Validation Statement
System Acceptance Certificate

Web 6.0

05 JUNE 2021

Crucial Data Solutions, Inc.

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Summary

TrialKit Web 6.0 was developed using the following languages and framework:

Web – C# in .NET and MVC

The database is written with PL/pgSQL for PostgreSQL

Development was performed by qualified and trained staff following an approved software development lifecycle including analysis, design, development, validation, and release of the final product.

The development and validation process is regulated by SOPs and related guidelines and templates which are under version control by Quality Assurance. Those documents used during this validation are:

- FM-5910-Web 6.0 Validation Plan
- P-2070 - ER/ES Compliance
- SOP-G-3050 - Controlled Documents
- SOP-QA-3170 - Computer System Security
- SOP-QA-3190 - Product Change Control
- SOP-QA-3150 – Ticket Management
- SOP-PD-3410 - CDS SDLC and Computer System Validation Process
- SOP-QA-3120 - Computer System Validation Documentation Management Process

Overall validation activities are performed by Quality Assurance and the Software Validation Group in compliance with SOPs listed above and 21 CFR Part 11 detailed in Appendix A.

The complete coverage of TrialKit Web 6.0system functionality is demonstrated by the traceability between the User Requirements, Functional Requirements, Test Case results (Test Executions), and User Acceptance Tests. This traceability is maintained in two ways:

- For newly developed features (if applicable) in TrialKit Web 6.0, all traceable items were linked to each other by the use of standard functionality within the CDS's Application Lifecycle Management system (ALM).
- For features part of this version, traceability is maintained through a matrix hosted in CDS's ALM All Functional Requirements were tested by the Software Validation Group and Software Development through formal Test Cases. All traceability has been approved by Quality Assurance when reviewing Test Executions or by directly approving the Traceability Matrix.

To guarantee the independence of testing, Quality Assurance reviewed the testing process to ensure that a Software Developer could only test requirements that they did not code themselves.

Quality Assurance provided oversight to all testing activities, reviewing test strategy, verifying qualifications and independence of testers and provided guidance and instruction regarding the depth of testing, testing coverage, and the capture of objective evidence of actual test results.

Testing was performed in accordance with applicable SOPs and Guidelines and based on a Validation/QA Plan describing the test strategy, expected results, defect handling, and responsibilities for testing.

Test actions for all listed requirements were based on Test Cases or documented in individual tickets. Test Case templates and test results were tracked in CDS's ALM and reviewed exhaustively by Quality Assurance.

All defects related to this software release were tracked using CDS's ALM. Defects found and fixed during the validation have been retested through formal Test Executions, and the information is provided as a comment in the ticket.

Operational Qualification and Study Validation

In Addition to verification activities directly supporting the changes in this version, a comprehensive re-validation has been performed and documented to cover the following functional areas across 85 Tests using a common study configuration. The web 6.0 test plan and execution is evidence of this validation.

- User Access controls
  - Sign In and security
  - Session Timeout
  - User Management
  - Study and site access
  - Roles and permissions
- Data validation (subject records)
  - Data saving - Clinician
  - Data saving - Patient
  - Edit checks
  - Data exports
- Audit histories (subject records)
  - Subject form events and data changes
  - Site and user access
  - Roles and permission settings
  - Field blinding
- Form functions
  - Freeze
  - Configure Risk based monitoring
  - Lock all fields
- Query management and routing
- Data review workflows
  - Partial Monitoring
  - Field source verification
  - Batch review
- eSignatures
- Key reports
  - Action Items Report
  - Queries Report
  - Dashboard Report
- ePRO access and notifications
- Electronic consent
- Site Documents
  - Saving
  - Subject enrollment rules
  - Site enrollment goals
- Study Documents
  - Saving
- Randomization
  - Defining
  - Triggering and blinding
  - Allocation table
- Product Tracking
  - Workflows
  - Site activation and distribution

    - Subject assignment
    - IP Audit history
- Site Payment Tracking
    - Payment rules
    - Payment management and transaction history

Validation Statement / System Acceptance

After execution of the actions described above, it is concluded that TrialKit Web 6.0 has been developed according to the CDS Quality System, following written procedures dealing with all relevant phases of the Software Development Lifecycle, and in compliance with the regulatory framework from ICH, FDA and the European Union, including, but not limited to:

- FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule – Detailed in appendix below
- FDA Guidance for Industry; Computerized Systems Used In Clinical Investigations
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff
- National regulations as applicable for individual clinical studies

Installation Qualification (IQ)

IQ documentation was developed and approved prior to the implementation.
Successful implementation will be verified by executing the IQ documentation and approved by Quality Assurance as required by SOP-QA-3190

Maintenance Stage

Future software upgrades resulting from identified software defects and/or additional requirements will be initiated by CDS management and are following a predefined process described in written procedures.

Any changes to the system after formal product release will be addressed in accordance with appropriate change control procedures and validated by Quality Assurance before releasing into production.

Any non-compliance and associated corrective actions will be documented via established SOP’s.

Security

TrialKit Web 6.0 is built on AWS cloud architecture comprised of database, application, and user interface.

Amazon Web Services are used across varying regions for data hosting and network redundancy.

Data is transferred between client and server using 256-bit SSL or greater encryption technology, along with 2-Factor Password-protected and biometric user access controls permissions.

Password security features include but are not limited to defined minimum length, alphanumeric composition, and device tokenization. Network architecture involves utilizing clustered firewalls and security appliances to protect user access that is distributed (balanced) across multiple application servers' farm.

30 days of five-minute backups are kept on-site at the primary datacenter for fast recovery if necessary and sent monthly to a geographically separated location with mirrored security and compliance standards.

The power infrastructure provides uninterrupted power supplies backed up by a generator. A validated disaster recovery and a business contingency plan are in place. The primary datacenter provides SOC type I and II audit certifications along with a variety of globally-acknowledged security certification programs.

New Features and Changes Included in this release

Issue Type Key Functional Area (release notes) Release Notes Description Change risk Summary	
Sub-Requirement TK1-1257 Form Saving Added Save and New option to log forms for faster data entry of repeating forms Low TK1-543 Save and New - Log forms	1
Sub-Requirement TK1-1072 Form Rendering Support for sketch pad field type. On the web this will display as a static image. Users must be on the app for drawing. Low TK1-154 Field rendering/display - Sketch pad	2
Sub-Requirement TK1-1071 Form Rendering Rendering of static image labels for user reference during data entry Low TK1-154 Field rendering/display - Image label	3
Sub-Requirement TK1-1069 Form Rendering Support for vertical slider - displayed on web as number field TK1-154 Field rendering/display - Vertical slider	4
Sub-Requirement TK1-1048 Form Rendering Support for multi-select field. Now available in both web and mobile app. Low TK1-154 Field rendering/display - Multi-select	5
Sub-Requirement	6

TK1-389
Subject ePRO
Email address checks added to web for correct formatting and verification that the address is not a duplicate in the same study
Low
TK1-581 Subject Email field to create ePRO/patient users

7

Sub-Requirement
TK1-535
ePRO/eDiary Configurations
Interval type diaries now enforce max forms on a per diary basis rather than per form.
Low
TK1-144 eDiary - Interval

8

Requirement
TK1-1240
Form Building
Added support for configuring and mapping help buttons
Low
Field Properties - Help button

9

Requirement
TK1-1141
Form Building
Added support for Vertical Slider. This will only render as a numeric field on the web at this time, but can be configured in the form builder. Full functionality is available on the app.
Low
Field properties - Vertical slider

10

Requirement
TK1-1140
Form Building
Support for static image labels (user reference images on a form)
Low
Field properties - Image label

11

Requirement
TK1-1139
Form Building
Support for sketch pad field. Displays similar to image label on web. Draw function only available on mobile app at this time.

Field properties - Sketch pad

12

Requirement
TK1-1082
Form Saving

Support for saving multiple coded values in mult-select fields
Low
Saving Data - Multi-select choices

13

Requirement

TK1-1068

Form Building
Ability to map multi-select field to inventory list
Low
Field properties - multi-select (select multiple choices)

14

Requirement

TK1-531

Action Items Report
Missing records now updates the count for the current site when the user opens the list.
Low
Action Items - Missing Records - Required Forms past due

15

Requirement

TK1-395

Audit Reports
Added Field change audit report to the web
Low
Field Change Audit - Table of data changes made between save events

16

Requirement

TK1-394

Audit Reports
Updated transaction audit report to the web to follow the same table seen in the mobile app. The legacy audit report interface is still available.
Low
Transaction Audit - Table of transactions/events on records

17

Requirement

TK1-390

Low
Email field formatting

18

Requirement

TK1-283

Signing In
Enhanced for smaller window sizes and using enter key to target sign in trigger
Low
User Interface - Sign In

19

Requirement

TK1-266

Form Building

Added permission for using version override on published study versions. Version override added on iOS form builder.

Low

Form builder version enforcement

20

Requirement

TK1-253

User and Site Management

Deactivated Sites can now access forms, but will be unable to save changes.

Low

Site activation/suspension

21

Requirement

TK1-212

Randomization

Support for blinding randomization allocation based on role - including randomization triggering and report builder

Low

Triggering randomization on subjects

22

Requirement

TK1-209

Randomization

Randomizations can now be configured to blind only specific user roles. Existing studies are assumed fully blinded.

Low

Define randomization trigger and behaviors

23

Requirement

TK1-208

Query Management

Added permission and support for new permission to disable query distribution role editing when users are creating new manual queries.

Low

Query routing and Distribution

24

Requirement

TK1-203

Queries Report

Added Filter for role distribution. Now filter for queries based on the role(s) the query was distributed to.

Low

Filter and export queries lists

25

Requirement

TK1-202

Low
Take individual and bulk action on queries

26

Requirement

TK1-201

Queries Report
Queries which are part of blinded fields or forms no longer display to the blinded user role. Updated report on web.
Low
View Queries and details

27

Requirement

TK1-198

PDF Exports
Support for new multi-select field type
Low
Export pages containing data to PDF

28

Requirement

TK1-187

Data Management/Monitoring Reports
Monitor report updated to blind data based on current user role - Following form view and field blinding permissions. Report updated on web with improved UI.
Low
Monitor Report - View table of records awaiting/completed first review level

29

Requirement

TK1-85

Audit Reports
Added Study Events report to the web. This can be found under Audit Reports option.
Low
Study Events Report - Table of events that have occurred on records

30

Requirement

TK1-179

Inventory Management
Added ability to assign multiple inventory items to a subject, and to remove items from subjects and re-allocate them.
Low
Assigning items to patients

31

Requirement

TK1-139

Data Exports
Field blinding is now supported in exported data based on the role performing the export
Low

Export by form - Access to specific form data

32

Requirement

TK1-138

Data Exports

Support for field blinding based on role running the export. Also added a permission to control this function rather than the previous rule of Admin role dependency.

Low

Export All Data

33

Bug

TK1-1313

PDF Exports

Signature Image page still included for blinded signature field

Low

Web - PDF export - Signature image page still displays signature when field is blinded

34

Bug

TK1-1301

Data Exports

File repository bulk exports getting error when all file parameters are not always present

Low

Web - File Repository: Files without visit name are producing an error when exported in ZIP

35

Bug

TK1-1288

Action Items Report

Site filter not getting cleared when user had not site set

Low

Web - Site displayed in action item filter needs to be cleared if WS has set zero

36

Bug

TK1-1278

Query Management

User not getting prompted to save data changes before opening the query window to post a response

Low

Web - Opening the query window after changing data causes the data to revert back

37

Bug

TK1-1269

Dashboard Report

Site filters sometimes conflicting with the filter which the user had set in action items

Low

Web - Site filters not returning correct records/counts

38

Bug

TK1-1262
Action Items Report
Action items not returning data when user only belongs to Admin site
Low
WS - Site level role is not seeing items it action items when site is Admin site
39
Bug

TK1-1261
Action Items Report
If a form is missing in subject records because the original record was deleted, it was not getting counted as missing in the missed visits metric.
Low
WS - Deleted records are not accounted for by the missing visits compuation
40
Bug

TK1-1260
Query Management
Query window updated to display 10 queries by default (Increased from 5)
Low
Web - Unable to gain access to queries in the query window when there are more than 5
41
Bug

TK1-1249
PDF Exports
Data overlap occurring when large tables span multiple pages
Low
Web - Study closeout PDF export - normalized table data overlaps audit table
42
Bug

TK1-1241
Form Rendering
Improved synchronization between the web and app with regard to text labels and form layout
Low
Web - Labels saved on app form builder display on web with different attributes/spacing
43
Bug

TK1-1224
Form Rendering
Long signature images outside boundaries of signature box were getting cut off.
Low
Web - Signature autogenerate function does not fit long text within box
44
Bug

TK1-1221
Study Configuration
Issue with links on study home page not redirecting properly within the system

Low
Web - Using link from home screen returns error on subjecttrans.aspx
45
Bug
TK1-1201
Batch Imports
Importing Time data into a time only field was not parsing correctly to account for no date
Low
Web - Importing a time only is not getting imported (fails to parse date/time)
46
Bug
TK1-1190
Signing In
Minimum password requirements displaying correct server settings when user's are setting a new password
Low
Web - Minimum requirements for password need to follow system settings
47
Bug
TK1-1186
Form Building
Prevention of creating new forms in a published version
Low
Web - New form can be created in a published version
48
Bug
TK1-1179

Low
Web - Sign In Buttons not working on smaller screens
49
Bug
TK1-1178
Subject ePRO
Incomplete consent was now allowing participant to re-open existing record
Low
Incomplete consent record needs to reopen when user leaves and returns
50
Bug
TK1-1169
Site and Study Documents
Error not getting cleared from upload fields when file is added later
Low
Web - Required upload fields inside tables on Site and Study type forms display required message even when file exists
51
Bug

TK1-1164

Low
Web - Saving an external variable - Causes email notification to fire

52

Bug
TK1-1143
Form Building
Removed unsupported hyperlink properties for text labels
Low
Web - Options for hyperlink labels need to exclude popup window and current window options

53

Bug
TK1-1126
Subject Records
Log form headers displayed HTML when a reporting label was not defined for forms built in the mobile app
Low
Web - Log table header displays label HTML if no reporting label exists

54

Bug
TK1-1106
User and Site Management
Updating user name in the user manager was not getting displayed in the mobile app automatically
Low
Web - Updating user name does not update both server and TOC. Web service still displays old name

55

Bug
TK1-1103
Subject Records
Page erroring if not scheduled visits existed to display
Low
Web - Page errors if there are no scheduled visit forms being displayed

56

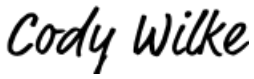
Bug
TK1-1096
Data Management/Monitoring Reports
Record Status report was showing status of Missing if study exit had been completed
Low
Web - Record status report missing status needs to account for exceptions

57

Bug
TK1-1016
Dashboard Report
Error loading record list for review levels in specific scenarios

Low
Bypass review listing on dashboard report does not show the correct forms
58
Bug
TK1-1312
User and Site Management
Site By User Report not displaying last sign in
Low
Web - Site by user report last sign in date not getting captured
59
Bug
TK1-1283
ePRO/eDiary Configurations
ePRO notification text support for non-english characters
Low
Web - ePRO messages don't save correctly with other language characters
60
Bug
TK1-1281
Form Building
Data dictionary export including site and study forms when they were not selected in the version dropdown
Low
Web - Version selection is not filtering out site/study type forms

Approvals

Director, Quality Assurance	Executive Approval
Cody Wilke	Paul Grady
Director, Quality Assurance	CEO
	
05 Jun 2021	05 Jun 2021

Appendix A

21 CFR Part 11 Statement

Electronic Records;
Electronic Signature;
Final Rule

Including Crucial Data Solutions (CDS) Comments For
TrialKit Web 6.0 and all underlying subversions/minor releases

CDS Comments in Blue

21 CFR Part 11 - Table of Contents

Subpart A – General Provisions

Sec. 11.1 Scope

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.

(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and

other general signings as required by agency regulations, unless specifically excepted by regulation(s) effective on or after August 20, 1997.

(d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with 11.2, unless paper records are specifically required.

(e) Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.

(f) This part does not apply to records required to be established or maintained by 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(g) This part does not apply to electronic signatures obtained under 101.11(d) of this chapter.

(h) This part does not apply to electronic signatures obtained under 101.8(d) of this chapter.

(i) This part does not apply to records required to be established or maintained by part 117 of this chapter. Records that satisfy the requirements of part 117 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(j) This part does not apply to records required to be established or maintained by part 507 of this chapter. Records that satisfy the requirements of part 507 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(k) This part does not apply to records required to be established or maintained by part 112 of this chapter. Records that satisfy the requirements of part 112 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(l) This part does not apply to records required to be established or maintained by subpart L of part 1 of this chapter. Records that satisfy the requirements of subpart L of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(m) This part does not apply to records required to be established or maintained by subpart M of part 1 of this chapter. Records that satisfy the requirements of subpart M of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

(n) This part does not apply to records required to be established or maintained by subpart O of part 1 of this chapter. Records that satisfy the requirements of subpart O of part 1 of this chapter, but that also are

required under other applicable statutory provisions or regulations, remain subject to this part.

(o) This part does not apply to records required to be established or maintained by part 121 of this chapter. Records that satisfy the requirements of part 121 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

Sec. 11.2 Implementation.

(a) For records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.

(b) For records submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that:

(1) The requirements of this part are met; and

(2) The document or parts of a document to be submitted have been identified in public docket No. 92S-0251 as being the type of submission the agency accepts in electronic form. This docket will identify specifically what types of documents or parts of documents are acceptable for submission in electronic form without paper records and the agency receiving unit(s) (e.g., specific center, office, division, branch) to which such submissions may be made. Documents to agency receiving unit(s) not specified in the public docket will not be considered as official if they are submitted in electronic form; paper forms of such documents will be considered as official and must accompany any electronic records. Persons are expected to consult with the intended agency receiving unit for details on how (e.g., method of transmission, media, file formats, and technical protocols) and whether to proceed with the electronic submission.

Sec. 11.3 Definitions.

(a) The definitions and interpretations of terms contained in section 201 of the act apply to those terms when used in this part.

(b) The following definitions of terms also apply to this part:

(1) Act means the Federal Food, Drug, and Cosmetic Act (secs. 201-903 (21 U.S.C. 321-393)).

(2) Agency means the Food and Drug Administration.

(3) Biometrics means a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable.

(4) Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

(5) Digital signature means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

(6) Electronic record means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

(7) Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

(8) Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(9) Open system means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

Subpart B - Electronic Records

Sec. 11.10 Controls for closed systems.

Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following:

(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

Compliant

TrialKit is validated through CDS's internal Validation process, as spelled out in the company SOP's, which ensures accuracy, reliability, and consistent intended performance. TrialKit, functions according to its specifications, as verified in the Validation process.
The audit log or records saved in TrialKit ensures the ability to discern invalid or altered records as well as providing accountability for each action.

(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.

Compliant

TrialKit generates accurate and complete copies of records in both human readable and electronic form through its standard export utility.

(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.

Compliant

Records are protected and retrievable throughout the study and during their retention period via online or electronic CRFs, tape backup or electronic media archival methods. After the study is completed, records are provided directly to the Client and retained per our official archival process.

(d) Limiting system access to authorized individuals.

Compliant

Software system access is limited to authorized individuals through the use of unique usernames, in addition to passwords and roles. Hardware system access is governed by official policies and procedures.

(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at

least as long as that required for the subject electronic records and shall be available for agency review and copying.

Compliant

TrialKit utilizes secure, computer-generated, time-stamped audit trails that identify the time and date of operator entries, previous and current values and the reason for change for all modifications to the system.
The audit log is included in the archival process and is stored in the trial records.
Deleted records are removed to a deleted bin, but are not permanently deleted from the system.

(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

Compliant

TrialKit guides the user through operational checks as defined in the protocol. Validation or edit checks are used to alert system users of potential deviations from the protocol.

(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

Compliant

The TrialKit system provides authority checks through the use of unique usernames, passwords, and assigned roles.

(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

Compliant

Data from external sources must transmit through the web service API and is treated as any other authenticated user.

(i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.

Compliant

This is guaranteed by the employment of qualified personnel and regular internal/external training. All training and skills documentation for CDS employees are maintained in their employee files per SOP-G-3020, Employee Qualifications and Training.

It is the Sponsor's responsibility to guarantee appropriate training of study staff that will use TrialKit functionality.

Compliant

(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

Compliant

It is the Sponsor's responsibility to provide written policies and train to Sponsor's staff participating in the study in using electronic signature functionality.
Also, CDS's End User License Agreement, which is signed by all users of the system, holds individuals accountable and responsible for actions initiated under their electronic signature.
Internally, CDS adheres to Policy P-2070, ER/ES Compliance.

Compliant

(k) Use of appropriate controls over systems documentation including:
(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.
(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

Compliant

CDS employs the following controls over system documentation (SOP-QA-3120, Computer System Validation Documentation Process):

1. **Distribution of and access to controlled documents is restricted**
2. **All system documentation is version controlled and updated with each release.**

Sec. 11.30 Controls for open systems.

Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.

Compliant

Procedures to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records, from the point of their creation to the point of their receipt, are deployed by CDS.
In addition to employing controls for closed systems, CDS implements 256-bit SSL encryption, and username and password for unique digital signature to ensure record authenticity, integrity, and confidentiality.

Sec. 11.50 Signature manifestations.

(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:
(1) The printed name of the signer;
(2) The date and time when the signature was executed; and
(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

Compliant

For each electronic signature (users of the system) the following information is captured in the audit log:

1. **The printed name of the signer.**
2. **The date and time the signature was executed.**
3. **The meaning associated with the signature.**

(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

Compliant

All above information is included in human readable form in the audit log as well as on the screen or as a result of the archive process.

Sec. 11.70 Signature/record linking.

Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.

Compliant

Electronic signatures executed to electronic records are linked to their respective electronic record(s) in the audit log of the form to which the signature was applied, thus ensuring that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means. If a top level form is signed, the signature applies to all forms beneath the signed form.

Subpart C - Electronic Signatures

Sec. 11.100 General requirements.

(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.

Compliant

Each electronic signature is unique to one individual, as CDS does not allow duplicate user IDs. Usernames are not deleted from the underlying relational database management system (RDBMS), which is an integral part of the system; thus ensuring they cannot be 'reassigned.'

(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.

Compliant

Noted and understood for CDS internal use.
It is the Sponsor's responsibility to verify the identity of Sponsor's staff that is participating in the study. In addition, CDS's End User License Agreement, which is signed by all users of the system, holds individuals accountable and responsible for actions initiated under their electronic signature.

(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.
(1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.
(2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

Compliant

CDS's End User License Agreement, which is signed by all users of the system hold individuals accountable and responsible for actions initiated under their electronic signature.
For systems documentation to be used within Crucial Data Solutions, Inc., this certification was submitted on May 10, 2015, to the Office of Regional Operations (HFC-100).

Sec. 11.200 Electronic signature components and controls.

(a) Electronic signatures that are not based upon biometrics shall:
(1) Employ at least two distinct identification components such as an identification code and password.
(i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.
(ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.
(2) Be used only by their genuine owners; and
(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.

Compliant

As CDS does not use biometrics, it employs the following components and controls:

1. **Access to TrialKit requires both a username and password. The username is always unique thus providing two distinct identification components. TrialKit requires both components of the electronic signature to be entered for all signings, regardless if the signature is executed in a single, continuous period of controlled system access or not.**
2. **TrialKit only issues access information to the genuine owner. Users are encouraged not to share their password, use password-protected screen savers and other security measures to protect the integrity of the data.**
3. **CDS's use of a unique username and password combination and processes ensures that attempted use of an individual's electronic signature by anyone other than its genuine owner requires the collaboration of two or more individuals. Using deductive reasoning, it may be proven that attempted use of an individual's electronic signature by anyone other than its genuine owner requires the collaboration of two or more individuals. All passwords are only given to the genuine owner of the password. Collaboration is 'To work together, especially in a joint intellectual effort.' Therefore, to share the password with someone else, the owner**

must collaborate with someone else. The owner and someone else constitutes two or more persons.

(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.

Compliant

Biometric functions provided by the mobile applications only function for a single user on a unique device token. If more than one user has attached to that device, biometric capabilities are disabled. Electronic signatures obtained via biometrics are stored with the label "Biometrics".

Sec. 11.300 Controls for identification codes/passwords.

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

Compliant

TrialKit maintains the uniqueness of each combined username and password by not allowing duplicate usernames.
Usernames are not deleted from the from the underlying relational database management system (RDBMS), which is an integral part of the system; therefore, they cannot be re-assigned. Thus, no two individuals can have the same combination of identification code and password.

(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

Compliant

To ensure that passwords are periodically revised, TrialKit supports them use of password aging in its user profiles.

(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.

Compliant

CDS does not issue tokens, cards or other devices that bear or generate identification code or password information.

(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

Compliant

To prevent unauthorized access to the system, TrialKit supports the use of locking user accounts after a defined number of unsuccessful login attempts.

(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.

Compliant

CDS does not issue tokens, cards or other devices that bear or generate identification code or password information.