



WORK INSTRUCTION

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SDTM and ADaM Specification Development and Maintenance

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Document No.: VV-QDOC-75311 Version: 1.0, Effective Date: 01 May 2023

1. PURPOSE

This work instruction (WI) to describe how to generate, review and approve the SDTM and ADaM Specifications in support of clinical studies at BeiGene. Also, to describe how to track changes of SDTM and ADaM Specifications after data readout.

2. SCOPE

This work instruction applies to all Global Statistic and Data Science (GSDS) personnel at all BeiGene locations who work directly on the development and maintenance of SDTM and ADaM Specifications of all clinical studies sponsored by BeiGene, for CSR or any unblinding and/or critical Database lock, per [SOP \(VV-QDOC-00697 Statistical Programming Development and Verification\)](#).

3. ABBREVIATIONS AND DEFINITIONS

3.1 **ADaM:** Analysis Dataset Model

3.2 **CSR:** Clinical Study Report

3.3 **DBL:** Database Lock

3.4 **SAP:** Statistical Analysis Plan

3.5 **SDTM:** Study Data Tabulation Model

3.6 **TFLs:** Table, Figure and Listings

4. RESPONSIBILITIES

4.1 Statistical Programmer (SP)

4.1.1 Creates, develops, maintains and archives SDTM Specification and ADaM Specification

4.1.2 Coordinates the review and approval of SDTM Specification and ADaM Specification

4.2 Study Statistician

4.2.1 Reviews and approves SDTM Specification (as needed) and ADaM Specification.

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5. INSTRUCTION**5.1 SDTM Specification and ADaM Specification Development and Review**

- 5.1.1 Study SP generates study SDTM and ADaM specifications per protocol, SAP and TFLs Shell, etc., within the recommended timeline (refer to Appendix 1).
- 5.1.2 Study Statistician reviews the combined ADaM Specification (and SDTM specification when deemed necessary) and provides comments. The 1st round of review should be completed before 1st dry run.
- 5.1.3 Study SP addresses the comments and makes updates.
- 5.1.4 Repeat steps [5.1.2](#) and [5.1.3](#) till all issues are addressed.

Note: It's up to the team whether to re-review the whole document or only focus on some of the key updates.

5.2 SDTM Specification and ADaM Specification Approval and Archive

- 5.2.1 Prior to DBL/snapshot, study SP routes the approval form using [Template \(VV-QDOC-75312 Specification Approval Form\)](#) through DocuSign.
- 5.2.2 Approvers for Specifications
 - 5.2.2.1 Study Lead Programmer or delegate is the approver for SDTM specification.
 - 5.2.2.2 Study Statistician is the approver for ADaM specification, which should be approved after SAP approval and TFLs Shell finalization. Study SP also signs off the ADaM Specification Approval form as the author.
- 5.2.3 Study SP archives the study SDTM Specification and ADaM Specification along with approval forms in the analysis-level AWS folder prior to soft-locking the folder.

5.3 SDTM Specification and ADaM Specification Maintenance

Upon first approval, all SDTM and ADaM specification changes should be tracked.

- 5.3.1 Study SP reviews and evaluates the change request.

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- 5.3.2 Study SP documents all updates since the first approval in the study-level “programming_spec_revision_tracker” using [Template \(VV-QDOC-76804 Specification Revision Tracker\)](#) cumulatively.
- 5.3.3 Study SP archives a copy of the tracker in the analysis-level AWS folder prior to soft-locking the folder.
- 5.3.4 Repeat step [5.1](#) and [5.2](#).

6. REFERENCES**6.1 Controlled Documents**

- 6.1.1 SOP (VV-QDOC-00697 Statistical Programming Development and Verification)
- 6.1.2 Template (VV-QDOC-75312 Specification Approval Form)
- 6.1.3 Template (VV-QDOC-76804 Specification Revision Tracker)

6.2 Regulatory References

- 6.2.1 N/A

6.3 Other References

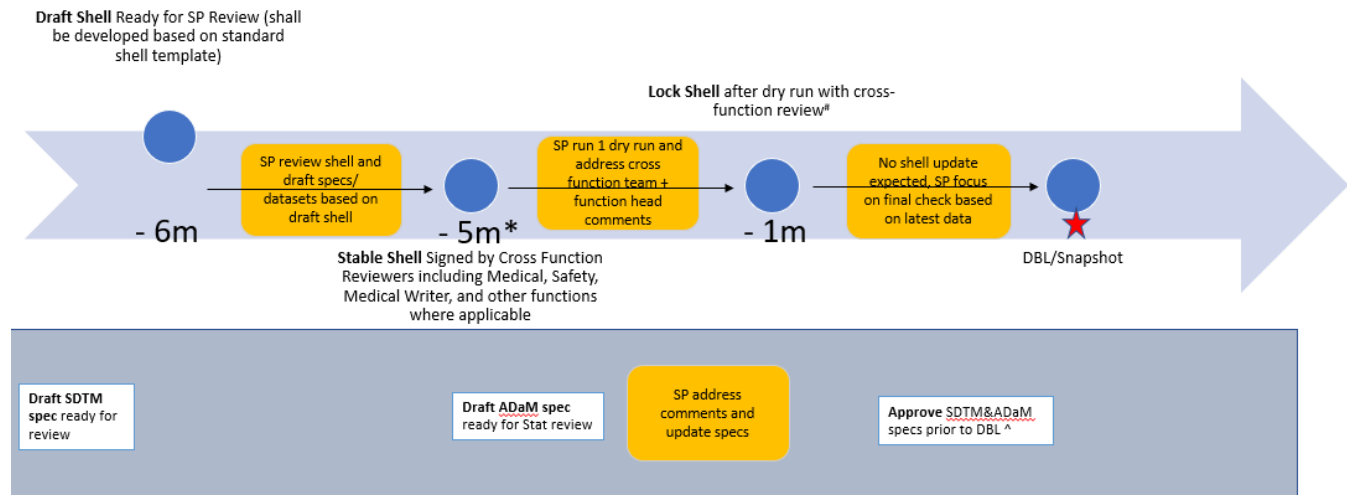
- 6.3.1 N/A

7. APPENDICES**7.1 Appendix 1: Timeline relative to TFL Shell**

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Appendix 1: Timeline relative to TFL Shell**Timelines Relative to TFL Shell (per the TFL standard Timeline)**

* This is proposed by NDA efficiency taskforce, to be released later.

Signature of reviewer is required to confirm 'lock shell'.

^ Needs to happen after SAP & Shell approval.

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8. DOCUMENT HISTORY PAGE

Version	Effective Date	Brief Description of Change
1.0	01 May 2023	Original Work Instruction.

Document Approvals

Approved Date: 24 Mar 2023

Task: SME Approval Verdict: Approve changes & release	Hui1 Liu, (hui1.liu@beigene.com) Document Owner 23-Mar-2023 06:53:13 GMT+0000
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