U.S. FOOD & DRUG ADMINISTRATION

Technical Rejection Criteria for Study Data – Preliminary Findings

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Background

- CDER SDTM data was assessed for conformance to the two high-level errors as described in the Technical Rejection Criteria for Study Data
- SDTM data submitted in eCTD applications from January 1, 2017 – March 31, 2017 was assessed regardless of study start date
- These findings will not be used for future regulatory decisions – any intentions to enforce the technical rejection criteria for study data will be announced at least 30 days prior to going into effect.

Technical Rejection Criteria Research

yes	NO
Help FDA have an understanding of current landscape of study data	Result in rejection of applications
Check all SDTM and SEND data - regardless of study start date	Have any regulatory repercussions
Check all SDTM and SEND Data submitted in an NDA, BLA, or IND	Discriminate between eCTD applications submitted before or after May 2017
Include all SDTM and SEND data submitted between January 1, 2017 and March 31, 2017	Discriminate between studies with start dates before or after December 17, 2016
	Assess Legacy Data

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 is being added to the existing eCTD validation criteria to enforce the submission of standardized study data
- FDA will give the industry 30 days' notice on the eCTD website prior to the criteria becoming effective.

[1] Guidance to Industry: "Providing Regulatory Submissions In Electronic Format — Standardized Study Data

Technical Rejection Criteria for Study Data

- 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 starts after December 17, 2017
- The requirement to submit NDAs, ANDAs, and BLAs electronically becomes effective 24 months after May 5, 2015, the original date of finalization of this guidance.
- The requirement for INDs to be filed electronically takes place 36 months after May 5, 2015. [1]

[1]Guidance to Industry - Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications

Technical Rejection Criteria for Study Data

- Study data validation WILL APPLY to the following eCTD sections:
  - 4.2 Study Reports
  - 5.3 Clinical Study Reports and Related Information

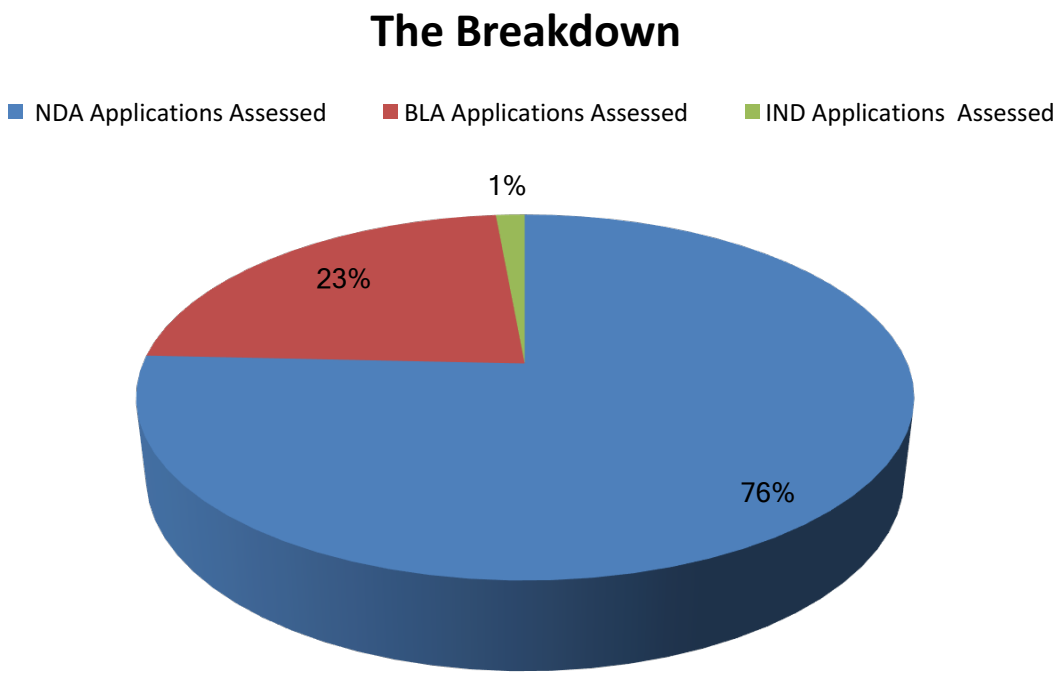
Technical Rejection Criteria for Study Data

- Study data validation WILL NOT APPLY to the following eCTD sections:
- 4.2.1 Pharmacology
- 4.2.2 Pharmacokinetics
- 4.2.3.3 Genotoxicity
- 4.2.3.5 Reproductive and Developmental Toxicity
- 4.2.3.6 Local Tolerance
- 4.2.3.7 Other Toxicity Studies
- 5.3.1.3 In Vitro – in Vivo correlation Study reports and related information
- 5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies
- 5.3.2 Reports of studies pertinent to pharmacokinetics using human biomaterials
- 5.3.3.5 Population PK study reports and related information
- 5.3.5.3 Reports of Analyses of Data from More than One Study
- 5.3.5.4 Other Study Reports and Related Information
- 5.3.6 Reports of Postmarketing Experience

SEND Data

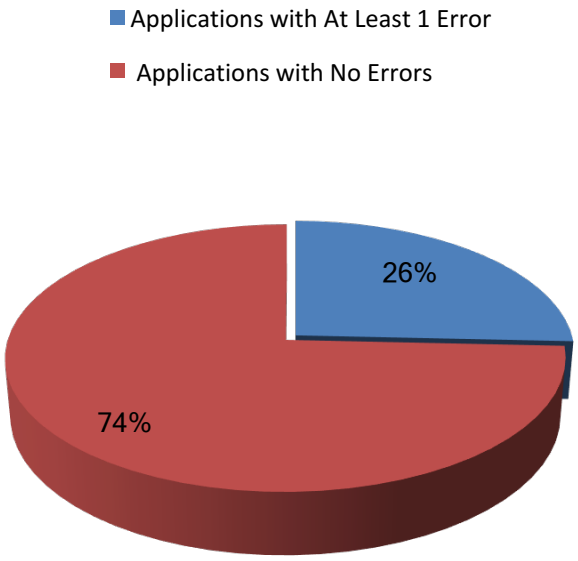
- 1 IND with SEND Data: No Errors

70 CDER Applications Assessed



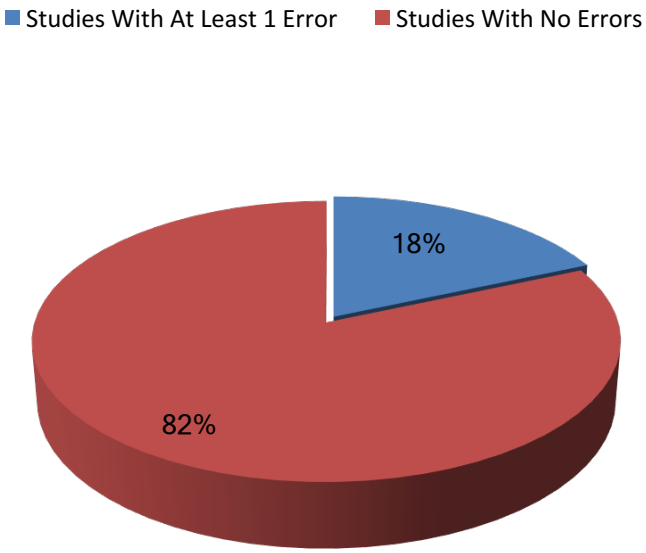
Errors by Application and Study

Potential Rejections



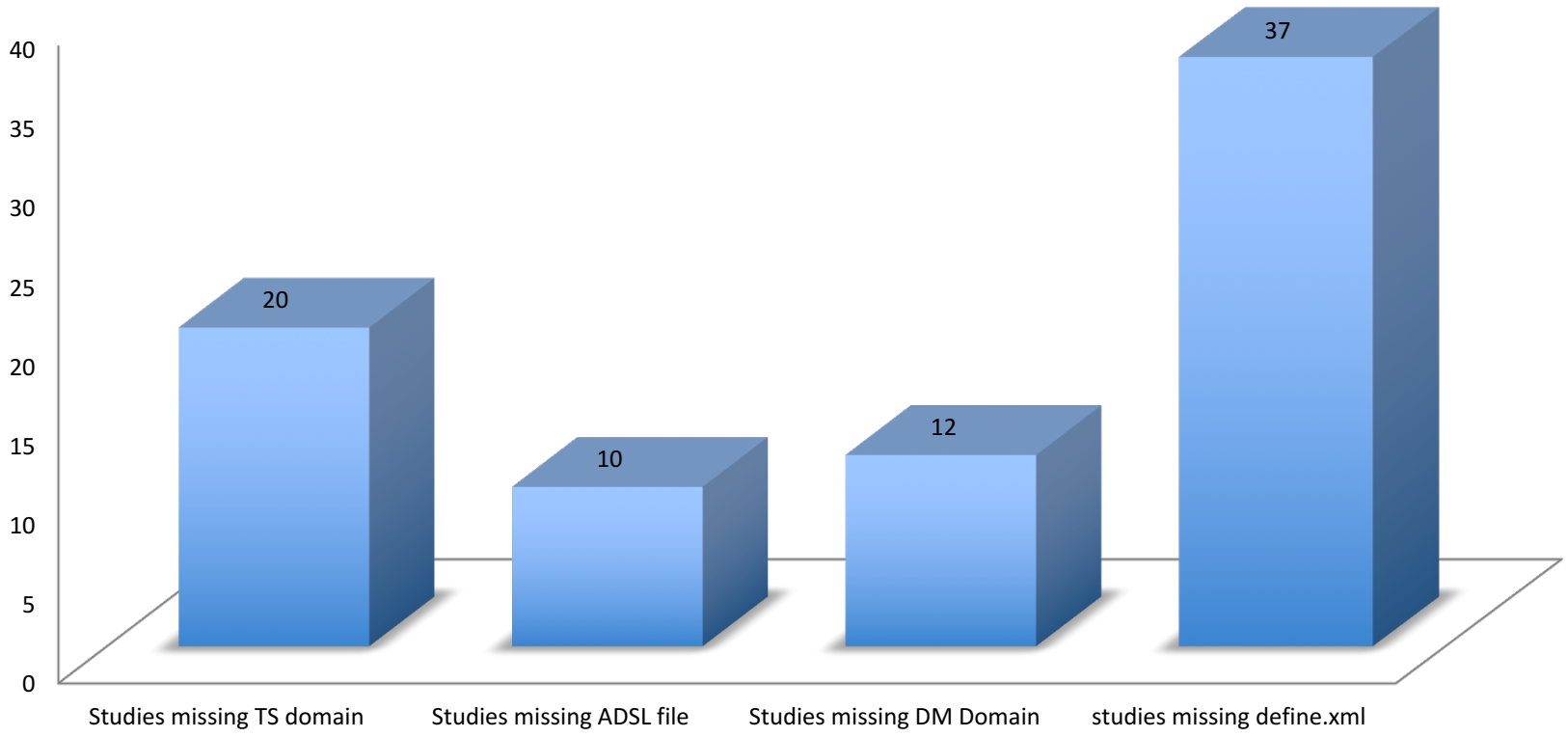
*70 Applications Assessed

Study Errors



*222 Studies Assessed

Errors by Technical Rejection Criteria



*Each Study Could Have Multiple Errors

Newly Published Conformance and Business Rules[1]

5. Business Rules

Validation activities occur at different times during submission and review of study data, including submission receipt and at the beginning of the regulatory review. Validation of study data that occurs upon receipt of a submission follows the process for Technical Rejection Criteria for Study Data.

The rules below support regulatory review and analysis of study data:

- **Business Rules**
  The Business Rules help ensure that the study data are compliant, useful, and will support meaningful review and analysis. This applies to SDTM formatted clinical studies and SEND formatted non-clinical studies. For more information see Section 8 of the Technical Conformance Guide.
- **Validator Rules**
  The Validator Rules are used by the FDA to ensure data are standards compliant and support meaningful review and analysis.

[1]FDA Business Rules and Validator Rules on the Study Data Standards Resources Webpage: https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm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