



WORK INSTRUCTION

Page 1 of 6

Statistical Programming Study Close-out

Company Confidential

Document No.: VV-QDOC-29633 Version: 3.0, Effective Date: 22 Nov 2023

1. PURPOSE

This document provides statistical programming team a guidance on how to utilize Study Close-out Checklist to ensure that all necessary aspects of study closure and archival have been addressed.

Study Lead Programmer and statistical programmer may use this guidance as a starting point for customizing a protocol/study specific checklist for study closure activities.

2. SCOPE

This work instruction applies to all BeiGene studies that Clinical Study Reports (CSR) have been signed-off or work on formal milestone analysis has been completed, such as but not limited to:

- Clinical study reports and regulatory submissions
- Data Monitoring Committee (DMC)
- Publications, abstracts, and presentations associated with seminars and congresses

3. ABBREVIATIONS AND DEFINITIONS

- 3.1 **AWS:** Amazon Web Services Workspace. A secured virtual environment/directory in which Statistical and Clinical programs are developed and maintained.
- 3.2 **CSR:** Clinical Study Report
- 3.3 **CST:** Clinical Study Team
- 3.4 **DMC:** Data Monitoring Committee
- 3.5 **SME:** Subject Master Expert
- 3.6 **SPPL:** Statistical Programming Product Lead
- 3.7 **TFL:** Table, Figure and Listing
- 3.8 **VDF:** Verification Documentation Form

4. RESPONSIBILITIES

- 4.1 Study Lead Programmer is responsible for coordinating the cleanup and document of study directories, with CST members (usually Data Manager, Statistician and Clinical Pharmacologist as needed)



WORK INSTRUCTION

Page 2 of 6

Statistical Programming Study Close-out

Company Confidential

Document No.: VV-QDOC-29633 Version: 3.0, Effective Date: 22 Nov 2023

- 4.1.1 Initiates the study specific close-out activities with Study Close-out Checklist and customizes per the specific needs and requirements of the study.
- 4.1.2 Coordinates study directories cleanup and documentation.
- 4.1.3 Collaborates with other functional area SMEs (including but not limited to Data Manager, Statistician, and the PK Scientist) to complete the Study Close-out Checklist.
- 4.1.4 Forwards the completed Study Close-out Checklist to Statistical Programming Product Lead (SSPL) for approval, while informing study statistician as needed.
- 4.1.5 Submits the Study Lock request to IT
- 4.1.6 Archives the completed Study Close-out Checklist and the signed Approval Form.
- 4.2 Statistical Programming Product Lead (SPPL)
 - 4.2.1 Reviews the study specific close-out checklist and signs Approval Form.
- 4.3 System Administrators (GTS, normally known as IT)
 - 4.3.1 Provides technical support to lock down the study folder per request.

5. INSTRUCTION

- 5.1 Close-out Preparation
 - 5.1.1 Before the completion of the CSR, Study Lead programmer creates and completes [Template \(VV-QDOC-02099 Verification Documentation Form\)](#) and files the signed VDF per [WI \(VV-QDOC-00698 Verification of Statistical Programming Deliverables\)](#).
 - 5.1.2 For milestone analyses other than CSR complete, Study Lead Programmer works with statistical programmers and Study Statistician to verify study specified [Template \(VV-QDOC-11820 Programming QC Project Tracker\)](#) has been finalized with appropriate information.

NOTE: Each analysis including CSR and other milestone analyses should have its own QC document.

**Statistical Programming Study Close-out**

Company Confidential

Document No.: VV-QDOC-29633 Version: 3.0, Effective Date: 22 Nov 2023

5.1.3 Soft Lock of Analysis Folder(s)

Upon the completion of milestone analysis(s), the analysis folder should be soft locked.

5.1.3.1 Study Lead Programmer decides the target folder to be locked and the soft lock timeframe.

5.1.3.2 Study Lead Programmer verifies all required files (documents and programs) are in appropriate locations by completing required sections of [Template \(VV-QDOC-29634 Statistical Programming Study Close-out Checklist\)](#).

5.1.3.3 Archives the completed Study Close-out Checklist in AWS under the folder below:

For Analysis lock: /build/<product>/<study>/<analysis>/docs

5.1.3.4 Study Lead Programmer conducts soft lock, self-check lock success, then inform Statistical Programming team by email.

5.1.3.5 Based on study needs (i.e., updates required, new requests received), statistical programmer informs Study Lead Programmer and unlocks the analysis folder.

5.1.3.6 Upon changes are completed, Study Lead Programmers shall conduct soft lock to the analysis folder again following the steps from section [5.1.3.1](#).

5.2 When a study CSR has been signed-off or when work on milestone analysis(s) has been completed, Study Lead Programmer verifies all required files (documents and programs) are in appropriate locations by completing [Template \(VV-QDOC-29634 Statistical Programming Study Close-out Checklist\)](#).

5.2.1 Customizes the Study Close-out Checklist per study-specific needs and requirements of the study.

5.2.2 Study-specific close-out activities/tasks can be added as needed, mark as "N/A" for those mandatory elements that are not applicable.

5.2.3 In some instances, documentation may not be available or complete. If deemed acceptable, acknowledge the absence or deficiency within the Comments section of the checklist to demonstrate awareness.



WORK INSTRUCTION

Page 4 of 6


Statistical Programming Study Close-out

Company Confidential

Document No.: VV-QDOC-29633 Version: 3.0, Effective Date: 22 Nov 2023

NOTE: If the study is closing early, contact the Statistical Programming Product Lead (SPPL) for additional guidance.

- 5.2.4 For milestone analyses, Final and Interim analysis, Study Lead Programmer or delegate stores all relevant Production and Development macros/utilities used to AWS appropriate folders to ensure exact replication of results per [WI \(VV-QDOC-00169 Statistical Programming\)](#).
- 5.3 Sends the Study Close-out Checklist to Statistical Programming Product Lead (SPPL) for review, also Statistician as needed.
- 5.4 Archives the completed Study Close-out Checklist in AWS under the folder below:
- For Study lock: /build/<product>/<study>/docs
- For Analysis lock: /build/<product>/<study>/<analysis>/docs
- 5.5 Study Lead Programmer prepares the Approval Form using [Template \(VV-QDOC-29635 Statistical Programming Study Close-out Approval Form\)](#) and sends to Lead Statistician, Study Lead Programmer and Statistical Programming Product Lead (SPPL) for approval.
- NOTE:** Only final Study Lock requires signed Approval Form
- 5.6 Study Lead Programmer Contacts IT Service Desk at AskIT@beigene.com to request to lock down the whole study folder by setting the folder to read-only.
- 5.7 IT set the whole study folder to read-only and signs the approval form. Then IT informs Study Lead Programmer upon completion.
- 5.8 Study Lead Programmer confirms required study folder(s) have been locked.
- 5.9 Study Lead Programmer archives the signed Approval Form in the appropriated central location: /build/<product>/docs/99_closeout.
- 5.10 Study Lead Programmer informs CST the completion of Statistical Programming Study Close-out.
- 5.11 Additional analysis after study close-out, e.g., requested by a Global Health Authority at any time during the review of an ongoing application defense, contacts the Statistical Programming Product Lead (SPPL) for additional guidance.

 BeiGene	WORK INSTRUCTION	Page 5 of 6
Statistical Programming Study Close-out		
Company Confidential		Document No.: VV-QDOC-29633 Version: 3.0, Effective Date: 22 Nov 2023

6. REFERENCES

6.1 Controlled Documents

6.1.1 Template (VV-QDOC-02099 Verification Documentation Form)

6.1.2 Template (VV-QDOC-11820 Programming QC Project Tracker)

6.1.3 Template (VV-QDOC-29634 Statistical Programming Study Close-out Checklist)

6.1.4 Template (VV-QDOC-29635 Statistical Programming Study Close-out Approval Form)

6.1.5 WI (VV-QDOC-00169 Statistical Programming)

6.1.6 WI (VV-QDOC-00698 Verification of Statistical Programming Deliverables)

6.2 Regulatory References

6.2.1 N/A

6.3 Other References

6.3.1 N/A

7. APPENDICES

7.1 N/A

**BeiGene****WORK INSTRUCTION****Page 6 of 6****Statistical Programming Study Close-out**

Company Confidential

Document No.: VV-QDOC-29633 Version: 3.0, Effective Date: 22 Nov 2023

8. DOCUMENT HISTORY PAGE

Version	Effective Date	Brief Description of Change
1.0	25 Dec 2022	Original Work Instruction.
2.0	22 Nov 2023	<ul style="list-style-type: none">Added new section 5.1.3 for soft lock of analysis folder(s).Updated section 5.3 – 5.8 for more detailed instruction.Administrative update to remove the not applicable abbreviation.

Document Approvals
Approved Date: 18 Oct 2023

Task: SME Approval Verdict: Approve changes & release	Edward Jin, (edward.jin@beigene.com) Functional Area Representative 16-Oct-2023 00:33:42 GMT+0000
Task: SME Approval Verdict: Approve changes & release	Hui1 Liu, (hui1.liu@beigene.com) Document Owner 16-Oct-2023 01:57:07 GMT+0000
Task: SME Approval Verdict: Approve changes & release	Cindy Song, (cindy.song@beigene.com) Functional Area Representative 16-Oct-2023 17:30:11 GMT+0000
Task: SME Approval Verdict: Approve changes & release	Kelly Shart, (kelly.shart@beigene.com) Functional Area Representative 17-Oct-2023 18:08:08 GMT+0000
Task: SME Approval Verdict: Approve changes & release	Hong Tian, (hong.tian@beigene.com) Functional Area Representative 18-Oct-2023 17:58:05 GMT+0000
Task: QA Approval Verdict: Approve changes & release	Khosheh Sanglaji, (khosheh.sanglaji@beigene.com) QA Approval 18-Oct-2023 18:13:16 GMT+0000