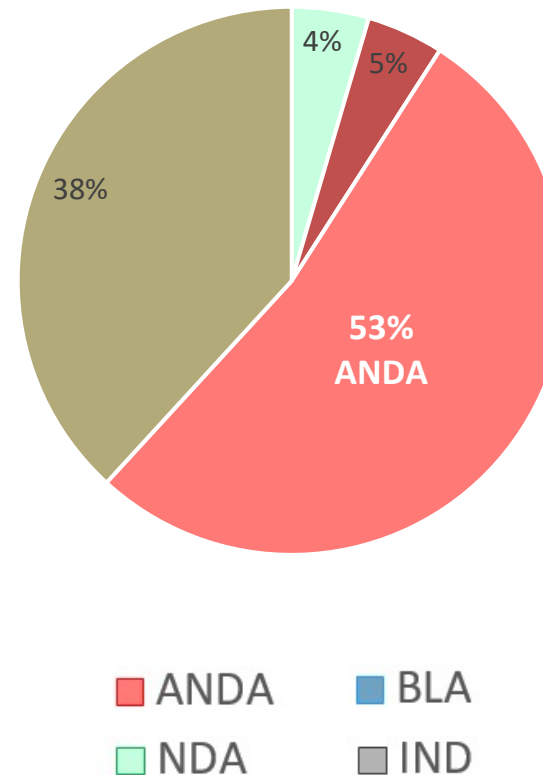
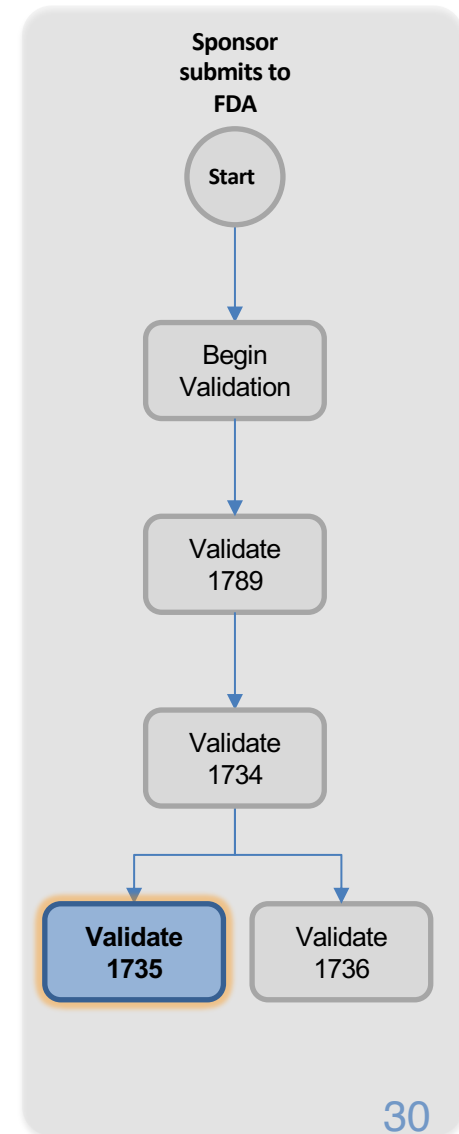
Validation Rule 1735

The correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections*

- ✓ Standardized dataset domains
(e.g., adsl.xpt, dm.xpt) are tagged as:
 - “data-tabulation-dataset-sdtm” for SDTM
 - “analysis-dataset-adam” for ADaM
 - “data-tabulation-dataset-send” for SEND
- ✓ Define.xml files are tagged as:
 - “data-tabulation-data-definition”
for SDTM & SEND
 - “analysis-data-definition” for ADaM

ANDA submissions have the highest number of 1735 errors*

Submission Types for 1735 Errors*



Tools to Help Industry

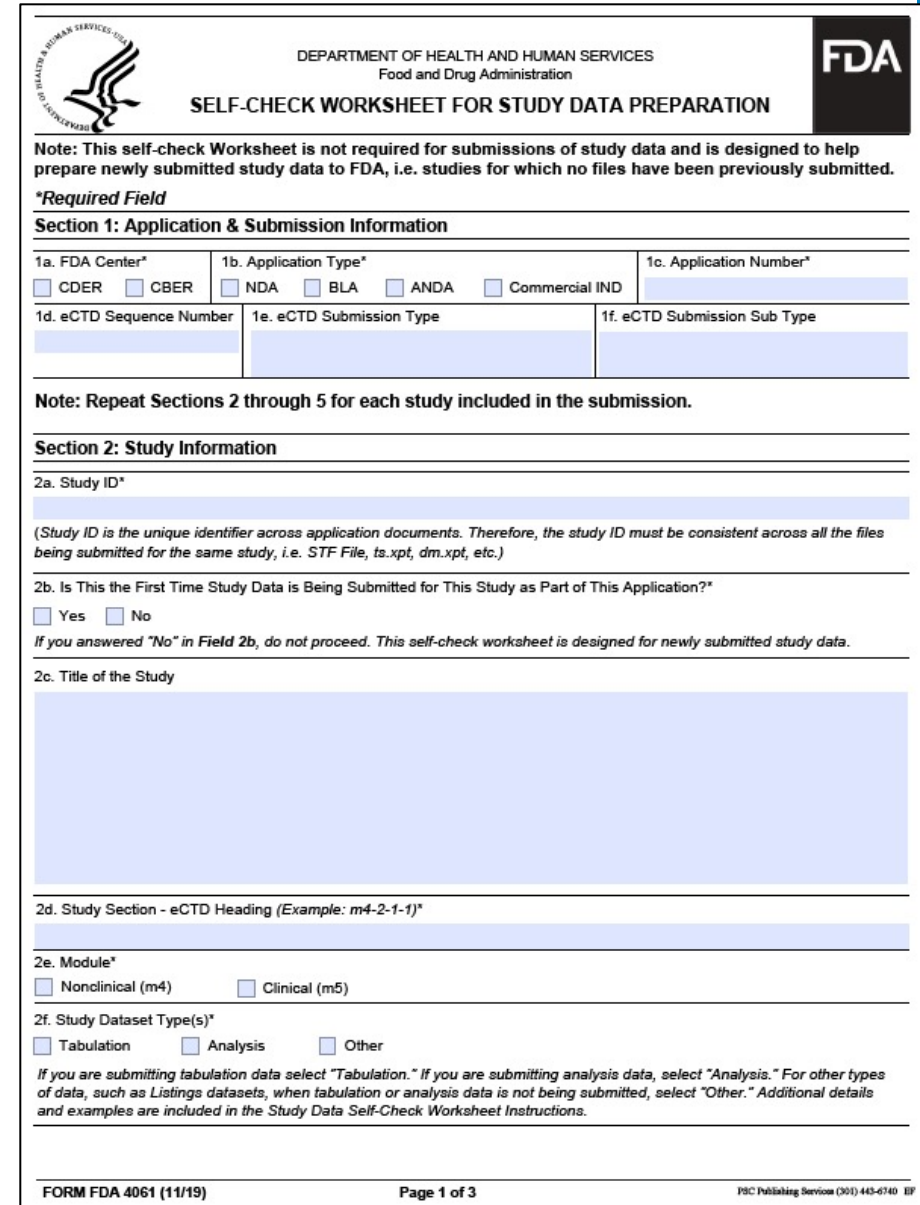
The Self-Check Worksheet

- Designed to walk sponsors through each step of sdTRC validation process
- Dynamically guides sponsors through study data requirements based on study information entered
- Helps sponsors prepare study data to submit to the FDA for the first time

[Demonstration Videos & Other Supporting Material](#)

[Technical Rejection Criteria Self-Check Worksheet](#)

[Self-Check Worksheet Instructions](#)



The screenshot shows the 'SELF-CHECK WORKSHEET FOR STUDY DATA PREPARATION' form from the FDA. It includes a header with the FDA logo and the Department of Health and Human Services. The form is divided into sections: Section 1: Application & Submission Information, and Section 2: Study Information. Section 1 includes fields for FDA Center (CDER, CBER, NDA, BLA, ANDA, Commercial IND), Application Type (NDA, BLA, ANDA, Commercial IND), Application Number, eCTD Sequence Number, eCTD Submission Type, and eCTD Submission Sub Type. Section 2 includes fields for Study ID, a question about whether this is the first time study data is being submitted, the title of the study, the study section (eCTD heading), the module (Nonclinical (m4), Clinical (m5)), and the study dataset type(s) (Tabulation, Analysis, Other). The form also includes a note about the purpose of the worksheet and a footer with the form number (FORM FDA 4061 (11/19)), page number (Page 1 of 3), and publication date (PSC Publishing Services (301) 443-6740 IF).

The Simplified ts.xpt Creation Guide



❖ Helps industry create simplified TS files using free and open-source software, R and Python

- Provides step by step instructions to install the necessary software
- Users can copy and paste code samples from the guide into R or Python
- Available on FDA's web page, [Study Data for Submission to CDER and CBER](#)
- Demonstration video also available at [Study Data for Submission to CDER and CBER](#)
- Additionally, a publicly available tool was developed by PHUSE:

[Simplified ts.xpt File Generator](#)
(https://geotiger.shinyapps.io/07_genTS/)

The image displays two pages from a guide titled 'Simplified ts.xpt Creation Guide'. The left page is for R and the right page is for Python. Both pages include step-by-step instructions, code samples, and screenshots of the respective software interfaces.

Left Page (R):

- Section 3: If a Study Start Date is not available or applicable, delete "YYYY-MM-DD", keeping the question marks and next to "TSVALNF", enter "NA".
- Code sample for RStudio showing the creation of a ts.xpt file.
- Step 4: After updating the code, run the code by selecting "Run All" from the Edit Menu. A Simplified TS File in .xpt format will be saved in the folder location you provided.
- Screenshot of the RStudio interface showing the code and the output.
- Text: The file path, i.e. where the Simplified TS File will be saved, can be changed to your preferred location by replacing "C:/Simplified TS File" with a different location where you would like to save the file.
- Code sample for R showing the file path.
- Text: Please Note - When adding a new file path, be sure the slash marks are forward slashes (/). Backward slashes will result in an error when running the code.

Right Page (Python):

- Section b) Option 2: Use Python.
- Section i) Pre-Requirement: Install Python and IDLE.
- Text: To install Python and IDLE, please refer to www.python.org/downloads/ and follow installation instructions.
- Screenshot of the Python.org download page.
- Text: Please Note - IDLE is an integrated development environment for Python, which has been bundled with the default installation of Python.
- Text: Launch Command Prompt in Windows (Windows Key+R) and type "cmd".
- Screenshot of the Run dialog box in an IDE.
- Section 1: At the CMD use command line interface, type in the following command and press ENTER: cd C:/Program Files/Python37/Scripts.
- Text: Please Note - This path may vary depending upon the directory where python was installed.
- Section 2: Type in: python -m pip install --upgrade pip (to ensure pip is at the latest version).
- Text: Please Note - This step is optional.
- Section 3: Type in: pip install xport (to install the xport module).

References

- ❖ **Study Data Standards Resources** [<https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>]
 - Providing Regulatory Submissions In Electronic Format - Standardized Study Data: Guidance For Industry [June 2021]
 - Study Data Technical Conformance Guide [August 2021]
 - FDA Data Standards Catalog [March 2021]
- ❖ **Study Data for Submission to CDER and CBER** [<https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber>]
 - Technical Rejection Criteria For Study Data [August 2021]
 - Technical Rejection Criteria Self-Check Worksheet
 - Technical Rejection Criteria Self-Check Worksheet Instructions
- ❖ **Electronic Common Technical Document (eCTD)** [<https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd>]
 - Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications: Guidance for Industry [February 2020]
 - eCTD Submission Standards [August 2021]
 - Specifications for eCTD Validation Criteria [August 2021]
- ❖ **Providing Regulatory Submissions In Electronic Format - Submissions Under Section 745a(a) Of The FD&C Act: Guidance For Industry** [<https://www.fda.gov/regulatory-information/search-fda-guidance-documents>]

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