U.S. FOOD & DRUG ADMINISTRATION

Submitting Data to CDER: Requirements for your Application

Heather Crandall

R/Pharma 2021

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FDA Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

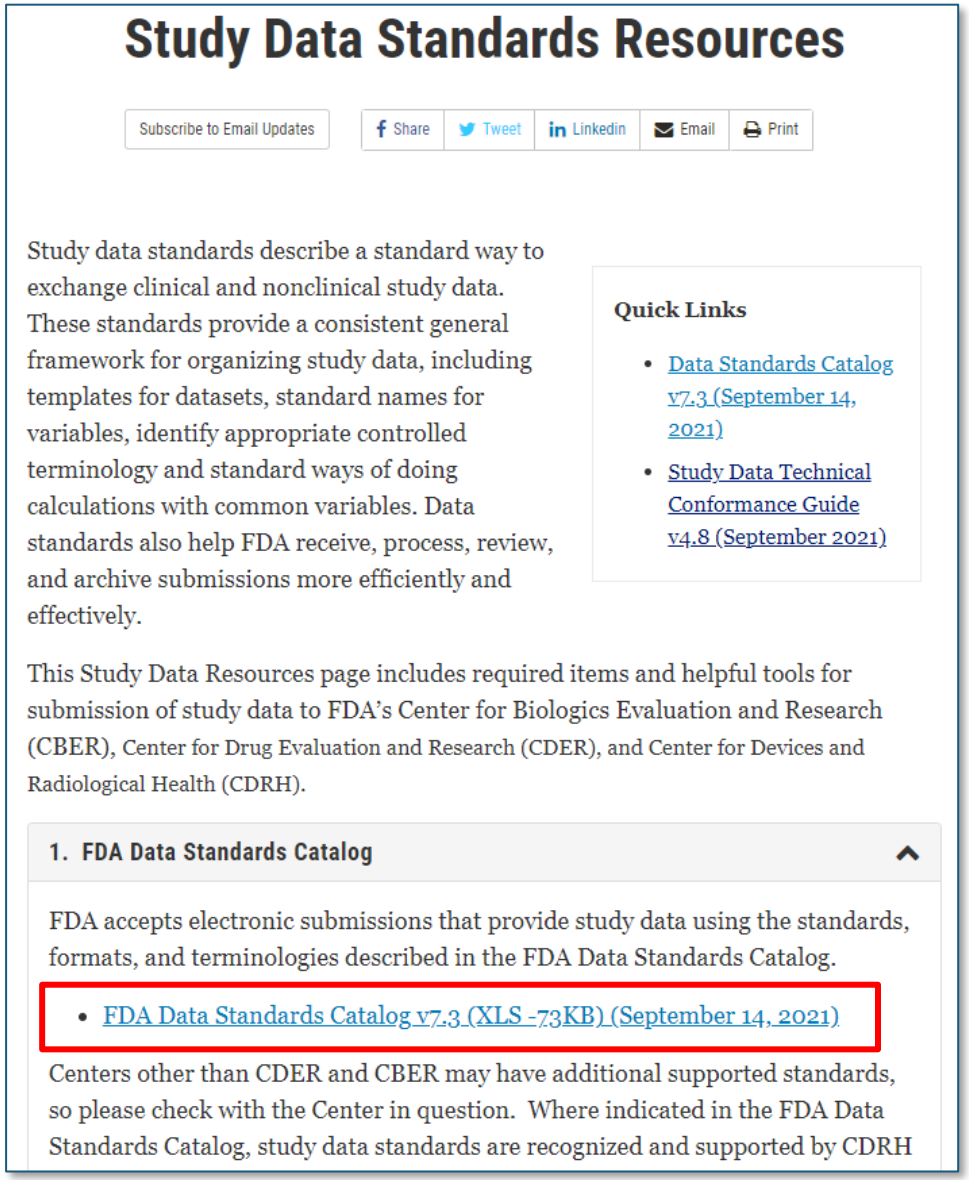
Agenda

- Electronic Submissions to CDER
- eCTD Requirements
- Study Data Requirements
- Addressing the Most Common Error Reason

Electronic Submissions to CDER

Requirements for Electronic Submissions

- Electronic submissions to CDER must conform to standards in the FDA Data Standard Catalog
- **Section 745A(a)** of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that submissions under section 505(b), (i), or (j) of the FD&C Act and submissions under section 351(a) or (k) of the Public Health Service Act (PHS Act) be submitted in electronic format
- Submissions to NDA, BLA, ANDA, Commercial IND and Master Files* must be in eCTD format



Study Data Standards Resources

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Study data standards describe a standard way to exchange clinical and nonclinical study data. These standards provide a consistent general framework for organizing study data, including templates for datasets, standard names for variables, identify appropriate controlled terminology and standard ways of doing calculations with common variables. Data standards also help FDA receive, process, review, and archive submissions more efficiently and effectively.

Quick Links

- Data Standards Catalog v7.3 (September 14, 2021)
- Study Data Technical Conformance Guide v4.8 (September 2021)

This Study Data Resources page includes required items and helpful tools for submission of study data to FDA's Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH).

1. FDA Data Standards Catalog

FDA accepts electronic submissions that provide study data using the standards, formats, and terminologies described in the FDA Data Standards Catalog.

- FDA Data Standards Catalog v7.3 (XLS -73KB) (September 14, 2021)

Centers other than CDER and CBER may have additional supported standards, so please check with the Center in question. Where indicated in the FDA Data Standards Catalog, study data standards are recognized and supported by CDRH

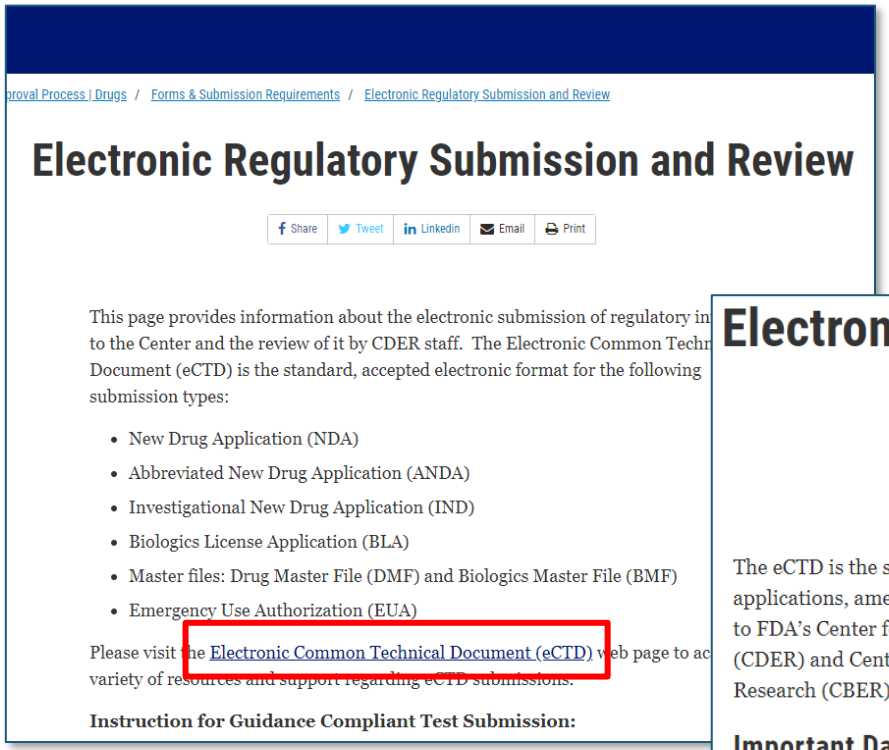
**excluding Non-Commercial IND and DMF Type III*

Electronic Submissions to CDER

Electronic submissions can be submitted to CDER in one of two ways:

- Electronic Submission Gateway (ESG)
  - eCTD submission to NDA, BLA, ANDA, IND, DMF applications
  - Non-eCTD submission to Research IND applications
  - Non-eCTD submission to applications granted eCTD Waiver
- CDER NextGen
  - Non-eCTD submission to Research IND applications
  - Non-eCTD submission to applications granted eCTD Waiver
  - Non-eCTD submission of EUA or Pre-submission Correspondence

eCTD is the standard format for submitting applications, amendments, supplements, and reports to CDER



oval Process | Drugs / Forms & Submission Requirements / Electronic Regulatory Submission and Review

Electronic Regulatory Submission and Review

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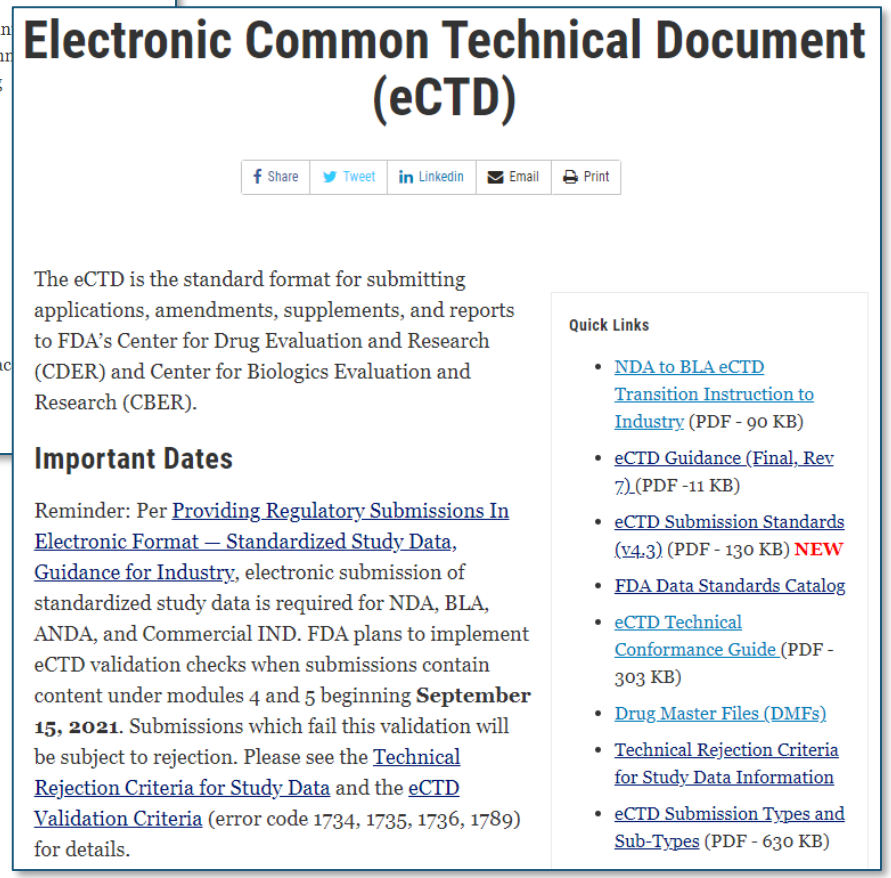
This page provides information about the electronic submission of regulatory in to the Center and the review of it by CDER staff. The Electronic Common Techn Document (eCTD) is the standard, accepted electronic format for the following submission types:

- New Drug Application (NDA)
- Abbreviated New Drug Application (ANDA)
- Investigational New Drug Application (IND)
- Biologics License Application (BLA)
- Master files: Drug Master File (DMF) and Biologics Master File (BMF)
- Emergency Use Authorization (EUA)

Please visit the Electronic Common Technical Document (eCTD) web page to ac variety of resources and support regarding eCTD submissions.

Instruction for Guidance Compliant Test Submission:



Electronic Common Technical Document (eCTD)

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The eCTD is the standard format for submitting applications, amendments, supplements, and reports to FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

Important Dates

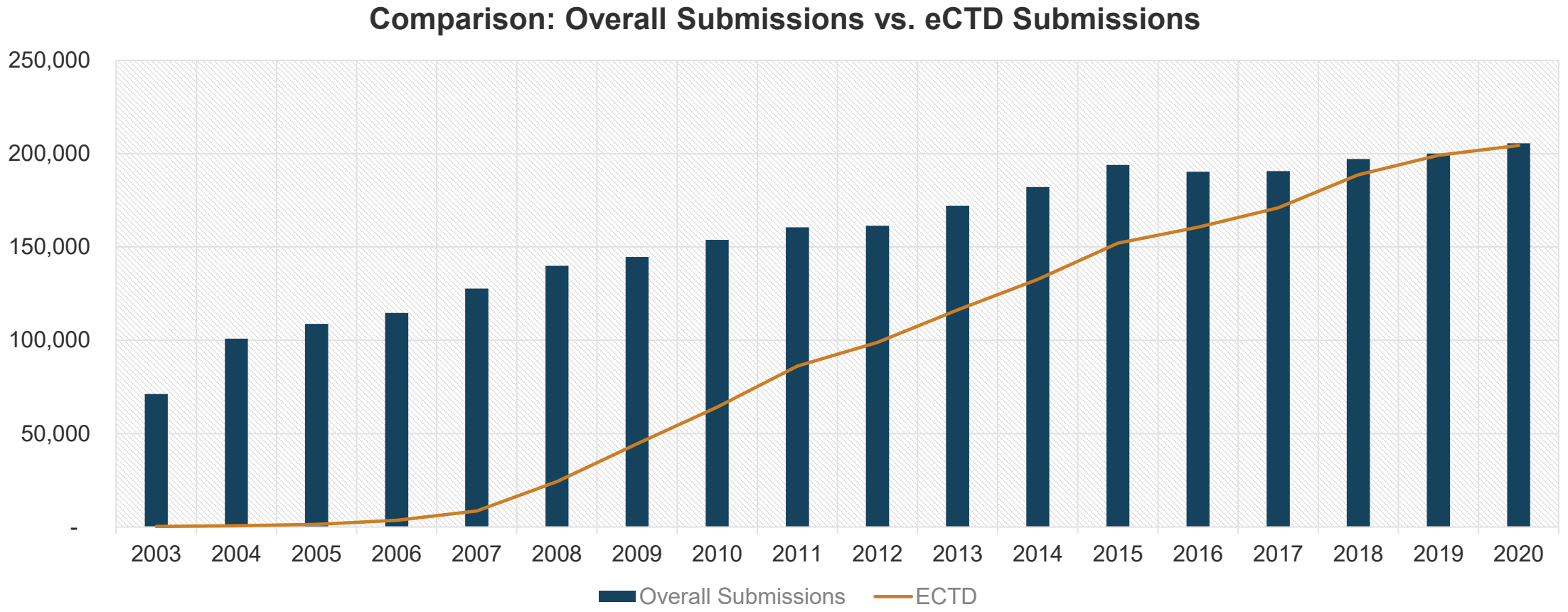
Reminder: Per Providing Regulatory Submissions In Electronic Format — Standardized Study Data, Guidance for Industry, electronic submission of standardized study data is required for NDA, BLA, ANDA, and Commercial IND. FDA plans to implement eCTD validation checks when submissions contain content under modules 4 and 5 beginning **September 15, 2021**. Submissions which fail this validation will be subject to rejection. Please see the Technical Rejection Criteria for Study Data and the eCTD Validation Criteria (error code 1734, 1735, 1736, 1789) for details.

Quick Links

- NDA to BLA eCTD Transition Instruction to Industry (PDF - 90 KB)
- eCTD Guidance (Final, Rev 7) (PDF -11 KB)
- eCTD Submission Standards (v4.3) (PDF - 130 KB) **NEW**
- FDA Data Standards Catalog
- eCTD Technical Conformance Guide (PDF - 303 KB)
- Drug Master Files (DMFs)
- Technical Rejection Criteria for Study Data Information
- eCTD Submission Types and Sub-Types (PDF - 630 KB)

Electronic Submissions to CDER

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

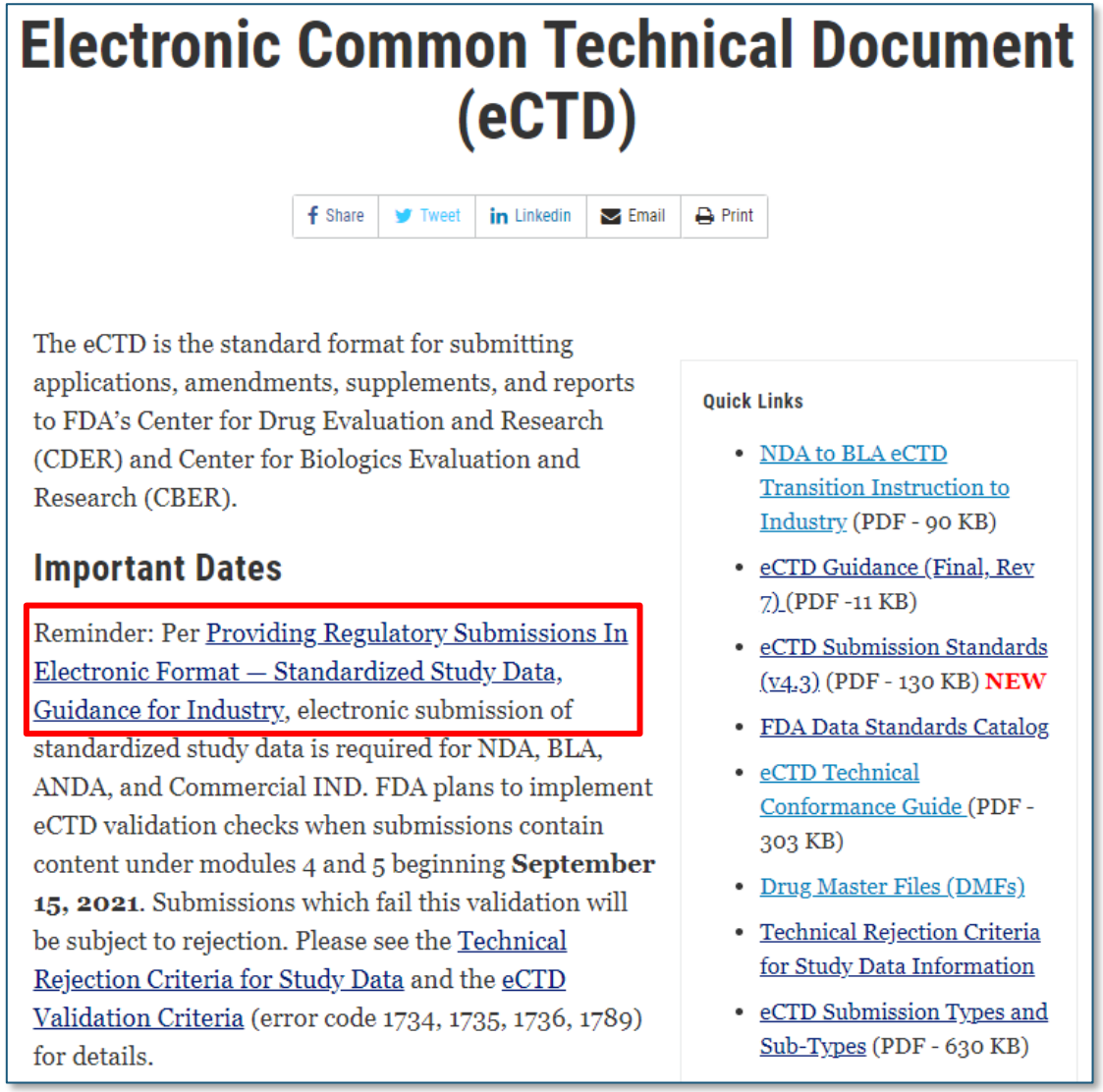


*excludes Non-Commercial IND and DMF Type III

Study Data Requirements

Study Data Requirements

- Study Data Guidance specifies that study data submitted to CDER must be in standardized format:
  - **For NDAs, BLAs, ANDAs, studies that started after Dec. 17th, 2016**
  - **For Commercial INDs, studies that started after Dec. 17th, 2017**
- Clinical Data Interchange Standards Consortium (CDISC) study data standards:
  - Study Data Tabulation Model (SDTM) for clinical trial tabulations data
  - Standard Exchange for Nonclinical Data (SEND) for non-clinical trial tabulations data
  - Analysis Data Model (ADaM) for clinical trial analysis data
- Study datasets should be provided in .xpt format



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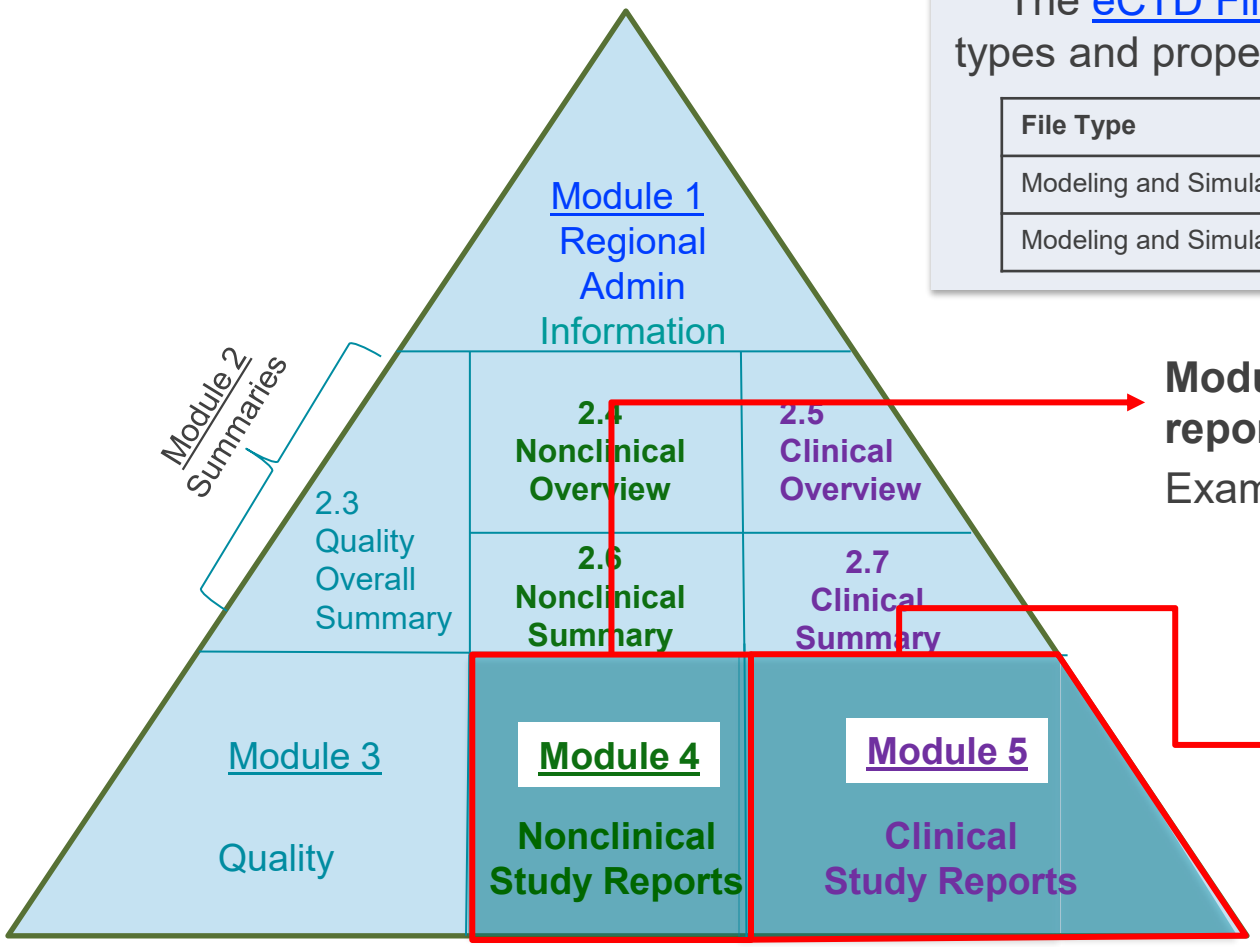
eCTD Placement of Study Data Files

- Most study data files should be submitted in eCTD Module 4 (non-clinical) and Module 5 (clinical)
- The proper placement of the datasets should follow the Comprehensive Table of Headings and Hierarchy

The eCTD File Format Types Specifications provides accepted file types and proper eCTD locations for those file types. Examples include:

File Type	File Format	Format Name	Accepted eCTD location
Modeling and Simulation	.rmd	R Markdown file	M5
Modeling and Simulation Reporting	.r	R Script file	M3 – M5



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The CTD Triangle

Module 4 - Non-clinical studies and components such as reports, datasets, protocols, etc.

Example:

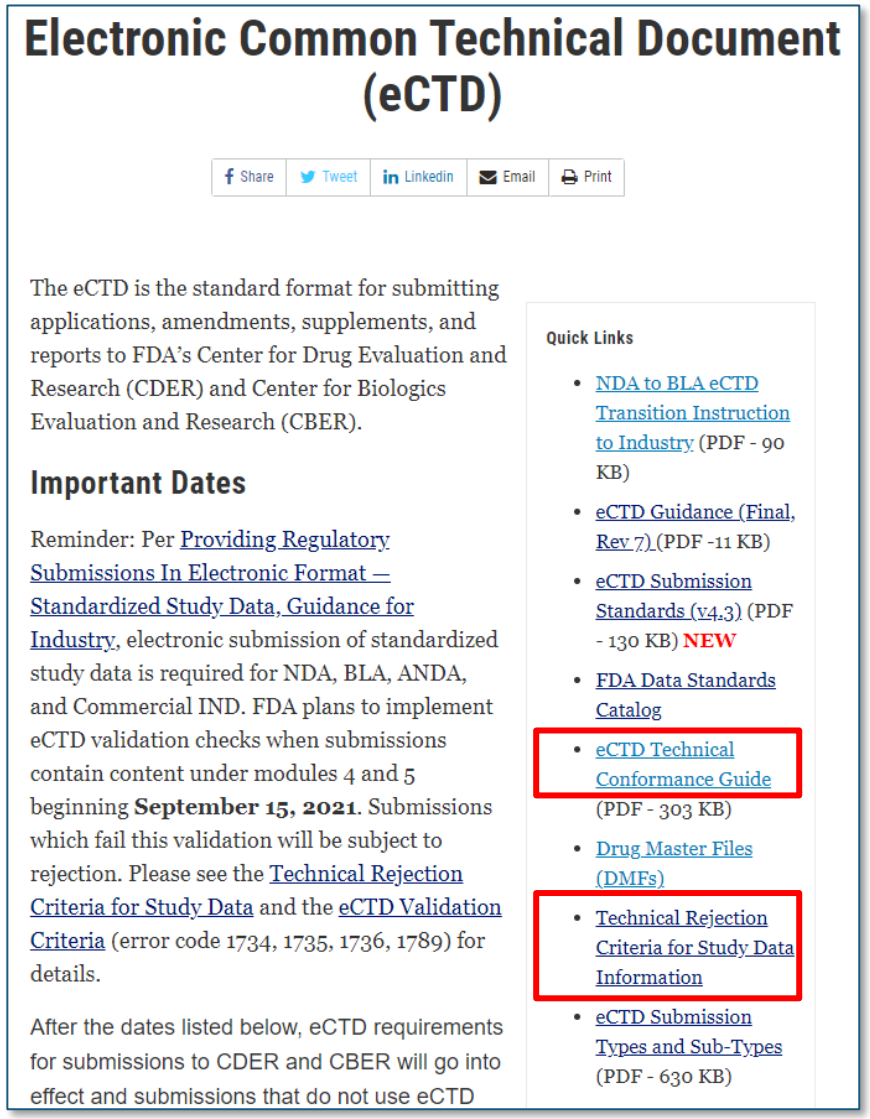
4.2.3 Toxicology
- 4.2.3.1 Single dose toxicity
- 4.2.3.2 Repeat dose toxicity

Module 5 - Clinical studies and components such as reports, datasets, protocols, etc.

Example:

5.3.1 Biopharmaceutic Studies
- 5.3.1.1 Bioavailability (BA) Study reports
- 5.3.1.2 Comparative BA and bioequivalence (BE) Study reports

eCTD & Study Data Resources



Electronic Common Technical Document (eCTD)

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After the dates listed below, eCTD requirements for submissions to CDER and CBER will go into effect and submissions that do not use eCTD

Quick Links

- NDA to BLA eCTD Transition Instruction to Industry (PDF - 90 KB)
- eCTD Guidance (Final, Rev 7) (PDF -11 KB)
- eCTD Submission Standards (v4.3) (PDF - 130 KB) **NEW**
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- eCTD Technical Conformance Guide (PDF - 303 KB)
- Drug Master Files (DMFs)
- Technical Rejection Criteria for Study Data Information
- eCTD Submission Types and Sub-Types (PDF - 630 KB)

- **eCTD Technical Conformance Guide** (eCTD TCG) provides technical recommendations for submitting files in eCTD
- **Technical Rejection Criteria for Study Data** (TRC) provides the conditions under which FDA will not accept submissions with study data
- **Study Data Technical Conformance Guide** (SD TCG) provides technical recommendations for submitting study data according to CDISC standards
  - Planning and Providing Standardized Study Data
  - Exchange Format: Electronic Submissions
  - Study Data Submission Format: Clinical and Nonclinical
  - Therapeutic Area Standards
  - Terminology
  - Electronic Submission Format
  - Study Data Validation and Traceability

Overview of Technical Rejection Criteria

The TRC are eCTD validation criteria to determine compliance with requirements for submitting standardized study data in required sections in Modules 4 and 5, including:

- 4.2.3.1, 4.2.3.2, 4.2.3.4
- 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

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	

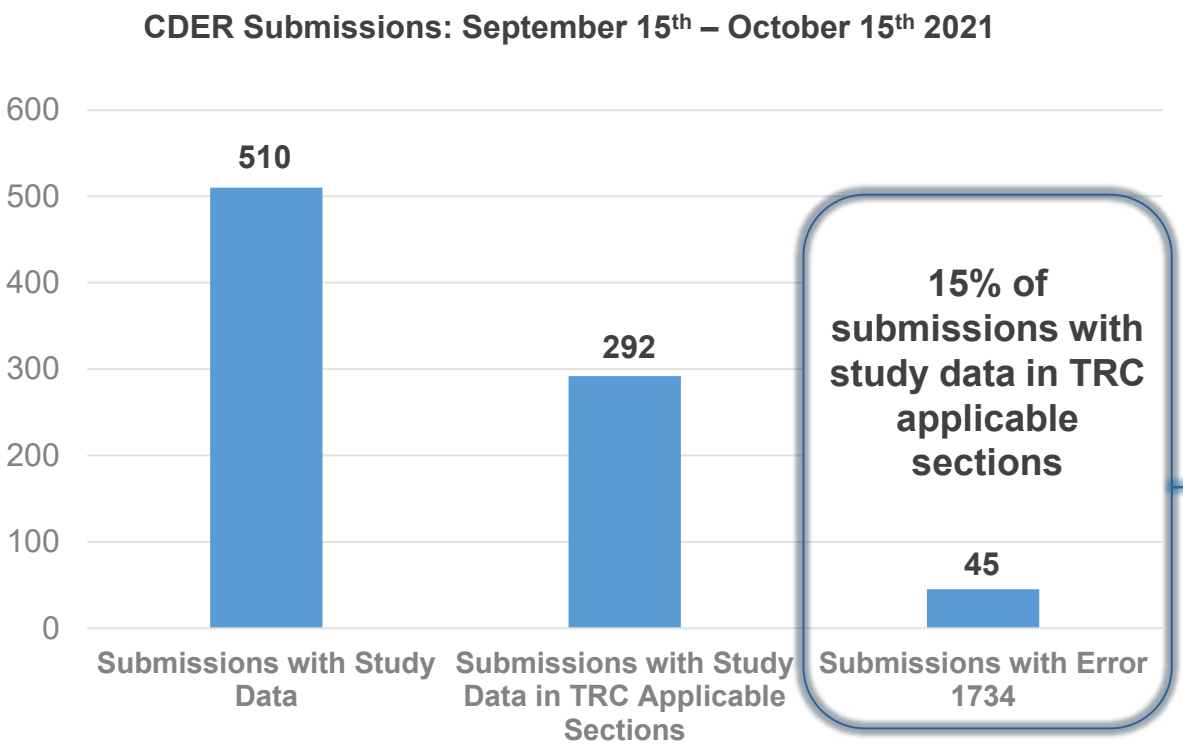
- Between September 15th and October 15th, 2021, **65% of TRC related rejections were caused by 1734 errors**

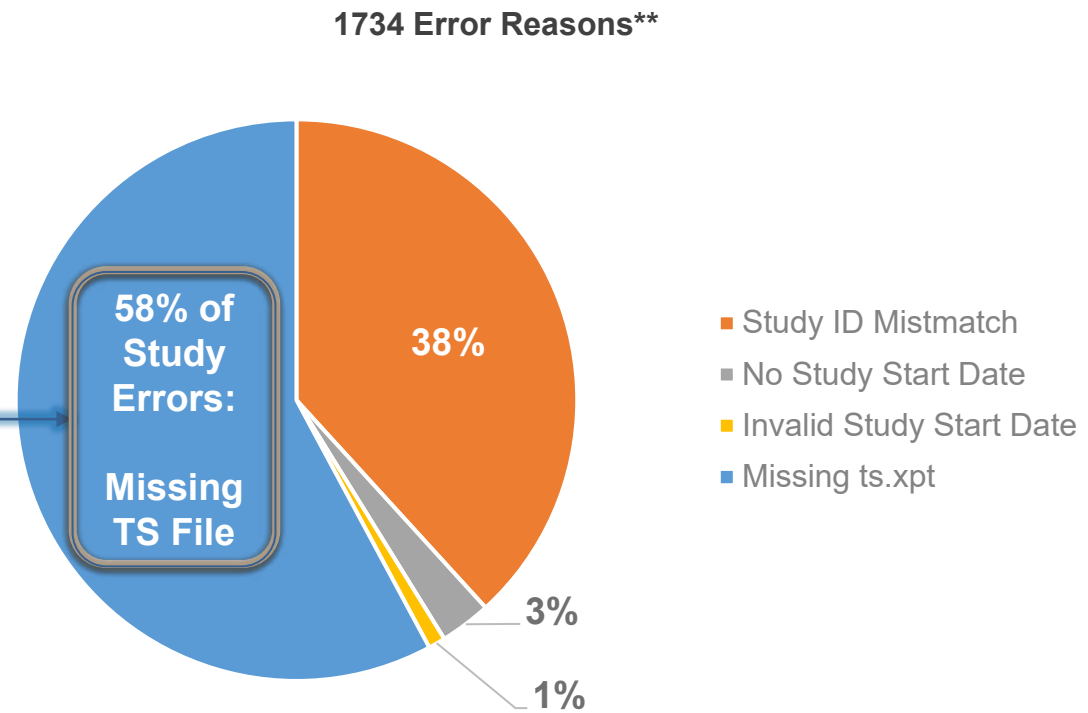
Addressing the Most Common Error Reason

Causes of 1734 Errors

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





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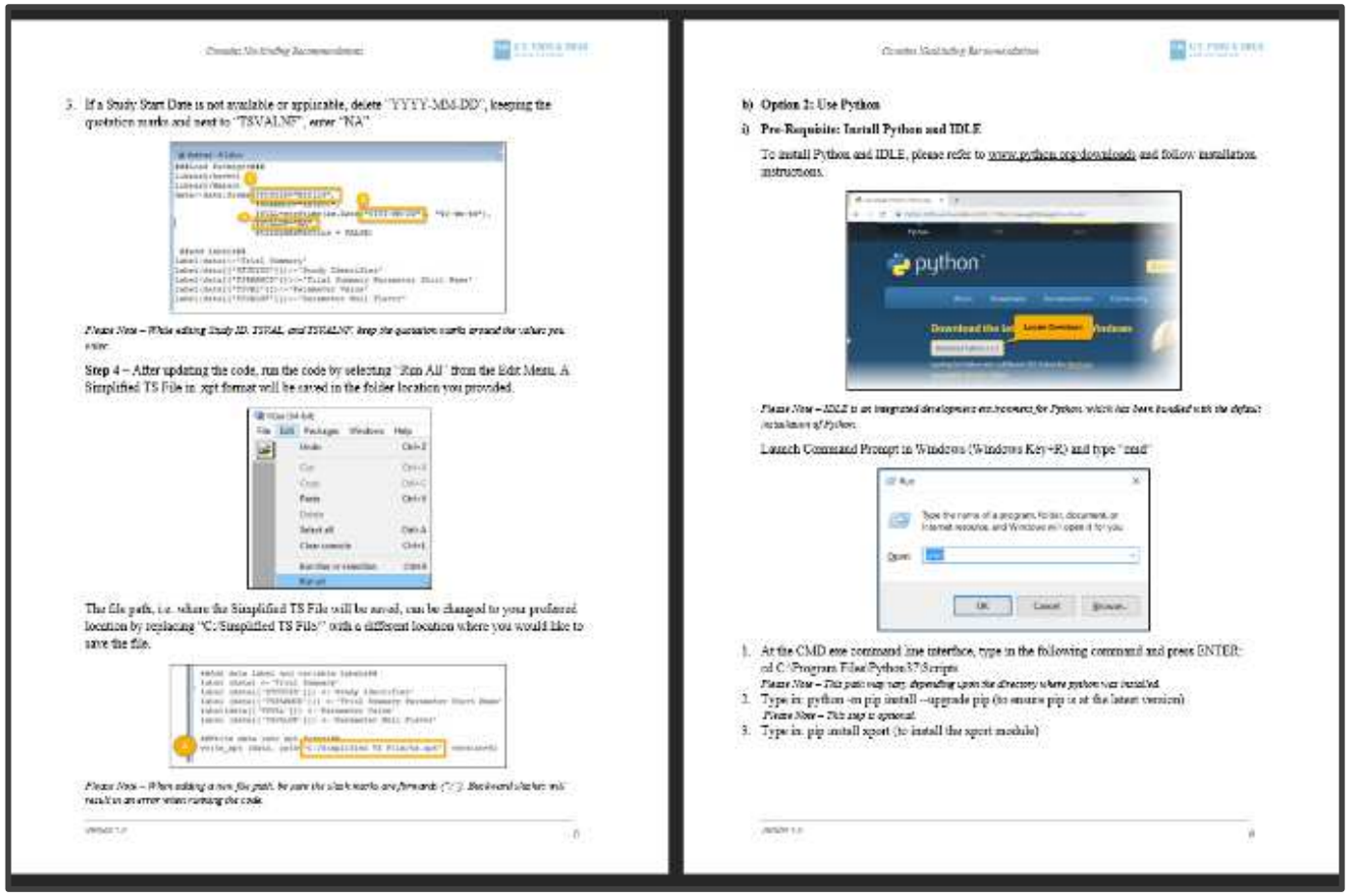
** Module 4 sections: 4.2.3.1, 4.2.3.2, 4.2.3.4*
Module 5 sections: 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2

***102 Studies in 45 Submissions with Error 1734 (September 15th – October 15th, 2021)*

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/*)



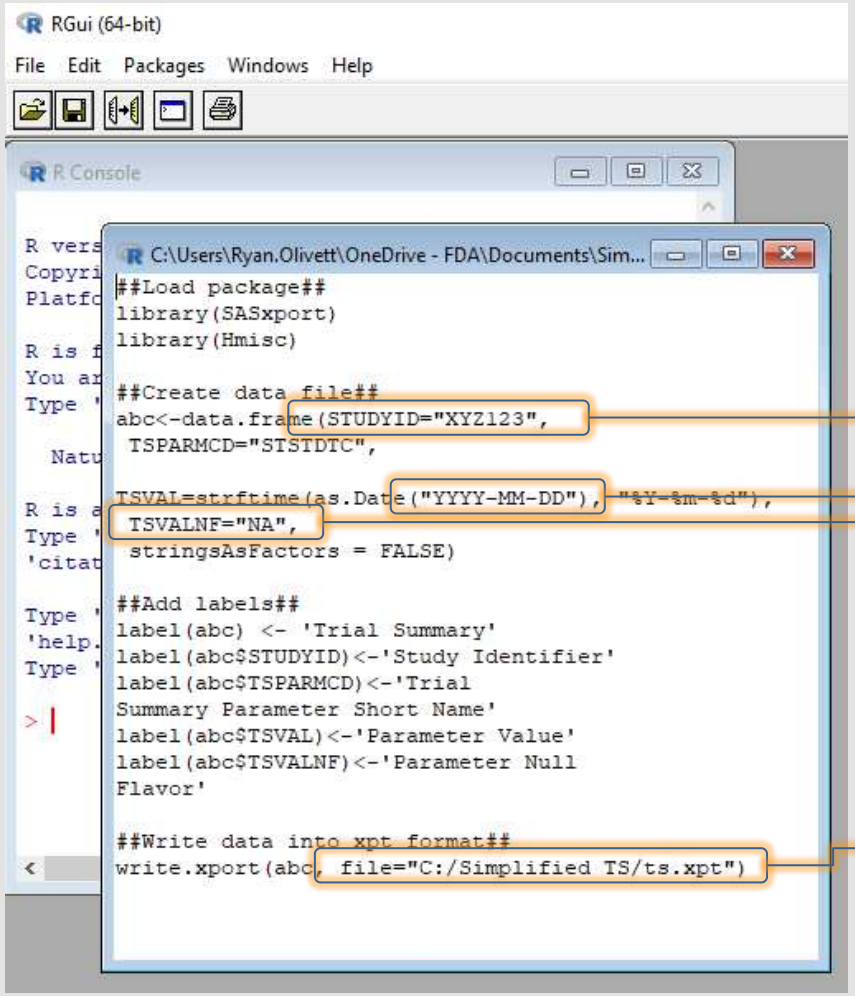
Option 1: Use the Simplified ts.xpt Creation Guide

1. Copy and paste code from the Guide into R Editor to create a script

Table 2: Code for Creating ts.xpt Using R : Option B - Using the SASxport Package

R Package	Clinical Study	Non-clinical Study
Option B: Using the SASxport Package	##Load package## library(SASxport) library(Hmisc) ##Create data file## abc<-data.frame(STUDYID="XYZ123", TSPARMCD="SSTDTC", TSVAL=strftime(as.Date("YYYY-MM-DD"), "%Y-%m-%d"), TSVALNF="NA", stringsAsFactors = FALSE) ##Add labels## label(abc) <- 'Trial Summary' label(abc$STUDYID)<-'Study Identifier' label(abc$TSPARMCD)<-'Trial Summary Parameter Short Name' label(abc$TSVAL)<-'Parameter Value' label(abc$TSVALNF)<-'Parameter Null Flavor' ##Write data into xpt format## write.xport(abc, file="C:/Simplified TS File/ts.xpt")	##Load package## library(SASxport) library(Hmisc) ##Create data file## abc<-data.frame(STUDYID="XYZ123", TSPARMCD="STSTDTC", TSVAL=strftime(as.Date("YYYY-MM-DD"), "%Y-%m-%d"), TSVALNF="NA", stringsAsFactors = FALSE) ##Add labels## label(abc) <- 'Trial Summary' label(abc$STUDYID)<-'Study Identifier' label(abc$TSPARMCD)<-'Trial Summary Parameter Short Name' label(abc$TSVAL)<-'Parameter Value' label(abc$TSVALNF)<-'Parameter Null Flavor' ##Write data into xpt format## write.xport(abc, file="C:/Simplified TS File/ts.xpt")

Simplified TS File Creation Guide



2. Edit the Study ID

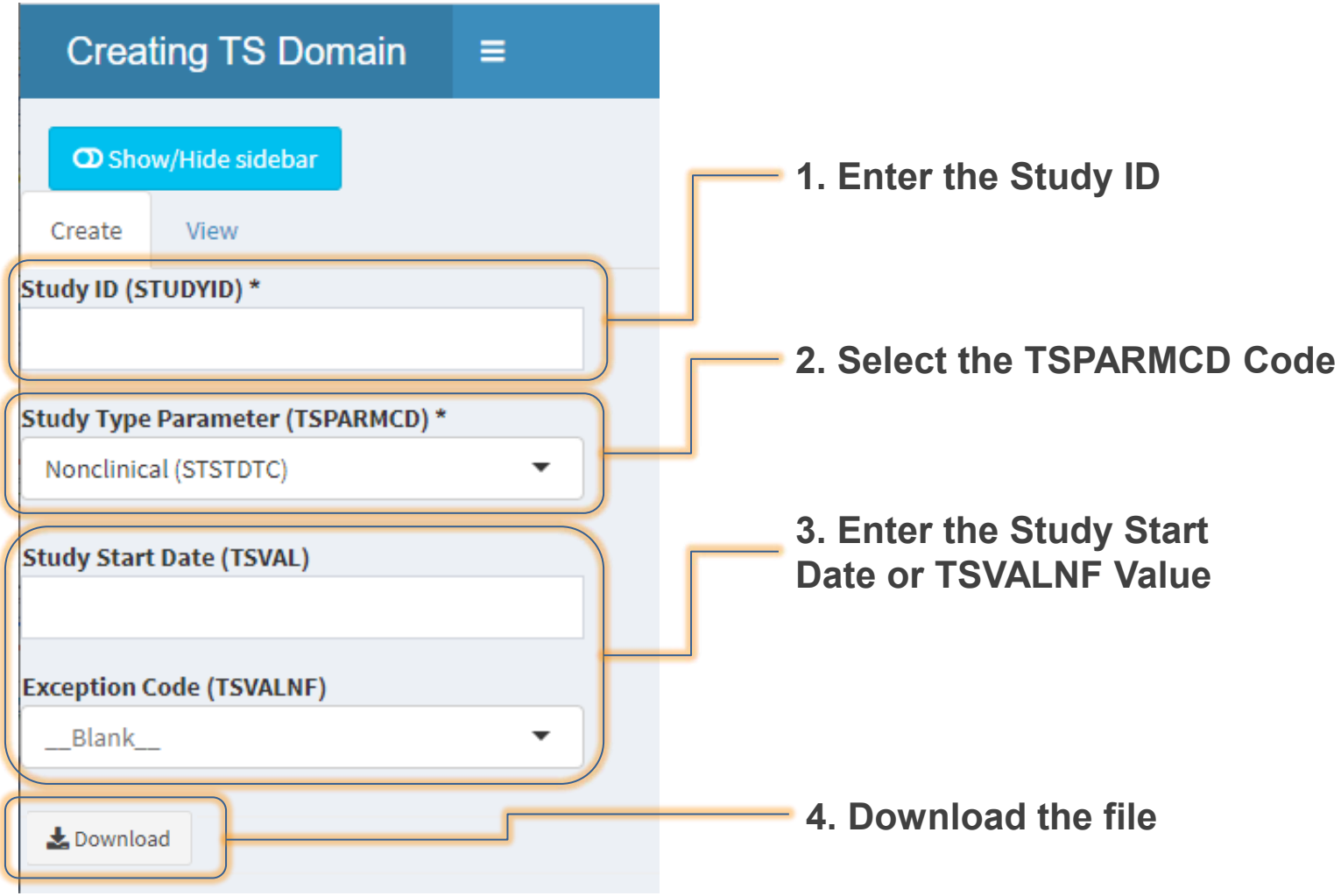
3. Edit the Study Start Date and TSVALNF Value

4. Edit where to save the file

R Application

Option 2: Use the PHUSE Utility

Example using the online PHUSE Utility to generate a Simplified TS File:



PHUSE Utility

Thank you!

References

❖ Study Data Standards Resources

- Providing Regulatory Submissions In Electronic Format - Standardized Study Data: Guidance For Industry [Jun 2021]
- Study Data Technical Conformance Guide [Sep 2021]
- FDA Data Standards Catalog [Sep 2021]
- Link: https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources

❖ Study Data for Submission to CDER and CBER

- Technical Rejection Criteria For Study Data [August 2021]
- Technical Rejection Criteria Self-Check Worksheet
- Technical Rejection Criteria Self-Check Worksheet Instructions
- Link: https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber

❖ Providing Regulatory Submissions In Electronic Format - Submissions Under Section 745a(a) Of The FD&C Act: Guidance For Industry

- Link: Providing Regulatory Submissions in Electronic Format

Questions

For Questions Please Contact:

- Study Data Questions:
  edata@fda.hhs.gov

- eCTD Questions:
  esub@fda.hhs.gov

Acknowledgements

The author would like to thank Ethan Chen, Jonathan Resnick, Nitin Guptan, Anthony Fata, Ryan Olivett, Jiang Xu, Lina Cong, and other FDA staff for their time and effort in helping collect and analyze data and information as presented here.

What Comes Next?
An overview of the role of data in FDA Approval Processes

Paul Schuette

Scientific Computing Coordinator

FDA/CDER/OTS/OB/IO/AIS

Paul.Schuette@fda.hhs.gov

Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

CDER Reviews

What happens after a submission package is delivered to the Center for Drug Evaluation and Research (CDER) in the US Food and Drug Administration (FDA)?

- Standard Review, 10-month clock
- Priority Review, 6-month clock

Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review

FDA

Fast Track

Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need.
Fast Track

Breakthrough Therapy

A process designed to expedite the development and review of drugs which may demonstrate substantial improvement over available therapy.
Breakthrough Therapy

Accelerated Approval

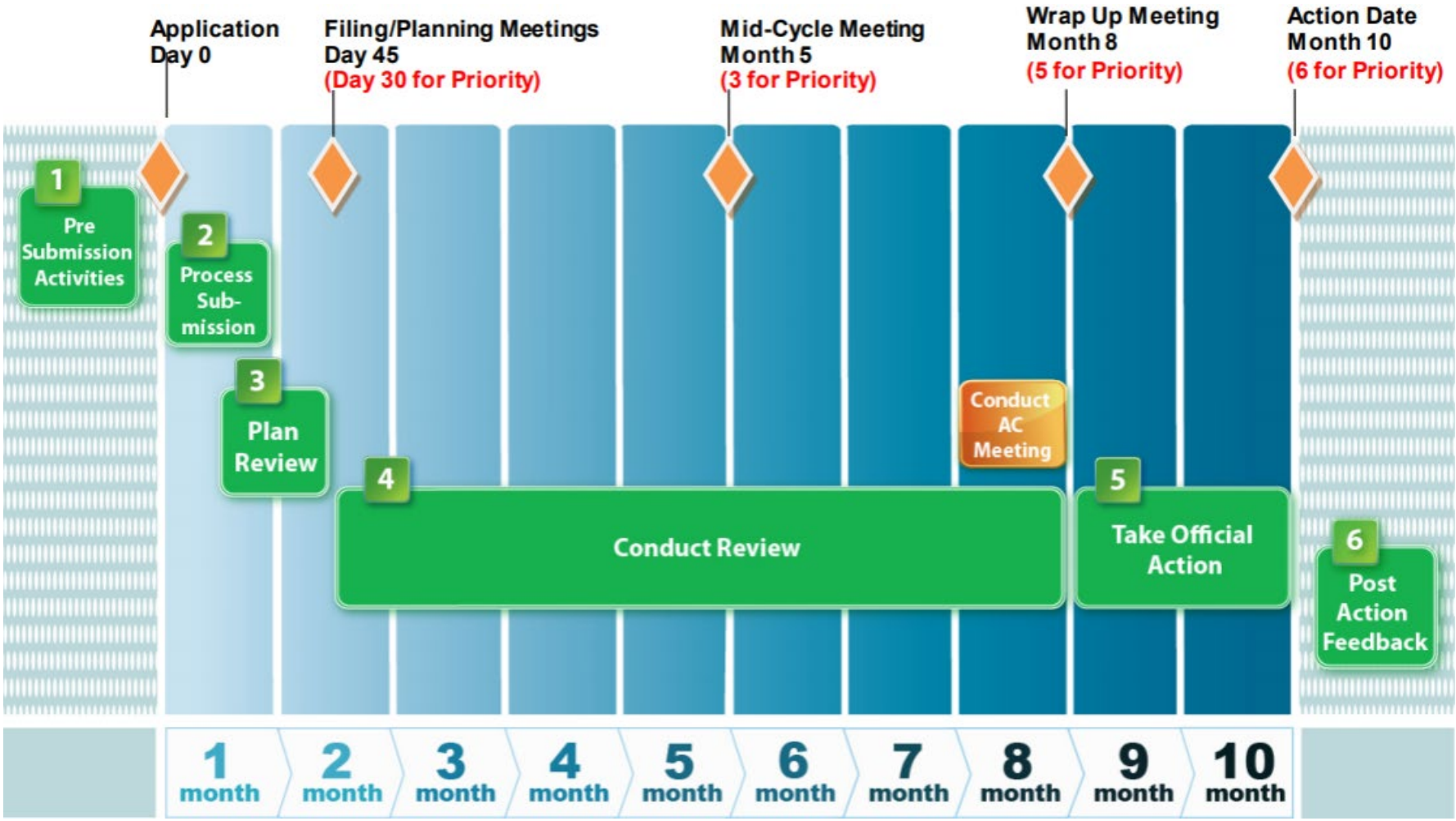
These regulations allowed drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint.
Accelerated Approval

Priority Review

A Priority Review designation means FDA's goal is to take action on an application within 6 months.
Priority Review

Link

Major Steps
(21st Century Review)



Integrated Review Template

Three main components:

1. Executive Summary
2. Interdisciplinary Assessment
3. Discipline Specific Appendices

"New roles to support the review team and allow reviewers to focus on the science and regulatory aspects of the application- clinical data scientists will support clinical safety data verification and analyses, and medical editors will provide editing and formatting services" link

CDER Submissions

- Submissions to CDER and CBER for studies begun after December 17, 2016, are required to conform to CDISC standards (SDTM, ADaM).
- Other FDA Centers (CDRH, CTP, CVM and CFSAN) have different procedures and processes.
- The Study Data Technical Conformance Guide lays out technical expectations, in addition to adherence to CDISC standards.

Who uses NDA/BLA data?

- Office of Biostatistics (OB)
- Office of Clinical Pharmacology (OCP)
- Office of Pharmaceutical Quality (OPQ)
- Office of New Drugs (OND)
- Office of Scientific Investigations (OSI)
- Office of Computational Sciences (OCS)
- Office of Study Integrity and Surveillance (OSIS)

Data Checks and Fileablity

- OCS Jumpstart/DataFit: Pinnacle 21 software used to evaluate CDISC compliance
- CluePoints Cooperative Research and Development Agreement (CRADA): data anomaly detection, data quality assessment
- Reviewer/Analyst applied tests
  - Format, completeness
  - Missing Data
  - Outliers
- Identify sites for inspection

Filing Meeting

"Each discipline makes a recommendation on fileability of the application at the filing meeting that is held by day 45 of the review (day 30 for priority reviews). If the application is found fileable a planning meeting is held to further discuss timelines, high-level labeling revisions and review activities."

CDER 21st Century Review Process Desk Reference Guide

Refuse to File

"Complex significant deficiencies that cannot be corrected before filing and that may result in a refusal to file pursuant to § 314.101(d)(3) and other authorities. Examples of such deficiencies include, but are not limited to: …

Required content is not submitted electronically where the FDA has specified the format of such submissions in guidance pursuant to section 745A of the FD&C Act or required content is not submitted in an electronic format that the FDA can review, process, and archive, where such electronic submissions are required by an applicable regulation. Electronic submission issues that CDER considers to be filing issues include particular organization, file format, coding, or formatting problems that are specified in applicable guidances issued pursuant to section 745A(a) of the FD&C Act."

Refuse to File:NDA and BLA Submissions to CDER, Guidance for Industry, 2017

Analyses

- Can the sponsor's results be independently replicated based on the stated protocol and statistical analysis plan?
- Sponsor's code can help navigating the "garden of diverging paths"
- Other analyses
  - Sensitivity Analyses
  - Safety

Study Data Technical Conformance Guide

4.1.2.10 Software Programs

Sponsors should provide the software programs used to create all ADaM datasets and generate tables and figures associated with primary and secondary efficacy analyses. Furthermore, sponsors should submit software programs used to generate additional information included in Section 14 CLINICAL STUDIES of the Prescribing Information, if applicable. The specific software utilized should be specified in the ADRG. Refer to FDA Statistical Software Clarifying Statement for more information. The main purpose of requesting the submission of these programs is to understand the process by which the variables for the respective analyses were created and to confirm the analysis algorithms and results. Sponsors should submit software programs in ASCII text format. Executable file extensions should not be used. Link

Statistical Software Clarifying Statement

"FDA does not require use of any specific software for statistical analyses, and statistical software is not explicitly discussed in Title 21 of the Code of Federal Regulations [e.g., in 21CFR part 11]. However, the software package(s) used for statistical analyses should be fully documented in the submission, including version and build identification."

Statistical Software Clarifying Statement, cont

"As noted in the FDA guidance, E9 Statistical Principles for Clinical Trials …`The computer software used for data management and statistical analysis should be reliable, and documentation of appropriate software testing procedures should be available.' Sponsors are encouraged to consult with FDA review teams and especially with FDA statisticians regarding the choice and suitability of statistical software packages at an early stage in the product development process."

Link

Information Requests (IR)

"An IR letter is a letter sent to an applicant during an application review to request further information or clarification that is needed or would be helpful to allow completion of the discipline review. FDA does not consider IR letters to be action letters because they do not represent a complete review of the submission and therefore do not stop the user fee review clock."

Guidance for Industry Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act

Internal Meetings

- Joint Assessment Meetings (JAM)
  - Established as part o the Integrated Review Process
  - Includes disciplines working on review
  - Identifies review issues/deficiencies
  - JAM meetings are scheduled throughout the review process
  - Labelling Meeting(s)
- Midcycle Meeting

Midcycle Meetings

"Objectives of the meeting are to:

- Present status and key findings of all reviews, consults, and inspections.
- Confirm the decision that was made regarding the need for an Advisory Committee meeting.
- Identify any issues that could preclude an approval action.
- Begin high-level discussion of labeling (e.g., are major claims supported) and need for PMRs and/or PMCs.
- Determine if a REMS is needed (if not already determined) and, if so, the goals and the elements of the REMS.
- Revise the review plan and interim timelines, if needed."

CDER 21st Century Review Process Desk Reference Guide

Advisory Committees

"Advisory committees provide independent advice and recommendations to the Food and Drug Administration (FDA) on scientific and technical matters related to the development and evaluation of products regulated by the Agency. Through the advisory committee system, FDA is able to secure independent professional expertise in accomplishing its mission and maintaining the public trust. CDER and CBER request advice from advisory committees on a variety of matters, including various aspects of clinical investigations and applications for marketing approval of drug products. Although the committees provide recommendations to the Agency, final decisions are made by FDA."

Guidance for Industry Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997

Complete Response

21CFR part 314

"Complete response letter. FDA will send the applicant a complete response letter if the agency determines that we will not approve the application or abbreviated application in its present form for one or more of the reasons given in § 314.125 or § 314.127, respectively.

(1) Description of specific deficiencies. A complete response letter will describe all of the specific deficiencies that the agency has identified in an application or abbreviated application, except as stated in paragraph (a)(3) of this section.

(2) Complete review of data. A complete response letter reflects FDA's complete review of the data submitted in an original application or abbreviated application (or, where appropriate, a resubmission) and any amendments that the agency has reviewed. The complete response letter will identify any amendments that the agency has not yet reviewed.

(3) Inadequate data. If FDA determines, after an application is filed or an abbreviated application is received, that the data submitted are inadequate to support approval, the agency might issue a complete response letter without first conducting required inspections and/or reviewing proposed product labeling."

Emergency Use Authorization (EUA)

"During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.

Before the FDA can issue an EUA, the Secretary of Health and Human Services must make a declaration of emergency or threat justifying authorization of emergency use for a product."

FAQs on Emergency Use Authorizations (EUAs) for Medical Devices During the COVID-19 Pandemic

Also see Emergency Use Authorization of Medical Products and Related Authorities Guidance for Industry and Other Stakeholders

COVID-19

COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders

COVID-19 Lessons Learned:

- Utility of Master Protocols/Platform trials
- Value of large pragmatic trials
- Value of decentralized clinical trials

Questions and Comments?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Open Source

Open-source: denoting software for which the original source code is made freely available and may be redistributed and modified. (Oxford)

Some open-source software:

- R
- Python
- Linux