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| Title | **A two-part, Phase 1b/2a study to investigate the safety and efficacy of topical Medi‑Solfen for wound analgesia and antisepsis, when used prior to Standard of Care (SOC) (including suture repair) of small to medium, simple skin lacerations in adults** |
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| Approved: | Anna Zaremba  Statistical Programmer |

# **Purpose**

The purpose of this Performance Qualification (PQ) Report is to ensure that the system performs reliably under expected operational conditions using real clinical data, workflows, and test scenarios.

# **Scope**

This PQ report applies to the installation of RStudio on Windows and macOS.

# **Responsibilities**

* **Tester:** Execute PQ tests as per defined procedures and document results.
* **Reviewer:** Verify test results and ensure compliance with acceptance criteria.
* **Approver:** Approve the PQ report.

# **Prerequisites**

Installation Qualification (IQ) and Operational Qualification (OQ) completed and approved.

Test environment prepared with necessary dependencies, including the RStudio IDE and required R packages.

Clinical dataset for STDM ADaM Pilot Project is available.

Overview of the Dataset Used in the Performance Qualification Report

The STDM ADaM Pilot Project is an initiative aimed at evaluating and streamlining the implementation of Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) standards in clinical trials. It focuses on optimizing data flow, improving consistency, and ensuring regulatory compliance while enhancing efficiency in data analysis and reporting. The project serves as a foundation for refining best practices in standardized clinical data submission.

The dataset used in the STDM ADaM Pilot Project consists of standardized clinical trial data following CDISC SDTM and ADaM formats. It includes subject demographics, medical history, adverse events, laboratory results, and efficacy assessments, ensuring consistency and traceability from raw data to analysis-ready datasets. The dataset is designed to evaluate data transformation processes, compliance with regulatory requirements, and the effectiveness of ADaM structures in supporting statistical analyses.

The dataset and all the supporting documentation are available publicly:

<https://github.com/cdisc-org/sdtm-adam-pilot-project/tree/master/updated-pilot-submission-package/900172/m5>.

# **Test Plan**

**Data Loading and Exploration**

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| --- | --- | --- | --- | --- | --- |
| **ID** | **Test** | **Test Objective** | **Test result** | **Pass** | **Comments** |
| 1 | Data Import | Ensure the clinical datasets are imported without errors. | Demographic and laboratory datasets are loaded successfully into RStudio as dataframes, headers are displayed. |  |  |
| 2 | Data Integrity | Validate that all variables and rows are intact in demographic, laboratory data and the join is performed correctly. | Variable names and data types are loaded fully, dataframes are joined correctly. |  |  |

**System Performance**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ID** | **Test** | **Test Objective** | **Test result** | |  | | --- | | **Pass** | | **Comments** |
| 3 | Summary Table | Verify that the summary table is generated correctly after data has been cleaned by arm for demographic data. | Baseline summary and summary by arm and visit are displayed. |  |  |
| 4 | Linear model and linear mixed model | Check if the LM and LMM run correctly. | Models ran without errors, tables is displayed. |  |  |
| 5 | Visualization of laboratory results by arm and visit and predicted effects of arm on laboratory results | Test if the plots are generated correctly. | Combined plot is displayed. |  |  |

**Response Time**

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| --- | --- | --- | --- | --- | --- | --- |
| **ID** | **Test** | **Test Objective** | **Test result** | |  | | --- | | **Pass** | | **Comments** |
| 6 | Response Time | Measure system response time for computing heavy queries. | Response time for generating 1000 logistical models is within acceptable limits (<30 sec). |  |  |

**Data Security and Compliance**

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| --- | --- | --- | --- | --- | --- |
| **ID** | **Test** | **Test Objective** | **Test result** | **Pass** | **Comments** |
| 7 | User Access Controls | Verify that only HTTPS code grants access the system. | Unauthorized access with wrong HTTPS code is denied. |  |  |
| 8 | |  | | --- | | Audit Trails | | Ensure changes to the data are logged and traceable. | Repository logs record data modifications. |  |  |
| 9 | |  | | --- | | Data Security |  |  | | --- | |  |  |  | | --- | |  | | Test that data remains unaltered during analysis with checksums. | Data integrity is intact. |  |  |
| 10 | Consistency across different software | Data and test results in R Studio are consistent with those in SAS. | SAS-appendix has been provided by team lead, data and test results are consistent across different software. |  |  |

# **Checksum and Its Role in Data Integrity**

A checksum is a unique string of characters generated by applying a hash function to a dataset or file. It acts as a digital signature of the data. It is used to verify data integrity by ensuring that the data remains unaltered during processing or analysis. If even a small change is made to the data, the checksum will change, allowing for easy detection of any modifications.

By comparing the checksum value before and after data analysis, we can confirm whether the data has been tampered with or remains unchanged. This process ensures the reliability and authenticity of the data

# **Exceptions and Deviations**

Document any exceptions or deviations encountered during the performance process and their resolutions.

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| --- | --- | --- |
| **Deviation** | **Resolution** | **Date Resolved** |
|  |  |  |

# **Attachments**

Output file generated during testing:

* PQ\_sym\_report\_OS.docx

# **Conclusions**

The Performance Qualification (PQ) tests were conducted as per the test plan, simulating real-world conditions to assess the system’s performance under operational loads. Key metrics such as data security, user access controls, and system stability were evaluated against predefined criteria.

**Validation Status:**

* Successful Validation: If all performance criteria are met, the PQ stage is successful, confirming the system meets regulatory and operational requirements for production use.
* Unsuccessful Validation: If any tests fail, the PQ stage is incomplete. The system will undergo further review and retesting to address deviations.

**Actions for Non-Compliance:**

* In the event of an unsuccessful validation, the following actions should be taken:
* Document the details of the failure or deviation, including the specific functionality affected, the observed behavior, and any potential root causes.
* Conduct a thorough investigation to identify the root cause of the failure.
* Implement corrective actions such as reconfiguring the system, adjusting workflows, or installing patches to address the root cause of the failure.
* Verify that the corrective actions have been implemented correctly and that they align with the system’s original specifications.
* Re-execute the affected PQ tests to confirm that the corrective actions resolve the issue and that the system now meets all acceptance criteria.
* Ensure that all retests meet the acceptance criteria before proceeding with the next phase or concluding the PQ stage.

**Recommendations:**

The following situations may require a revalidation of the PQ stage:

* Any significant changes to workflows or system configurations that could affect system performance.
* Installation of major updates, including new features, patches, or upgrades to underlying system software.
* Any prolonged system downtime or issues with system performance that may affect its reliability.
* Modifications in regulatory requirements that may affect the system’s compliance with applicable standards.

**Next Steps:**

Upon successful PQ completion, the system will be validated and ready for deployment. It will transition to routine use with ongoing performance monitoring and regular audits.

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| Validation Status | Validation Successful |