



Validation Summary Report

Certara Integral Web Application 24.4.1

Version: 1

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1. Introduction

This report summarizes the outcome of all validation activities conducted by Certara to ensure the validation of the Certara Integral 24.4.1 Software release has been completed successfully. This includes verification that the system operates as intended and in accordance with the documented requirements of the Validation Plan Certara Integral 24.4.1.

2. Summary of Validation Activities

- 2.1. The Pre-production environment (Staging) was upgraded to the Certara Integral 24.4.1 version.
- 2.2. The requirements are revised and updated to include the latest updates of the Certara Integral 24.4.1 configuration.
- 2.3. The requirements traceability matrix was revised and updated to include the latest updates of the requirements specifications and protocols.
- 2.4. Installation Qualification protocol (IQ) are executed to ensure that system components are installed correctly according to manufacturer's specifications. IQ testing was executed in the Production environment. No test incidents were recorded and testing completed successfully.
- 2.5. Operational Qualification protocol (OQ) were executed to ensure selected components of the computerized system function as intended within representative or anticipated operating ranges. OQ testing was executed in the Production environment. No test incidents were recorded and testing completed successfully.

3. Deviations

None.

4. Validation Deliverables

The following deliverables were developed during execution of the Certara Integral 24.4.1 validation activities:

Document	Version	Approval Date
Certara Integral 24.4.1– Validation Plan	1	09-MAY-2024
Certara Integral 24.4.1 IQ/OQ-1 (Staging) – Tests Execution LINK	1	N/A
Certara Integral 24.4.1 – Traceability Report	1	09-MAY-2024



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5. Status of Validation

Based on the successful execution of the validation activities and completion of the validation deliverables defined in the Validation Plan, the validation of Certara Integral 24.4.1 has been completed successfully.

Certara Integral 24.4.1 is approved for intended use.