

SEND Load Errors

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FDA
April 2026



BACKGROUND



Office of Computational Sciences (OCS)

- Provide CDER reviewers solutions that improve the scientific review process by integrating data, tools, and training
- Drives modernization of CDER's scientific review process through the implementation of tools, services, and training to enable reviewers to apply their expertise to information
- OCS is under the Office of Translational Sciences in CDER
- OCS supports multiple Offices across the Center

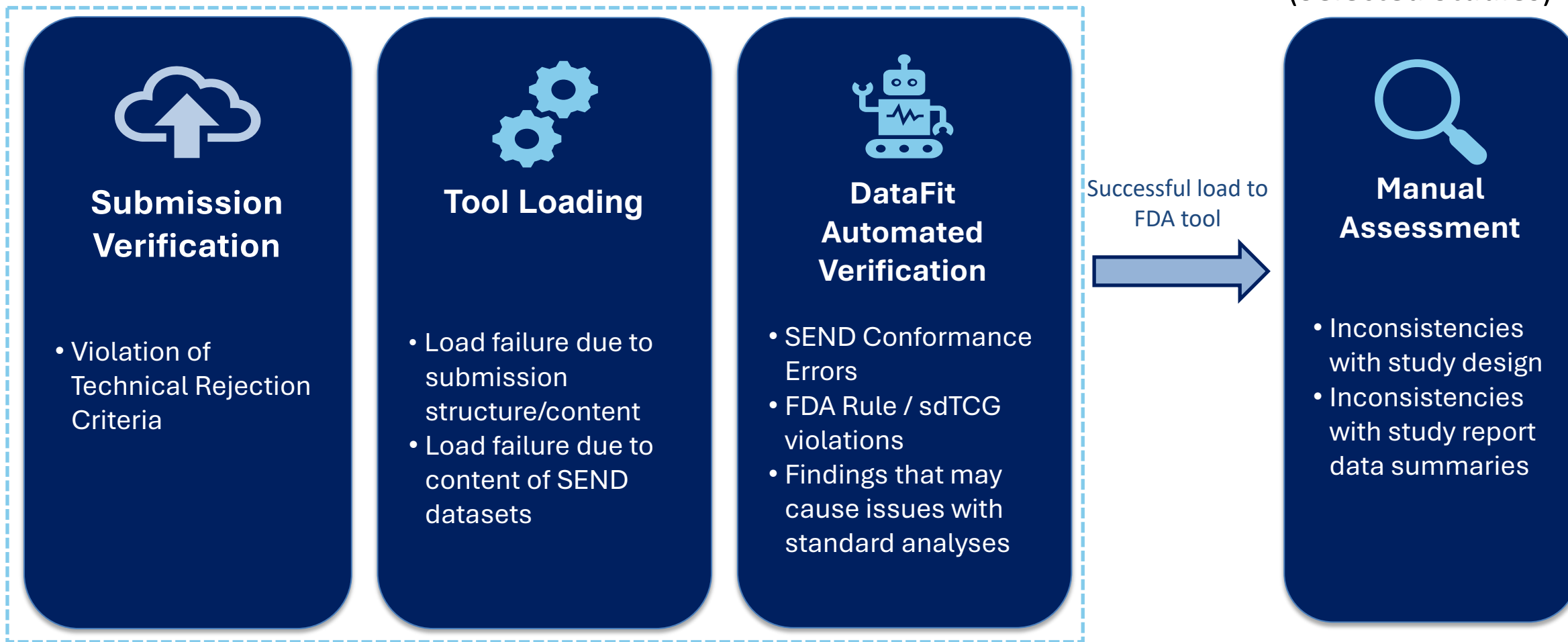


SEND VERIFICATION

SEND Verification for FDA CDER

SEND package in \m4\datasets\All Studies)

SEND in FDA Tool
(**Selected Studies**)



All issues found through automated methods are manually assessed

Results of FDA SEND Verification

For September 15, 2024 – September 12, 2025:

- 5,964 SEND packages assessed
- 2.9% failed to load into SEND review/analysis tools at FDA
 - Submission issues
 - SEND content issues
- Systematic automated assessment of all incoming SEND packages for issues that may impact analysis on loaded studies started January 2025
 - 1.5% of studies loaded had errors identified that affected review



Tool Loading Failures Due to Submission Issues

September 15, 2024 – September 12, 2025

Issue	104
Missing file(s)	33
File name inconsistent with contents / incorrect file name	32
Files in incorrect folder structure	25
File from wrong study included in SEND package	8
Corrupt file(s) / Unreadable file(s)	4
Abbreviated TS sent with a full SEND package	2

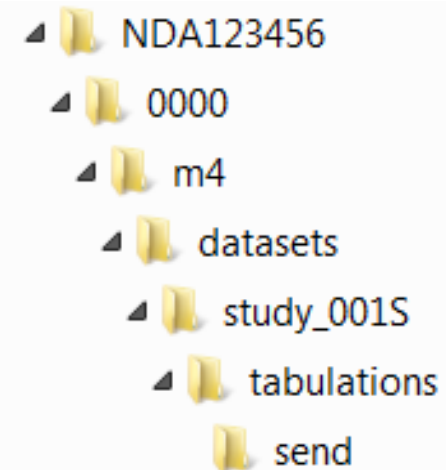
Identifying Missing Files

- Compare the files listed in `define.xml` with the files in *study tabulations\send* folder
 - Will also identify misplaced and misnamed files
- Look for key files, regardless of what is in `define.xml`
 - TS, TX, DM, DS, EX and at least one findings dataset
 - Parent record for supplemental qualifiers, comments, related records
- Look for missing `define.xml`

Incorrect SEND Submission Folder Used

- Count likely understated; entire eCTD for each submission is not searched for misplaced SEND files
- Automated daily verification finds packages split between correct and incorrect folders
- Misplaced files may be identified when reviewer requests studies not present in FDA SEND tools
- Otherwise, misplaced SEND study packages may go undetected.

Folder structure for SEND submissions is described in the Study Data Technical Conformance Guide

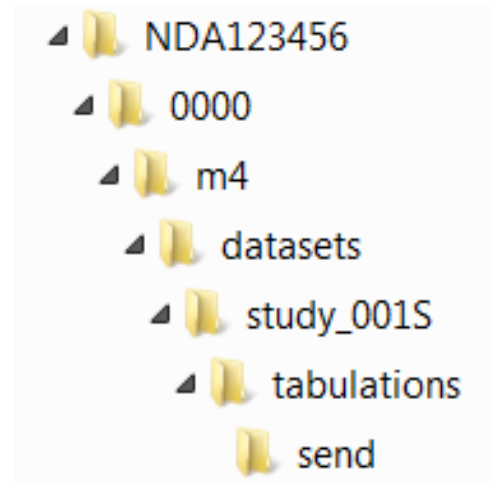


Incorrect SEND Submission Folder Used

Example Locations with SEND

- In the study report folder
- In the tabulations folder
- In an SDTM (instead of SEND) folder under the tabulations folder
- In a folder named 'final' under the *tabulations\send* folder
- In a send folder under a tabulation (rather than tabulations) folder
- In a send folder under the study ID folder (no tabulations folder)

Folder structure for SEND submissions is described in the Study Data Technical Conformance Guide



Invalid File Names – Some Examples

123456_lb.xpt ← Study identifier included in file name

tsxpt.xpt ← File extension included in file name

mi1.xpt ← sequence number included in file name

bw-body-weights-data-tabulation-dataset-xpt-send.xpt

Suppc.xpt

Poldef.xpt

bw.xpt containing clinical observations ← name does not match content

eCTD software can “hide” the file names by showing only the title defined in the index.xml - additional steps may need to be taken to view names of submitted files



Tool Loading Failures Due to SEND Content Issues

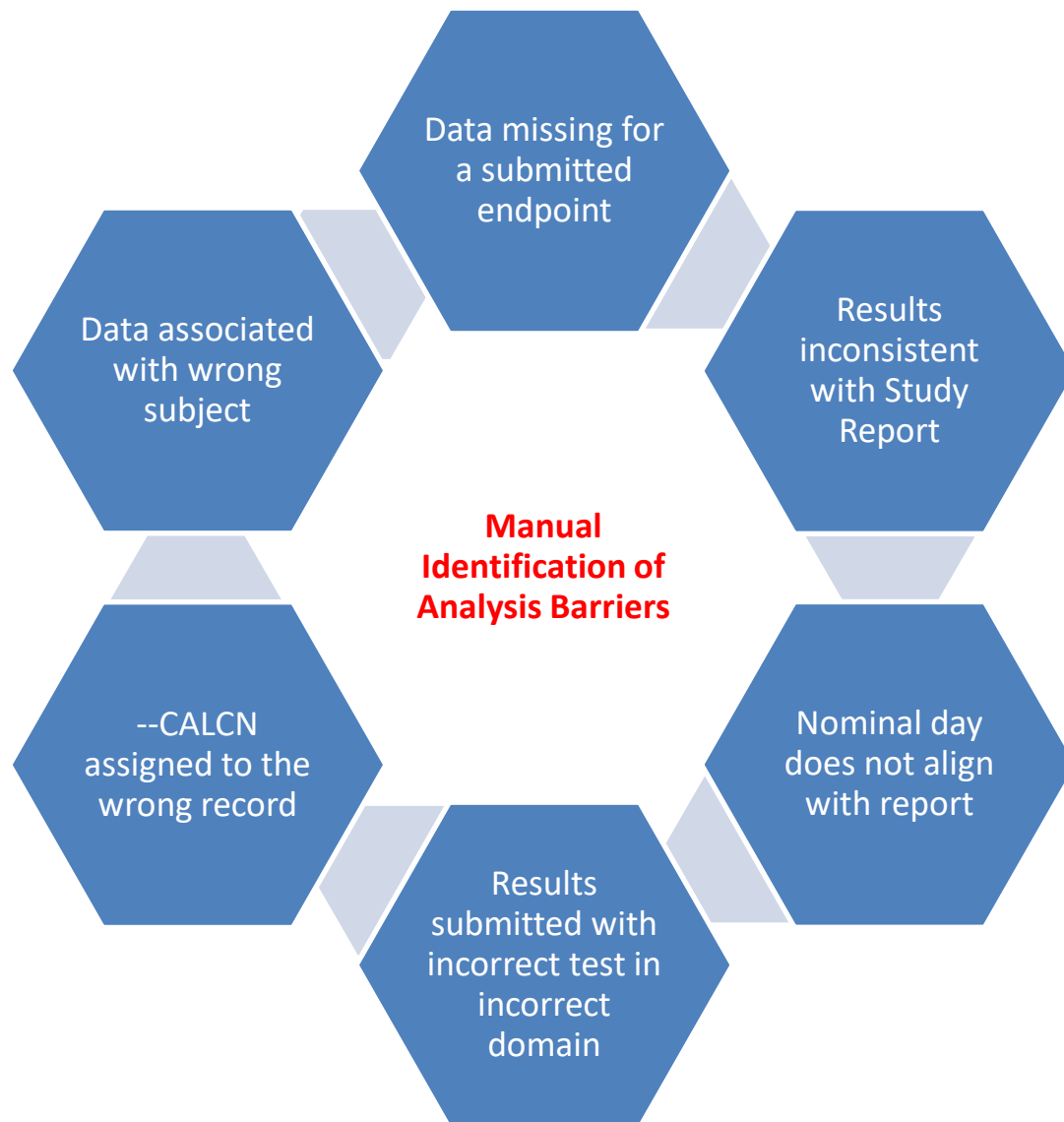
September 15, 2024 – September 12, 2025

Issue	66
Duplicate –SEQ in findings, duplicate record in TX, TE, SE, or POOLDEF	26
Missing required variable value	15
Variable value longer than allowed length	15
Invalid references between files	4
More than one STUDYID value used but all are data from the same study	3
Invalid value for a TX parameter	2
Invalid date (ex: 2024-02-30)	1

Key Issues in SEND Impacting Analysis Use Found through Automated Verification

Issue
Incorrect, missing, or unusable sponsor group code
Incorrect, missing, or unusable treatment name and/or dose Level
Sets do not correctly separate terminal, recovery, and TK animals
Terminal and recovery sacrifice animals have the same disposition code
Endpoint not differentiated by a variable used in analysis
Multiple scheduled collection times per day, no TPT value used
Non-ASCII characters in standardized findings variables
Impossible negative result values

Additional automated validation tests are being added to find analysis issues before the start of CDER Reviews



OCS Nonclinical Services: Providing manual verification of SEND submissions for CDER reviewers

Summaries in FDA SEND analysis tools are scanned for anomalous results

Summaries are spot-checked against study report tables

More detailed check is warranted when errors in SEND are found

Activities to Promote Submission Improvements

- New information added to sdTCG to reflect issues seen in incoming SEND packages and expectations for verification prior to submission
- Recommendations made for nSDRG content focusing on documentation of SEND verification
- FDA OCS continues to enhance automated monitoring techniques

Goal is to ensure FDA Reviewers can confidently use SEND as part of their nonclinical safety review and high-quality data is available for FDA research activities