|  |  |
| --- | --- |
| 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** |
| Author: | Anna Zaremba  Statistical Programmer |
|  |  |
| Reviewed: | Marius Ardelean  Senior Statistician |
|  |  |
| Approved: | Oleksandr Savuliak  Junior Statistician |

# **Purpose**

To verify that R-Studio is correctly installed and configured on the target environment. This qualification process covers verification of system prerequisites, validation of installation procedures, confirmation of functional operability post-installation.

# **Scope**

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

# **Responsibilities**

* **Installer:** Responsible for installing RStudio as per the documented procedures.
* **Validator:** Responsible for reviewing the installation and ensuring compliance with specifications.
* **Approver:** Responsible for approving the IQ report.

# **Hardware requirements compliance**

|  |  |  |  |
| --- | --- | --- | --- |
| **Requirement** | **Specification** | **Met** | **Comments** |
| **Processor (CPU)** | At least an Intel Core i3 or equivalent AMD processor |  |  |
| **RAM** | Minimum of 8 GB of RAM |  |  |
| **Storage** | At least 256 GB of SSD storage |  |  |

# **Installation Procedure**

**Step1:** Download the RStudio installer from the official website: <https://posit.co/products/open-source/rstudio/> .

**Step 2:** Ensure the system meets the prerequisites listed in Section 4.

**Step 3:** Execute the installer and follow the prompts to install RStudio in the default directory or a specified location.

**Step 4:** Verify the successful completion of the installation.

# **Installation procedure compliance**

|  |  |  |  |
| --- | --- | --- | --- |
| **Requirement** | **Expected Outcome** | **Met** | **Comments** |
| |  | | --- | | Installation Path Verification | | |  | | --- | | RStudio installed in the specified location. | |  |  |
| Application Launch Verification | RStudio launches without errors. |  |  |
| Version Verification | Installed version matches the required one. |  |  |
| Dependency Check | Required R version is accessible. |  |  |
| Plugin/Package Manager Functionality | Packages can be installed and loaded. |  |  |

# **Exceptions and Deviations**

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

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

|  |  |  |
| --- | --- | --- |
|  |  |  |

# **Configuration details**

|  |  |
| --- | --- |
| R Version | **4.4.3** |
| R Studio Version | **2024.12.1 build 563** |

# **Conclusions**

The Installation Qualification (IQ) tests were conducted as outlined in the test plan, and all predefined acceptance criteria were evaluated. The system components, including hardware and software are compliant to the specifications.

**Validation Status:**

* Successful Validation: If the acceptance criteria are met, the Installation Qualification stage is deemed successful, and the system is ready to proceed to the Operational Qualification (OQ) stage.
* Unsuccessful Validation: If any tests fail to meet the acceptance criteria, the IQ stage is considered incomplete until all deviations are resolved.

**Actions for Non-Compliance:**

If validation is unsuccessful, the following steps should be taken:

* Record the details of the failure or deviation, including affected components, observed behavior, and potential root causes.
* Identify the root cause of the failure.
* Perform corrective actions, such as hardware replacement, software reconfiguration, or environment adjustments.
* Verify that the corrective actions align with predefined specifications.
* Re-execute the affected IQ tests to confirm that the issue has been resolved.
* Ensure that all retests meet the acceptance criteria before proceeding to the next qualification stage.

**Recommendations:**

Revalidation of the IQ stage is recommended under the following conditions:

* Significant hardware upgrades or replacements.
* Major software updates or reconfigurations.
* Relocation of the system to a different physical environment.
* Prolonged system inactivity or downtime.

**Next Steps:**

The next stage of the validation process will be the Operational Qualification (OQ). This stage will test the system's functionality and performance under simulated operational conditions to ensure it meets the requirements of end-users and regulatory standards.

|  |  |
| --- | --- |
| Validation status | Successful Validation |