**Performance Qualification Report**

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| **Project 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 |
| **Project code:** | MEDISOLFEN\_H\_06 |
| **Sponsor:** | Medi-Solfen Pty Ltd |
| **Version:** | 1.0 |
| **Date:** | 30.01.2025 |
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# **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 with 107 observations and 13 variables is accessible.

# **Overview of the Package and Dataset Used in the Performance Qualification Report**

## Package medicaldata

The medicaldata package includes 15 medical datasets for teaching reproducible research with R. These datasets range from historical data like James Lind’s 1757 scurvy dataset to more recent trials, including a 2012 RCT on indomethacin and 2020 SARS-CoV-2 cohort data.

## Dataset strep\_tb

The strep\_tb dataset is from a 1948 randomized controlled trial comparing Streptomycin (2 grams daily) versus placebo for treating tuberculosis in 107 young patients. This dataset is used for demonstrating statistical techniques in medical research, including survival analysis and mixed-effects modeling.

# **Test Plan**

Data Loading and Exploration

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| --- | --- | --- | --- | --- | --- |
| **ID** | **Test** | **Test Objective** | **Test result** | **Pass** | **Comments** |
| 1 | Data Import | Ensure the clinical dataset is imported without errors. | Data is loaded successfully into RStudio as a dataframe, header is displayed. |  |  |
| 2 | Data Integrity | Validate that all 13 variables and 107 rows are intact. | Variable names and data types match the description. |  |  |

System Performance

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ID** | **Test** | **Test Objective** | **Test result** | |  | | --- | | **Pass** | | **Comments** |
| 3 | Baseline Summary Table | Verify that the baseline summary table is generated correctly by arm. | Summary table is displayed. |  |  |
| 4 | Mixed-Effects Model | Check if the mixed-effects model runs correctly to assess predictors of radiologic improvement. | Model ran without errors, table is displayed. |  |  |
| 5 | Group Comparison Between Arms | Ensure the group comparison summary for radiologic outcomes by arm is correct. | Group comparison table is displayed. |  |  |
| 6 | Visualization of radiologic response and predicted interaction effects | Test if the radiologic response boxplot and predicted interaction effects plot are generated correctly. | Plot is displayed. |  |  |
| 7 | Logistic regression, mixed model and Kaplan-Meier Survival Analysis are performed and visualized | Ensure that the Logistic regression, mixed model and Kaplan-Meier survival analysis run and produce plots. | Plot is displayed. |  |  |

Response Time

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| --- | --- | --- | --- | --- | --- | --- |
| **ID** | **Test** | **Test Objective** | **Test result** | |  | | --- | | **Pass** | | **Comments** |
| 8 | Response Time | Measure system response time for computing heavy queries. | Response time for generating 1000 logistical models is within acceptable limits (<10 sec). |  |  |

Data Security and Compliance

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| --- | --- | --- | --- | --- | --- |
| **ID** | **Test** | **Test Objective** | **Test result** | **Pass** | **Comments** |
|  | User Access Controls | Verify that only HTTPS code grants access the system. | Unauthorized access with wrong HTTPS code is denied. |  |  |
|  | |  | | --- | | 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. |  |  |

# **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\_AZ.

# **Conclusions**

## Summary of Results

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 | Successful Validation |

# **Approval**

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| --- | --- | --- | --- |
| Role | Name | Signature | Date |
| Prepared By | Anna Zaremba |  | 30.01.2025 |
| Reviewed By | Oleksandr Savuliak |  | 30.01.2025 |
| Approved By | Marius Ardelean |  | 30.01.2025 |