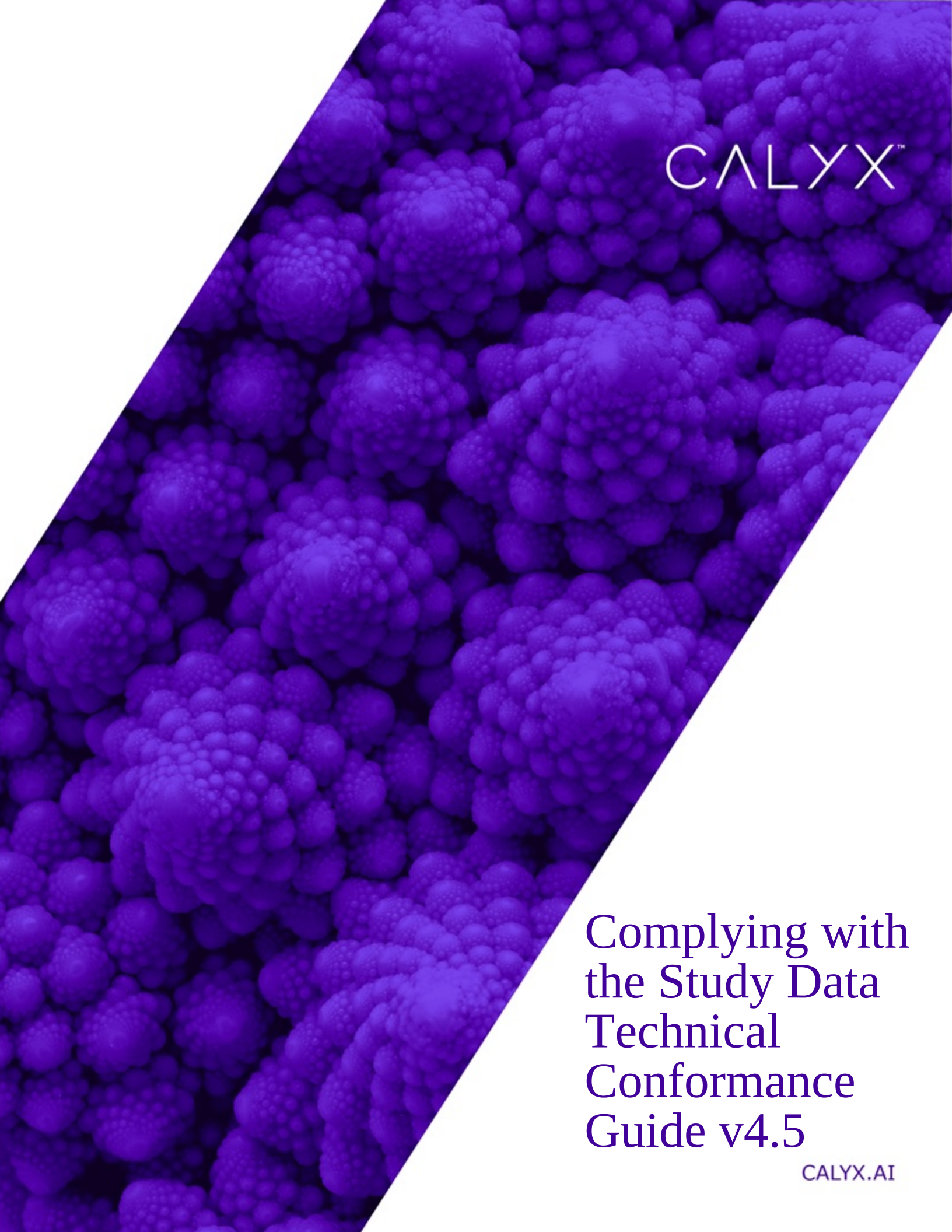


Complying with the Study Data Technical Conformance Guide v4.5

CALYX.AI

1 Contents

2 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)

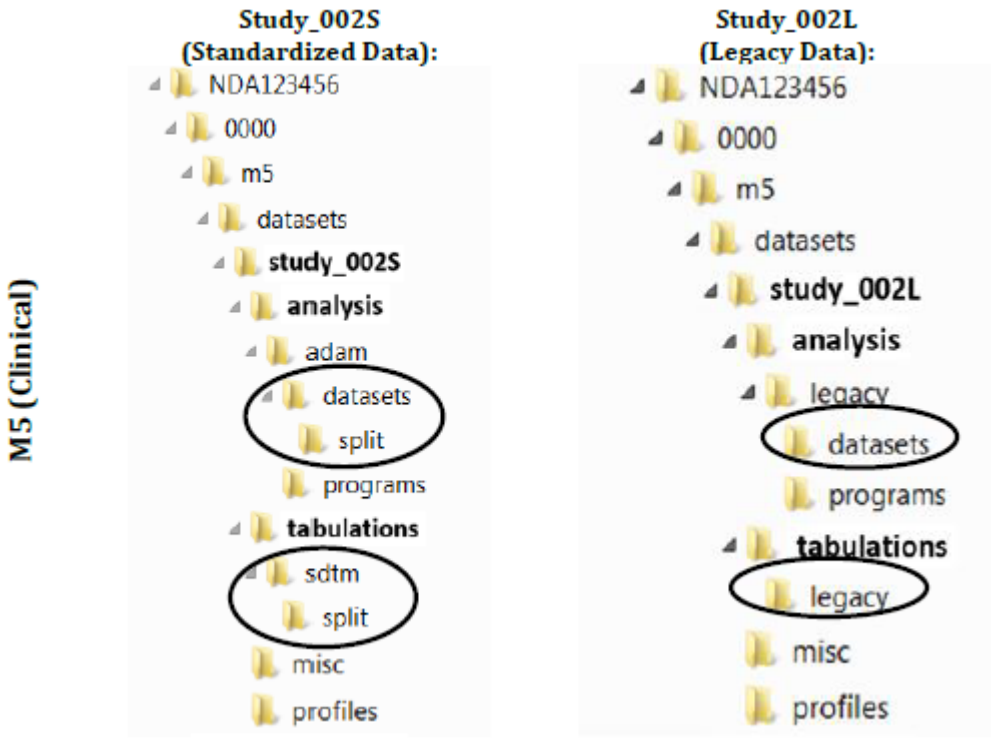
2.1 Summary of Changes in the Study Data Technical Conformance Guide v4.5

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:
  - Schizoprhrenia
  - Major Depressive Disorder
  - Traumatic Brain Injurty
  - Duchenne Muscular Dystrophy
  - Vaccines Therapeutic Area
  - Chronic Obstructive Pulmonary Disease
  - Colorectal Cancer
  - Huntingdon’s Disease
  - Post Traumatic Stress Disorder
  - Clostridium Difficile Associated Diarrhea

2.2 Folder Structure Changes

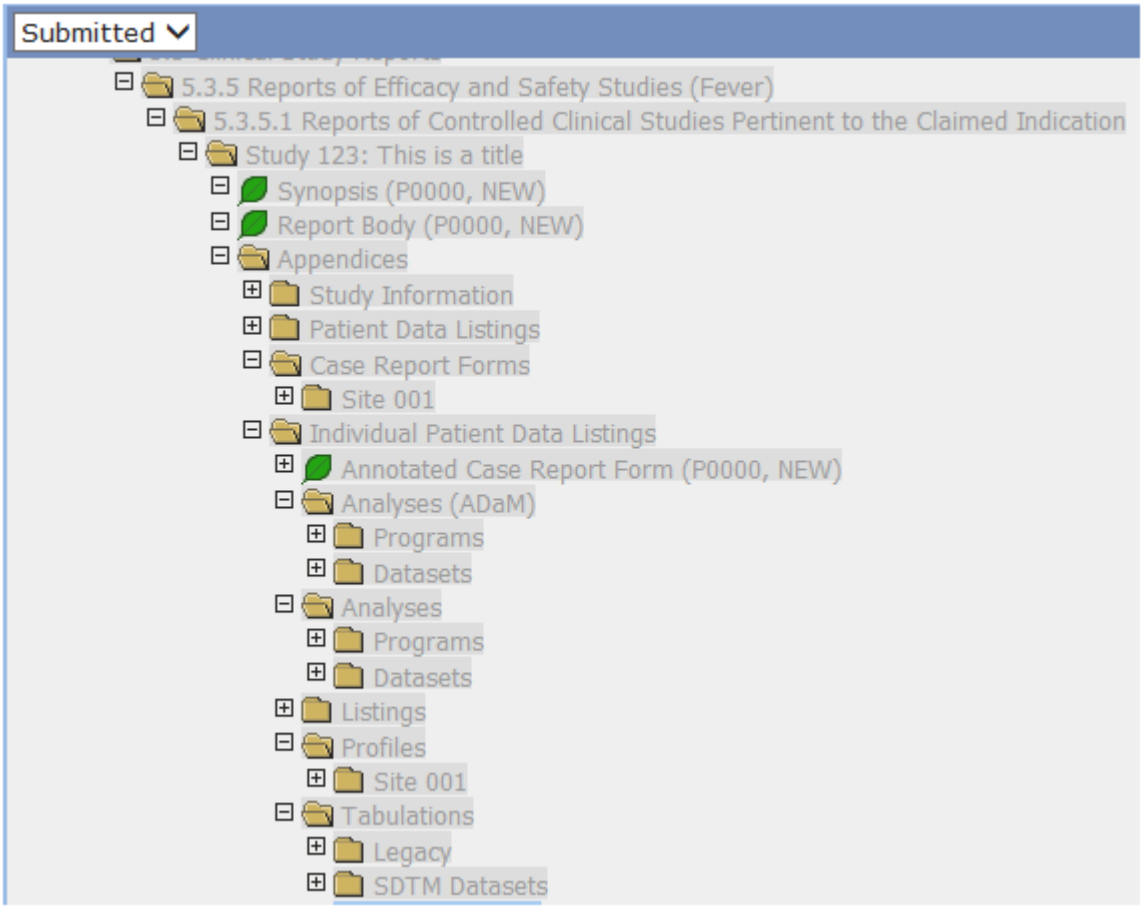
The following shows the differences between the folder structures based on the superseded and the new Study Data specifications.



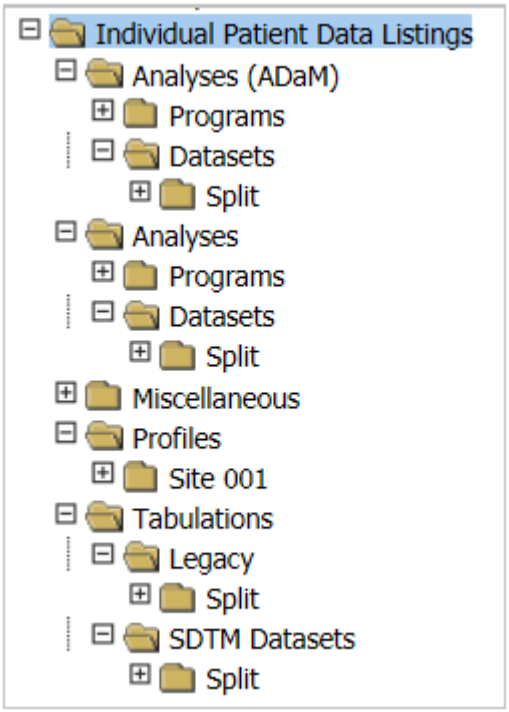
2.3 Modifying a Clinical Study Report Structure to Comply with the Study Data Technical Conformance Guide v4.5

To comply with the Study Data Technical Conformance Guide v4.5, change an assembly structure in the Submitted View.

Pre-v4.1 Clinical Study Report Structure



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:
    - Name: Miscellaneous
      Abbreviated Name: Miscellaneous
    - Output Folder: misc
    - 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:
    - Name: Split
    - Abbreviated Name: Split
    - Output Folder: split
18. Click **Save**.
    Demote the folder **Split** to make it a subfolder of the folder **Datasets**.