



**U.S. FOOD & DRUG
ADMINISTRATION**



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What's New: Submitting Study Data in eCTD

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Agenda

1. **What's New: Submitting Study Data in eCTD**
2. **Common Errors for eCTD Submissions containing Study Data**



What's New: Submitting Study Data in eCTD



What's New: Submitting Study Data in eCTD

- CDER and CBER are accepting **new regulatory applications in eCTD v4.0 format as of September 16, 2024.**
 - More information can be found on the [eCTD](#) page
 - eCTD v4.0 [samples](#) can be submitted for technical feedback
- Future implementation phases:
 - Forward compatibility for existing v3.2.2 applications
 - Two-way communication
 - [Electronic Common Technical Document \(eCTD\) v4.0 | FDA](#)

Region	Technical Pilot ¹	Implementation Dates ²	Implementation Documents
FDA, United States	2022 - 2Q 2023 (Completed)	2024 (Voluntary) 2029 (Mandatory)	FDA, United States regional implementation page

This information will be updated biannually based on the progress of ongoing implementation activities.

[Updated in July 2025]

What's New: Submitting Study Data in eCTD

- When submitting Study Data in eCTD format, use the following file-tags (v3.2.2) or document type keywords (v4.0):

eCTD Version	Document Type	File Name	Tag/Keyword
v3.2.2	Study Data Reviewer's Guide	sdrg.pdf	study-data-reviewers-guide
	Analysis Data Reviewer's Guide (ADaM)	adrg.pdf	analysis-data-reviewers-guide
	Data Definition File (SDTM/SEND)	define.xml	data-tabulation-data-definition
	Data Definition File (ADaM)	define.xml	analysis-data-definition
v4.0	Study Data Reviewer's Guide	sdrg.pdf	study data reviewers guide (ich_document_type_66, clear document title)
	Analysis Data Reviewer's Guide (ADaM)	adrg.pdf	analysis data reviewers guide (ich_document_type_67, with clear document title)
	Data Definition File (SDTM/SEND)	define.xml	data tabulation data definition (ich_document_type_48)
	Data Definition File (ADaM)	define.xml	analysis data definition (ich_document_type_53)

Common Errors for eCTD Submissions Containing Study Data

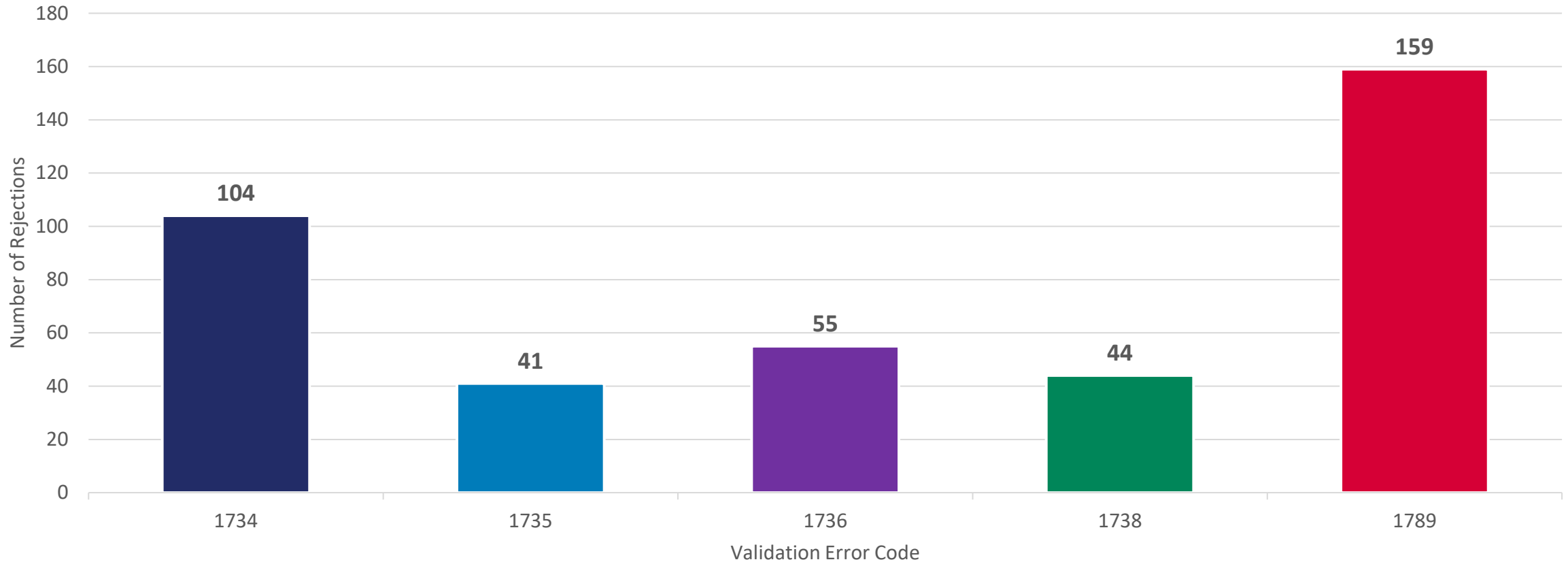


Total eCTD Submissions to CDER



Roughly only **1%** of eCTD submissions that contain study data are rejected

January 01, 2024 through December 31, 2025



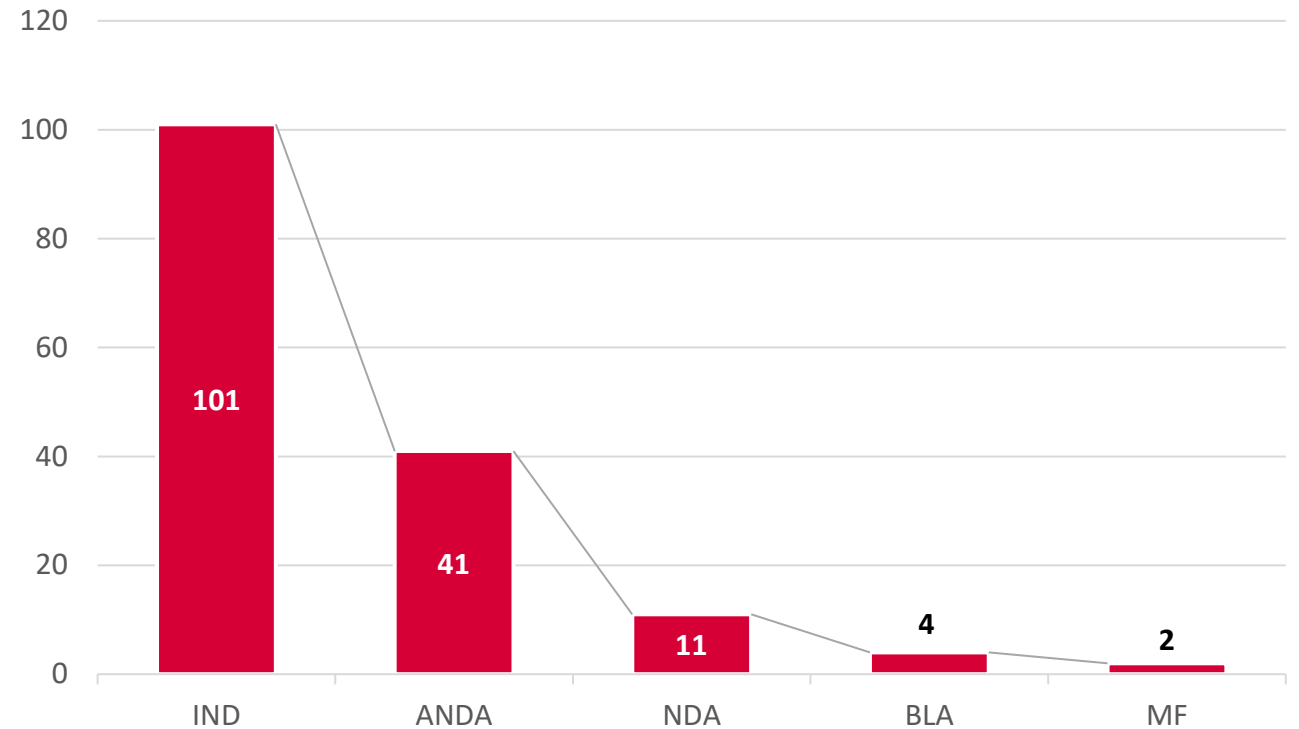
1789 Error



A file has been submitted in a study section without providing an STF file

- 159 Submissions that contained Study Data-related sections failed for error 1789
 - 64% of errors are from IND submissions

1789 Errors by Application Type



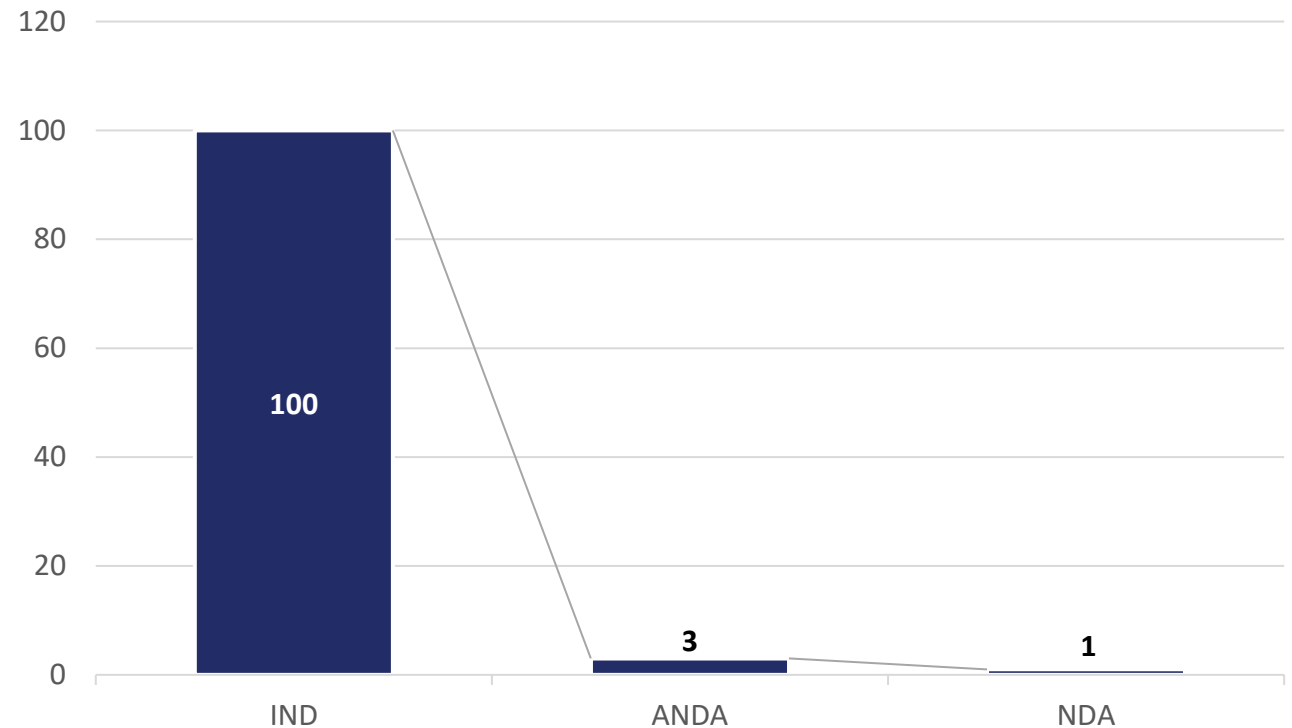
1734 Error



A dataset named ts.xpt with information on study start date must be present for each study in a TRC-applicable section

- 104 Submissions with SEND data failed for error 1734
 - 80% of errors because **NO ts.xpt is found**
 - 20% of errors are because **no Study Start Date or null value** found within ts.xpt

1734 Errors by Application Type



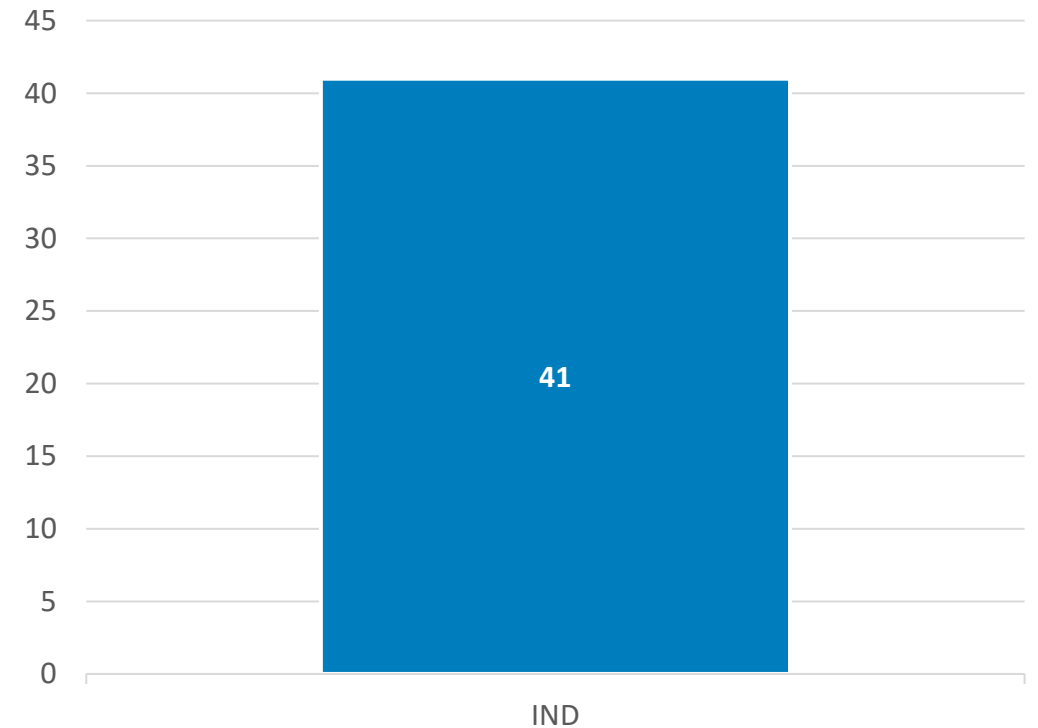
1735 Error



The correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in a TRC-applicable section

- 41 Submissions with SEND data failed for error 1735
 - 61% of errors because an incorrect file-tag used for **define.xml**
 - 39% of errors are because an incorrect file-tag used for **dm.xpt**

1735 Errors by Application Type



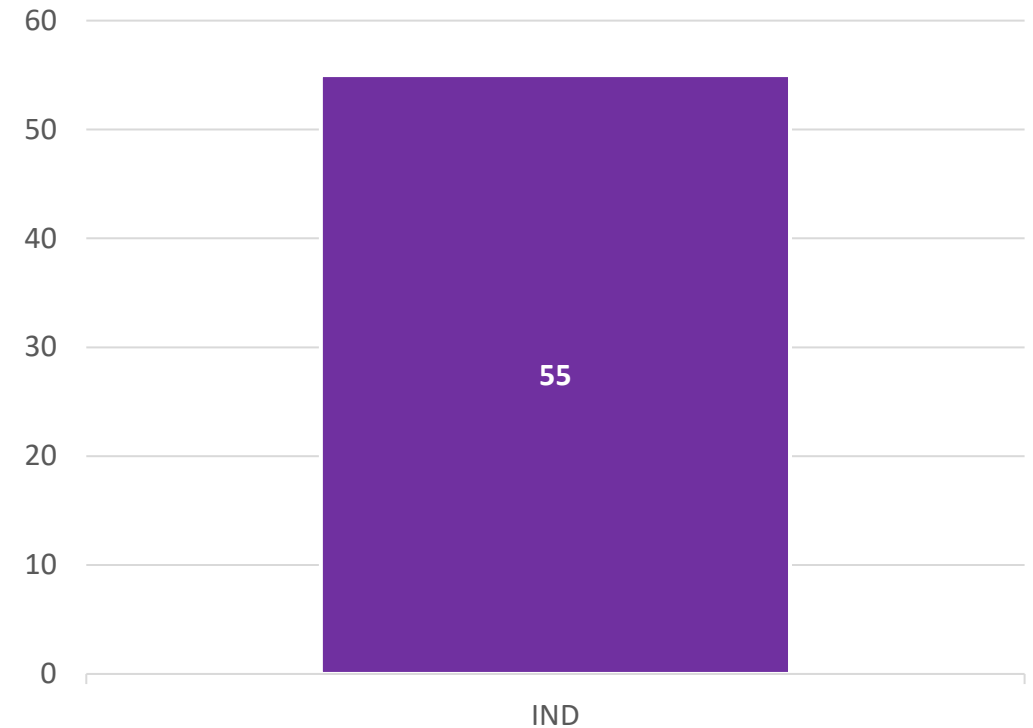
1736 Error



For SEND data, a Demographic (DM) dataset and define.xml must be submitted for studies in TRC-applicable Module 4 sections

- 55 Submissions with SEND data failed for error 1736
 - 20% of errors because **no dm.xpt**
 - 80% of errors are because **no define.xml**

1736 Errors by Application Type

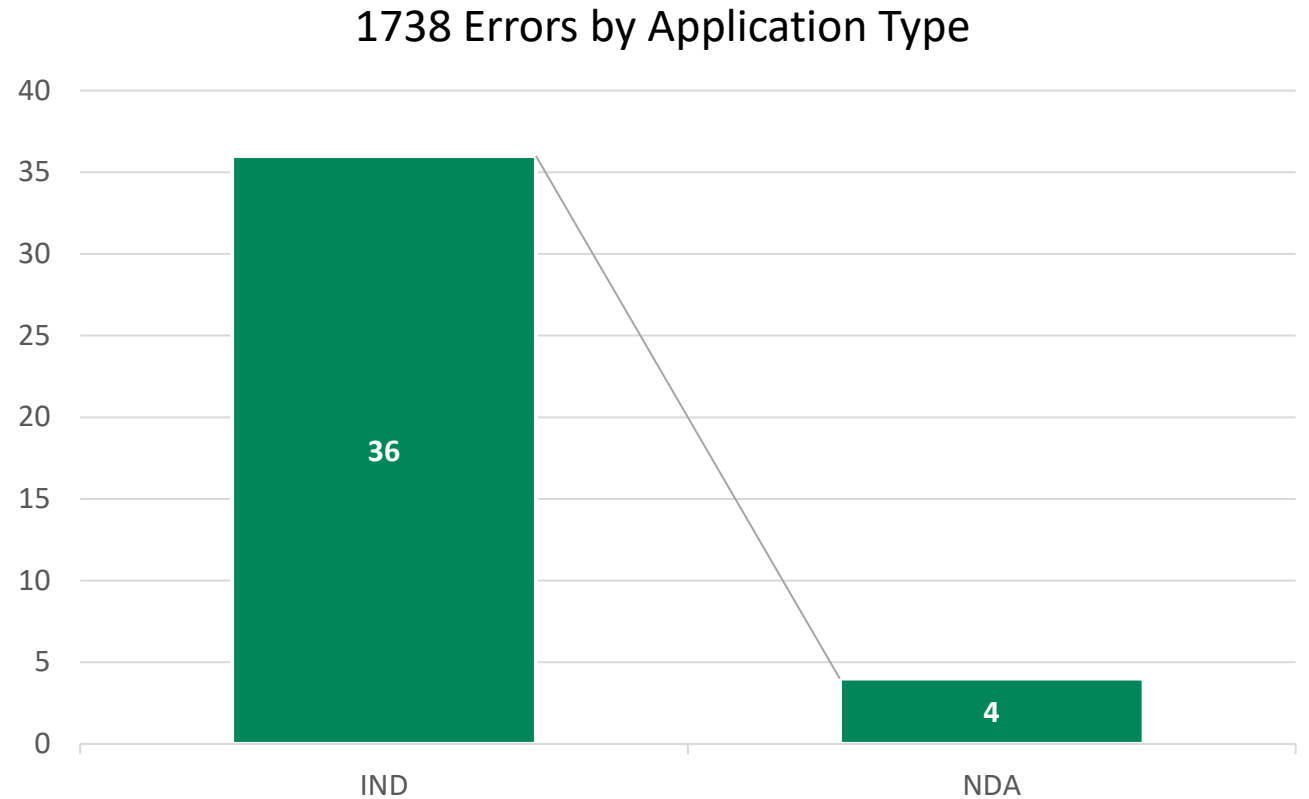


1738 Error



STF Study ID should match STUDYID or SPREFID listed in the referenced Trial Summary (ts.xpt) file

- 40 Submissions with SEND data failed for error 1738
 - 90% of errors are from IND submissions



Resources

- Study Data Standards
 - [Study Data Standards Resources](#)
 - [Study Data Sample submissions](#)
 - [Study Data Technical Conformance Guide - Technical Specifications Document | FDA](#)

- Electronic Common Technical Document (eCTD)
 - [eCTD Guidance](#)

- eCTD v3.2.2
 - [eCTD Submission Standards for eCTD v3.2.2 and Regional M1](#)

- eCTD v4.0
 - [eCTD Submission Standards for eCTD v4.0 and Regional M1](#)
 - [FDA's eCTD v4 implementation page](#)
 - [eCTD v4.0 Sample submissions](#)