Functional Requirements Specification For CRIO Site Software Version 20

Released 04 JUN 2021

CRIO Site Software Version 20

Signature Page

	Date
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1. System Overview

1.1 Application overview

CRIO's Site Software solution is an enterprise solution for clinical research investigators, consisting of two main modules:

- eSource, which refers to the electronic capture of original data used in clinical trials.
- eRegulatory, which refers to electronic binder management and delegation of duty logs.

Research sites may subscribe to one or the other module, or both. Both modules are web-based SAAS solutions sold on a subscription basis. The solution is hosted in a cloud database, on servers located in various regions of the world (currently U.S., Canada, Germany, Australia). CRIO clients access the solution using a web browser. CRIO optimizes for Google Chrome and conducts all tests in Chrome.

The two modules share a common codebase but are highly segregated in functionality and code. The main workflow that is shared across the two relate to user/account management, so the roles discussion below addresses both.

1.2 Data overview

The system will house two types of data.

Source: Source data refers to data used in a clinical research trial. For this type of data, the user will be able to define data fields, formatting, expected ranges, etc. Source data also includes files uploaded and e-signed PDF files in subject binders as well as the site's Investigator Site Files. Source data is subject to the requirements of 21 CFR Part 11, and therefore all new entries and modifications to source data must have a complete audit trail, among other requirements.

Other: Examples of other data include patient address, study descriptors, appointment times, user roles, etc. This data is not subject to the requirements of 21 CFR Part 11, and therefore no audit trial is legally mandated.

In addition, some type of data, both source and non-source, will constitute protected health information (PHI). Examples include patient names, addresses and phone numbers. PHI should be disguised to external users.

1.3 Roles overview

In CRIO, all individuals have their own personal account. Any individual qualified to gain access to CRIO is responsible for setting their own profile, including uploading their photo; setting their contact information; and defining their password. Each individual can be described as a "licensee" since they have to accept the terms of a license agreement with CRIO, and use and access the system on a licensing basis.

Each licensee has a role that is defined in relation to an organization or a study.

Organization: An Organization is a discrete organizational entity such as a research site or project team. Each Organization must have at least one Administrator and may house one or more sites that house one or more studies.

Site: A Site is a part of an Organization. The typical scenario would be a multi-site network where individual Sites are centrally managed under one common Organization. A Site may house one or more studies. Multiple Sites may be doing the same study, but each study will be treated as a separate instance.

Administrator: An Administrator has the ability to define organizational characteristics and invite users. Administrators may provision other administrators. There is no “lead” or “master” administrator; all administrators have similar rights. An Administrator resides at the Organization or Site level and can define and edit Sites and invite users to sites.

User: A User is a licensee invited to a Site by an Administrator. A User is likely to be an employee or independent contractor dedicated to the Site.

Each User has a specific role on each study and may have a default role on all studies specific to a Site.

Investigator: Investigators have read-write access to eSource and eRegulatory, meaning they can not only view study source data but edit it. This role designation connotes a Principal or Sub Investigator role.

Coordinator: Coordinators have read-write access to eSource and eRegulatory. This role designation connotes any source completion role other than an investigator.

Read Only: The User can read eSource but cannot edit it. The User has read-write access to eRegulatory. An example of a staff member who may have Read Only access is a Regulatory Specialist or Recruitment Director.

No Access: The User cannot view eSource or eRegulatory. An example of a staff member with this role would be a receptionist, who can schedule patients but does not need access to source data.

eReg Only: The User can read eSource and can only access the electronic delegation log in eRegulatory. This User type is usually reserved for third parties, such as an X-Ray Technician, outside the organization, who only need to sign the delegation log but otherwise do not need access to any other components of the study.

External: An External User is a licensee invited to a specific study. An External User has read only access to both eSource and eRegulatory, but can utilize the system’s QA module to affix comments. The prime example would be the CRA.

Designer: Study designers have the right to create and modify eSource study templates. This design right is independent of, and in addition to, the roles above.

2. This Document

2.1 Guide

At each release, and from time to time, the CRIO team specifies at the outset the requirements for that release. Each requirement is a description of expected behavior.

This document records the new and cumulative requirements associated with the release of Site Software v20. Each requirement is identified by the original release version with which it is associated. If a requirement no longer applies, this document will identify that requirement as “REMOVED”, along with the version (or date) at which it was removed. This ensures full traceability of every requirement across releases.

Requirements are organized thematically not by chronological release date.

CRIO maintains separate requirements document for eSource and eRegulatory requirements due to their separate nature.

A requirement may be associated with one or more ticket number. There are three possible ticket numbering systems in use:
1. Jira, designated with “J”: CRIO’s current ticketing system
2. Github, designated with “G”: CRIO’s previous ticketing system
3. URS: Requirements written in Word, usually at the outset of a new product design; subsequent to release, requirements are then captured in the ticketing system

In Jira and Github, a ticket describes a software feature that is assigned to an individual developer, and usually contains screen shots or videos to provide more detailed information to the developer of what to build. The tickets contain information about the full lifeycle of the item, including when the ticket passed each stage of the software development lifecycle.

2.2 Past versions

The following is a list of past versions and release dates.

- V1 20160831) (eSource release)
- V2 (20161031)
- V3 (20161201)
- V4 (20170215)
- V5 (20170404)
- V6 (20170502)
- V7 (20170512)
- V8 (20170705)
- V9 (20170727)
- V10 (20170918)
- V11 (20171013)
- V12 (20171026)
- V13 (20171113)
- V14 (20180128)
- V15 (20180311)
- V16 (20180929)
- V17 (20190401) (eRegulatory release)
- V18 (20210304)
- V19 (20210525)

2.3 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
Jxxx	Jira ticket number xxx
Gxxx	Github ticket number xxx
URS	User Requirements Specification; an original specification reserved for use on new product specifications

2.4 Reference Documents

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

3. New Functional Requirements 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.

Master Template Design and Publication

A site network wishing to utilize this feature should initiate a request to their CRIO Customer Success manager to provide Master Template publication rights to their designated site. A site network may designate an existing site already used as a master site. A site network should only use the master templating feature on new studies, since master templates cannot be used to update existing studies (i.e., the system will treat the master template as a separate study).

At this site, the study designer ("Designer") can, within a given study, create multiple versions of the template and label these versions. For example, the Designer could create version 1a and version 1b, both of which map to version 1.0 of the study protocol, with 1a being for sites that did not opt into an optional PK

sub-study, and 1b being for sites that did. The Designer can then publish version 1a to the sites in the network that did not opt in to the PK sub-study, and version 1b to the sites that did. In fact, the Designer can publish at different times to different sites, thus timing publication with each individual site's start-up schedule.

When the sponsor amends the study protocol and issues version 2.0, the Designer can copy and update both versions 1a and 1b to versions 2a and 2b, then publish those versions to the appropriate sites at the right time. A site that had received version 1a earlier now receives version 2a. All visits completed on version 1a are frozen on that template, and version stamped as 1a. All visits going forward will be associated with version 2a. All custom changes made by the site to 1a now appear in 2a.

Scheduling

One complicating factor is that CRIO integrates the Schedule with eSource - specifically, CRIO's eSource system requires the site users to schedule a visit, and then use that appointment to "call" the appropriate visit template. Therefore, the system needs to "know" how the prior visit structure maps to the new visit structure. For instance, the following is an example of an "old" template vs. a "new" template (the * is an anchor):

<u>From this scenario:</u>

BASELINE SCENARIO					
	1	Screening	-28	-7	-14
	2	Baseline	-14	0	0
*	3	Randomization			
	4	Week 2	14	3	3
	5	Week 4	28	3	3
	6	Week 8	56	5	5
	7	Week 16	112	5	5
*	8	EOT	240	7	7
*	9	EOS	28	5	5

<u>To this scenario:</u>

	1	SCRN	-28	-7	-14
	2	Baseline	-14	0	0
*	3	Randomization			
	4	Week 1	7	3	3
	5	Week 2 Treatment	14	3	3
	6	Week 4 Treatment	28	3	3
	7	Week 8 Treatment	56	5	5
	8	Week 12	84	5	5
	~~9~~	~~Week 16~~	~~112~~	~~5~~	~~5~~
*	9	EOT	240	7	7
*	10	EOS	28	5	5

In the above example, a subject previously scheduled for V4 Week 2 needs to be redirected to V5 Week 2 Treatment - note that the visit number and visit name have both changed, but it's clear from the visit structure that the two visits are the equivalents. It's also apparent that this subject may need to be scheduled for, and complete, Week 1 visit, depending on whether the window has passed or not.

A subject previously scheduled to V7 Week 16 now has no visit to point to. That appointment needs to be cancelled and a new one scheduled for V9 EOT, as the next visit to complete.

Thus, whenever a new version is created, the system will have a mapping structure in which each old visit is mapped to one and only one new visit or to a DELETED status, and every new visit is mapped to one and only one prior visit or has a NEW status. Upon study creation, the old and new visits are identical and therefore default to linked. Any newly created visit defaults to NEW status and any deleted visit maps to DELETED.

This mapping will be done "behind the scenes". Specifically, upon copying a template, the old and new visits are identical and therefore linked. Those visits remain linked, and any newly added visit defaults to NEW, and any deleted visit maps to DELETED.

It's important, therefore, that the Designer keep these rules in mind when copying templates. In the above example, the right way to set up the visit schedule for the second version is to:

1. Add a new visit called v4 WEEK 1.
2. Rename the visit from v4 WEEK 2 to v5 WEEK 2 TREATMENT.
3. Add a new visit called v8 WEEK 12.
4. Delete the visit labeled v7 WEEK 16.

Number	Requirement	Release Version	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
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: • Sponsor • Protocol Number • Indication • Market Name • Description • CRO • Sponsor IRB • Phase • Title	V20 (20210604)	J-EDC57 J-EDC58

	• CT Gov Identifier 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. 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.		
26.03	The Designer should be able to create a Version and name/rename it before publication.	V20 (20210604)	J-EDC30 J-EDC32
26.04	The Designer should be able to delete a Version before publication.	V20 (20210604)	J-EDC30 J-EDC32
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
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
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
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
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

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
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. *Note: This is a flip view of the above.*	V20 (20210604)	J-EDC123 J-EDC120

Sites Receiving Templates

When a template is published, a receiving site will inherit the template - there is no explicit need for the site to "accept" the template; it simply appears in the site's dashboard and will be designated visually as a master controlled template.

The site will be able to view the configuration inherited, but not be able to make any modifications to it. However, the site may update the configuration by adding a visit, a procedure, or a question to a specific procedure, or even an alert or disable logic that references an inherited question.

When a new version is received, it replaces the prior version.

As discussed above, there will be some implications to the scheduling module:

- Any visit from the old template, once opened and data saved, retains its old structure. So a completed visit that is now DELETED always remains. This is consistent with the principle that study data, once collected, is NEVER deleted.
- Any scheduled visit needs to re-map to the new equivalent visit.
- If a scheduled visit maps to a DELETED visit, the system should delete the appointment.

The following are the specific manifestation of the above rules:

	RULES WHEN	
Status	Visit maps to a modified visit	Visit is deleted
Completed	Retains status, displays completed data in prior version	Retains status, freezes prior version

Partially Completed	Retains status, calls prior version when opened	Retains status, freezes prior version
Screen Fail	Retains status, displays completed data in prior version	Retains status, freezes prior version
Paused	Retains status, calls prior version when opened	Retains status, freezes prior version
In progress	Retains status, calls prior version	Retains status, freezes prior version
Scheduled	Displayed as Scheduled, calls new version, target window updated (note: our window management may now flag this as out of window)	Displayed as Scheduled, but inactivates any source associated with it, visually denote this is for a visit that no longer exists
Cancelled	Displayed as Cancelled, calls new version, target window updated	Visit no longer available
Not Scheduled	Displayed as Not Scheduled, calls new version, target window updated	Visit no longer available
	BRAND NEW VISIT APPEARS AS Not Scheduled (note: our window management may now flag this as unscheduled but in window / window approaching / window past / etc.)	

CRIO has in its roadmap an out-of-window visit queue system to alert the site when a scheduled or completed visit is out-of-window. This queue system will help the site better manage visit window impact as they inherit new templates.

Number	Requirement	Release Version	Ticket
26.12	In the inherited study in the Receiving Site, the following attributes are pre-populated from the Master Site and non-editable: • Sponsor • Protocol Number • Market Name • Description • CRO • Sponsor IRB • Phase • Title • CT Gov Identifier	V20 (20210604)	J-EDC57 J-EDC58

	The site may populate all remaining fields in Study Overview (e.g., Site #, Nickname, Status, Target Enrollment...etc).		
26.13	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. Here is what the site can do: • 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?” Here’s what the site cannot do with respect to the inherited template: • 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	V20 (20210604)	J-EDC57 J-EDC58 J-EDC60
26.14	In study configuration, all elements that were configured by the site should be visually denoted.	V20 (20210604)	J-EDC57 J-EDC58
26.15	The version should be visible in the following areas and upon print-out:	V20 (20210604)	J-EDC30 J-EDC32

	• 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.		J-EDC120
26.16	When a new version is published, it replaces the prior version received.	V20 (20210604)	J-EDC30 J-EDC32
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
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
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
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
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
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

26.23	When a new version is published to a site that has added custom questions, these are the rules: • 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

4. Complete Functional Requirements

4.1 Study Overview

Every study has an overview section that houses basic descriptive information about the study, including study name, type, etc. This module is also where users upload and identify study documents, assign user roles and invite external users (e.g., CRA's).

Number	Requirement	Release Version	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
1.01a	The system should allow users to give the study a nickname.	20170705	G990
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
1.03	The user should be able to edit any of the fields.	20160831	URS 1.0 3.1.3
1.04	Each study should have a lifecycle attribute, such as Start Up, Enrolling, etc.	20160831	URS 1.0 3.1.4
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
1.06	For ease of use, active and inactive studies should be displayed separately.	20160831	URS 1.0 3.1.6
1.07	The user should be able to filter by lifecycle attribute.	20160831	URS 1.0 3.1.7

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
1.09	Users should be able to delete and replace study documents and edit attributes.	20160831	URS 1.0 3.1.9
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

4.2 Template

This is where the user creates the eSource template. The main part of the Template is the Schedule of Events, which is a matrix of:

- Visits, and
- Procedures

A Visit has a unique visit number and name, and must occur according to a set schedule. Typically, a visit "window" is expressed as a target number of days before or after another visit, with a permitted range around it.

A Procedure is one or more discrete tasks, such as "Central Labs", "Eligibility", or "Vitals". A Procedure may have instructions, one or more questions with required data entries, and various alerts and validations.

The Schedule of Events is a grid that indicates which Procedures are to occur on which Visits.

A Template in CRIO refers to a Schedule of Events for a study. The Template is used to create the eSource forms that the user populates.

To facilitate rapid template creation, the system will offer a "library" where users can store their favorite Procedures. This way, the user can select Procedures from the library, and then configure to the particular needs of the study.

Number	Requirement	Release Version	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
2.02	The system must allow the user to add a visit and edit previous entries.	20160831	URS 1.0 3.2.2
2.03	The user shall have the ability to specify one or more visits as "anchor" visits.	20160831	URS 1.0 3.2.3
2.03a	[REMOVED]	20161201	G2666

	Previously: 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.	Removed in V19 (20210525)	
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
2.04a	A visit that is an anchor visit may itself anchor off another visit.	V19 (20210525)	J-Dev778
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
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
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
2.07	Users may add or remove Procedures to or from the library.	20160831	URS 1.0 3.2.7
2.08	Users may re-order, delete, or duplicate Procedures.	20160831	URS 1.0 3.2.8
2.08a	Users may re-order Procedures by dragging and dropping.	20161201	G477, G582
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
2.10	Users may edit Procedures added to the Schedule of Events from the library.	20160831	URS 1.0 3.2.10
2.11	Users may create Procedures afresh, without having to refer to Procedures stored in the library.	20160831	URS 1.0 3.2.11
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
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
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	20160831 Android support terminated 27 July 2020	URS 1.0 3.2.15

	sandbox simulates the actual data entry process but does not save data entered.		
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 20180929	URS 1.0 3.2.14
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
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

4.3 Procedures and Questions

A Procedure should be thought of as a discrete workflow with required data entries. A Procedure contains instructions, one or more questions with associated answers, and various logics and alerts.

There are four answer types permitted:
- Single choice
- Multiple choice
- Free entry
- Calculated

A calculated answer is one where the system populates the answer by applying a calculation to one or more previously inputted answers.

Number	Requirement	Release Version	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
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
3.03	The User may create one or more questions with associated responses.	20160831	URS 1.0 3.3.3

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
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.3.5
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.3.6
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 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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.3.7
3.07a	For comment field, the User should be able to attach a list of entries. See 3.09a.	20170918	See 3.09a
3.08	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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.3.8
3.09	For Free Entry response types, the User may specify one of the following data formats: ● Text (no constraint) ● Numeric, with or without decimals ● Date without “Ongoing” as an option ● Date with “Ongoing” as an option ● Date-time In data collection mode, the entry type should be constrained as specified. *Modified to remove reference to Android.*	20160831 20161201 (for whole and decimal distinction)	URS 1.0 3.3.9
3.09a	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	20170918	G1501, G1503, G1514, G1515,

	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.		G1517, G1521, G1522, G1523, G1537, G1545
3.10	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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.3.10
3.11	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: ● 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 In data collection mode, the alert should appear as programmed. *Modified to remove reference to Android.*	20160831	URS 1.0 3.3.11
3.12	The system must allow the User to specify the following types of calculations: ● Sum ● Difference ● Product ● Division ● Average ● Age ● Fahrenheit to Celsius ● Inch to Centimeter ● Pound to Kilogram ● BMI ● Years Between Dates	20160831 For Years-between-dates, 20161201	URS 1.0 3.3.12

	In data collection mode, the field should calculate as programmed. *Modified to remove reference to Android.*		
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
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
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
3.13	The system must allow the User to disable questions when certain conditions are triggered. *Modified to remove reference to Android.*	20160831	URS 1.0 3.3.13
3.14	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. 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. In data collection mode, the question should appear in grid format as programmed. The User should be able to unselect Grid view. *Modified to remove reference to Android.*	20160831	URS 1.0 3.3.14
3.15	The system must allow the User to specify a Procedure as a Multi-Record type. A Multi-Record has the following properties: ● The user may specify that no records exist ● The user may enter one or more records The use case contemplated is for common forms such as Medical History, Adverse Events, or Concomitant Medications. A Multi-Record may have any number of questions and response types associated with it. In data collection mode, the question should appear in Multi-Record type. The User should be able to unselect Multi-Record type. *Modified to remove reference to Android.*	20160831	URS 1.0 3.3.15
3.16	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	20160831	URS 1.0 3.3.16

	for editing; only the most recent Procedure is available for editing. In data collection mode, the procedure should "carry forward" the prior record to the next record. *Modified to remove reference to Android.*		
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
3.16b	In Multi-Record, the records should carry forward when the procedure is part of an Unscheduled Visit.	20170502	G628
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
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
3.18	There should be an audit log displaying all changes made to the study template, including who made it and when.	20170918	G1458
3.19	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: ● 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. Permanent Procedure may have any number of questions and response types associated with it.	20180128	G1493
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
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
3.22	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. This feature is useful when you have optional procedures, such as optional informed consent, optional PK, etc.	20180311	G2023

	Note: cannot be used on Multi-Record or Permanent Procedure type.		
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

4.4 Subjects

A Subject is a patient that is screened in a study. A Subject is identified by name, initials, and a uniquely assigned Subject ID. Subjects have a Patient Status that begins with In Screening and proceeds to Enrolled or Screen Failed, and, once Enrolled, to Completed or Discontinued.

Some patients may have a pre-Subject designation for a study that indicates their interest and/or eligibility in a study – e.g., “Not Interested”, “Eligible”, “Not Eligible”. These lifecycle designations are part of the Patient database/recruiting process. Patients with these designations are not “Subjects” because they are not officially part of the study.

Number	Requirement	Release Version	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
4.02	The user must be able to view Subjects by Patient Status.	20160831	URS 1.0 3.4.2
4.03	The user must be able to view Subjects in Subject ID order.	20160831	URS 1.0 3.4.3
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
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
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
4.07	The user must be able to schedule Visits for a subject from the Subject tab.	20160831	URS 1.0 3.4.7
4.08	The subject’s middle initial should be viewed in data collection mode, and external views. *Modified to remove reference to Android.*	20170215	G2669
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

4.10	There should be a site-wide setting which enables the Administrator to display subject initials only in all source.	20170705	G990

4.5 Source data collection

Source data collection is the process by which eSource is completed per the published Template. Source data collection is performed in the application, while online.

Data collection should be optimized for each environment for both accuracy and ease of use. The design objective of CRIO is to use technology to facilitate rapid and accurate data entry.

The data collection should reflect what was programmed in the Template. All alerts programmed in the Template can be overridden by the user – in other words, these are “soft” alerts, not hard stops.

Number	Requirement	Release Version	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
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.2
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.3
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.4
5.05	In data collection mode, the system must also let the user complete Procedures in the order of their choice. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.5
5.06	In data collection mode, the system must allow a user to complete part or all of a Procedure and then save. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.6

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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.7
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.8
5.09	In data collection mode, the system must require, and must display, date values in the DD-MON-YYYY format. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.9
5.10	In data collection mode, the system must require, and must display, time values in 24 hour format. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.10
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.11
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". *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.12
5.13	In data collection mode, the system must allow the user to enter a date value in either direct entry or calendar form. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.13
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.14
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.15
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.5.16
5.17	In data collection mode, the system should allow multiple users to be editing the Visit at the same time, except that it	20170705	G859

	prevents users from being in the same procedure at the same time. *Modified to remove reference to Android.*		
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. *Modified to remove reference to Android.*	20170727	G1070, G1307, G1326

4.6 Patient status

The subject's Patient Status is a way of designating the subject's progression through the study. There are five set patient statuses:

- In Screening: connotes the subject has signed consent and has not yet enrolled
- Enrolled: connotes the subject has randomized or otherwise accomplished a milestone that indicates the subject's data is part of the data set used to evaluate the endpoint of the study
- Screen Failed: connotes the subject did not qualify for Enrollment
- Completed: connotes the subject enrolled and completed all visits as scheduled
- Discontinued: connotes the subject enrolled and did not complete all visits; examples may be subject withdrawal, discontinuation due to AE, etc.

Number	Requirement	Release Version	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
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
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
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

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
6.06	Subject Profile Changes audit trail should be updated to show the reason with the comment after it.	V18 (20210305)	J-Dev727

4.7 Visit completion

The user can close a Visit at any time, even when all procedures are not done. The system should have built-in logic to check for non-completed procedures. A Visit may be Fully or Partially Completed.

Number	Requirement	Release Version	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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.7.1
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.7.2
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
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
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

4.8 Progress notes

Progress note are free-form text entries that users utilize to document important information. Examples may include clinical assessments, medical events, patient education, or reason for a protocol deviation.

Progress notes “attach” to a visit or a procedure and can be saved in draft form prior to publication. Saving in draft forms allows the user time to work on the note – e.g., to gather information, to review in a quiet setting, etc.

Once published, notes are considered part of the source documentation and therefore should display with the source.

Number	Requirement	Release Version	Ticket
8.01	In data collection mode, the user should be able to add a progress note to either the Visit or the Procedure. *Modified to remove reference to Android.*	20160831	URS 1.0 3.8.1
8.01a	In the application, the user should be able to add a progress note at the Subject level.	20170502	G829
8.02	In data collection mode, the user should be able to save a Note as a draft. *Modified to remove reference to Android.*	20160831	URS 1.0 3.8.2
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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.8.3
8.04	In data collection mode, when published, the Note appears as part of the source document. *Modified to remove reference to Android.*	20160831	URS 1.0 3.8.4
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
8.06	The system should allow the user to perform text searches against published progress notes.	20160831	URS 1.0 3.8.6
8.07	The system should allow multiple users to sign the same progress note.	20171013	G1363

4.9 Comments

Comments are communication threads initiated by users (internal or external) to a study relating to source data. They are the electronic equivalent of the “sticky notes” many CRA’s use when conducting quality assurance. Comments allow the initiator to leave behind questions, and for respondents to answer.

Comments are not part of the source documentation. They should not appear in any print-out of source.

Either internal or external users can generate a Comment. However, an internally generated Comment always stays within the internal user set; an externally generated Comment always stays within the internal and external user set. This is designed so that internal users can perform their QA in privacy (e.g., they may want to reference patient names, leave behind their cell to call, provide performance feedback, etc.).

Number	Requirement	Release Version	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
9.01a	The system should allow the user to post a comment to a progress note.	20170215	G711
9.01b	The system should allow the user to post a comment to a file.	20170512	G835
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
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
9.04	The system must then display the comment next to the source data in question.	20160831	URS 1.0 3.9.4
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
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
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
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
9.09	The user should be able to hide closed Comments.	20160831	URS 1.0 3.9.9
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
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
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
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

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. It 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

4.10 Informed Consent Workflow

Keeping track of Informed Consent Form (ICF) version execution is cumbersome in a paper-based environment. All new patients must be consented on the latest version, and all previously consented patients must be “re-consented” on any new version issued. Coordinators devise various work-arounds to ensure they remember which patients need to re-consent on which versions.

The system has a workflow that is designed to keep track of, and ensure proper execution of, appropriate ICF versions. This workflow integrates the study document functionality, where Informed Consents are uploaded and version tagged, with the scheduling and eSource functionalities.

In the study document upload module, users may upload an ICF version and then name the ICF and version-tag it. Each unique name-version becomes an “Executable”. (Most studies have one single ICF, but some studies have multiple ICF’s, each with their own versioning history – hence the name-version taxonomy.)

Number	Requirement	Release Version	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: ● 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
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
10.03	If there is an outstanding Executable ICF and the 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). *Modified to remove reference to Android.*	20160831	URS 1.0 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

4.11 Source data review and editing

Once saved, source data should always be viewable and editable. All source data is subject to an audit trail that displays all past values and the username, date/time and reason for modification.

Until the data is locked, there is no limit to the number of times or the manner in which source data can be modified.

Number	Requirement	Release Version	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. *Modified to remove reference to Android.*	20160831	URS 1.0 3.11.1
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
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
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
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
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
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 "Other", which requires a comment.	20160831	URS 1.0 3.11.4
11.05	The system should permit the user to download and print completed source.	20160831	URS 1.0 3.11.5
11.05a	The printed source should display the PI name and visit date.	20170215	G702

11.06	The system's print mode should be optimized for printer-friendliness.	20160831	URS 1.0 3.11.6
11.07	The system should permit the user to create a separate pop-up window for each completed procedure.	20170705	G983
11.08	The system should allow the user to download PDF's of all completed source within a study.	20170705	G822
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
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
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
11.11a	The system should have administrative settings that determine: - 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
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
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
11.14	The system should have administrative settings that determine whether this QA workflow is enabled or not.	20171113	G1857

4.12 Schedule

The system is to have a centralized scheduling system that lets user add and manage appointments. The schedule actually has two modes: one mode is for Patient Visits, and one mode is for all other appointments (e.g., training sessions, CRA visits, personal appointments, blocked time, etc).

The system should have a visual calendar look with easy-to-use point-and-click and drag-and-drop interfaces.

For patient visits, the system will integrate the Schedule with the programmed visit windows.

Number	Requirement	Release Version	Ticket
12.01	The system should assign an individual calendar to each user.	20160831	URS 1.0 3.12.1
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
12.03	The system should offer at least daily and monthly calendar views.	20160831	URS 1.0 3.12.3
12.04	Today's date should be highlighted for convenience.	20160831	URS 1.0 3.12.4
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
12.06	The system should have two types of appointments: Patient Visits and non-Visits.	20160831	URS 1.0 3.12.6
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
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
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
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
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
12.12	Patient Visit appointments can be marked as No Show or Cancelled.	20160831	URS 1.0 3.12.12
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.	20160831	URS 1.0 3.12.13

	Modified to remove reference to Android.		
12.13a	The user should be able to give an Unscheduled Visit a customized name.	20170918	G890
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
12.15	Appointments should be cancellable unless the Visit has started and there is some saved data.	20160831	URS 1.0 3.12.15

4.13 Tasks

The purpose of the Task module is to create a centralized place, across studies, that aggregate a user's to-do's.

The Task module will have the following tabs:
- Comments
- Draft Progress Notes
- To Do's

Number	Requirement	Release Version	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
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
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
13.04	Comments marked as resolved should be archived for later viewing in the Tasks module.	20160831	URS 1.0 3.13.4
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

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
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
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
13.09	Tasks that are coming due within 3 days should become “Immediate”, and tasks that are past due become “Overdue”.	20171013	G1580
13.10	To do’s should display in the Tasks tab, and Immediate and Overdue should appear in the dashboard.	20171013	G1580
13.11	A user should be able to mark a Task as Complete.	20171013	G1580

4.14 Logs

Logs are standard tables summarizing information contained elsewhere in the study. Common logs used in clinical research include Screening, Subject ID, or Informed Consent.

Number	Requirement	Release Version	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
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 telephone number.	20160831	URS 1.0 3.14.2
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
14.04	The system should permit the user to download and print logs.	20160831	URS 1.0 3.14.4
14.05	The system’s print mode should be optimized for printer-friendliness.	20160831	URS 1.0 3.14.5

4.15 Files

Files refer to subject-specific source documents whose original is collected manually and that are uploaded.

Number	Requirement	Release Version	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
15.02	The system must allow the user to delete or swap files or modify attributes.	20160831	URS 1.0 3.15.2
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
15.04	The system should permit the user to download files.	20160831	URS 1.0 3.15.4

4.16 Lab routing and uploading

The goal of the “Lab Routing” module is to permit research sites to upload, tag, route, annotate and e-sign third party documents such as labs, ECG tracings, medical records, etc. This module will render a significant portion of the remaining trial process paperless.

CRIO’s Lab Routing should allow the user user to:

- Upload documents
- Tag documents to the appropriate study, subject, visit and/or document type
- Route a document to another party (eg PI) for review/signature
- Make direct annotations to the documents
- Esign documents and make them part of the source record
- Share documents with CRA’s for review
- View documents by lifecycle for portfolio-level processing

Prior to e-signature, an uploaded document is considered a draft, and is not part of the study source. That means that users may edit or delete documents without an audit trail, and CRA’s cannot view the document. Once e-signed, the document becomes part of source, at which point an audit trail will capture all modifications made, and CRA’s can view the document.

CRIO is supporting documents in PDF file format. Users may upload other document formats (eg, XLS), but those documents cannot be routed, annotated or e-signed.

As with the rest of esource, the subject names are disguised to external users; only initials are visible to them.

The roles related to Lab Routing are inherited from the roles associated with the study: If a user is given access to a study, that user will be able to view, upload, route and edit files. If a user is not given access to a

study, that user will not be able to view the study's files. External users have read-only access to all e-signed files associated with studies they have been given access to.

For each file, there is an "Owner" and an "Assignee". The Owner is the person responsible for getting the document signed. The Assignee is the person responsible for signing the document. The Owner and Assignee can be the same person. The use contemplated is that the coordinator is the Owner, who is initiating a review request from the Principal Investigator, and the Principal Investigator is the Assignee.

Number	Requirement	Release Version	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
16.01a	The maximum file size should be 100MB.	20170215	G2671
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
16.02	Users should be able to give the document a more specific name.	20170214	URS 2.0 3.1.2
16.02a	Upon upload, the system grabs the original file name and displays that as a customized name, as a default.	20170727	G935
16.03	The username, date/time of uploaded document should appear.	20170214	URS 2.0 3.1.3
16.04	Users should be able to delete uploaded documents not yet signed.	20170214	URS 2.0 3.1.4
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
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
16.07	Users should be able to delete documents forwarded to the Incoming queue.	20170214	URS 2.0 3.1.7
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
16.09	Users may route documents that have already been uploaded.	20170214	URS 2.0 3.2.2

16.10	Users may route documents that are already e-signed, for another review and e-signature.	20170214	URS 2.0 3.2.3
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
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
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
16.13a	The user should be able to redact information on the page by applying a redaction element.	20170918	G1089
16.14	Users should be able to move elements.	20170214	URS 2.0 3.2.7
16.15	Users should be able to delete elements.	20170214	URS 2.0 3.2.8
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
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
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
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
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
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
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
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

16.21	Users should able to download a PDF of the file; if the file is e-signed, the e-signature (image of esignature, attestation, username, date/time of e-signature) should be a part of the PDF.	20170214	URS 2.0 3.2.14
16.22	Users should be able to view past documents of the same type when viewing the document.	20170918	G984

4.17 Viewing and modifying documents

After e-signature, a document is now part of the source record. It should no longer be deletable or modifiable without an audit trail. CRA's can view the e-signed files (but not non-signed files).

Number	Requirement	Release Version	Ticket
17.01	[REMOVED] Previously: E-signed files should not be deletable.	20170214 Removed in version 20180128	URS 2.0 3.3.1
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
17.02	Users should be able to modify esigned 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
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
17.04	CRA's should be able to view e-signed files, but not non-signed files.	20170214	URS 2.0 3.3.4

4.18 Portfolio level workflows for files

There should be simplified ways to view and access files that require an action, such as needing signature, draft form, etc.

Number	Requirement	Release Version	Ticket

18.01	Within a study, and across study, there should be tabs where files with the following statuses can be viewed: - 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
18.02	There should be a custom filter search capability that lets users retrieve files based on: - Documents assigned to a particular user for signature - Esigned vs. not esigned	20170214	URS 2.0 3.4.2
18.03	A user should be able to modify the owner.	20170214	URS 2.0 3.4.3

4.19 Dashboard

The user’s home page should be a central place to manage tasks and to-do’s across the entire portfolio of studies.

Number	Requirement	Release Version	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
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
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

19.03a	The home page should differentiate between “My Tasks” and “Prime Tasks”, as follows: A. My Tasks - Unresolved Comments 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. B. My Tasks - Draft Progress Notes The number of your draft progress notes. C. My Tasks - Assigned Documents Documents assigned to you. D. My Tasks - Owned Documents Document you own. E. PI/Prime Study Tasks – Unresolved Comments The number of unresolved comments for the studies in which you are a prime coordinator or principal investigator. F. PI/Prime Study Tasks – Draft Progress Notes The number of draft progress notes for the studies in which you are a prime coordinator or principal investigator. G. Incoming Documents Number of Incoming Documents for your site.	20170918	G1143
19.04	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.	20170215	G278

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4.20 Organization and user roles

The Organization is the entity that houses sites, which houses one or more studies. An Organization must have at least one Administrator.

Number	Requirement	Release Version	Ticket
20.01	The system must allow users to create their own account.	20160831	URS 1.0 3.16.1
20.02	The system must let the Administrator create an Organization and assign name and address.	20160831	URS 1.0 3.16.2

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
20.04	The system must allow the Administrator to provision other Administrators.	20160831	URS 1.0 3.16.4
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
20.06	The system must allow the Administrator to remove a user's access to studies.	20160831	URS 1.0 3.16.6
20.07	The Administrator may be able to restrict study design rights to certain users.	20170515	G2673
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
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

4.21 External user view

External users have a different view of the study than internal users.

Number	Requirement	Release Version	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
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
21.03	The system must allow the external user to generate comments.	20160831	URS 1.0 3.17.3
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

4.22 User profile

Each licensee of CRIO creates their own individual user account and profile. These accounts are then searchable by other licensees.

Number	Requirement	Release Version	Ticket
22.01	The system must allow each licensee to create their own username and password.	20160831	URS 1.0 3.18.1
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
22.03	A licensee may be a user for different organizations.	20160831	URS 1.0 3.18.3
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
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

4.23 Part 11 compliance

The system is subject to 21 CFR Part 11 requirements. Part 11 is to be documented in the validation.

Original requirements in sections 4.23 and 4.24 relating to 21 CFR 11 compliance have been removed from this document. Compliance is to be demonstrated in the validation.

4.24 Data management

Intentionally removed per comment in 4.23.

4.25 Security and performance

The system must fulfill typical standards of performance for enterprise grade, HIPAA regulated business system software. Detailed specifications and SOP's governing infrastructure, security, performance, data recovery, etc. are detailed in other controlled documents issued and maintained by CRIO.

Original requirements in this section have been removed from this document.

4.26 Master Template

Master Template Design and Publication

A site network wishing to utilize this feature should initiate a request to their CRIO Customer Success manager to provide Master Template publication rights to their designated site. A site network may designate an existing site already used as a master site. A site network should only use the master templating feature on new studies, since master templates cannot be used to update existing studies (i.e., the system will treat the master template as a separate study).

At this site, the study designer ("Designer") can, within a given study, create multiple versions of the template and label these versions. For example, the Designer could create version 1a and version 1b, both of which map to version 1.0 of the study protocol, with 1a being for sites that did not opt into an optional PK sub-study, and 1b being for sites that did. The Designer can then publish version 1a to the sites in the network that did not opt in to the PK sub-study, and version 1b to the sites that did. In fact, the Designer can publish at different times to different sites, thus timing publication with each individual site's start-up schedule.

When the sponsor amends the study protocol and issues version 2.0, the Designer can copy and update both versions 1a and 1b to versions 2a and 2b, then publish those versions to the appropriate sites at the right time. A site that had received version 1a earlier now receives version 2a. All visits completed on version 1a are frozen on that template, and version stamped as 1a. All visits going forward will be associated with version 2a. All custom changes made by the site to 1a now appear in 2a.

Scheduling

One complicating factor is that CRIO integrates the Schedule with eSource - specifically, CRIO's eSource system requires the site users to schedule a visit, and then use that appointment to "call" the appropriate visit template. Therefore, the system needs to "know" how the prior visit structure maps to the new visit structure. For instance, the following is an example of an "old" template vs. a "new" template (the * is an anchor):

<u>From this scenario:</u>

BASELINE SCENARIO				
	1	Screening	-28	-7	-14
	2	Baseline	-14	0	0
*	3	Randomization			
	4	Week 2	14	3	3
	5	Week 4	28	3	3
	6	Week 8	56	5	5
	7	Week 16	112	5	5
*	8	EOT	240	7	7
*	9	EOS	28	5	5

<u>To this scenario:</u>

	1	SCRN	-28	-7	-14
	2	Baseline	-14	0	0
*	3	Randomization			
	4	Week 1	7	3	3
	5	Week 2 Treatment	14	3	3
	6	Week 4 Treatment	28	3	3
	7	Week 8 Treatment	56	5	5
	8	Week 12	84	5	5
	~~9~~	~~Week 16~~	~~112~~	~~5~~	~~5~~
*	9	EOT	240	7	7
*	10	EOS	28	5	5

In the above example, a subject previously scheduled for V4 Week 2 needs to be redirected to V5 Week 2 Treatment - note that the visit number and visit name have both changed, but it's clear from the visit structure that the two visits are the equivalents. It's also apparent that this subject may need to be scheduled for, and complete, Week 1 visit, depending on whether the window has passed or not.

A subject previously scheduled to V7 Week 16 now has no visit to point to. That appointment needs to be cancelled and a new one scheduled for V9 EOT, as the next visit to complete.

Thus, whenever a new version is created, the system will have a mapping structure in which each old visit is mapped to one and only one new visit or to a DELETED status, and every new visit is mapped to one and only one prior visit or has a NEW status. Upon study creation, the old and new visits are identical and therefore default to linked. Any newly created visit defaults to NEW status and any deleted visit maps to DELETED.

This mapping will be done "behind the scenes". Specifically, upon copying a template, the old and new visits are identical and therefore linked. Those visits remain linked, and any newly added visit defaults to NEW, and any deleted visit maps to DELETED.

It's important, therefore, that the Designer keep these rules in mind when copying templates. In the above example, the right way to set up the visit schedule for the second version is to:

5. Add a new visit called v4 WEEK 1.
6. Rename the visit from v4 WEEK 2 to v5 WEEK 2 TREATMENT.
7. Add a new visit called v8 WEEK 12.
8. Delete the visit labeled v7 WEEK 16.

Number	Requirement	Release Version	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

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: • Sponsor • Protocol Number • Market Name • Description • CRO • Sponsor IRB • Phase • Title • CT Gov Identifier 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. 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.	V20 (20210604)	J-EDC57 J-EDC58
26.03	The Designer should be able to create a Version and name/rename it before publication.	V20 (20210604)	J-EDC30 J-EDC32
26.04	The Designer should be able to delete a Version before publication.	V20 (20210604)	J-EDC30 J-EDC32
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
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
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
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
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
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
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. *Note: This is a flip view of the above.*	V20 (20210604)	J-EDC123 J-EDC120

Sites Receiving Templates

When a template is published, a receiving site will inherit the template - there is no explicit need for the site to “accept” the template; it simply appears in the site’s dashboard and will be designated visually as a master controlled template.

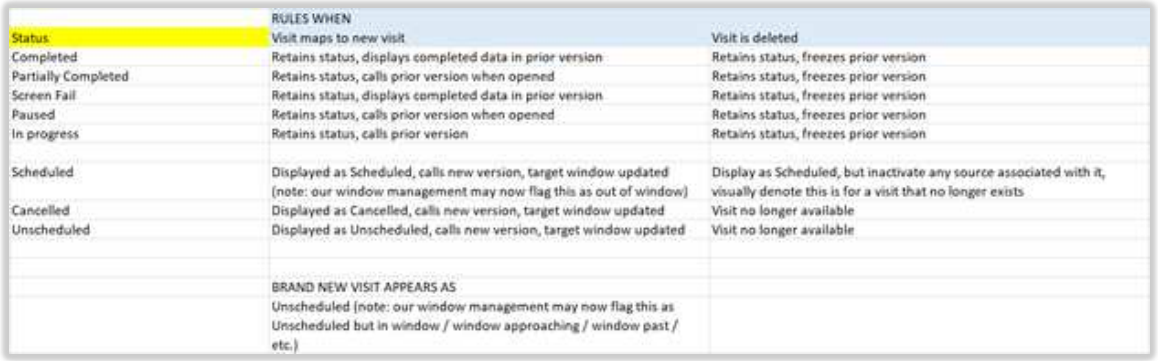
The site will be able to view the configuration inherited, but not be able to make any modifications to it. However, the site may update the configuration by adding a visit, a procedure, or a question to a specific procedure, or even an alert or disable logic that references an inherited question.

When a new version is received, it replaces the prior version.

As discussed above, there will be some implications to the scheduling module:

- Any visit from the old template, once opened and data saved, retains its old structure. So a completed visit that is now DELETED always remains. This is consistent with the principle that study data, once collected, is NEVER deleted.
- Any scheduled visit needs to re-map to the new equivalent visit.
- If a scheduled visit maps to a DELETED visit, the system should delete the appointment.

The following are the specific manifestation of the above rules:



	RULES WHEN	
Status	Visit maps to new visit	Visit is deleted
Completed	Retains status, displays completed data in prior version	Retains status, freezes prior version
Partially Completed	Retains status, calls prior version when opened	Retains status, freezes prior version
Screen Fail	Retains status, displays completed data in prior version	Retains status, freezes prior version
Paused	Retains status, calls prior version when opened	Retains status, freezes prior version
In progress	Retains status, calls prior version	Retains status, freezes prior version
Scheduled	Displayed as Scheduled, calls new version, target window updated (note: our window management may now flag this as out of window)	Display as Scheduled, but inactivate any source associated with it, visually denote this is for a visit that no longer exists
Cancelled	Displayed as Cancelled, calls new version, target window updated	Visit no longer available
Unscheduled	Displayed as Unscheduled, calls new version, target window updated	Visit no longer available
	BRAND NEW VISIT APPEARS AS	
	Unscheduled (note: our window management may now flag this as Unscheduled but in window / window approaching / window past / etc.)	

	RULES WHEN	
Status	Visit maps to a modified visit	Visit is deleted
Completed	Retains status, displays completed data in prior version	Retains status, freezes prior version
Partially Completed	Retains status, calls prior version when opened	Retains status, freezes prior version
Screen Fail	Retains status, displays completed data in prior version	Retains status, freezes prior version
Paused	Retains status, calls prior version when opened	Retains status, freezes prior version
In progress	Retains status, calls prior version	Retains status, freezes prior version
Scheduled	Displayed as Scheduled, calls new version, target window updated (note: our window management may now flag this as out of window)	Displayed as Scheduled, but inactivates any source associated with it, visually denote this is for a visit that no longer exists
Cancelled	Displayed as Cancelled, calls new version, target window updated	Visit no longer available
Not Scheduled	Displayed as Not Scheduled, calls new version, target window updated	Visit no longer available
	BRAND NEW VISIT APPEARS AS Not Scheduled (note: our window management may now flag this as	

	unscheduled but in window / window approaching / window past / etc.)	

CRIO has in its roadmap an out-of-window visit queue system to alert the site when a scheduled or completed visit is out-of-window. This queue system will help the site better manage visit window impact as they inherit new templates.

Number	Requirement	Release Version	Ticket
26.12	In the inherited study in the Receiving Site, the following attributes are pre-populated from the Master Site and non-editable: • Sponsor • Protocol Number • Market Name • Description • CRO • Sponsor IRB • Phase • Title • CT Gov Identifier The site may populate all remaining fields in Study Overview (e.g., Site #, Nickname, Status, Target Enrollment...etc).	V20 (20210604)	J-EDC57 J-EDC58
26.13	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. Here is what the site can do: • 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	V20 (20210604)	J-EDC57 J-EDC58 J-EDC60

	can have the "Yes" response trigger the site's custom-added question, "Was any blood clotting observed?" Here's what the site cannot do with respect to the inherited template: • Delete a visit • Move a visit • 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
26.15	The version should be visible in the following areas and upon print-out: • 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
26.16	When a new version is published, it replaces the prior version received.	V20 (20210604)	J-EDC30 J-EDC32
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
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

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
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
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
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
26.23	When a new version is published to a site that has added custom questions, these are the rules: • 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