



BEST PRACTICE: COMPLYING WITH THE STUDY DATA TECHNICAL CONFORMANCE GUIDE V4.5

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2 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov Business Consulting Team reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Ennov recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation

Software Version	Release/ Revision Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v7.3.1	28-Jun-2024	Update Best Practice for Ennov rebranding & for v7.3.1 – No Impact
v7.2	20-Jun-2023	Update Best Practice for v7.2 – No Impact
v7.1	13-Jan-2022	Update Best Practice for v7.1 – No Impact
v7.0	25-May-2021	Update Best Practice for v7.0 – Impact

3 Complying with the Study Data Technical Conformance Guide v4.5

In March 2020 the US Food and Drug Administration (FDA) released the Study Data Technical Conformance Guide v4.5. This guide replaces all the previous versions of:

- Study Data Specifications (Versions 1.0 - 2.0)
- CDER Study Data Common Issues (Versions 1.0 - 1.1)

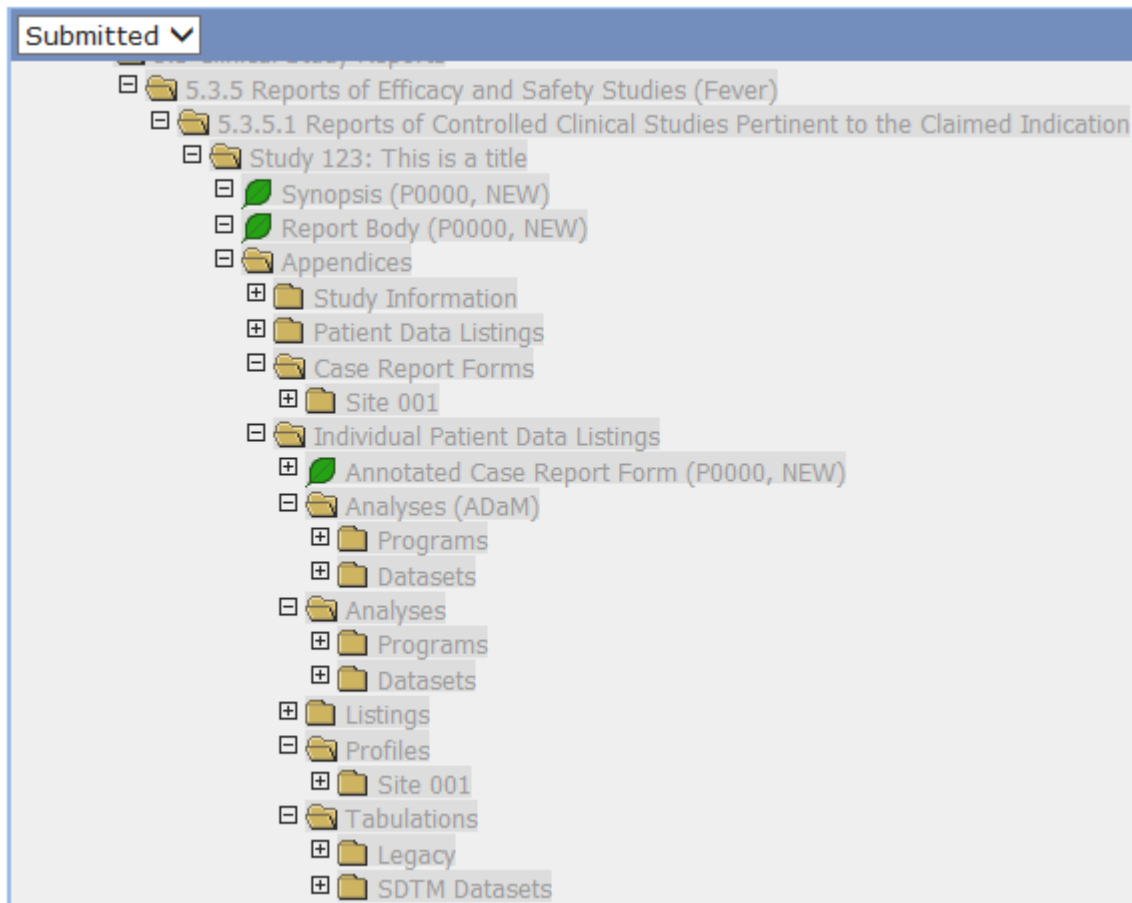
3.1 Summary of Changes in the Study Data Technical Conformance Guide v4.5

The following list describes the changes in the Study Data Technical Conformance Guide v4.5:

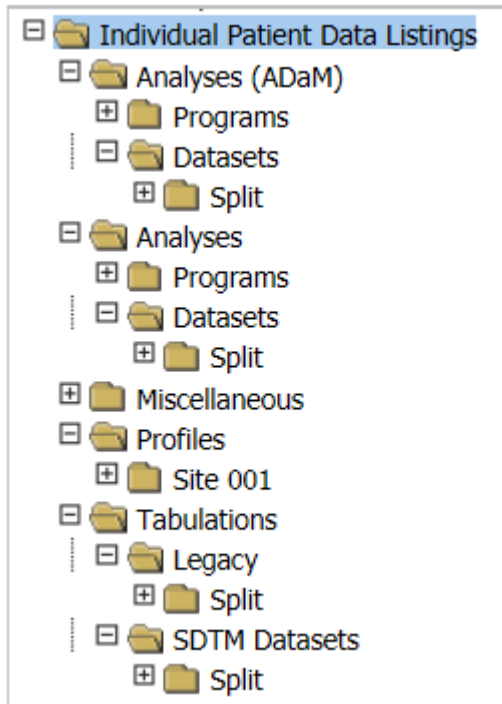
- SEND Domain Specification has been updated with new sub-sections and added clarifying text.
- Supported Therapeutic Area added new therapeutic areas:
 - Schizophrenia
 - Major Depressive Disorder
 - Traumatic Brain Injury
 - Duchenne Muscular Dystrophy
 - Vaccines Therapeutic Area
 - Chronic Obstructive Pulmonary Disease
 - Colorectal Cancer
 - Huntingdon's Disease
 - Post Traumatic Stress Disorder
 - Clostridium Difficile Associated Diarrhea

3.2 Folder Structure Changes

The following shows the differences between the folder structures based on the superseded and the new Study Data specifications.



New 4.1 Individual Patient Data Listings Structure within CSR



To modify the report structure:

1. Open the **Submitted View** of the US eCTD application that is associated with the assembly.
2. Unlock the **Submitted View**.

Note: You cannot unlock the Submitted View if a working assembly is associated with the application.

3. Click the Listings folder.
4. In the More list, click Change Type.
5. In the Extension list, click Default, and click OK.
6. When you see a warning message that says that changing the type will erase publishing information, click OK.
7. In the More list, click Change Type.
8. In the Extension list, click Study Patient Information, and click OK.
9. When you see a warning message that says that changing the type will erase publishing information, click OK.
10. Change the following attributes of the **Listings** folder to the values shown:
 - a. Name: Miscellaneous
Abbreviated Name: Miscellaneous
 - b. Output Folder: misc
 - c. Subject Matter: data-listing-dataset
11. Click **Save**.
12. Lock the modified **Submitted View**.

13. Create a new sequence.
14. Create a working assembly.
15. **If the current working assembly includes the Annotated** Case Report Form, make sure that the output file name is acrf.pdf.
16. If you need to submit split analysis or tabulation datasets, add a new child folder under the appropriate dataset folder.
17. Update the following attributes of the duplicate folder to the values shown:
 - d. Name: Split
 - e. Abbreviated Name: Split
 - f. Output Folder: split
18. Click **Save**. Demote the folder **Split** to make it a subfolder of the folder **Datasets**.