




**Functional Requirements Validation
Certification
For CRIO eSource version 20**

Released 04 JUN 2021


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Signature Page

	Date
<p>DocuSigned by: <i>Usha Sundaresan</i> 20D6BB0F5E0A4D2...</p> <p>Usha Sundaresan</p>	6/4/2021

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1. Objective

CRIO's SOP requires that CRIO validate every release version of the software. Validation is the process of ensuring that the software system operates as expected. This process is part of CRIO's Software Development Lifecycle.

This document describes the validation process and outcome with respect to the Functional Requirements Specification for this release. These requirements and testing activity are contained throughout the test matrix; they are aggregated in this section for the reader's benefit to provide clear traceability with respect to the FDA regulations.

2. Definitions and Reference Documentation

2.1 Definitions


Term	Definition
Requirement	A description of an expected behavior of the system
Release Version	The CRIO version at which the Requirement was first released
Ticket	The ticket number(s) in CRIO's internal software development platform that correlates with the Requirement; CRIO developers use this to track the lifecycle of each coding change
J-xxx	Jira ticket number xxx
Gxxx	Github ticket number xxx
URS	User Requirements Specification; a previously used document by CRIO to capture specifications; since replaced by ticketing systems
Cxxx	TestRail test script number

2.2 Reference Documents

Document Title	Document Number
<i>Electronic Records; Electronic Signatures, U.S. FDA, 21 CFR, Part 11</i>	N/A
Validation SOP	S-140
See other SOP's and documentation from CRIO	N/A

3. Validation Approach

3.1 Methodology

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CRIO performs validation per its Software Development Lifecycle and S-140 Validation SOP. Validation is the process of ensuring that the software behaves as expected; this is accomplished by developing and executing test scripts. A single requirement may have more than one test script associated with it, and a single test script may cover more than one requirement.

A test script describes a series of actions to be taken, and the expected outcome. For each test script, the tester must confirm that the observed outcome matches the expected outcome on each step. When the tester confirms that the expected and observed outcomes match, the tester makes a notation within the testing system (TestRail) of a "Pass" result.

3.2 Environment

Validation was completed in CRIO's United States QA environment, using a test organization and associated sites with non-client data. All test results stored on TestRail.

3.3 Testing Personnel

The following person performed testing:

Usha Sundaresan - QA Manager

Qualifications: Experienced senior software quality engineer, with Masters in Computer Science, and fifteen years of technology experience at Kayak.com, Accenture, Paytronix systems leading quality teams, managed quality assurance processes, and implementing QA automation frameworks.

3.4 Timing

Testing was completed on 04 JUN 2021.


4. Certification of Completion

I hereby certify that all Functional Requirements were successfully tested for this version of the CRIO software system. All test results are stored in TestRail.

Based on these results, this release is suitable for deployment.

Signed: _____

Date: _____


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5. This Release


This release contains our Master Template enhancement, giving site networks the ability to create a central study template, create multiple versions, and push those versions seamlessly to other sites within their network. It consists of three major components, each explained below: Master Template Design and Publication, Scheduling, Sites Receiving Templates, and the design/copy of the corresponding budget. There are no eRegulatory enhancements.

The following matrices list the requirements for this release and the associated test scripts run.

Number	Requirement	Release Version	Ticket	TestRail Ticket
26.01	<p>The CRIO Administrator should be able to designate one of the sites as the Master Site.</p> <p>The Master Site will have the publication functionality turned on.</p>	V20 (20210604)	J-EDC57 J-EDC58	C1705
26.02	<p>The Study Designer at the Master Site ("Designer") should be able to create a study. The Designer must complete these attributes for master templating as they will be transmitted to Receiving Sites and locked from editing:</p> <ul style="list-style-type: none"> • Sponsor • Protocol Number • Indication • Market Name • Description • CRO • Sponsor IRB • Phase • Title • CT Gov Identifier <p>When the Designer is creating a study, the system will include other attributes (e.g., Site #, Nickname, Status, Target Enrollment) but are not a part of master templating. Therefore these fields will not be transmitted to Receiving Sites.</p> <p>Note: If the attributes Sponsor Tracking Number and CRO Tracking Number need to be pushed to Receiving Sites, these two attributes are a part of master templating and must be completed in the Overview tab after initial study set up.</p>	V20 (20210604)	J-EDC57 J-EDC58	C1705 C1739

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26.03	The Designer should be able to create a Version and name/rename it before publication.	V20 (20210604)	J-EDC30 J-EDC32	C1705 C1739
26.04	The Designer should be able to delete a Version before publication.	V20 (20210604)	J-EDC30 J-EDC32	C1705
26.05	The Designer should be able to create a new version (whether published or unpublished) by copying an existing version.	V20 (20210604)	J-EDC30 J-EDC32	C1705
26.06	The Designer should be able to view all sites that the Designer has access to from a permissions perspective (i.e. all sites within an organization if the Designer is an administrator for that organization, plus any sites which that Designer is invited to as a site user).	V20 (20210604)	J-EDC30 J-EDC32 J-EDC65	C1705 C1739
26.07	The Designer may publish a template to one or more sites, or to all sites, that he/she has access to.	V20 (20210604)	J-EDC30 J-EDC32 J-EDC65	C1705 C1739
26.08	The site should receive a notification (banner at the top of My Dashboard page) that a new template has been published.	V20 (20210604)	J-EDC123	C1707
26.09	Once a template is in published status, it should be frozen from further editing. The user should not be able to edit procedures (including the name, sequence, questions, question order, and procedure logic), visits (including number, name, windows, notes or sequencing), overview fields, or procedure-visit combinations. The user cannot add any new procedures, questions, visits, or overview fields.	V20 (20210604)	J-EDC60	C1705
26.10	The system should have a log of every version published, and every site that inherited that version, and the date it inherited it. This log is available in Looker.	V20 (20210604)	J-EDC123 J-EDC120	C1703
26.11	The system should display every site on the system, the current version it has, the date it inherited that version, and the previous versions and dates inherited. This log is available in Looker. <i>Note: This is a flip view of the above.</i>	V20 (20210604)	J-EDC123 J-EDC120	C1709

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Receiving Sites:

Number	Requirement	Release Version	Ticket	TestRail Ticket
26.12	<p>In the inherited study in the Receiving Site, the following attributes are pre-populated from the Master Site and non-editable:</p> <ul style="list-style-type: none"> • Sponsor • Protocol Number • Market Name • Description • CRO • Sponsor IRB • Phase • Title • CT Gov Identifier <p>The site may populate all remaining fields in Study Overview (e.g., Site #, Nickname, Status, Target Enrollment...etc).</p>	V20 (20210604)	J-EDC57 J-EDC58	C1687
26.13	<p>When a site receives a new version, the Configure tab will automatically reflect the configuration pushed from the Master Site. The Receiving Site may perform additional configuration, but there are limitations to editing configuration as to what the site can do vs. cannot do.</p> <p>Here is what the site can do:</p> <ul style="list-style-type: none"> • Add a visit • Add a procedure • Add a question to a procedure • Add an edit check (alert rule), including one that references a locked question • Tie a procedural logic statement (disable logic or value reference) to the answer of a locked question; for instance, if the site inherits the question "Did site draw blood?" and if the site responds "Yes", the site can have the "Yes" response trigger the site's custom-added question, "Was any blood clotting observed?" <p>Here's what the site cannot do with respect to the inherited template:</p> <ul style="list-style-type: none"> • Delete a visit • Move a visit 	V20 (20210604)	J-EDC57 J-EDC58 J-EDC60	C1687 C1691 C1692

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	<ul style="list-style-type: none"> • Update Anchor visits for the study • Delete a procedure • Delete or modify a question • Delete or modify any edit checks (alert rule) • Create disable logic that could have the effect of disabling an inherited question • Delete or modify any inherited procedural logic statements (alert rules or disable rules). • Delete or modify any inherited instructions or question clarifications • Add text to the instructional box and add clarifications to inherited questions 			
26.14	In study configuration, all elements that were configured by the site should be visually denoted.	V20 (20210604)	J-EDC57 J-EDC58	C1691 C1708
26.15	The version should be visible in the following areas and upon print-out: <ul style="list-style-type: none"> • Procedure modal will have the version at the top next to the category. • Version is printed on the study pages (above the tabs). • Version is also displayed on the completed visit pages. 	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1693
26.16	When a new version is published, it replaces the prior version received.	V20 (20210604)	J-EDC30 J-EDC32	C1694
26.17	The site should receive a notification (banner at the top of My Dashboard page) that a new template has been published.	V20 (20210604)	J-EDC120 J-EDC123	C1707
26.18	On the Master site, if a visit is deleted from configuration, and the receiving site does not have data for that visit, scheduled visits which are now in DELETED status will be removed from the calendar. On the site-side Scheduling module, all scheduled Visits need to be mapped to the new Visits.	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1701
26.19	On the Master site, if a visit is deleted from configuration, and if that visit has data on the receiving site, the visit will not be removed from the receiving site. All data is retained for that visit on the receiving site. The visit row gets unlocked (editable) and will behave like an independent visit on the receiving site.	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1700

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26.20	All Completed visits are unaffected by publication of a new version. The data remains as collected.	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1699
26.21	All Partially Completed and Paused visits, when re-opened, reflect the most recent version, to the extent that the procedures have not been completed.	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1699
26.22	Visits that are In Progress will reflect the most recent version, to the extent that the procedures have not been completed.	V20 (20210604)	J-EDC30 J-EDC32	C1702
26.23	When a new version is published to a site that has added custom questions, these are the rules: <ul style="list-style-type: none"> • The system will “merge” the new results and custom questions together, meaning all custom questions added by the Receiving Site are preserved. 	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1708

6. 21 CFR compliance

CRIO has issued D-400, a controlled document that lists every regulatory requirement in 21 CFR 11 and how the CRIO system enables its clients to comply with those requirements. Many of those requirements have direct implications for the functional design, and those implications were considered from the outset of product development. As a result, requirements that enable compliance with 21 CFR 11 are embedded throughout the test matrix.


The following matrix lists those 21 CFR 11 requirements that directly impact product requirements, and the specific CRIO features that demonstrate compliance. For actual testing evidence indicating that the requirement is met, refer to the Test Matrix. For a complete view of 21 CFR 11 compliance, see D-400.

Section No.	21 CFR 11 Requirement	CRIO Functionality	CRIO requirements
11.10(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.	Source data stored electronically in the CRIO solution is capable of being downloaded and/or printed as PDF files for review. In addition, the client administrator may provide read-only, study-specific electronic	11.05 11.05a 11.06 11.08

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		access as required to external reviewers.	14.04 14.05 15.04 16.21 21.01
11.10(d)	Limiting system access to authorized individuals.	The Client Administrator is responsible for provisioning user access. Once granted access, individual users define their own userid and password, subject to minimum requirements on character length and type. Every userid must be unique. The Client Administrator is responsible for providing specific role-based access to individual users for individual studies.	20.05 20.06 20.07 20.08 22.01 22.05
11.10(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.	CRIO has these system features: 1. The system generates automatic, electronic audit trail information of who created or modified what data and when. 2. The audit trail functionality is part of the design and cannot be turned off by any user at any time. 3. The audit trail captures every user action that creates or modifies records. 4. When information is changed in a record, the audit trail records and saves the previous version. 5. Audit trail entries are made at the time the action/operation was performed. 6. Electronic audit trails (all or any part) are readily available for review and copying, and can be printed. Reference section 11.10(b) of this document. 7. The audit trail contains date and time stamps. The time is displayed in local time. 8. The audit trail is completely transparent to, and outside the control and access of, the user.	11.01 11.03 11.03a 11.03b 11.04 17.01a 17.02 17.03

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		9. Server time stamps are used for audit trails in all cases and are not available for change by anyone at the deploying organization.	
11.10(f)	Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	Individual users may present collection procedures in a desired sequence, and use instructions and alerts to cue the user as to the appropriate sequencing of steps, if any.	2.08 2.08a 3.11 5.04
11.50(a)	(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).	CRIO has these features: 1. The full name of the user (first and last) is displayed along with the date and time of signature. 2. The CRIO system requires that there is always a statement associated with any electronic signature, and that the user attests to the veracity of such statement. This ensures that the signature's meaning is clear and unambiguous.	16.18 16.18a 16.19 16.21
11.70	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.	CRIO provides all the technical controls to comply with these requirements. The CRIO system stores the signature with relational mapping to associated content.	16.19 17.03
11.200(a)	(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.	CRIO uses the unique User ID and password combination as the two distinct identification components for signatures.	16.17 22.05

7. Test Matrix

The following matrix lists the cumulative set of requirements and the associated test scripts run.

7.1 Study Overview

Number	Requirement	Release Version	Ticket	TestRail ticket
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Number	Requirement	Release Version	Ticket	TestRail ticket
1.01	The system must allow users to create studies with certain attributes, including protocol name, sponsor, CRO, indication, and phase.	20160831	URS 1.0 3.1.1	C213
1.01a	The system should allow users to give the study a nickname.	20170705	G990	C213
1.02	The system must allow the user to select from previously entered studies and leverage pre-populated data fields for name, CRO, sponsor, phase.	20160831	URS 1.0 3.1.2	C213
1.03	The user should be able to edit any of the fields.	20160831	URS 1.0 3.1.3	C180
1.04	Each study should have a lifecycle attribute, such as Start Up, Enrolling, etc.	20160831	URS 1.0 3.1.4	C213
1.05	The lifecycle attributes Start-Up or Enrolling or Maintenance define the study as "Active": attributes Pre-Closed, Closed, Suspended or Withdrawn define the study as "Inactive".	20160831	URS 1.0 3.1.5	C213
1.06	For ease of use, active and inactive studies should be displayed separately.	20160831	URS 1.0 3.1.6	C214
1.07	The user should be able to filter by lifecycle attribute.	20160831	URS 1.0 3.1.7	C214
1.08	The system should allow users to upload study documents and assign attributes, including document type, document name, version number, and version date.	20160831	URS 1.0 3.1.8	C174
1.09	Users should be able to delete and replace study documents and edit attributes.	20160831	URS 1.0 3.1.9	C182
1.10	When there are multiple versions of the same document, the system should display the most recent document first, and have an interface that requires user effort to download prior versions.	20160831	URS 1.0 3.1.10	C179

7.2 Template

Number	Requirement	Release Version	Ticket	TestRail ticket
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Number	Requirement	Release Version	Ticket	TestRail ticket
2.01	The system must allow the user to define one or more Visits, which shall contain a visit number, a visit name and, except for the first visit and an "anchor" visit, a target window.	20160831	URS 1.0 3.2.1	C99
2.02	The system must allow the user to add a visit and edit previous entries.	20160831	URS 1.0 3.2.2	C91
2.03	The user shall have the ability to specify one or more visits as "anchor" visits.	20160831	URS 1.0 3.2.3	C99, C91
2.03a	[REMOVED] The user shall be able to specify consecutive visits as anchor visits; in that case, the last visit serves as the anchor to subsequent visits.	20161201 Removed in V19 (20210525)	G2666	C99
2.04	The user shall have the ability to specify target windows, which are defined as a target number of days before or after an anchor date, with a permitted plus/minus range around the date.	20160831	URS 1.0 3.2.4	C99
2.04a	A visit that is an anchor visit may itself anchor off another visit.	V19 (20210525)	J-Dev778	C1710
2.04b	For a visit with a window, the window may be relative to any anchor visit, and is not limited to the last chronological anchor visit.	V19 (20210525)	J-Dev778	C1710
2.05	The system must allow the user to add one or more Procedure and then specify which Procedure(s) apply to which Visit(s).	20160831	URS 1.0 3.2.5	C92
2.06	The system must offer the user a "library" of Procedures, which represent commonly used Procedures. The user may select from the library as a way of populating the Procedures.	20160831	URS 1.0 3.2.6	C92
2.07	Users may add or remove Procedures to or from the library.	20160831	URS 1.0 3.2.7	C92
2.08	Users may re-order, delete, or duplicate Procedures.	20160831	URS 1.0 3.2.8	C92
2.08a	Users may re-order Procedures by dragging and dropping.	20161201	G477, G582	C92

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Number	Requirement	Release Version	Ticket	TestRail ticket
2.09	Users may preview individual Procedures. The preview should simulate how the procedure would appear to the User during the data collection process.	20160831	URS 1.0 3.2.9	C92
2.10	Users may edit Procedures added to the Schedule of Events from the library.	20160831	URS 1.0 3.2.10	C92
2.11	Users may create Procedures afresh, without having to refer to Procedures stored in the library.	20160831	URS 1.0 3.2.11	C848
2.12	Users may preview individual Visits. The preview should simulate how the Visit would appear to the User during the data collection process.	20160831	URS 1.0 3.2.12	C170
2.13	The system should allow the User to indicate that a Procedure is complete as a means of keeping track of which Procedures are done and which Procedures need to be reviewed/edited.	20160831	URS 1.0 3.2.13	C668
2.14	[REMOVED] Previously: The system should allow the User to test the Template on the Android tablet without creating actual source data by generating a sandbox environment. This is accomplished by generating a dedicated login on the tablet that gives the User access to all the Visits in one sitting. This sandbox simulates the actual data entry process but does not save data entered.	20160831 Android support terminated 27 July 2020	URS 1.0 3.2.15	N/A
2.15	[REMOVED] Previously: The system should allow the User to specify that certain Procedures may only be completed by certain Users, based on role or by individual name. These procedures should have a flag appear when someone other than that role or name calls it up for data entry (but not activated for data view only).	20170215 Removed in version <u>20180929</u>	URS 1.0 3.2.14	N/A
2.15a	The system should allow the User to specify that certain Procedures may only be completed by certain Users, based on role or individual name with a soft warning. These procedures will have a flag appear when someone other than that role or name calls it up for data entry, but will not block them from entering data if needed.	20180929	G2507	C128

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Number	Requirement	Release Version	Ticket	TestRail ticket
2.15b	The system should allow the User to specify that certain Procedures may only be completed by certain Users, based on role or individual name with a hard stop. These procedures will have a flag appear when someone other than that role or name calls it up for data entry, and will display in Read Only mode ie. blocking them from entering any data.	20180929	G2507	C127

7.3 Procedures and Questions

Number	Requirement	Release Version	Ticket	TestRail ticket
3.01	The User may assign a procedure to a category of procedures and create a description.	20160831	URS 1.0 3.3.1	C98
3.02	The User may create and edit instructions, which appear as text at the beginning of the Procedure.	20160831	URS 1.0 3.3.2	C100
3.03	The User may create one or more questions with associated responses.	20160831	URS 1.0 3.3.3	C848
3.04	The User must assign a variable name to the response. The variable name must be unique within that Procedure.	20160831	URS 1.0 3.3.4	C848
3.05	The system should allow for the specification of response type "Single Choice" and the taxonomy of available answers. Single choice permits the user to select one and only one answer from a dropdown of choices. In data collection mode, the question should appear as programmed. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.3.5	C101
3.06	The system should allow for the specification of response type "Multi Choice" and the taxonomy of available answers. Multi choice permits the user to select one or more answers from a dropdown of choices. In data collection mode, the question should appear as programmed. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.3.6	C102
3.07	For Single and Multi Choice question types, the User may specify that if a certain response is selected, then a free-text field appears for the User to populate. An example would be if a	20160831	URS 1.0 3.3.7	C105


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Number	Requirement	Release Version	Ticket	TestRail ticket
	<p>taxonomy of Heart, Lung or Other were offered; in this case, the User may wish to have the free-text field appear when "Other" is selected so the user can describe the body system. In data collection mode, the free-text field should appear as programmed.</p> <p><i>Modified to remove reference to Android.</i></p>			
3.07a	<p>For comment field, the User should be able to attach a list of entries. See 3.09a.</p>	20170918	See 3.09a	C848
3.08	<p>The system should allow for the specification of response type "Free Entry". Free entry permits the user to enter a response. In data collection mode, the question should appear as programmed.</p> <p><i>Modified to remove reference to Android.</i></p>	20160831	URS 1.0 3.3.8	C103
3.09	<p>For Free Entry response types, the User may specify one of the following data formats:</p> <ul style="list-style-type: none"> • Text (no constraint) • Numeric, with or without decimals • Date without "Ongoing" as an option • Date with "Ongoing" as an option • Date-time <p>In data collection mode, the entry type should be constrained as specified.</p> <p><i>Modified to remove reference to Android.</i></p>	20160831 20161201 (for whole and decimal distinction)	URS 1.0 3.3.9	C103
3.09a	<p>For Free Entry text type, the User should be able to attach a list of entries that auto-populate as the user types in the first letter(s). The list should have a "hard" setting where the user is constrained to the list, and a "soft" setting where the user can go off-list. When off-list entries are made, the system should display them in the list configuration section and permit the Administrator to add them to the master list, or remove them as a suggested addition.</p>	20170918	G1501, G1503, G1514, G1515, G1517, G1521, G1522, G1523, G1537, G1545	C107

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Number	Requirement	Release Version	Ticket	TestRail ticket
3.10	<p>The system should allow the User to add a Clarification to a question. A Clarification is a text pop-up that appears when the user calls it up, and is represented by the “?” symbol. In data collection mode, the pop-up should appear as programmed.</p> <p><i>Modified to remove reference to Android.</i></p>	20160831	URS 1.0 3.3.10	C117
3.11	<p>The system must allow the User to create an Alert. An Alert is a pop-up text that appears when certain conditions are triggered. The system must allow the User to program Alerts to appear when these conditions are triggered:</p> <ul style="list-style-type: none"> In Single or Multi Choice, a certain selection is made In Multi Choice, fewer than a target number of selections are made In Free Entry, a value is entered that is equal to, not equal to, greater than or less than a set threshold, where the threshold may be a set value, the value entered for another variable, or a formula that is based off the value entered for another variable In Calculated, a value is generated that is equal to, not equal to, greater than or less than a set threshold, where the threshold may be a set value, the value entered for another variable, or a formula that is based off the value entered for another variable <p>In data collection mode, the alert should appear as programmed.</p> <p><i>Modified to remove reference to Android.</i></p>	20160831	URS 1.0 3.3.11	C1655

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Number	Requirement	Release Version	Ticket	TestRail ticket
3.12	<p>The system must allow the User to specify the following types of calculations:</p> <ul style="list-style-type: none"> • Sum • Difference • Product • Division • Average • Age • Fahrenheit to Celsius • Inch to Centimeter • Pound to Kilogram • BMI • Years Between Dates <p>In data collection mode, the field should calculate as programmed. <i>Modified to remove reference to Android.</i></p>	20160831 For Years-between-dates, 20161201	URS 1.0 3.3.12	C115
3.12a	The system should allow the User to be able to specify the rounding rules for calculated fields – how many decimal points, and what rule (round up, round down).	20161201	G2667	C116
3.12b	The system should allow the User to specify a free-form formula where customized formulas such as (a*b)-5 can be programmed.	20161201	G615	C115
3.12c	The system should allow the User to do auto-scoring, such as answer A = 1 point, answer B = 2 points, etc.	20170705	G2668	C108
3.13	<p>The system must allow the User to disable questions when certain conditions are triggered.</p> <p><i>Modified to remove reference to Android.</i></p>	20160831	URS 1.0 3.3.13	C90


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Number	Requirement	Release Version	Ticket	TestRail ticket
3.14	<p>The system must allow the User to display a series of Single Choice questions with identical selection choices in "Grid" view. "Grid" view is a way of displaying the questions and answers in a matrix-like format.</p> <p>The use case contemplated is for common forms such as Physical Examination or Eligibility, where a number of rows appear and the user checks off the answer by selecting the appropriate column.</p> <p>In data collection mode, the question should appear in grid format as programmed.</p> <p>The User should be able to unselect Grid view.</p> <p><i>Modified to remove reference to Android.</i></p>	20160831	URS 1.0 3.3.14	C109
3.15	<p>The system must allow the User to specify a Procedure as a Multi-Record type. A Multi-Record has the following properties:</p> <ul style="list-style-type: none"> The user may specify that no records exist The user may enter one or more records <p>The use case contemplated is for common forms such as Medical History, Adverse Events, or Concomitant Medications.</p> <p>A Multi-Record may have any number of questions and response types associated with it.</p> <p>In data collection mode, the question should appear in Multi-Record type.</p> <p>The User should be able to unselect Multi-Record type.</p> <p><i>Modified to remove reference to Android.</i></p>	20160831	URS 1.0 3.3.15	C86
3.16	<p>Multi-Record should have a cumulative setting. When cumulative setting is enabled, then the Procedure appears at each Visit as a cumulative answer set (i.e., all past answers are displayed). The User has the option to indicate that no changes have occurred. Completed Procedures at past Visits are locked for editing; only the most recent Procedure is available for editing.</p> <p>In data collection mode, the procedure should "carry forward" the prior record to the next record.</p> <p><i>Modified to remove reference to Android.</i></p>	20160831	URS 1.0 3.3.16	C86

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Number	Requirement	Release Version	Ticket	TestRail ticket
3.16a	In Multi-Record, during data collection, the “no entry” checkbox should be disabled if there is one or more entry saved.	20170215	G741	C86
3.16b	In Multi-Record, the records should carry forward when the procedure is part of an Unscheduled Visit.	20170502	G628	C684
3.16c	In Multi-Record, when a User modifies the configuration to add a question, the new question should appear on future visits, but apply to previously entered records.	20170705	G1013	C86
3.17	When programming questions in a Procedure, the User should have, as a convenience, the ability to specify that a question should have the same answers and validation logic set as the prior question.	20160831	URS 1.0 3.3.17	C111
3.18	There should be an audit log displaying all changes made to the study template, including who made it and when.	20170918	G1458	C112
3.19	<p>The system must allow the User to specify a Procedure as a Permanent Procedure type. This is an upgrade from “Multi-Record” and has the following properties:</p> <ul style="list-style-type: none"> The user may specify that no records exist The user may enter one or more records Unlike Multi-Record, the procedure is permanent, in that a change to a record carries forward as well as backward. <p>Permanent Procedure may have any number of questions and response types associated with it.</p>	20180128	G1493	C86
3.20	In a Permanent Procedure, the User has the option to indicate that no changes have occurred, or indicate that changes have occurred, which then enables the User to make additions or modifications. Any such addition or modification ripples through backward and forward.	20180128	G1493	C685
3.21	When deleting an answer option in Permanent Procedure in configuration, the system will flag any previously populated entries that are impacted, and require the user to modify those answers before moving forward with the deletion.	20180128	G1493	C113

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Number	Requirement	Release Version	Ticket	TestRail ticket
3.22	<p>The user should be able to specify a procedure as skippable by turning on the Skip Procedure option. When enabled, the person doing data completion can elect to remove this Procedure from the current and all future visits for that subject.</p> <p>This feature is useful when you have optional procedures, such as optional informed consent, optional PK, etc.</p> <p>Note: cannot be used on Multi-Record or Permanent Procedure type.</p>	20180311	G2023	C114
3.23	The system will allow the user to “undo” a skipped procedure by re-adding it, as long as the visit is In Progress, Paused or Partially Complete.	20180311	G2023	C670

7.4 Subjects

Number	Requirement	Release Version	Ticket	TestRail ticket
4.01	The system must allow the user to add a patient to a study as a Subject. The user should be able to populate fields that include name, phone, email address, Subject ID, Randomization ID (optional), and Patient Status.	20160831	URS 1.0 3.4.1	C447
4.02	The user must be able to view Subjects by Patient Status.	20160831	URS 1.0 3.4.2	C447
4.03	The user must be able to view Subjects in Subject ID order.	20160831	URS 1.0 3.4.3	C137
4.04	The user must be able to view Subjects and the Visits they have completed or are scheduled to complete.	20160831	URS 1.0 3.4.4	C137
4.05	Users should be able to call a Subject by clicking on a phone icon next to the Subject.	20160831	URS 1.0 3.4.5	C426
4.06	Users should be able to email a Subject by clicking on an email icon next to the Subject.	20160831	URS 1.0 3.4.6	C391
4.07	The user must be able to schedule Visits for a subject from the Subject tab.	20160831	URS 1.0 3.4.7	C139

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Number	Requirement	Release Version	Ticket	TestRail ticket
4.08	The subject's middle initial should be viewed in data collection mode, and external views. <i>Modified to remove reference to Android.</i>	20170215	G2669	C671
4.09	The user should be able to move a subject from one study to another study prior to collection of any data.	20170215	G2670	C166
4.10	There should be a site-wide setting which enables the Administrator to display subject initials only in all source.	20170705	G990	C1654


7.5 Source data collection

Number	Requirement	Release Version	Ticket	TestRail ticket
5.01	[REMOVED] Previously: In the Android tablet, the system should display a list of Visits scheduled for the day and allow the User to select a Visit for source data collection.	20160831 Android support terminated 27 July 2020	URS 1.0 3.5.1	N/A
5.02	In data collection mode, the system must display the applicable Procedures for the Visit and then display each Procedure on its own page for data population. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.2	C668
5.03	In data collection mode, the system should allow the User to change or clear selected answers before finalizing their answer set for saving. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.3	C668
5.04	In data collection mode, when a user completes a Procedure, the system should move to the next Procedure as sequentially ordered in the Template. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.4	C668
5.05	In data collection mode, the system must also let the user complete Procedures in the order of their choice. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.5	C668

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Number	Requirement	Release Version	Ticket	TestRail ticket
5.06	In data collection mode, the system must allow a user to complete part or all of a Procedure and then save. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.6	C674
5.07	In data collection mode, when a user completes part of a Procedure, the system should assign an icon to the Procedure indicating that it is partially completed. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.7	C674
5.08	In data collection mode, when a user completes all required questions of a Procedure, the system should assign an icon to the Procedure indicating that it is fully completed. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.8	C666
5.09	In data collection mode, the system must require, and must display, date values in the DD-MON-YYYY format. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.9	C659
5.10	In data collection mode, the system must require, and must display, time values in 24 hour format. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.10	C672
5.11	In data collection mode, the system must allow the user to click one or two buttons to populate a date value with today's date. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.11	C653
5.12	In data collection mode, the system must allow the user to click one or two buttons to populate a date value with "ONGOING". <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.12	C653
5.13	In data collection mode, the system must allow the user to enter a date value in either direct entry or calendar form. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.13	C653
5.14	In data collection mode, the system must allow the user to specify a date with an unknown day and/or an unknown month. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.14	C653

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Number	Requirement	Release Version	Ticket	TestRail ticket
5.15	In data collection mode, the system must allow the user to click one button to populate a time value with the current time. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.15	C672
5.16	In data collection mode, the system should have a "history" view that allows the user to view past responses for the same Procedure for the Subject. For example, if a user were on Visit 6 and in the Weight procedure, they may view the history of past Weight values on previous visits to get a sense of the trendline. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.5.16	C621
5.17	In data collection mode, the system should allow multiple users to be editing the Visit at the same time, except that it prevents users from being in the same procedure at the same time. <i>Modified to remove reference to Android.</i>	20170705	G859	C619
5.18	In data collection mode, the system should flag incomplete fields and offer the user the ability to designate them as "Not Done", which completes the procedure. <i>Modified to remove reference to Android.</i>	20170727	G1070, G1307, G1326	C680

7.6 Patient status

Number	Requirement	Release Version	Ticket	TestRail ticket
6.01	[REMOVED] Previously: In data collection mode, the system must require that, at the end of each Visit, the user select or re affirm the patient's Status. Replaced with 6.04, more comprehensive requirement	20160831	URS 1.0 3.6.1	C636
6.02	[REMOVED] Previously: The system must allow the user to modify the Patient Status at any time, outside of a Visit. Replaced with 6.05, more comprehensive requirement	20160831	URS 1.0 3.6.2	C167

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Number	Requirement	Release Version	Ticket	TestRail ticket
6.03	The system should allow the user to configure options for the reason entered when a subject is changed from one status to another.	V18 (20210305)	J-Dev524	C1681
6.04	Within the data collection for a visit, if the user changes the status, the reason configuration from the study Configure tab should populate as follows: For a status that is unconfigured or is configured as a Free Entry, a free-text input will appear. For a status that is configured as a Single Select, the configured answer options will appear as radio buttons. If the user selects an option that requires a comment, a free-text input field will appear underneath that answer option.	V18 (20210305)	J-Dev525	C1682
6.05	On editing of Subject Profile, the system should display the reason configuration from the study Configure tab as follows: For a status that is unconfigured or is configured as a Free Entry, a free-text input will appear. For a status that is configured as a Single Select, the configured answer options will appear as radio buttons.	V18 (20210305)	J-Dev525	C1683
6.06	Subject Profile Changes audit trail should be updated to show the reason with the comment after it.	V18 (20210305)	J-Dev727	C1684

7.7 Visit completion

Number	Requirement	Release Version	Ticket	TestRail ticket
7.01	In data collection mode, when all procedures are completed, the system should have the user complete Patient Status, and then offer the user the option to confirm close-out before closing the visit. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.7.1	C636
7.02	In data collection mode, when all procedures are not completed, and the user indicates the visit is to be completed, the system should create an alert that lists all procedures that are not completed to confirm prior to moving to Patient Status. Procedures that are partially completed and left completely blank should both be flagged. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.7.2	C680


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Number	Requirement	Release Version	Ticket	TestRail ticket
7.03	When a visit has all Procedures complete, it is identified in the system as fully completed. When a visit has one or more Procedures not complete, it is identified in the system as partially completed.	20160831	URS 1.0 3.7.3	C674
7.03a	When a visit is partially complete, but the subject's status is Screen Fail, the system should display that visit differently, indicating it's a SF with some data fields left blank.	20170705	G733	C143
7.04	The system should treat the Completed visit date as the Scheduled visit date; if the visit was scheduled on 2 different dates, it should display both.	20170705	G975	C1616

7.8 Progress notes


Number	Requirement	Release Version	Ticket	TestRail ticket
8.01	In data collection mode, the user should be able to add a progress note to either the Visit or the Procedure. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.8.1	C631
8.01a	In the application, the user should be able to add a progress note at the Subject level.	20170502	G829	C157
8.02	In data collection mode, the user should be able to save a Note as a draft. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.8.2	C673
8.03	In data collection mode, when saved as draft, the Note does not appear on the source, and is visible only to internal users. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.8.3	C673
8.04	In data collection mode, when published, the Note appears as part of the source document. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.8.4	C631
8.05	The system should have a separate section where all progress notes across a study are displayed so they can be filtered by subject, visit or procedure.	20160831	URS 1.0 3.8.5	C225
8.06	The system should allow the user to perform text searches against published progress notes.	20160831	URS 1.0 3.8.6	C158

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Number	Requirement	Release Version	Ticket	TestRail ticket
8.07	The system should allow multiple users to sign the same progress note.	20171013	G1363	C196

7.9 Comments


Number	Requirement	Release Version	Ticket	TestRail ticket
9.01	The system must allow either internal or external users to post a comment, which is a free-form text field, and attach the comment to any Procedure, question within a Procedure or Visit.	20160831	URS 1.0 3.9.1	C202
9.01a	The system should allow the user to post a comment to a progress note.	20170215	G711	C201
9.01b	The system should allow the user to post a comment to a file.	20170512	G835	C231
9.02	The system must designate each thread as internal or external based on whether the initial comment thread is limited to internal users or contains an external user.	20160831	URS 1.0 3.9.2	C202
9.03	The Comment should always say internal or external. No user may add an external user to an internal Comment.	20160831	URS 1.0 3.9.3	C202
9.04	The system must then display the comment next to the source data in question.	20160831	URS 1.0 3.9.4	C227
9.05	Internal comments should be visible to all internal users with read-only access (regardless of who it was addressed to).	20160831	URS 1.0 3.9.5	C9
9.06	External comments should be visible to all internal and external users with read-only access (regardless of who it was addressed to).	20160831	URS 1.0 3.9.6	C9
9.07	The system must allow anyone on the Comment thread to post a response, visible to all on the Comment thread.	20160831	URS 1.0 3.9.7	C206
9.08	The system must allow anyone on the Comment thread to close out the Comment by marking it as resolved.	20160831	URS 1.0 3.9.8	C206
9.09	The user should be able to hide closed Comments.	20160831	URS 1.0 3.9.9	C28

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Number	Requirement	Release Version	Ticket	TestRail ticket
9.10	The user should be able to see all Comments associated with a visit in one place.	20160831	URS 1.0 3.9.10	C22
9.11	The user should be able to see all Comments associated with a Study in one place.	20160831	URS 1.0 3.9.11	C22
9.12	The user should be able to see all Comments associated with all studies they are on in one place.	20160831	URS 1.0 3.9.12	C59
9.13	When creating a comment, a user should be able to "direct" the comment to another user. This means the comment thread displays who it's directed to, and the recipient receives an email alert.	20161031	G592	C228
9.14	For any given study, a user should be able to set their preference in their account profile on whether to be notified by email of any comments created. If they opt to receive an email alert, they should receive an email when a comment is created. Principal Investigators and Prime Coordinators should automatically default to Subscribe.	20161201	G603	C229

7.10 Informed Consent Workflow

Number	Requirement	Release Version	Ticket	TestRail ticket
10.01	The system must identify when a subject needs to execute an ICF version by identifying the unique name-version according to the following rules: <ul style="list-style-type: none"> If the subject has not executed a named ICF, the system will identify the latest uploaded version of that named ICF; If the subject has executed a named ICF, the system will compare the latest version executed by the subject to the latest uploaded version, and identify the latest uploaded version 	20160831	URS 1.0 3.10.1	C683
10.02	In the Template module, the system should allow the user to identify which visits the ICF Workflow does not apply to. Examples might be telephonic visits or visits conducted at a third party facility.	20160831	URS 1.0 3.10.2	C92
10.03	If there is an outstanding Executable ICF and the	20160831	URS 1.0	C683

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	visit is one that is not identified as exempt from the ICF Workflow, then, in data collection mode, the appointment should have a visible identifier present that lists the Executable ICF(s). <i>Modified to remove reference to Android.</i>		3.10.3	
10.04	The system should support multiple ICF's within the same study – eg, "Main" and "Substudy". Each document should have separate versioning.	20161201	G592	C184


7.11 Source data review and editing

Number	Requirement	Release Version	Ticket	TestRail ticket
11.01	In data collection mode, prior to visit close, the user may edit previously saved data, but the system should require the user to indicate the reason for the change. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.11.1	C655
11.02	In the application, the system should allow the user to view and edit all saved source data.	20160831	URS 1.0 3.11.2	C655
11.02a	In the version, the system should allow a user to retrieve and edit multi-record logs from the Subject profile page, without having to open a visit.	2070705	G1010	C86
11.03	The system should offer the user a view with or without "audit trail". When displayed without audit trail, only the most recent responses are displayed. When displayed with audit trail, then all username and date/timestamps are displayed, along with past values and reasons for modification.	20160831	URS 1.0 3.11.3	C29
11.03a	For multi-record procedures, the audit trail should display a history of all actions taken, including changes and "saved without modification" actions.	20170705	G1072	C86
11.03b	For Permanent Procedures, the audit trail should display the most recent response, and past responses, to the question of whether there was a change made.	20180128	G1493	C685
11.04	When a user makes an edit, the system must require the user to indicate a reason for the edit. The reason should be the choices "Error correction" or "New information/clarification" or	20160831	URS 1.0 3.11.4	C655

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	"Other", which requires a comment.			
11.05	The system should permit the user to download and print completed source.	20160831	URS 1.0 3.11.5	C82
11.05a	The printed source should display the PI name and visit date.	20170215	G702	C82
11.06	The system's print mode should be optimized for printer-friendliness.	20160831	URS 1.0 3.11.6	C82
11.07	The system should permit the user to create a separate pop-up window for each completed procedure.	20170705	G983	C666
11.08	The system should allow the user to download PDF's of all completed source within a study.	20170705	G822	C82
11.09	The system should have a tool that enables rapid PI sign-off on each visit. Upon execution, the system stamps the PI signature, which is visible to the CRA.	20171026	G1579	C83
11.10	The system should create a tab in the Home page for the PI that lists up all visits that need to be signed off on.	20171026	G1579	C1645
11.11	The system should have a view for study users to see what visits have been PI-signed, and what visits are left for PI signature.	20171113	G1579	C135
11.11a	The system should have administrative settings that determine: <ul style="list-style-type: none"> - Whether to enable this workflow or now - If yes, whether PI is to sign off only on fully completed visits (as opposed to full & partial) - If yes, whether PI is to sign off only on visits that have been QA'd - If yes, from what point in time 	20171113	G1857	C186
11.12	The system should have a tool that enables rapid QA sign-off on each visit. Upon execution, the system marks the visit as QA'ed, and this is not visible to the CRA.	20171026	G1620	C84
11.13	The system should have a view for study users to see what visits have been QA'd, and what visits are left for QA review.	20171026	G1620	C135
11.14	The system should have administrative settings that determine whether this QA workflow is	20171113	G1857	C256

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	enabled or not.			

7.12 Schedule


Number	Requirement	Release Version	Ticket	TestRail ticket
12.01	The system should assign an individual calendar to each user.	20160831	URS 1.0 3.12.1	C217
12.02	The system should allow the user to select which individual's calendar or group of individuals' calendars to display, with the user's own calendar as the default. Each user should be able to specify their own color, which color codes the appointments.	20160831	URS 1.0 3.12.2	C217
12.03	The system should offer at least daily and monthly calendar views.	20160831	URS 1.0 3.12.3	C219
12.04	Today's date should be highlighted for convenience.	20160831	URS 1.0 3.12.4	C219
12.05	The system should allow point-and-click scheduling, whereby the user simply points at a given user's calendar and clicks to add an appointment.	20160831	URS 1.0 3.12.5	C219
12.06	The system should have two types of appointments: Patient Visits and non-Visits.	20160831	URS 1.0 3.12.6	C219
12.07	When in Patient Visit mode, the system should color code the days that are in window.	20160831	URS 1.0 3.12.7	C221
12.08	When in Patient Visit mode, the applicable data fields are Study, Subject, Visit Number, Date/Time, individual calendar-holder, and length of appointment.	20160831	URS 1.0 3.12.8	C139
12.09	When in Non-Visit mode, the applicable data fields are Topic, Date/Time, individual calendar-holder, and length of appointment.	20160831	URS 1.0 3.12.9	C845
12.10	When in Non-Visit mode, there should be a Recurring feature which allows the user to program the appointment as recurring on a set schedule.	20160831	URS 1.0 3.12.10	C845
12.11	The time, length and assigned calendar-holder of an existing appointment should be easily modifiable through a drag-and-drop interface.	20160831	URS 1.0 3.12.11	C845

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Number	Requirement	Release Version	Ticket	TestRail ticket
12.12	Patient Visit appointments can be marked as No Show or Cancelled.	20160831	URS 1.0 3.12.12	C345
12.13	In addition to programmed Visits, the system must allow the user to schedule an "Unscheduled" Visit, which is an additional, ad hoc visit at which a specified sub-set of procedures are completed. The system must allow the user to select from the menu of all procedures one or more procedures that attach to the Unscheduled Visit. In data collection mode, the system should create source template for that visit specifically with those procedures chosen. The Unscheduled Visit should be displayed in the Subject view. <i>Modified to remove reference to Android.</i>	20160831	URS 1.0 3.12.13	C140
12.13a	The user should be able to give an Unscheduled Visit a customized name.	20170918	G890	C140
12.14	Appointments should be re-schedulable unless they are in progress or in pause mode. If the user reschedules a Partially Completed visit, the system should allow the user to open up that visit on the day of the visit and complete source. The source record should complete as one cumulative record and until it reaches Completed status. However, the visit should have an annotation present that indicates it was split over multiple visits.	20160831	URS 1.0 3.12.14	C1616
12.15	Appointments should be cancellable unless the Visit has started and there is some saved data.	20160831	URS 1.0 3.12.15	C660

7.13 Tasks


Number	Requirement	Release Version	Ticket	TestRail ticket
13.01	The system must create an aggregated "inbox" for each user that displays all Comments on studies they are a part of.	20160831	URS 1.0 3.13.1	C59
13.02	In the comments inbox, the first words of the comment should appear along with the study, patient, visit, procedure (if any), Internal vs. External and originator.	20160831	URS 1.0 3.13.2	C59

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Number	Requirement	Release Version	Ticket	TestRail ticket
13.03	In the comments inbox, the user should be able to jump to the section of the eSource where the comment resides, and respond to and resolve the comment from there.	20160831	URS 1.0 3.13.3	C59
13.04	Comments marked as resolved should be archived for later viewing in the Tasks module.	20160831	URS 1.0 3.13.4	C59
13.05	The system must create an aggregated "inbox" for all draft progress notes started by the user.	20160831	URS 1.0 3.13.5	C60
13.06	In the draft progress note inbox, the first words of the note should appear along with the study, subject, visit and date/time of creation.	20160831	URS 1.0 3.13.6	C60
13.07	In the draft progress note inbox, the user should be able to jump to the section of the eSource where the draft progress note resides, and complete and publish the note from there.	20160831	URS 1.0 3.13.7	C60
13.08	The system should permit the user to create a to-do that is subject specific. The user should be able to specify the task, assign one or more users, and specify a due date/time.	20171013	G1580	C149, C150, C151
13.09	Tasks that are coming due within 3 days should become "Immediate", and tasks that are past due become "Overdue".	20171013	G1580	C150, C151
13.10	To do's should display in the Tasks tab, and Immediate and Overdue should appear in the dashboard.	20171013	G1580	C154
13.11	A user should be able to mark a Task as Complete.	20171013	G1580	C154

7.14 Logs

Number	Requirement	Release Version	Ticket	TestRail ticket
14.01	For each study, the system should automatically generate a running Screening log which lists subject ID, subject initials, date of birth, gender, date of screening, status and status reason.	20160831	URS 1.0 3.14.1	C208
14.02	For each study, the system should automatically generate a running Subject ID log which lists subject ID, subject initials, date of birth, gender, subject first name, subject last name and subject	20160831	URS 1.0 3.14.2	C209

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Number	Requirement	Release Version	Ticket	TestRail ticket
	telephone number.			
14.03	For each study, the system should automatically generate a running ICF log which lists subject ID, subject initials, ICF name-version executed, and date of execution.	20160831	URS 1.0 3.14.3	C210
14.04	The system should permit the user to download and print logs.	20160831	URS 1.0 3.14.4	C211
14.05	The system's print mode should be optimized for printer-friendliness.	20160831	URS 1.0 3.14.5	C211

7.15 Files

Number	Requirement	Release Version	Ticket	TestRail ticket
15.01	The system must allow the user to upload a file and assign the file to a study, subject and visit and describe the type and assign a name.	20160831	URS 1.0 3.15.1	C232
15.02	The system must allow the user to delete or swap files or modify attributes.	20160831	URS 1.0 3.15.2	C239
15.03	The system must allow the user to review and filter for all files for a study in one place.	20160831	URS 1.0 3.15.3	C233
15.04	The system should permit the user to download files.	20160831	URS 1.0 3.15.4	C232

7.16 Lab routing and uploading

Number	Requirement	Release Version	Ticket	TestRail ticket
16.01	Users are able to upload a PDF file and, upon upload, identify the study, subject, visit (if applicable), and document type, along with basic free text description.	20170214	URS 2.0 3.1.1	C232

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Number	Requirement	Release Version	Ticket	TestRail ticket
16.01a	The maximum file size should be 100MB.	20170215	G2671	N/A
16.01b	Users should be able to upload a PDF file from within a completed visit page, and the system should auto-populate the tags accordingly.	20170705	G1101	C1646
16.02	Users should be able to give the document a more specific name.	20170214	URS 2.0 3.1.2	C239
16.02a	Upon upload, the system grabs the original file name and displays that as a customized name, as a default.	20170727	G935	C232
16.03	The username, date/time of uploaded document should appear.	20170214	URS 2.0 3.1.3	C234
16.04	Users should be able to delete uploaded documents not yet signed.	20170214	URS 2.0 3.1.4	C235
16.05	Users should be able to edit each of the metadata fields associated with the document prior to e-signature, including study, subject, visit, document type, document name.	20170214	URS 2.0 3.1.5	C239
16.06	Users should be able to forward emails with attached documents to a site-assigned email address; once forwarded, an "Incoming" queue should allow users to view and tag documents.	20170214	URS 2.0 3.1.6	C241, C243
16.07	Users should be able to delete documents forwarded to the Incoming queue.	20170214	URS 2.0 3.1.7	C242
16.08	Upon upload, the user may assign the document to a user and include a message to the user.	20170214	URS 2.0 3.2.1	C232
16.09	Users may route documents that have already been uploaded.	20170214	URS 2.0 3.2.2	C236
16.10	Users may route documents that are already e-signed, for another review and e-signature.	20170214	URS 2.0 3.2.3	C236
16.11	A user who is assigned a document should receive an email that has a link to the document along with the message.	20170214	URS 2.0 3.2.4	C236
16.12	User should view an image of the document along with the associated study, subject, visit, document type, and who and when it was assigned to, along with the assignment message, in addition to the username and date/time of initial upload.	20170214	URS 2.0 3.2.5	C247

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Number	Requirement	Release Version	Ticket	TestRail ticket
16.13	The user who is reviewing the document should be able to: add "NCS" text, add "CS" text, add free text, add drawing elements (including square, line, circle, arrow and free-form) on top of the document, in an area of their choosing, through point-and-click interface. (These added-on elements to be defined as "elements".)	20170214	URS 2.0 3.2.6	C247
16.13a	The user should be able to redact information on the page by applying a redaction element.	20170918	G1089	C247
16.14	Users should be able to move elements.	20170214	URS 2.0 3.2.7	C247
16.15	Users should be able to delete elements.	20170214	URS 2.0 3.2.8	C247
16.16	Users should be able to show the underlying document, such that elements do not obscure the original.	20170214	URS 2.0 3.2.9	C247
16.17	Users should be able to esign the document using either username/password method, or a hand-drawn method.	20170214	URS 2.0 3.2.10	C1648
16.17a	Users should be able to esign the document upon upload, and not necessarily after being assigned the task of e-signing.	20170502	G2672	C244, C1648
16.18	When e-signing, if there has been a change, the user should be forced to certify this attestation: "I attest to the veracity of all statements made and agree that this electronic document, including all markings and comments by me, is a true and correct original."	20170214	URS 2.0 3.2.11	C244, C1648
16.18a	When e-signing, if there has been no change to the document, the user should be forced to certify this attestation: "I certify that this document is a true and correct copy."	20170214	URS 2.0 3.2.11	C244, C1648
16.19	Upon e-signature, the username who signed, the attestation, the image of the esignature, and the date/time of the esignature should be visible.	20170214	URS 2.0 3.2.12	C244, C1648
16.19a	Upon e-signature, an email should go to the document owner alerting the owner that the document was signed, who signed it, when it was signed, and listing out all the text comments that were affixed.	20171026	G1422	C248

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Number	Requirement	Release Version	Ticket	TestRail ticket
16.20	Users should be able to save a file in draft form, and access it later, at which point all markings will have been preserved.	20170214	URS 2.0 3.2.13	C247
16.21	Users should be able to download a PDF of the file; if the file is e-signed, the e-signature (image of e-signature, attestation, username, date/time of e-signature) should be a part of the PDF.	20170214	URS 2.0 3.2.14	C244, C1648
16.22	Users should be able to view past documents of the same type when viewing the document.	20170918	G984	C1646

7.17 Viewing and modifying documents

Number	Requirement	Release Version	Ticket	TestRail ticket
17.01	[REMOVED] Previously: E-signed files should not be deletable.	20170214 Removed in version <u>20180128</u>	URS 2.0 3.3.1	N/A
17.01a	E-signed files should be deletable by the user; however, the actual file should no longer be visible, although, for audit trail purposes, the fact of deletion should be visible.	20180128	G1649	C238
17.02	Users should be able to modify e-signed files, and, upon signature, an audit trail should generate asking for a reason for the change. The reason should specify either error or new information and be able to enter free-text for reason/comment.	20170214	URS 2.0 3.3.2	C244, C1648
17.03	Upon modification, the audit trail should display: latest e-signature information, plus reason recorded for change (error/change history selection plus comment), along with an audit trail of any text comments added or deleted.	20170214	URS 2.0 3.3.3	C244, C1648
17.04	CRA's should be able to view e-signed files, but not non-signed files.	20170214	URS 2.0 3.3.4	C25

7.18 Portfolio level workflows for files

Number	Requirement	Release Version	Ticket	TestRail ticket
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Number	Requirement	Release Version	Ticket	TestRail ticket
18.01	<p>Within a study, and across study, there should be tabs where files with the following statuses can be viewed:</p> <ul style="list-style-type: none"> - All files - Files that the user is required to sign - Files that the user is the owner of - Files that are in draft form (ie, markings made and saved, but not esigned) - Files that have been sent to the site email and are in "Incoming" status 	20170214	URS 2.0 3.4.1	C233
18.02	<p>There should be a custom filter search capability that lets users retrieve files based on:</p> <ul style="list-style-type: none"> - Documents assigned to a particular user for signature - Esigned vs. not esigned 	20170214	URS 2.0 3.4.2	C233
18.03	A user should be able to modify the owner.	20170214	URS 2.0 3.4.3	C239

7.19 Dashboard

Number	Requirement	Release Version	Ticket	TestRail ticket
19.01	The home page of the user should now display visits scheduled for the day; from here the user may open a visit for source data collection.	20170215	G278	C63
19.02	The home page should have a list of overdue visits, which are visits not in Complete or Partially Complete status that are prior to today.	20170215	G278	C61
19.03	The home page should have a list of tasks, including draft progress notes, comments where the user is invoked, assigned documents	20170215	G278	C59, C60, C57


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Number	Requirement	Release Version	Ticket	TestRail ticket
19.03a	<p>The home page should differentiate between “My Tasks” and “Prime Tasks”, as follows:</p> <p>A. My Tasks - Unresolved Comments</p> <p>The number of unresolved comments that you originated that has been replied to, anything you originated that has not been replied to for 5 days, and anything in which you have been @ mentioned in the last comment.</p> <p>B. My Tasks - Draft Progress Notes</p> <p>The number of your draft progress notes.</p> <p>C. My Tasks - Assigned Documents</p> <p>Documents assigned to you.</p> <p>D. My Tasks - Owned Documents</p> <p>Document you own.</p> <p>E. PI/Prime Study Tasks – Unresolved Comments</p> <p>The number of unresolved comments for the studies in which you are a prime coordinator or principal investigator.</p> <p>F. PI/Prime Study Tasks – Draft Progress Notes</p> <p>The number of draft progress notes for the studies in which you are a prime coordinator or principal investigator.</p> <p>G. Incoming Documents</p> <p>Number of Incoming Documents for your site.</p>	20170918	G1143	C59, C60, C57
19.04	<p>The home page should display study tiles for all active studies, with a “P” in the upper left corner for any study that the user is Principal Investigator or Prime Coordinator on.</p>	20170215	G278	C57

7.20 Organization and user roles


Number	Requirement	Release Version	Ticket	TestRail ticket
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Number	Requirement	Release Version	Ticket	TestRail ticket
20.01	The system must allow users to create their own account.	20160831	URS 1.0 3.16.1	C260
20.02	The system must let the Administrator create an Organization and assign name and address.	20160831	URS 1.0 3.16.2	C1
20.03	The system must allow for the creation of more than one site affiliated with the Organization.	20160831	URS 1.0 3.16.3	C254
20.04	The system must allow the Administrator to provision other Administrators.	20160831	URS 1.0 3.16.4	C252
20.05	The system must allow the Administrator to invite one or more internal users to be a part of a site and specify default role. Upon addition, the user should appear as default role during study creation process, and the user should see the studies on their dashboard.	20160831	URS 1.0 3.16.5	C260, C213, C1650
20.06	The system must allow the Administrator to remove a user's access to studies.	20160831	URS 1.0 3.16.6	C1650
20.07	The Administrator may be able to restrict study design rights to certain users.	20170515	G2673	C1651
20.08	The Administrator should be able to create a default setting for the site whereby study configuration is a restricted or unrestricted right for users.	20170515	G2673	C1652
20.09	When a user does not have configuration right, the user should still have access to a sandbox environment to preview the configured template.	20171113	G1860	C258

7.21 External user view

Number	Requirement	Release Version	Ticket	TestRail ticket
21.01	The system must restrict the external user's view of the study to the eSource documentation.	20160831	URS 1.0 3.17.1	C41
21.02	The system must provide read-only access. The external user must not be able to edit eSource.	20160831	URS 1.0 3.17.2	C41
21.03	The system must allow the external user to generate comments.	20160831	URS 1.0 3.17.3	C22

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Number	Requirement	Release Version	Ticket	TestRail ticket
21.04	The system must not allow the external user to see the patient's full name, telephone or other contact information, draft progress notes, or internal comments.	20160831	URS 1.0 3.17.4	C41


7.22 User profile

Number	Requirement	Release Version	Ticket	TestRail ticket
22.01	The system must allow each licensee to create their own username and password.	20160831	URS 1.0 3.18.1	C260
22.02	The system must allow each user to define their own profile including their personal photo, their title, phone number and email address.	20160831	URS 1.0 3.18.2	C260
22.03	A licensee may be a user for different organizations.	20160831	URS 1.0 3.18.3	C263
22.04	Registered user profiles should be searchable as User or External User and can be invited to a study.	20160831	URS 1.0 3.18.4	C261
22.05 (formerly 23.09)	The system must ensure that user code/password combinations (used for security, audit trails, and/or electronic signatures) are unique to one individual and cannot be reused by another individual.	20160831	URS 1.0 3.19.9	C610

7.23 Part 11 compliance – REMOVED; addressed above

7.24 Data management


Number	Requirement	Release Version	Ticket	TestRail ticket
24.01	Electronic records and associated audit trails and metadata must be able to be maintained for the retention intervals required by relevant predicate rules.	20160831	URS 1.0 3.20.1	N/A; addressed in archiving SOP

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Number	Requirement	Release Version	Ticket	TestRail ticket
24.02	Audit trails and electronic signatures must be permanently associated with its related record, and must meet the same retention and review requirements.	20160831	URS 1.0 3.20.1	N/A; addressed in archiving SOP
24.03	Users must not be able to permanently delete electronic records, or their associated audit trails and/or electronic signatures.	20160831	URS 1.0 3.20.2	N/A
24.04	If the system utilizes intranet or internet connections, the system must support encryption technology to ensure the security and authenticity of electronic records.	20160831	URS 1.0 3.20.3	N/A
24.05	The application must be encrypted at rest.	20160831	URS 1.0 3.20.4	N/A

7.25 Security and performance

Number	Requirement	Release Version	Ticket	TestRail ticket
25.01	The system should have security and privacy safeguards that fulfill HIPAA requirements.	20160831	URS 1.0 3.21.1	N/A
25.02	[REMOVED] Previously: The system should reside on the company's owned servers, with access and control policies consistent with best practice.	20160831 Moved to cloud environment on 9 MAR 2020; IQ validation subsequently performed	URS 1.0 3.21.2	N/A
25.03	The system should have automated back-up capabilities consistent with best practice.	20160831	URS 1.0 3.21.3	N/A
25.04	The system should have reliability, performance, response time, throughput, speed and error analytics capabilities commensurate with enterprise-grade software solutions.	20160831	URS 1.0 3.21.4	N/A
25.05	[REMOVED] Previously: The system must be scaleable to support a use case with at least 100 research sites, conducting 2,000 active discrete studies,	20160831 CRIO has exceeded this volume	URS 1.0 3.21.5	N/A

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	with 30,000 subjects and 30 million data points.	and will maintain load times consistent with customer expectations		
25.06	[REMOVED] Previously: The system should time out a user from the browser after 30 minutes of inactivity.	20170215 Removed in version <u>20180128</u>	G630	N/A
25.06a	The system should time out a user from the application after 120 minutes of inactivity. <i>Modified to remove reference to Android.</i>	20180128	G2674	N/A


7.26 Master Template

Number	Requirement	Release Version	Ticket	TestRail Ticket
26.01	The CRIO Administrator should be able to designate one of the sites as the Master Site. The Master Site will have the publication functionality turned on.	V20 (20210604)	J-EDC57 J-EDC58	C1705
26.02	The Study Designer at the Master Site ("Designer") should be able to create a study. The Designer must complete these attributes for master templating as they will be transmitted to Receiving Sites and locked from editing: <ul style="list-style-type: none"> • Sponsor • Protocol Number • Indication • Market Name • Description • CRO • Sponsor IRB • Phase • Title • CT Gov Identifier 	V20 (20210604)	J-EDC57 J-EDC58	C1705 C1739

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	<p>When the Designer is creating a study, the system will include other attributes (e.g., Site #, Nickname, Status, Target Enrollment) but are not a part of master templating. Therefore these fields will not be transmitted to Receiving Sites.</p> <p>Note: If the attributes Sponsor Tracking Number and CRO Tracking Number need to be pushed to Receiving Sites, these two attributes are a part of master templating and must be completed in the Overview tab after initial study set up.</p>			
26.03	The Designer should be able to create a Version and name/rename it before publication.	V20 (20210604)	J-EDC30 J-EDC32	C1705 C1739
26.04	The Designer should be able to delete a Version before publication.	V20 (20210604)	J-EDC30 J-EDC32	C1705
26.05	The Designer should be able to create a new version (whether published or unpublished) by copying an existing version.	V20 (20210604)	J-EDC30 J-EDC32	C1705
26.06	The Designer should be able to view all sites that the Designer has access to from a permissions perspective (i.e. all sites within an organization if the Designer is an administrator for that organization, plus any sites which that Designer is invited to as a site user).	V20 (20210604)	J-EDC30 J-EDC32 J-EDC65	C1705 C1739
26.07	The Designer may publish a template to one or more sites, or to all sites, that he/she has access to.	V20 (20210604)	J-EDC30 J-EDC32 J-EDC65	C1705 C1739
26.08	The site should receive a notification (banner at the top of My Dashboard page) that a new template has been published.	V20 (20210604)	J-EDC123	C1707
26.09	Once a template is in published status, it should be frozen from further editing. The user should not be able to edit procedures (including the name, sequence, questions, question order, and procedure logic), visits (including number, name, windows, notes or sequencing), overview fields, or procedure-visit combinations. The user cannot add any new procedures, questions, visits, or overview fields.	V20 (20210604)	J-EDC60	C1705

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26.10	The system should have a log of every version published, and every site that inherited that version, and the date it inherited it. This log is available in Looker.	V20 (20210604)	J-EDC123 J-EDC120	C1703
26.11	The system should display every site on the system, the current version it has, the date it inherited that version, and the previous versions and dates inherited. This log is available in Looker. <i>Note: This is a flip view of the above.</i>	V20 (20210604)	J-EDC123 J-EDC120	C1709

Receiving Sites:

Number	Requirement	Release Version	Ticket	TestRail Ticket
26.12	<p>In the inherited study in the Receiving Site, the following attributes are pre-populated from the Master Site and non-editable:</p> <ul style="list-style-type: none"> • Sponsor • Protocol Number • Market Name • Description • CRO • Sponsor IRB • Phase • Title • CT Gov Identifier <p>The site may populate all remaining fields in Study Overview (e.g., Site #, Nickname, Status, Target Enrollment...etc).</p>	V20 (20210604)	J-EDC57 J-EDC58	C1687
26.13	<p>When a site receives a new version, the Configure tab will automatically reflect the configuration pushed from the Master Site. The Receiving Site may perform additional configuration, but there are limitations to editing configuration as to what the site can do vs. cannot do.</p> <p>Here is what the site can do:</p> <ul style="list-style-type: none"> • Add a visit 	V20 (20210604)	J-EDC57 J-EDC58 J-EDC60	C1687 C1691 C1692

**CONTROLLED DOCUMENT**

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	<ul style="list-style-type: none"> • Add a procedure • Add a question to a procedure • Add an edit check (alert rule), including one that references a locked question • Tie a procedural logic statement (disable logic or value reference) to the answer of a locked question; for instance, if the site inherits the question “Did site draw blood?” and if the site responds “Yes”, the site can have the “Yes” response trigger the site’s custom-added question, “Was any blood clotting observed?” <p>Here’s what the site cannot do with respect to the inherited template:</p> <ul style="list-style-type: none"> • Delete a visit • Move a visit • Update Anchor visits for the study • Delete a procedure • Delete or modify a question • Delete or modify any edit checks (alert rule) • Create disable logic that could have the effect of disabling an inherited question • Delete or modify any inherited procedural logic statements (alert rules or disable rules). • Delete or modify any inherited instructions or question clarifications • Add text to the instructional box and add clarifications to inherited questions 			
26.14	In study configuration, all elements that were configured by the site should be visually denoted.	V20 (20210604)	J-EDC57 J-EDC58	C1691 C1708
26.15	The version should be visible in the following areas and upon print-out: <ul style="list-style-type: none"> • Procedure modal will have the version at the top next to the category. • Version is printed on the study pages (above the tabs). • Version is also displayed on the completed visit pages. 	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1693
26.16	When a new version is published, it replaces the prior version received.	V20 (20210604)	J-EDC30 J-EDC32	C1694
26.17	The site should receive a notification (banner at the top of My Dashboard page) that a new template has been published.	V20 (20210604)	J-EDC120 J-EDC123	C1707

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26.18	<p>On the Master site, if a visit is deleted from configuration, and the receiving site does not have data for that visit, scheduled visits which are now in DELETED status will be removed from the calendar.</p> <p>On the site-side Scheduling module, all scheduled Visits need to be mapped to the new Visits.</p>	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1701
26.19	<p>On the Master site, if a visit is deleted from configuration, and if that visit has data on the receiving site, the visit will not be removed from the receiving site. All data is retained for that visit on the receiving site. The visit row gets unlocked (editable) and will behave like an independent visit on the receiving site.</p>	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1700
26.20	<p>All Completed visits are unaffected by publication of a new version. The data remains as collected.</p>	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1699
26.21	<p>All Partially Completed and Paused visits, when re-opened, reflect the most recent version, to the extent that the procedures have not been completed.</p>	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1699
26.22	<p>Visits that are In Progress will reflect the most recent version, to the extent that the procedures have not been completed.</p>	V20 (20210604)	J-EDC30 J-EDC32	C1702
26.23	<p>When a new version is published to a site that has added custom questions, these are the rules:</p> <ul style="list-style-type: none"> • The system will “merge” the new results and custom questions together, meaning all custom questions added by the Receiving Site are preserved. 	V20 (20210604)	J-EDC30 J-EDC32 J-EDC120	C1708