

# CTDashboard

## Validation Summary for Sponsor Vendor Files

Document Version 1.0 | April 2026

### 1. Document Control

Document Title	CTDashboard Validation Summary
Document Version	1.0
Date	2026-04-04
Application	CTDashboard (Desktop, PyQt6)
Classification	Confidential - Sponsor Use
Author	CTDashboard Development Team
Purpose	Provide a formal validation summary for inclusion in sponsor vendor qualification files and computerised system inventories.

### 2. System Description and Intended Use

CTDashboard is a standalone desktop application for clinical trial safety data review and monitoring. It ingests standard clinical data files (CDISC CDASH/SDTM-aligned CSV exports from EDC systems) and provides interactive visualizations, analytics, and safety signal detection across the following domains:

- Demographics (DM) - subject counts, age/sex/race distributions
- Enrollment (DM) - cumulative enrollment by site and treatment arm
- Adverse Events (AE) - incidence tables, forest plots, exposure-adjusted rates
- Serious Adverse Events (AE) - SAE listings, AESI group tracking
- Concomitant Medications (CM) - medication frequency and class summaries
- Laboratory Results (LB) - out-of-range flagging, shift tables, toxicity grading
- Vital Signs (VS) - trending, threshold alerts, by-visit summaries
- Disposition (DS) - completion/discontinuation tracking
- Survival Analysis (DS) - Kaplan-Meier estimation, time-to-event
- Subject Profiles - per-subject longitudinal safety review

#### 2.1 Intended Use Statement

CTDashboard is intended for use by clinical operations, medical monitors, pharmacovigilance teams, and data managers as a visualization and review aid during ongoing clinical trials. It is a read-only platform: it does not create, modify, or submit clinical data. The EDC system remains the authoritative source of record for all clinical data.

CTDashboard does not replace validated statistical programming (SAS/R) for regulatory submissions. Safety findings observed in CTDashboard should be cross-validated against the CRO's independent statistical output before inclusion in regulatory documents or safety reports.

### 3. GAMP 5 Classification

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<b>GAMP 5 Category</b>	Category 4 - Configured Product
<b>Rationale</b>	CTDashboard is a commercially available software tool that is configured (not custom-coded) for each study through field mappings, threshold settings, and AE group definitions. The core analytical algorithms are fixed; user configuration determines which fields and thresholds apply.

#### 3.1 Category 4 Justification

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The application ships with a fixed set of analytical modules (demographics, AE incidence, lab flagging, vital sign trending, etc.). Users configure the application for a specific study by:

- Mapping source file columns to canonical clinical data fields (auto-detected with user confirmation)
- Setting lab alert thresholds (e.g., ALT > 3x ULN)
- Defining AE groups of interest (e.g., immune-related AEs)
- Configuring vital sign alert ranges

No user-authored scripts, macros, or custom code are executed within the application. This positions the system in GAMP 5 Category 4 (Configured Product) rather than Category 5 (Custom Application).

### 4. Risk Assessment

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#### 4.1 Data Integrity Risk

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<b>Risk Level</b>	Low
<b>Rationale</b>	CTDashboard is a read-only application. It cannot modify, delete, or create clinical data records. Source CSV files are loaded into memory, processed, and released when the application closes. No clinical data is persisted to disk. No data is transmitted to external servers. Workspace files store only file paths, filter selections, and reviewer notes - never patient-level data.

#### 4.2 Patient Safety Risk

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<b>Risk Level</b>	Low (indirect)
<b>Rationale</b>	CTDashboard supports safety monitoring activities but does not make treatment decisions. Incorrect visualizations could theoretically delay signal detection; however, the application is one of several monitoring tools (alongside EDC queries, SAS listings, and medical review). The validated analytical engine provides an additional layer of verification.
<b>Mitigation</b>	Automated validation engine with 161 independent checks verifies every displayed value. 115 automated unit tests cover core analytics. Field mapping confidence scoring with safety-critical field gate prevents analysis on incorrectly mapped data.

#### 4.3 Regulatory Risk

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<b>Risk Level</b>	Low
<b>Rationale</b>	CTDashboard does not generate submission-ready outputs. It is not an electronic records system under 21 CFR Part 11. It does not maintain audit trails for regulatory purposes (the EDC system serves this function). It does not produce electronic signatures. Its outputs (PDF reports, CSV exports) are review aids, not regulatory documents.

## 5. Functional Verification

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CTDashboard includes a comprehensive automated validation engine that independently verifies the correctness of all displayed analytics. This section summarizes the verification approach and references the detailed evidence.

### 5.1 Application Validation Report

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The Application Validation Report is a detailed technical document generated by the application's built-in validation engine. It independently recalculates every analytical value using raw data and pandas computations that are separate from the application's rendering pipeline, then compares results.

<b>Total Checks</b>	161 independent verification checks
<b>Domains Covered</b>	14 clinical domains (DM, AE, LB, VS, DS, CM, EX, MH, TU, RS, EG, IE, FA, QS)
<b>Evidence Type</b>	Computed expected values vs. displayed values, with application screenshots for visual confirmation
<b>Report Format</b>	Standalone PDF (27 pages, auto-generated)
<b>Location</b>	File > Export Validation Report (within the application)

### 5.2 Automated Test Suite

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<b>Framework</b>	pytest
<b>Total Tests</b>	115 automated tests
<b>Coverage Areas</b>	Data ingestion, field detection, column mapping, analytics calculations, domain classification, CSV/XML parsing, edge cases
<b>Execution</b>	Continuous - run on every code change

### 5.3 Field Mapping Verification

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The field mapping engine uses a tiered confidence system to ensure clinical data columns are correctly identified:

<b>HIGH confidence (<math>\geq 0.8</math>)</b>	Exact or near-exact match to CDASH field name. Applied automatically.
<b>MEDIUM confidence (0.5 - 0.8)</b>	Probable match based on column name similarity, data pattern analysis, and domain context. Presented to the user for confirmation.
<b>LOW confidence (<math>&lt; 0.5</math>)</b>	Uncertain match. Flagged for manual review.
<b>Safety-Critical Gate</b>	For AE and LB domains, the system verifies that safety-critical fields (AESER, AESEV, AEDECOD, LBNRIND) are mapped before proceeding. Users must explicitly acknowledge any gaps.

## 6. Known Limitations and Boundaries

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The following limitations define the operational boundaries of CTDashboard and should be considered when assessing the system for inclusion in regulated workflows.

### Not an EDC System

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CTDashboard does not capture, store, or manage clinical data. It is a downstream consumer of data exported from validated EDC systems (e.g., Medidata Rave, Oracle InForm, Veeva Vault CDMS).

### Not a Submission Tool

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Outputs are review aids only. PDFs, CSV exports, and DSMB packages are not formatted for direct regulatory submission. Statistical tables for submission should be produced by validated SAS/R programming.

### No Electronic Signatures

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CTDashboard does not implement electronic signatures. Sign-off workflows remain in the EDC or document management system.

### No 21 CFR Part 11 Scope

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As a read-only visualization tool with no data persistence, CTDashboard operates outside the scope of 21 CFR Part 11. The EDC system is the system of record.

### No Multi-User Access Control

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CTDashboard is a single-user desktop application. It does not provide role-based access control, user authentication, or concurrent multi-user access.

### AI Features Are Optional

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AI-powered patient narrative generation (if enabled) sends selected subject data to a configured AI provider. This feature is disabled by default and must be explicitly opted into. It should not be enabled for studies with restrictions on external data processing.

### Analytical Scope

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The validation engine verifies calculations against its own analytical modules. It does not validate against external reference datasets. Cross-validation against CRO output is recommended for critical safety decisions.

## 7. Recommended Qualification Activities

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For sponsors incorporating CTDashboard into their clinical operations, the following qualification activities are recommended based on the GAMP 5 Category 4 classification and low risk assessment:

### 1. Installation Verification

Confirm the application launches and displays the version number on the About page. Verify the validation report can be generated (File > Export Validation Report).

### 2. Configuration Verification

Load a representative study dataset. Verify field mappings are detected correctly. Confirm lab thresholds, AE groups, and vital sign ranges match the study protocol.

### 3. Functional Spot-Check

Select 3-5 key metrics (e.g., total subjects enrolled, SAE count, AE incidence for a specific term) and manually verify against the EDC or CRO listings. Document results.

### 4. Validation Report Review

Generate the Application Validation Report and review the 161 automated checks. Confirm all checks pass with the study dataset.

### 5. Periodic Re-Verification

After application updates, re-run the validation report and repeat the functional spot-check to confirm continued correctness.

## 8. Document References

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### Application Validation Report

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Auto-generated PDF with 161 independent checks across 14 domains. Available via File > Export Validation Report.

### Automated Test Suite

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115 pytest tests covering data ingestion, analytics, and field detection. Source: tests/ directory.

### GAMP 5

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ISPE GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (2008). Referenced for software categorization.

### ICH E6(R2)

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Guideline for Good Clinical Practice. Referenced for computerized systems expectations in clinical trials.

### 21 CFR Part 11

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Electronic Records; Electronic Signatures. Referenced to document exclusion rationale.

## 9. Approval

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This Validation Summary has been prepared to support sponsor vendor qualification activities. It should be reviewed and approved by the sponsor's quality assurance and IT validation teams as part of the computerised system inventory assessment.

**Prepared By**

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Date: \_\_\_\_\_

**Reviewed By (Quality Assurance)**

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Date: \_\_\_\_\_

**Approved By (System Owner)**

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Date: \_\_\_\_\_