



CLINCAPTURE

USER'S GUIDE

Version 2.1.0

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1 INTRODUCTION TO CLINCAPTURE

This document describes the features of ClinCapture 2.1.0. You access the ClinCapture software using a web browser. For a list of supported web browsers, consult the [Compatibility and System Requirements](#) page on ClinCapture’s community website.

ClinCapture was initially released in 2009 and was based on the OpenClinica code base, originally developed by Akaza Research in 2005. Clinovo made use of its own expertise as a clinical research organization and the feedback from its customers to greatly improve the code quality while, at the same time, transforming it into a simpler and more intuitive system to use. Today, ClinCapture is the world’s most advanced [open-source software for clinical research](#).

Keeping up with the open source spirit, Clinovo has established a community where users and developers can freely collaborate to further improve and enrich the system, as well as access the source code and the documentation. Clinovo cordially invites you to visit the [ClinCapture Community](#), learn how to use its various clinical research resources, and actively participate!

1.1 Target Audience

This document is intended for clinical researchers involved in data collection, submission, monitoring, management, and extraction. As such, it does not cover advanced configuration and programming topics that are fully discussed in the *ClinCapture Administrator’s Guide* and the *ClinCapture Programmer’s Guide*.

1.2 Document Organization

After the Introduction, Key Concepts, and Getting Started sections, the body of this document is organized according to the modules in the ClinCapture **Task Menu**, excluding the Study Setup and Administration modules, which are covered in the *ClinCapture Administrator’s Guide*:

- Submit Data
- Monitor and Manage Data
- Extract Data

1.3 Typographical Conventions

Example	Description
User Roles	Blue, underlined font indicates a hyperlink inside this document or on the Web.

Forgot Password	Light blue, underlined font indicates a hyperlink inside the ClinCapture system.
Submit	Bold font indicates verbatim text from ClinCapture, often used to identify a button, icon, or field.
<i>Home</i>	Italics font indicates a webpage, document name, or emphasis.

1.4 License Information

ClinCapture is distributed under the GNU Lesser General Public License (GNU LGPL). The GNU Lesser General Public License is a free software license; as such, it grants you the following freedoms:

- The freedom to run the program for any purpose.
- The freedom to study how the program works, and to adapt it to your needs.
- The freedom to redistribute copies so you can help your neighbor.
- The freedom to improve the program and release your improvements to the public, so that the whole community benefits.
- You may exercise the freedoms specified here, provided that you comply with the expressed conditions of this license. The LGPL is intended for software libraries, rather than executable programs. The principal conditions are:
 - You must conspicuously and appropriately publish on each copy distributed an appropriate copyright notice and disclaimer of warranty and keep intact all the notices that refer to this license and to the absence of any warranty; and give any other recipients of the program a copy of the GNU LGPL along with the program. Any translation of the GNU LGPL must be accompanied by the GNU LGPL.
 - If you modify your copy or copies of the library or any portion of it, you may distribute the resulting library provided you do so under the GNU LGPL. However, programs that link to the library may be licensed under terms of your choice, so long as the library itself can be changed. Any translation of the GNU LGPL must be accompanied by the GNU LGPL.
 - If you copy or distribute the library, you must accompany it with the complete corresponding machine-readable source code or with a written offer, valid for at least three years, to furnish the complete corresponding machine-readable source code. You need not provide source code to programs which link to the library.
- Any of these conditions can be waived if you get permission from the copyright holder. Your fair use and other rights are in no way affected by the above.
- For details see <http://www.gnu.org/licenses/lgpl-2.1.html>, or LICENSE.txt provided with the ClinCapture distribution.



1.5 Referencing ClinCapture

If you used ClinCapture to capture data for your study, you can reference it as follows:

“Data collection and management for this study was performed using ClinCapture, an open source system, version 2.1.0.”

2 KEY CONCEPTS

This section introduces the key concepts embodied in ClinCapture, presents a typical Electronic Data Capture (EDC) workflow, and describes the role-based user interface and functionality.

2.1 Functional Overview

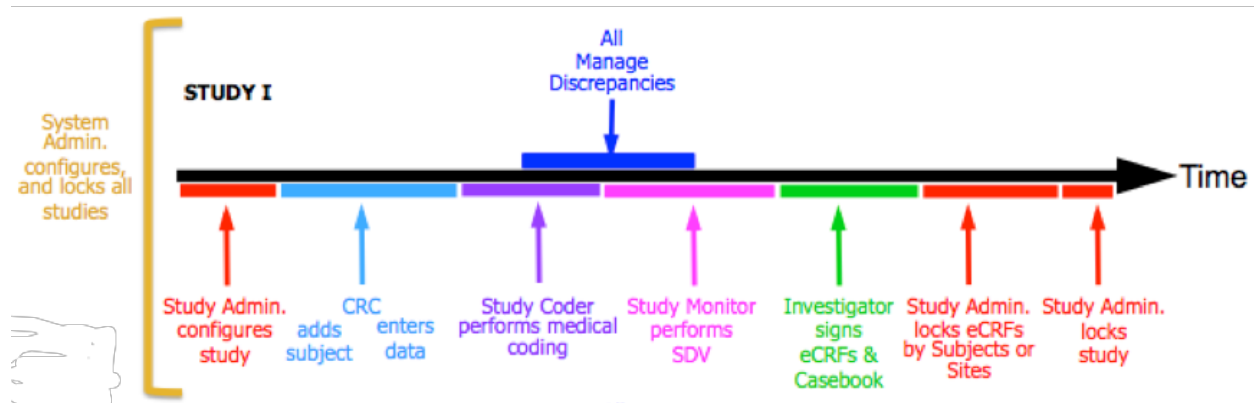
ClinCapture provides a comprehensive set of role-based features to perform EDC during clinical trials, including:

- Creating and managing studies
- Creating and managing users and sites
- Adding and randomizing subjects
- Scheduling Events, also known as visits
- Entering clinical data in Electronic Case Report Forms (eCRFs)
- Optionally performing double data entry
- Optionally performing CRF evaluation
- Performing medical coding
- Raising and resolving Notes & Discrepancies, also known as queries
- Performing Source Data Verification (SDV)
- Applying electronic signatures
- Creating and managing datasets
- Importing and exporting data
- Interfacing programmatically through a web service API to other eClinical systems such as ePRO, CTMS, IWRS, and Core Labs

2.2 Typical EDC Workflow

The figure below illustrates a typical EDC workflow in ClinCapture from Study configuration, to data locking.

Figure 1: Typical EDC Workflow in ClinCapture



This workflow can be changed to meet your specific study requirements. For example, an Investigator or Study Administrator may enter the data, or the data may be imported from an external source, such as a core lab. Subjects may be added automatically when ClinCapture is integrated with a CTM system. Discrepancy management may not be enabled, etc.

2.3 Color Themes

ClinCapture can be configured with different colors to avoid possible confusion between the different instances: Development, Training, and Production, as illustrated in Figure 2. This avoids entering training data in the Production instance, for example. The actual color chosen for your specific implementation may vary and you should consult your case report form (CRF) completion guidelines for details.

There are four color themes you can choose from: Blue, Dark Blue, Green, and Violet.

Figure 2: Typical color theme assignment



This screenshot shows the 'Subject Matrix for Stanford Medical Clinic' interface with a green color theme. The table lists various subjects with columns for 'Subject ID', 'Study ID', 'Treatment 1', 'Treatment 2', 'Treatment 3', 'Treatment 4', 'Treatment 5', 'Treatment 6', 'Treatment 7', 'Treatment 8', and 'Action'. The data rows are color-coded with green and white, and the table header is green.

Development Instance



This screenshot shows the 'Subject Matrix for Stanford Medical Clinic' interface with a blue color theme. The table structure and data are identical to the development instance, but the header and row colors are blue and white.

Training Instance



This screenshot shows the 'Subject Matrix for Stanford Medical Clinic' interface with a purple color theme. The table structure and data are identical to the other instances, but the header and row colors are purple and white.

Production Instance

2.4 Interface Language

The ClinCapture interface can be configured to display in different languages.

There are two languages you can choose from: English and Russian.

2.5 About Users

In ClinCapture, each user is assigned a user level, type, and role. The user level, type, and role combination determines the ClinCapture Modules shown in the **Tasks** menu and the features the user can access.

2.5.1 User Levels

Each user is assigned to a single user level: System-level, Study-level, or Site-level. The user level is determined when the user is created and assigned to either a Study or a Site, and cannot be changed thereafter.

- System-level** users can perform tasks across all Studies, including performing tasks at each Site within that Study. These users can set their current scope to any Study or any Site within a Study. The user role and user type cannot be changed.
- Study-level** users can perform tasks at the Study level, including performing tasks at each Site within that Study. These users can set their current scope to the Study or any Site within the Study. They can also be assigned to multiple studies.
- Site-level** users can only perform tasks at a Site for which they have been assigned. A Site-level user can be assigned to multiple Sites.

2.5.2 User Types

ClinCapture has two user types: *Administrator* and *User*. A user type is assigned when the user is created, and can be changed at any time.

The assigned user type applies to all Studies and Sites in the system. That is, a user cannot have different user types for different Studies and Sites.

User Type: Administrator

Administrator user types have access to the features in the Administration module and can perform the following tasks:

- Create new Studies
- Work with information across multiple Studies
- Manage User accounts
- Schedule data import and export jobs

Administrator user types can create, modify, and remove users, except for the System Administrator (root).

User Type: User

User user types cannot access the features in the Administration module. They can access features to work on Studies or Sites they have been granted access to, such as adding Study Subjects, scheduling Study Events, and completing CRFs.

2.5.3 User Roles

User roles in ClinCapture are based on the roles typically found in clinical trials and in other forms of clinical research. The user role determines the features a user can access within a particular Study or Site. The user roles supported by ClinCapture are:

- System Administrator (root)
- Study Administrator
- Study Monitor
- Site Monitor
- Study Coder (only visible if Study parameter, **Allow medical coding**, is **yes**)
- Study Evaluator (only visible if System or Study parameter, **Allow CRF evaluation**, is **yes**)
- Investigator
- Clinical Research Coordinator

The user roles available at the Study-level are different from the roles available at the Site-level. A user can have a different role in the Study or Site in which they are assigned, as long as the new role remains in the same level (Study or Site) as the initial role.

Table 1: ClinCapture supported user level, role, and type combinations

User Level	User Role	User Type
System Level	System Administrator	Administrator
Study Level	Study Administrator	Administrator
	Study Monitor	User
	Study Coder	User
	Study Evaluator	User
Site Level	Investigator	User
	Clinical Research Coordinator	User
	Study Evaluator	User
	Site Monitor	User

2.5.4 CRF Masking

When site level users are created in ClinCapture, either Clinical Research Coordinators or Monitors, the study administrator has the option to mask, or hide, one or more CRFs from the user. When a CRF is masked, the user cannot take any action on the masked CRFs.

Note that masking is disabled for users with a role of Investigator.

2.6 ClinCapture Modules

Table 2 lists the ClinCapture Modules and main tasks available for each user role. When your user type or role is not allowed to access a particular ClinCapture Module or task, it does not appear in the **Tasks** menu.

Table 2: Available Modules and Tasks per User role

User Role	ClinCapture Module	Tasks
System Administrator	Submit Data	<ul style="list-style-type: none"> Subject Matrix Notes & Discrepancies Import Data Schedule Event View Events
	Monitor and Manage Data	<ul style="list-style-type: none"> Source Data Verification Study Audit Log Rules Groups CRFs Code Reports
	Extract Data	<ul style="list-style-type: none"> Datasets
	Study Setup	<ul style="list-style-type: none"> View and Build Study Assign Users System
	Administration (only available for Administrator user types)	<ul style="list-style-type: none"> Studies Sites Users CRFs Jobs Subjects
	Other	<ul style="list-style-type: none"> Update Profile Help

		<ul style="list-style-type: none"> • Support • Log Out • Forums • About
Study Administrator	Submit Data	<ul style="list-style-type: none"> • Subject Matrix • Notes & Discrepancies • Import Data • Schedule Event • View Events
	Monitor and Manage Data	<ul style="list-style-type: none"> • Source Data Verification • Study Audit Log • Rules* • Groups* • CRFs* • Code • Reports
	Extract Data	<ul style="list-style-type: none"> • Datasets
	Study Setup	<ul style="list-style-type: none"> • View and Build Study • Assign Users • System
	Administration (only available for Administrator user types)	<ul style="list-style-type: none"> • Sites • Users* • CRFs* • Jobs* • Subjects*
	Other	<ul style="list-style-type: none"> • Update Profile • Help • Support • Log Out • Forums • About
Study Monitor	Monitor and Manage Data	<ul style="list-style-type: none"> • Subject Matrix • View Events • Source Data Verification • Notes & Discrepancies • Study Audit Log • Reports
	Extract Data	<ul style="list-style-type: none"> • Datasets
	Other	<ul style="list-style-type: none"> • Update Profile • Help

		<ul style="list-style-type: none"> • Support • Log Out • Forums • About
Study Coder	Monitor and Manage Data	<ul style="list-style-type: none"> • Code
	Other	<ul style="list-style-type: none"> • Update Profile • Help • Support • Log Out • Forums • About
Study Evaluator	Monitor and Manage Data	<ul style="list-style-type: none"> • Evaluate CRF • Notes & Discrepancies
	Other	<ul style="list-style-type: none"> • Update Profile • Help • Support • Log Out • Forums • About
Investigator	Submit Data	<ul style="list-style-type: none"> • Subject Matrix • Add Subject • Notes & Discrepancies • Schedule Event • View Events • Import Data
	Extract Data	<ul style="list-style-type: none"> • Datasets
	Other	<ul style="list-style-type: none"> • Update Profile • Help • Support • Log Out • Forums • About
Clinical Research Coordinator	Submit Data	<ul style="list-style-type: none"> • Subject Matrix • Add Subject • Notes & Discrepancies • Schedule Event • View Events • Import Data
	Other	<ul style="list-style-type: none"> • Update Profile • Help

		<ul style="list-style-type: none"> • Support • Log Out • Forums • About
Site Monitor	Monitor and Manage Data	<ul style="list-style-type: none"> • Subject Matrix • View Events • Source Data Verification • Notes & Discrepancies • Study Audit Log
	Extract Data	<ul style="list-style-type: none"> • Datasets
	Other	<ul style="list-style-type: none"> • Update Profile • Help • Support • Log Out • Forums • About

* Available from Study-level only

2.7 Changing the Current Scope

ClinCapture limits the information you can access based on the current scope. The current scope is either the Study-level or Site-level.

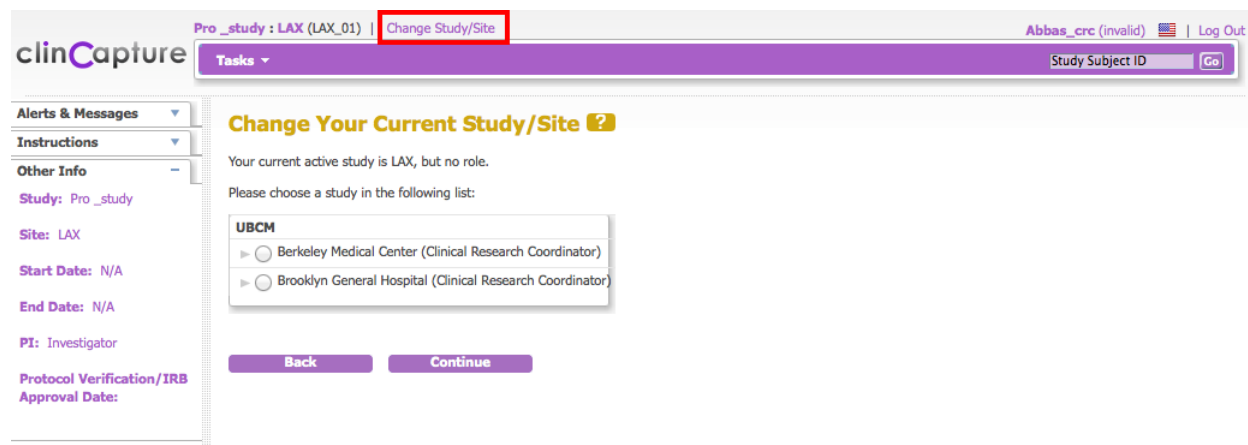
Note: A Study can include one or more Sites.

At the Study-level, you have access to information from all the Sites included in the Study. However, at the Site-level you can only access information specific to a particular Site. Therefore, if you work with more than one Study or Site, it is important to set your scope according to the task you want to perform.

To change the current scope:

1. Click the [Change Study/Site](#) link, just above the Navigation Bar.
2. Select the desired Study or Site. Site names are indented under the Study name.
3. Click [Change Study/Site](#) to open the *Confirm Changing Study* page.
4. Click **Continue**.
5. Click **Submit** to confirm your scope change.

Figure 3: Change current Study/Site page



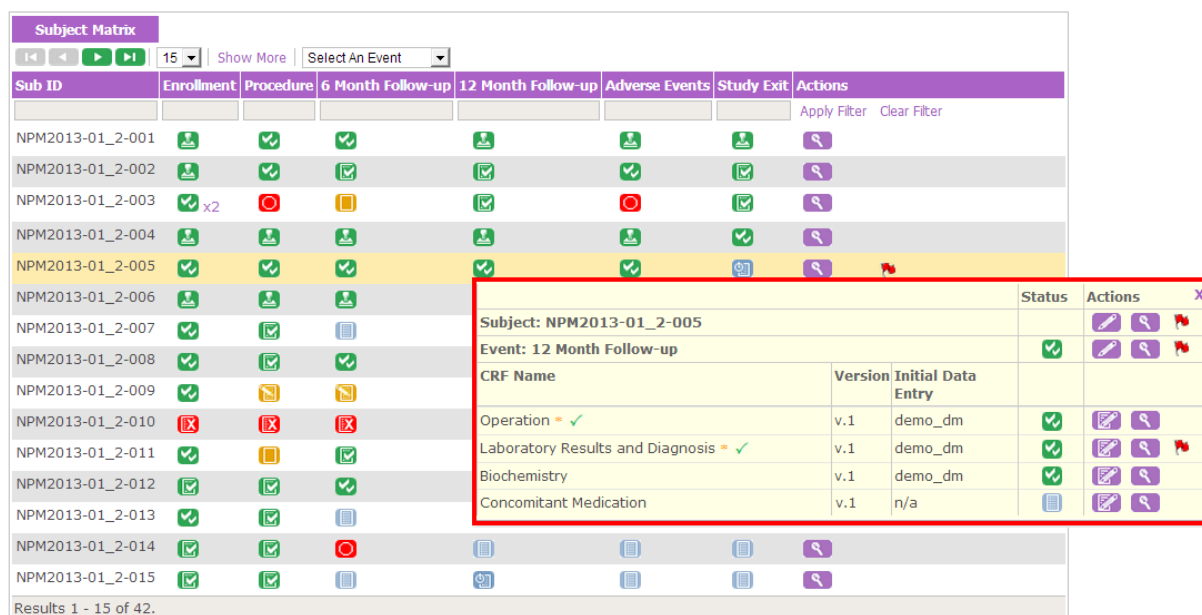
To automatically select a Study when you login, set it as the Default Current Study in your User Profile.

2.8 One-Click Access™

The ClinCapture One-Click Access™ feature allows you to perform many essential functions in just one click from the Subject Matrix, such as data entry, scheduling events, performing Source Data Verification (SDV), and signing eCRFs.

To trigger One-Click Access, position your cursor over a Study Event status icon and after a short delay a pop-up will appear. For a faster reaction, click the icon.

Figure 4: One-Click Access popup



Sub ID	Enrollment	Procedure	6 Month Follow-up	12 Month Follow-up	Adverse Events	Study Exit	Actions
NPM2013-01_2-001							
NPM2013-01_2-002							
NPM2013-01_2-003							
NPM2013-01_2-004							
NPM2013-01_2-005							
NPM2013-01_2-006							
NPM2013-01_2-007							
NPM2013-01_2-008							
NPM2013-01_2-009							
NPM2013-01_2-010							
NPM2013-01_2-011							
NPM2013-01_2-012							
NPM2013-01_2-013							
NPM2013-01_2-014							
NPM2013-01_2-015							

Subject: NPM2013-01_2-005			Status	Actions
Event: 12 Month Follow-up				
CRF Name	Version	Initial Data Entry		
Operation	v.1	demo_dm		
Laboratory Results and Diagnosis	v.1	demo_dm		
Biochemistry	v.1	demo_dm		
Concomitant Medication	v.1	n/a		



The pop-up only contains the action icons valid for your role and the clinical data status. For example if your role is Investigator, a **Sign** icon appears only if the following conditions have been met:

- All the required CRFs have been completed
- The data has been verified according to the SDV requirement
- All the queries are closed

Notes and Discrepancies are also directly accessible from the pop-up. Click the flag icon to view the list of discrepancies related to a particular subject, event, or CRF. The flag color indicates the status of the discrepancy, see [Discrepancy Note Status](#). When multiple discrepancy statuses exist, **New** takes precedence over **Updated**, which has precedence over **Closed**. **Annotations** and **Reason For Changes** notes are not reported in the pop-up. For details about notes, see [Notes & Discrepancies](#).

One-Click Access saves time by drastically reducing the number of clicks and accelerating your data collection, verification, and approval processes.

3 GETTING STARTED

This section shows you how to get started using ClinCapture. It explains how to login, reset your password, change your user profile, and logout.

3.1 How to Login

To access the ClinCapture *Login* page, use the URL provided in your CRF Completion Guidelines, or through your Study Administrator. Please note that your company logo may appear instead of the Clinovo logo at the bottom of the *Login* page.

Figure 5: ClinCapture login page



Useful resource links available at the lower left of the page include:

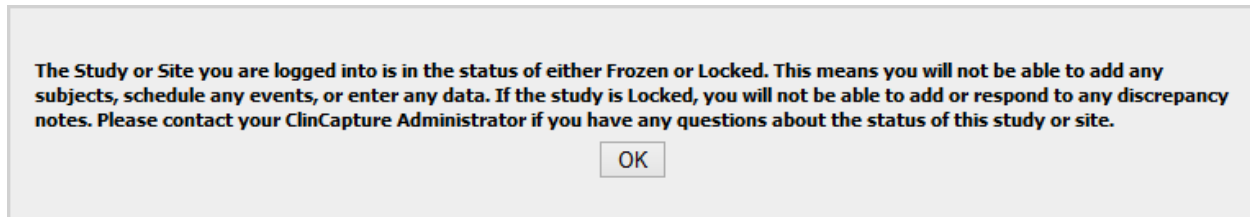
- ❑ **About:** Display the ClinCapture license. See [License Information](#) for details.
- ❑ **Support:** Get support for any technical issue. Fill out the form and click **Submit** to send a message to the Study Administrator. You can also use the [Community](#) or [Forums](#) links on the login page to share your current issue or question with other ClinCapture users and developers.
- ❑ **Forums:** Open the ClinCapture Forum page where users can discuss all things ClinCapture.
- ❑ **Community:** Open the ClinCapture Community page which provides valuable information and links to the developers' workspace, getting started with ClinCapture, forums, news and upcoming events, a CRF library, and much more.

The ClinCapture software version appears at the lower right of the page.

To login, enter your user name and password, and click **Login**. If the credentials you entered are valid, the home page appears, see [Home Page Framework](#).

If the Study (or Site) you are working with is locked or frozen, that is they are no longer accepting data entry, the following message appears.

Figure 6: Frozen/Locked message



3.1.1 Login Problems

Your account may be administratively locked if you tried to login too many times, or if you have not logged in for an extended period of time. In this case, contact your Study administrator or click the [Support](#) link to get help with your account.

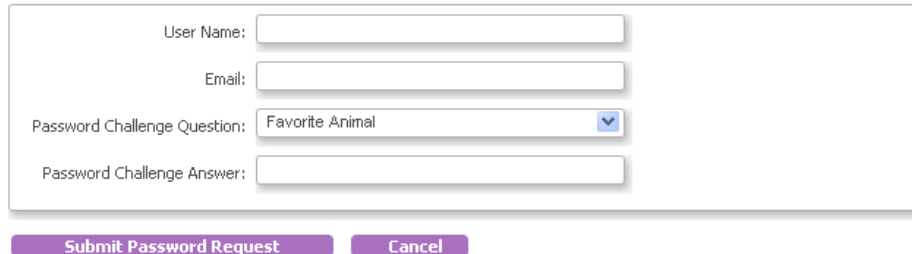
If you simply forgot your password, you can request a new one, as follows:

1. Click the [Forgot Password](#) link on the *Login* page to open the *Request Password Form* page.

Request Password Form

You must have a valid ClinCapture user account to receive a password. Please fill out all the fields in the following form. ClinCapture will use the e-mail address associated with your account to send you the password. If you still have questions, please contact your ClinCapture Administrator for help.

All fields are required.



2. Enter your User Name, Email, and your Challenge Question/Answer.
3. Click **Submit Password Request**.

If the information you provided was correct, you will receive an email with your temporary password. This temporary password allows you to login to establish a new password. See [Changing Your Password](#) for details.

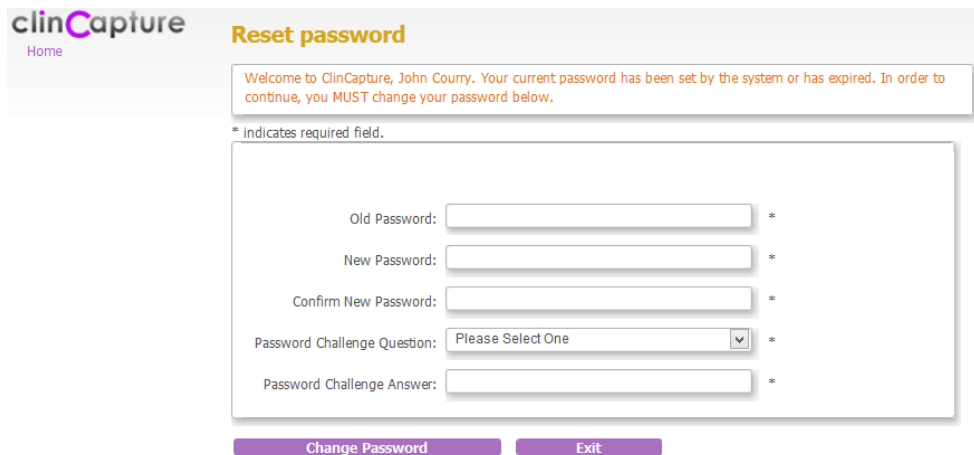
If you do not receive an email with a temporary password, contact your Study Administrator (you can click the [Support](#) link on the *Login* page to send your Study Administrator a message).

3.1.2 Changing Your Password

Your new password must meet the password policy set by your Administrator and may require a combination of upper case and special characters. Please note that the system may also have a policy of preventing you from reusing previously used passwords. Please contact your Study Administrator for details on the password policy.

To reset your password:

1. Click the link in the email you received to open the *Reset password* page.



2. Enter your old (or temporary) password.
3. Enter your new password, ensuring it meets the system password policy.
4. Confirm your new password by entering it again.
5. Set your challenge question and answer.
6. Click **Change Password**.

3.1.3 Updating Your User Profile

To update your user profile:

1. On the Navigation Bar, select **Tasks > Update Profile** to open the *Change User Profile* page.

Change User Profile ?

ClinCapture is currently being displayed in the English / United States language.

* indicates required field.

First Name:	<input type="text" value="CC"/>	*
Last Name:	<input type="text" value="Admin"/>	*
Email:	<input type="text" value="studyadmin@example.com"/>	*
Institutional Affiliation:	<input type="text" value="Clinovo"/>	*
Default Active Study:	<input type="text" value="Default Study"/>	
Password Challenge Question:	<input type="text" value="Favorite Color"/>	*
Password Challenge Answer:	<input type="text" value="blue"/>	*
Current Password:	<input type="text"/>	*
New Password:	<input type="text"/>	
Confirm New Password:	<input type="text"/>	(leave it blank if you don't want to change password)
Phone:	<input type="text"/>	
	(ex: +375295002030)	

[Back](#) [Continue](#)

2. Make the necessary changes to your name, email address, default active Study, password challenge question, password, and/or phone number, and click **Continue**.

Confirm User Profile Updates

First Name:	CC
Last Name:	Admin
Email:	studyadmin@example.com
Institutional Affiliation:	Clinovo
Default Active Study:	Default Study
Password Challenge Question:	Favorite Color
Password Challenge Answer:	blue
Phone:	

[Back](#) [Submit](#)

3. Verify the information, and click **Submit** to save the changes, or click **Back** to make additional changes. A message in the Alerts and Messages areas of the *Left Panel* notifies you that your profile was updated successfully.

3.1.4 Logging Out

Click the Log Out link to exit ClinCapture.














3.2 ClinCapture Icons

ClinCapture uses icons to represent the state of certain objects, such as Study Events and CRFs, or to initiate an operation on them, for example to apply an electronic signature on a Subject’s casebook.

The color of the icons depends on your ClinCapture color scheme. For details, see [Color Themes](#).









3.2.1 Status Icons

The Status Icons indicate the status of a particular Study Event and its Case Report Forms (CRFs). The Study Event status is based on the overall and total status of the CRFs in a Study. That is, if three CRFs in a Study were completed, but a fourth one just started data entry, the Event status shows the Data entry started icon. The Event status also indicates if the CRFs are Completed or Source Data Validated.















Icon	Meaning
	Not started
	Scheduled
	Data Entry Started
	Stopped
	Skipped
	Completed
	Initial Data Entry Completed
	Coded
	Not Coded
	Source Data Validated (SDV)
	Signed
	Locked
	Removed






3.2.2 Frequently Used Icons

The availability of a particular icon and its action when you click it are dependent on your user role. They are customized to your needs and responsibilities.

Icon	Meaning	Description
	View	Click to see the details of the function associated with the icon.
	Edit	Click to change the descriptions associated with the function.
	Set Role	Click to assign roles for the User within the Study.
	Remove	Click to remove a function.
	Lock	Click to lock subject records.
	Unlock	Click to unlock subject records.
	Restore	Click to restore a function that was previously removed. (The icon appears only after a function has been removed.)
	Print	Click to send output to a pop-up window then use your browser print function to send this output to the printer, or click on the Print button inside some windows.

3.2.3 Other Icons

Icon	Meaning
	Administrative editing
	Archive
	Calendar
	Create new
	Delete
	Discrepancy Note: Add
	Discrepancy Note: New
	Discrepancy Note: Not Applicable
	Discrepancy Note: Closed
	Discrepancy Note: Updated
	Download
	Export/Test/View in context
	Form contains changed/unsaved data
	Form has unchanged data

	Help
	New version
	Reassign
	Remove
	Un-archive

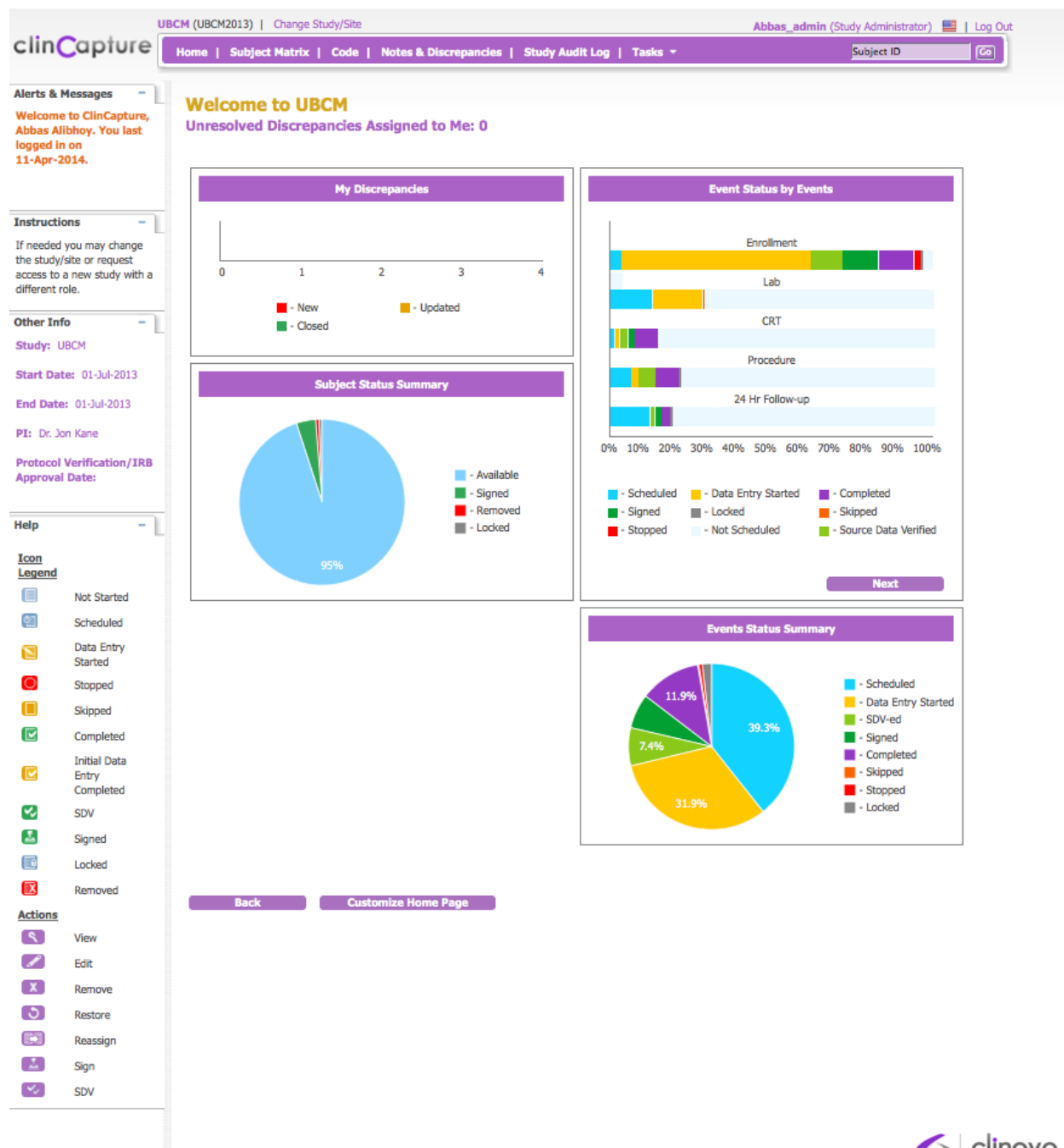
3.3 Home Page Framework

The ClinCapture *Home* page displays after you log in, change a Study (or Site), or click [Home](#) in the Navigation Bar. What you see on the *Home* page, and the tasks available to you, depend on your user role and user type.

Regardless of the user role, the *Home* page contains the following common areas:

- Header
- Navigation Bar
- Side Panel
- Main Body
- Footer

Figure 7: ClinCapture Home page



UBCM (UBCM2013) | Change Study/Site Abbas_admin (Study Administrator) | Log Out

clinCapture Home | Subject Matrix | Code | Notes & Discrepancies | Study Audit Log | Tasks

Alerts & Messages
Welcome to ClinCapture, Abbas Alibhoy. You last logged in on 11-Apr-2014.

Instructions
If needed you may change the study/site or request access to a new study with a different role.

Other Info
Study: UBCM
Start Date: 01-Jul-2013
End Date: 01-Jul-2013
PI: Dr. Jon Kane
Protocol Verification/IRB Approval Date:

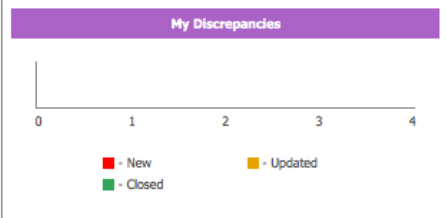
Help
Icon Legend

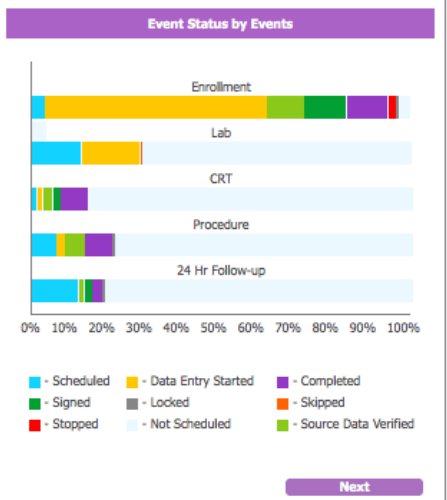
- Not Started
- Scheduled
- Data Entry Started
- Stopped
- Skipped
- Completed
- Initial Data Entry Completed
- SDV
- Signed
- Locked
- Removed

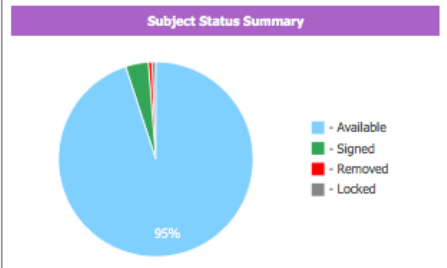
Actions

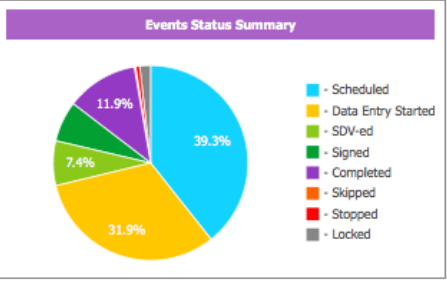
- View
- Edit
- Remove
- Restore
- Reassign
- Sign
- SDV


Welcome to UBCM
Unresolved Discrepancies Assigned to Me: 0

My Discrepancies


Event Status by Events


Subject Status Summary


Events Status Summary


V. 2.0.2 Rev: 1360 

3.3.1 Home Page Header

The *Home* page header is the top area, just above the Navigation Bar. It contains:

- ❑ **Name of Current Study:** The current Study name, and the current Site if one is selected. Click the name to read more information about the Study or Site.
- ❑ **Change Study/Site:** Allows you to change the current Study or Site. See [Changing the Current Scope](#) for more details.
- ❑ **User Name and Role:** The name of the user currently logged in to ClinCapture and their assigned role, such as Study Monitor.
- ❑ **Flag:** Indicates the language locale for the system.
- ❑ **Log Out:** Ends your ClinCapture session.

3.3.2 Navigation Bar

The Navigation Bar, at the top of the *Home* page, provides access to the most commonly used ClinCapture features based on your user role.

- ❑ **Home:** Shows the *Home* page for the current Study or Site.
- ❑ **Subject Matrix:** Shows the Events status for all Subjects within your current scope: Study or Site. You can view and perform various operations on Subjects, Events, and associated CRFs. There is one Subject per row, starting with the Study Subject ID in the first column. The other columns are for each Event Definition in the Study. Each cell contains a colored icon that identifies the status of the Event(s) for the Study Subject. Move the cursor over an icon in the matrix to view and access a Subject's Data and Actions for that Event. Refer to the icon legend in the Side Panel for icon descriptions. See [Subject Matrix](#) for more details.
- ❑ **Code:** Allows you to perform medical coding on medical terms that have been reported in CRFs.
- ❑ **SDV:** Allows a Study or Site Monitor to view the source data verification information for subjects and data in a Site or Study. This feature only appears in the Navigation Bar for Study or Site Monitor roles. See [Source Data Verification](#) for more details.
- ❑ **Add Subject:** Allows you to add a new Subject to a Study. This item only appears in the Navigation Bar for Investigator and CRC roles. See [Add Subject](#) for more details.
- ❑ **Notes & Discrepancies:** Serves as a venue for query and discrepancy management. This feature allows you to verify the accuracy and completeness of data gathered in a particular clinical trial. Use this set of tools to flag and track issues, such as incomplete and inaccurate data, that arise when capturing, monitoring, and managing data in a Study. This could also be used to facilitate communication between Users, such as Clinical Research Coordinators and Monitors, to resolve and clarify critical issues with dispatch. See [Notes and Discrepancies](#) for more details.
- ❑ **Study Audit Log:** Provides a history of actions for Subjects in the Study. See [Study Audit Log](#) for more details.
- ❑ **Tasks:** Contains a menu of actions you can perform in ClinCapture. The actions are grouped into modules in the **Tasks** menu. Modules and items included in the **Tasks** menu depend on the allowable activities linked and assigned to your user role.
- ❑ **Search Box and Go Button:** Allows you to view a history of Events for a particular Subject and to access other information about the Subject. Enter the Study Subject ID in the search box, and click **Go**.

3.3.3 Side Panel

The Side Panel is the area along the left edge of the page. The Side Panel is separated into sections which can be expanded and collapsed. Click the downward facing triangle (▼) to the right of the section name to expand a section and show its information, or click the minus sign (–) to collapse a section and hide its information.

- ❑ **Alerts and Messages:** Displays alerts and message when you perform actions in ClinCapture. For example, after you log in, a message reports the date you last logged in. Look here for confirmation that an action you performed was successful, or to see if there were any errors.
- ❑ **Instructions:** Provides brief directions or a summary of what you can do at that point in ClinCapture. For more information, click the **Help** button (🔍) in the body of the page.
- ❑ **Other Information:** Shows the name of the current Study or Site, start and end date of the Study, the name of the Principal Investigator, and the Protocol Verification/IRB Approval Date, if applicable. Click the Study or Site name to see its details.
- ❑ **Help:** Shows the icons relevant to the current page and describes what each icon means. This section appears only when icons are used in the body of the page, such as for the Subject Matrix.

3.3.4 Main Body

The Main Body of the *Home* page is identical for all user roles. It contains interactive dashboards for the current Study or Site, showing statistics such as: My Discrepancies, Event Status by Events, Events Status Summary, and Subject Status Summary.

- ❑ **My Discrepancies:** Provides a graphical presentation of the number of new, updated, and closed discrepancies for the current Study or Site.
- ❑ **Event Status by Events:** Displays a graphical summary of Events for the current Study or Site, reporting the progress that has been made within each Event. Event progress is described in percentages using a stacked bar graph, with the corresponding Event Statuses shown in different colors.
- ❑ **Events Status Summary:** Presents a summary of the Status of Events in the Study as a pie chart with the percentage of Events at a given Status in the Study.
- ❑ **Subject Status Summary:** Presents a summary of the status of Subjects in the Study as a pie chart with the percentage of Subjects that are available, signed, removed, and locked.

The **Customize Home Page** button at the bottom of the page allows users to change the *Home* page layout via a drag and drop action.

3.3.5 Home Page Footer

The *Home* page footer is the bottom area, just below the Main Body. It shows the current ClinCapture version number.

3.4 Last Row Accessed

As you perform actions in ClinCapture, the system remembers your last row accessed and highlights that row in orange. Even if you navigate away from a page, and then return to that page within the current session, the last row accessed will still be highlighted in orange.

This feature is provided throughout all tables in ClinCapture.

For example, in the following image, the last action taken on the Subject Matrix page was for Subject ID S01-004, so that row is highlighted in orange.

Subject Matrix for Demo Study

Subject ID	Event Status	Event Date	Eligibility Criteria	Demographics	Randomization Form	Pain Score	02_Baseline Assessment	Actions	
NPM20-14-001		28-Oct-2014							
S01-001		09-Jun-2014							
S01-002		09-Jun-2014							
S01-003		09-Jun-2014							
S01-004		20-Jan-2012							
S01-005		08-Jun-2014							
S01-006		08-Jun-2014							
S01-007		08-Jun-2014							
S01-008		08-Jun-2014							
S01-009		21-Jan-2013							
S01-010		08-Jun-2014							
S01-011		09-Jun-2014							
S01-012		09-Jun-2014							
S01-013		09-Jun-2014							
S01-014		09-Jun-2014							

Results 1 - 15 of 133.

4 SUBMIT DATA

The ClinCapture Submit Data tasks allow users to track Subjects in the current Study, add new Subjects to the Study, view and schedule Events, enter and change information about Subjects and Events, create Notes & Discrepancies, and import data. To access the Submit Data features from the Navigation Bar, select **Tasks**, and select the feature you want to use.

Consult the [Glossary](#) for a full description of terms used in this chapter.

4.1 Subject Matrix

To access the Subject Matrix, click the [Subject Matrix](#) link in the Navigation Bar.

The *Subject Matrix* page contains the Event information for all Subjects within your current scope: Site or Study. You can perform any action appropriate and allowable to your role, including viewing and entering information, performing Source Data Verification (SDV), and signing CRFs for Study Events and Subjects.

Each row contains one Subject. The first column is the Study Subject ID, the last column contains the available actions for the Subject, and the other columns are for each Event Definition in the Study. Each cell in the matrix contains an icon that describes the status of the Event for the Study Subject. The Event Status is a composite of the CRF's status and requirements configuration designed to bring your attention to the next logical task for an event. This is explained in greater details in [Event Status](#).

When the current scope is set to the Study level, the matrix shows all Subjects in the Study. When the current scope is set to a Site, the matrix shows only Subjects at that Site. See [Changing the Current Scope](#) for details.

4.1.1 Subject Matrix Pop-up

If you place your cursor over an Event status icon, a pop-up appears after a short delay. For a faster reaction, click the icon. The pop-up remains visible if you click inside it—a move that gives you additional time to scroll or adjust the window. The pop-up disappears if you click anywhere outside of it.

If you place your cursor over an unscheduled Event, the following Pop-Up appears:

Figure 8: Scheduling an Event using the pop-up

Schedule Study Event for BGH-003

* indicates required field.

Subject ID: **BGH-003**
 Study Event Definition: Lab (non-repeating) *

Schedule Another Event: (optional)
 Schedule Another Event: (optional)
 Schedule Another Event: (optional)
 Schedule Another Event: (optional)


Note: The pop-up appears differently from time to time because the fields inside it are configurable. For instance, your Study may require collection of the location and the end date.

If you place your cursor over a scheduled Event, the pop-up contains the Action icons that are valid for, and related to, your role, and appropriate for the current status of the Subject, Event, and CRFs.


















You can also skip the event scheduling altogether and start collecting data right away by clicking on **Start Data Entry**. In this case, the *View Event* page appears allowing you to enter data in any CRF related to this study event.

Figure 9: View Event page

View Event: Lab for Subject BGH-003

Subject ID	BGH-003 
Study Event	Lab
Subject Event Status	scheduled
Last Updated by	Abbas_admin (21-Mar-2014)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Actions
Laboratory Evaluation * 	v. 1			  
Technologist *	v. 1			  
QA *	v. 2			  
Cardiologist/Radiologist *	v. 1			  

Workflow

Study Event Overview

→




















Data Entry

→

Mark Event CRF Complete

After an event is scheduled, if you position your pointer over the status icon, a Scheduled Event pop-up appears.

Figure 10: Sample Scheduled Event pop-up

			Status	Actions	X
Subject: BGH-003				  	
Event: Lab				  	
CRF Name	Version	Initial Data Entry			
Laboratory Evaluation * ✓	v. 1			 	
Technologist *	v. 1			 	
QA *	v. 2			 	
Cardiologist/Radiologist *	v. 1			 	

The icons in the first row are for actions valid for the Subject. Depending on your role and the status of the CRFs, you can Edit, View, Remove, SDV, Sign, or Re-Assign a Subject.

The icons in the second row relate to actions affecting the Event. Depending on your role and the status of the CRFs, various actions can be effected, such as: Edit, View, Remove, SDV, or Sign an Event.







Starting with the third row, the action icons relate to managing the CRFs. Depending on your role, various actions can be taken, such as Edit, View, Enter data, Print, Remove, or Delete a CRF.





The orange asterisk (*) at the end of a CRF name indicates that data must be submitted to the CRF.

The green check mark (✓) indicates that a full or partial SDV must be performed after data collection has been completed.

4.1.2 Subject Matrix Pop-up Action Icons

In the Subject Matrix pop-up, click the action icon to operate on the Subject, the Event, or CRF. The icons that appear depend on the status of the Subject, the Event, the CRFs, and your user role.

Icon	Meaning	Description
	Edit	Edit or modify an object such as a Subject or an Event.
	Enter Data	Allows users to enter data into a CRF.
	View	Displays information on an object such as a Subject, an Event, a Site or a CRF.
	SDV	Allows a Study or Site Monitor to verify the data was correctly entered and submitted. SDV can be performed by CRF, Event, or by Subject.
	Sign	Allows an Investigator to sign the entire Subject's casebook or an Event.
	Remove	Removes an object such as a Subject, an Event, a Site from the Study or Site. You can restore these objects to the Study or Site later.

	Restore	Restores an object that was previously removed. Restore brings back the object into the Study or the Site without data loss.
	Delete	Allows a Study Administrator to permanently delete an object, such as a CRF.
	Reassign Study Subject	Allows a Study Administrator to reassign a Study Subject to a different Site in the Study.
	Print	Print an object such as a CRF or a Note & Discrepancy.

4.1.3 Adding a Subject

Investigator and CRC users can add new Subjects. To add a Subject to a Study, click the [Add Subject](#) link in the Navigation Bar (or select **Tasks > Add Subject**). See [Add Subject](#) for more details.

Note: To work with a Subject across multiple Studies, or to change information about a Subject that cannot be changed using the Submit Data module, request help from your Study Administrator. These topics are covered in detail in the *ClinCapture Administrator's Guide*.

4.1.4 Scheduling a Subject

Before you can enter data, you must schedule a Subject for an Event. To schedule a Subject for an Event, click or position your pointer over the Event you want to schedule to display the Scheduled Study Event pop-up (see Figure 8).

You can schedule a Subject for up to five events at a time. When ready to schedule the Events and return to the Subject Matrix, click **Schedule Event**.

Optionally, to start capturing data for the scheduled Events, click **Start Data Entry**.

To dismiss the pop-up without making any changes, click **Cancel**.

4.1.5 Locking or Unlocking a Subject Record

A Study Administrator can lock or unlock the entire casebook for a Subject. The Lock icon appears in the Subject Matrix when a Subject is scheduled for their first event. See [User Roles](#) for details.



Icon	Meaning	Description
	Lock	Lock a Subject casebook.
	Unlock	Unlock a Subject casebook.

Figure 11: Lock/Unlock Subject icons in Subject Matrix

Subject Matrix for UBCM

Subject ID	Enrollment	Lab	CRT	Procedure	24 Hr Follow-up	1 Month Follow-up	2 Month Follow-up	3 Month Follow-up	End of Study	Common	Actions	
BGH-104												
BGH-103												
BGH-102												
BGH-101												
BGH-100												
BMC-100												
BGH-099												
BGH-098												
BMC-099												
BMC-059												
BMC-058												
BMC-057												
BMC-056												
BMC-055												
BMC-054												

If Notes & Discrepancies exist for the Subject, you can view the data in the CRF, and access and resolve the Notes & Discrepancies. However, the CRF data cannot be changed.

Note: You can also lock data at the Site and Study levels. See the *ClinCapture Administrator's Guide* for details.

4.1.6 Dynamic Groups

























































































































































In ClinCapture, you can associate specific Study Events with a Dynamic Group. For example, to create multiple treatment arms, different Dynamic Groups can be configured with different Study Events.

Dynamic Groups include the following features:

- The Dynamic Group name is located just above its associated Event names. In Figure 12, the Dynamic Group names are Screening, Radio Therapy, and Surgery.
- You can define a default Dynamic Group that is automatically assigned to a new Subject. In Figure 12, Screening is the default Dynamic Group.
- To avoid confusion while scheduling Study Events, the icons representing the Study Events state are not visible in the Subject Matrix until the Subject is assigned to that Dynamic Group. In Figure 12, no Subjects have been assigned to the Radio Therapy Dynamic Group.
- Dynamic Groups can work in conjunction with the randomization function to automatically assign a randomized Subject to a Dynamic Group. See [Subject Randomization](#) for more details.
- Users have the option to manually set or override Dynamic Group assignments. See [Editing Study-specific Information](#) for instructions.

Figure 12: Dynamic Groups in a Subject Matrix

Subject Matrix for Berkeley Medical Center 

Subject ID	Screening		Radio Therapy	Surgery		1 Month Follow-up	2 Month Follow-up	3 Month Follow-up	Common	End of Study	Test	EOS	Reference Visit 11
	Enrollment	Lab	CRT	Procedure	24 Hr Follow-up								
BMC-051													
BMC-050													
BMC-049													
BMC-048													
BMC-047													
BMC-046													
BMC-045													
001-005													
BMC-044													
BMC-043													
BMC-042													
BMC-041													
BMC-040													
BMC-039													
BMC-038													

Results 1 - 15 of 51.

4.1.7 Submitting Data for a Subject

You can submit data for a Subject after they are added and scheduled for an Event. Click the desired event to bring up the applicable pop-up, and click the **Enter Data** icon for the CRF you want to submit data.

4.1.8 Show More Subject Information

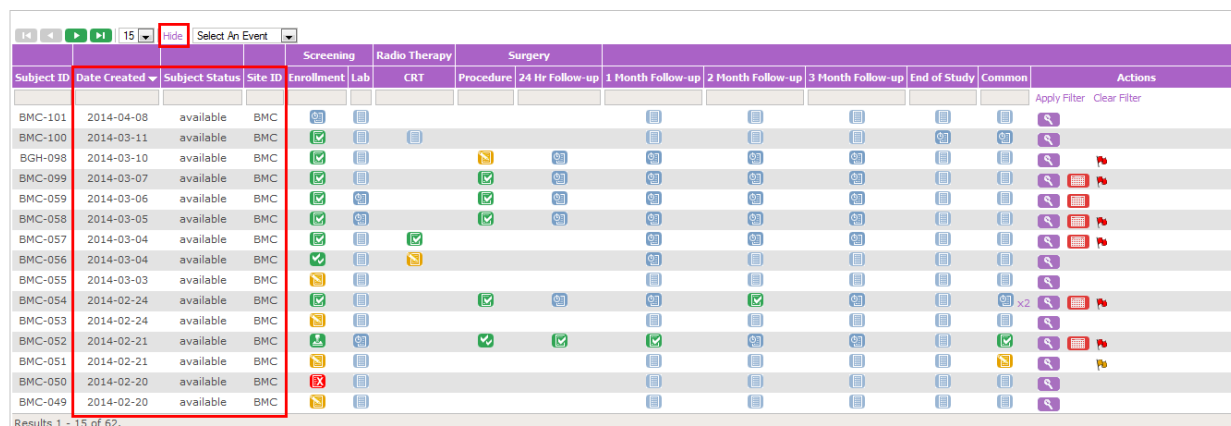
To see more information about Subjects in the Subject Matrix, click [Show More](#). The matrix widens to add the Date Created, Subject Status, and Site ID.

Note: Field names may be configured differently to meet your protocol specification.

When the Subject Matrix is expanded, click [Hide](#) to stop showing the additional columns.

Figure 13: Show More Subject Information

Subject Matrix for Berkeley Medical Center



Subject ID	Date Created	Subject Status	Site ID	Screening		Radio Therapy		Surgery			End of Study	Common	Actions
				Enrollment	Lab	CRT	Procedure	24 Hr Follow-up	1 Month Follow-up	2 Month Follow-up			
BMC-101	2014-04-08	available	BMC										
BMC-100	2014-03-11	available	BMC										
BGH-098	2014-03-10	available	BMC										
BMC-099	2014-03-07	available	BMC										
BMC-059	2014-03-06	available	BMC										
BMC-058	2014-03-05	available	BMC										
BMC-057	2014-03-04	available	BMC										
BMC-056	2014-03-04	available	BMC										
BMC-055	2014-03-03	available	BMC										
BMC-054	2014-02-24	available	BMC										
BMC-053	2014-02-24	available	BMC										
BMC-052	2014-02-21	available	BMC										
BMC-051	2014-02-21	available	BMC										
BMC-050	2014-02-20	available	BMC										
BMC-049	2014-02-20	available	BMC										

4.1.9 Finding and Organizing Data

The Subject Matrix has the following features to help you find and organize data for the Study Subjects.

Number of Subjects per Page

The bottom left corner shows the total number of Subjects and the number currently in view. When there are more Subjects in the Study than can be listed on the page, use the green arrows to scroll through the pages of Subjects.

When there is only one page of Subjects, the arrows are disabled (gray). To change the number of Subjects shown on a page, click the drop-down list next to the arrows and select a value: 15, 25, or 50 per page.

Sort Data by Column

By default, the Subject Matrix is sorted by Subject ID, in descending order with the last entered Subject first. To sort the data by a column, click the column header. Some columns do not allow sorting by, in which case, the pointer does not change shape when you position it over the column header. To reverse the sort order, click the column header again. An arrow next to the column header indicates the current sort order: up for ascending and down for descending.

For example, in Figure 13 the Subject Matrix is sorted by the Date Created column in descending order.

Filter Data to Show Only Matches for Specified Criteria

You can filter the information shown in the Subject Matrix to show only Subjects whose data match the criteria you specify. You can specify the criteria for one Event column, and any of the other columns.

- ❑ For the column whose data you want to filter, click the gray field below the column header.
- ❑ If a drop-down list displays, select the value you want to use as the filter. If no list displays, type in the string of characters you want to include, and press **Enter** or click [Apply Filter](#) (located to the far right of the gray fields).

For instance, you can type 003 in the gray field below the Subject ID, indicating that you want a list of Subjects with Subject ID containing 003, and click [Apply Filter](#).

You can add more filters, if necessary.

To remove filtering for a column, clear the text you entered, or from a drop-down list, select the blank (top) item.

When filtering is applied, the Subject Matrix shows only those Subjects that contain the data you specified. To clear all filtering and show all data, click [Clear Filter](#) (located to the far right of the gray fields).

Figure 14: Subject Matrix filtered by Subject ID

Subject Matrix for Berkeley Medical Center ?

Subject Matrix for Berkeley Medical Center ?										
<input type="text" value="50"/> <input type="button" value="Hide"/> <input type="text" value="Select An Event"/>										
Subject ID	Date Created	Subject Status	Site ID	Screening		Radio Therapy	Surgery			
				Enrollment	Lab	CRT	Procedure	24 Hr Follow-up	1 Month Follow-up	2 Month Follow-up
02										
BMC-029	2014-01-08	available	BMC							
BMC-028	2013-12-19	available	BMC							
BMC-027	2013-11-07	available	BMC							
BMC-026	2013-11-06	available	BMC							
BMC-025	2013-10-02	available	BMC							
BMC-024	2013-09-30	available	BMC							
BMC-023	2013-09-26	available	BMC							
BMC-022	2013-09-25	available	BMC							
BMC-021	2013-09-24	available	BMC							
BMC-020	2013-09-23	available	BMC							
BMC-002	2013-09-18	available	BMC							

Results 1 - 11 of 11.

[Back](#)

Figure 15: Subject Matrix with multiple filters

Subject Matrix for Berkeley Medical Center ?

Subject ID	Date Created	Subject Status	Site ID	Enrollment	Lab	CRT	Procedure	24 Hr Follow-up	1 Month Follow-up	2 Month Follow-up
02					data entry started					
BMC-028	2013-12-19	available	BMC							
BMC-026	2013-11-06	available	BMC			✓				
BMC-025	2013-10-02	available	BMC							
BMC-021	2013-09-24	available	BMC			✓				
BMC-020	2013-09-23	available	BMC					✓	✓	





















Results 1 - 5 of 5.

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4.1.10 View Event Details

To view the details of a Study Event from within the Subject Matrix, bring up the pop-up and click the **View** icon for the Event.


























Figure 16: View Event icon in Event Details pop-up

			Status	Actions	X
Subject: BMC-048				   	
Event: Enrollment				  	
CRF Name	Version	Initial Data Entry			
Demographics * ✓	v. 1			 	
Patient Eligibility * ✓	v. 1			 	
Pain Scale *	v. 1.3			 	
Drug Administration * ✓	v. 2			 	

4.1.11 Study Subject Record

To view the details of a Subject from within the Subject Matrix, bring up the pop-up. Click the **Edit** icon to modify the Subject record, or click the **View** icon to display the Subject record.

Figure 17: Edit Subject and View Subject icons in Event Details pop-up

			Status	Actions	X
Subject: BMC-048				   	
Event: Enrollment				  	
CRF Name	Version	Initial Data Entry			
Demographics * 	v. 1			 	
Patient Eligibility * 	v. 1			 	
Pain Scale *	v. 1.3 			 	
Drug Administration * 	v. 2 			 	





























































































The View Subject page contains all study information for the selected Subject in the following sections: Study Subject Record, Subject Casebook, and Events.

Figure 18: View Subject Record page

View Subject Record: S01-102

- Study Subject Record
- Subject Casebook
- Events

Page 1 of 1

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Screening (1)	19-Dec-2014		data entry started	  	Demographics *  v.1   
					Eligibility Criteria *  v.2      
					Randomization Form * v.1     
					Pain Score *  v.2   
					O2_Baseline Assessment *  v0.19   
					Randomization z *  1.0.0    
					PE1 * 1.0   
					Form99 *  5.0.1.1    
					Enrollment *  1.5   
					Local Laboratory Results *  V1.0    
					1Options Test *  3    
					2228_TO *  v.1    
					Visit Date (2229) *  v. 1    
					Visit Test (2229) *  v. 1   
IMG_2233 *  V1   					
Ticket # 2198 Test Form #2 *  v.1   					
Ticket #2198 Test Form #1 *  v. 1   					
6-Month Visit	29-Apr-2015	Austin	scheduled	   	Laboratory Results *  v.1   
					Pain Score *  v.2   

By default, the Events section is expanded. Click the plus or minus sign next to a section to show or hide information in that section.

The following buttons may appear at the bottom of the page:

- Subject's Discrepancies:** View all Notes & Discrepancies related to this Subject.
- Subject's Audit Log:** View all captured transactions for the Subject.

Study Subject Record Section

The Study Subject Record section contains general information on the Subject, including Status, Person ID, and Date of Birth.

Figure 19: Study Subject Record section

Study Subject Record

Subject ID	BMC-048	Person ID <small>PK</small>	
		Date of Birth <small>PK</small>	Not Used
Status	available		
Study Name	UBCM	Site Name	Berkeley Medical Center

Dynamic Group Class	Events	Status
Default Group (Screening)	Enrollment, Lab	available

To change the Study Subject information, click the **Edit** icon to open the *Update Study Subject Details* page, where you can edit global information, such as the Subject ID, Person ID, and group assignments.

You can also lock all data for a subject by clicking on the **Lock** icon.

Figure 20: Update Study Subject Details page

UBCM (UBCM2013) | Change Study/Site Abbas_admin (Study Administrator) | Log Out

Home | Subject Matrix | Code | Notes & Discrepancies | Study Audit Log | Tasks Subject ID Go

Update Study Subject Details

Subject ID: * indicates required field.

Dynamic Group Class:

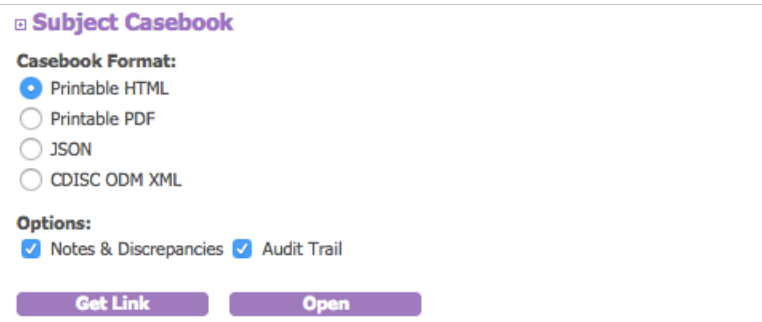
Events:

Subject Casebook Section

View all CRF data collected for the subject so far.

Note: If CRF masking functionality is being used, the CRFs that have been masked from you will not display on the subject casebook.

Figure 21: Subject Casebook section



Subject Casebook

Casebook Format:

- Printable HTML
- Printable PDF
- JSON
- CDISC ODM XML

Options:

- Notes & Discrepancies
- Audit Trail

Get Link **Open**

To view the subject casebook:

1. Select the casebook format.
 - Printable HTML
 - Printable PDF
 - JSON
 - CDISC ODM XML
2. Select the option(s).
 - Notes & Discrepancies – Select to include the subject’s Notes & Discrepancies in the casebook.
 - Audit Trail – Select to include the subject’s Audit Trail in the casebook.
3. Click Open.

The subject casebook opens in the selected format. You can use your browser’s print feature to print the casebook.

Note: Depending on the size of your data, it may take several minutes to generate the casebook.

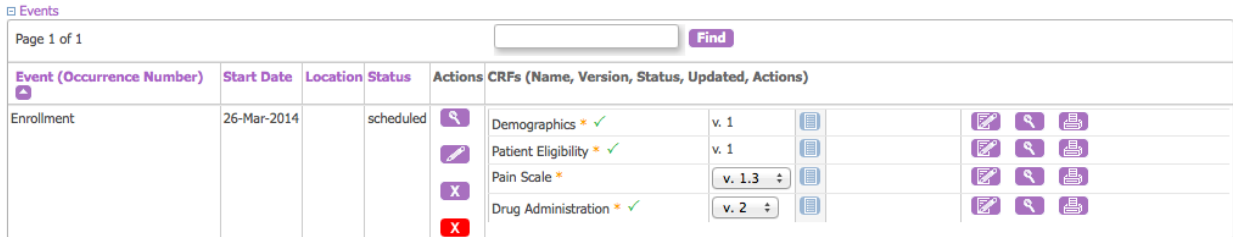
To generate a link to the subject’s casebook:





















































1. Click **Get Link**.
2. Copy the displayed URL to link to or bookmark the subject casebook.

Events Section

The Events section shows information about all the events currently in progress for a Study Subject.

Figure 22: Events section



Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)																								
Enrollment	26-Mar-2014		scheduled	   	<table border="1"> <tr> <td>Demographics * ✓</td> <td>v. 1</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Patient Eligibility * ✓</td> <td>v. 1</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Pain Scale *</td> <td>v. 1.3</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Drug Administration * ✓</td> <td>v. 2</td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	Demographics * ✓	v. 1					Patient Eligibility * ✓	v. 1					Pain Scale *	v. 1.3					Drug Administration * ✓	v. 2				
Demographics * ✓	v. 1																												
Patient Eligibility * ✓	v. 1																												
Pain Scale *	v. 1.3																												
Drug Administration * ✓	v. 2																												

To search for Events by name or location, enter the value you are looking for in the text box, and click **Find**.

Each row shows details for a specific Event, including:

- Start Date
- Location
- Status
- Actions, represented by icons that you can click for the Event
- CRFs for the Event

For each CRF in the Event, the following information is available:

- Name
- Version
- Status, represented by icons
- Updated, indicates the date when the CRF was last updated and who made the changes
- Actions, represented by icons that you can click to perform operations on the CRF

You can remove a CRF for a Subject, and the CRF is marked as Removed. You can restore a CRF that has been removed without losing data; however, the CRF status will be Initial Data Entry Started. You must re-inspect the data and mark the CRF complete again.

For more details about editing a CRF, see [Entering CRF Data](#).

By default, Events are ordered by Start Date, with the most recent Start Date first. Click a column header to order the Events by that column. Click again in that column to reverse the sorting order.

4.2 Add Subject

When you add a Subject to a Study or Site, you create a Study Subject record and schedule one or more Events for the Subject. There are two ways to add a Subject to a Study or Site:

- From the Subject Matrix:** Use to add a Subject and schedule the first Event.
- From the Tasks menu:** Use to add multiple Subjects or schedule multiple Events.

Before you can add a Subject to a Study or Site, the Study or Site must exist and the Study status must be available. See your Study Administrator if you do not see the [Add Subject](#) link in the Navigation Bar.

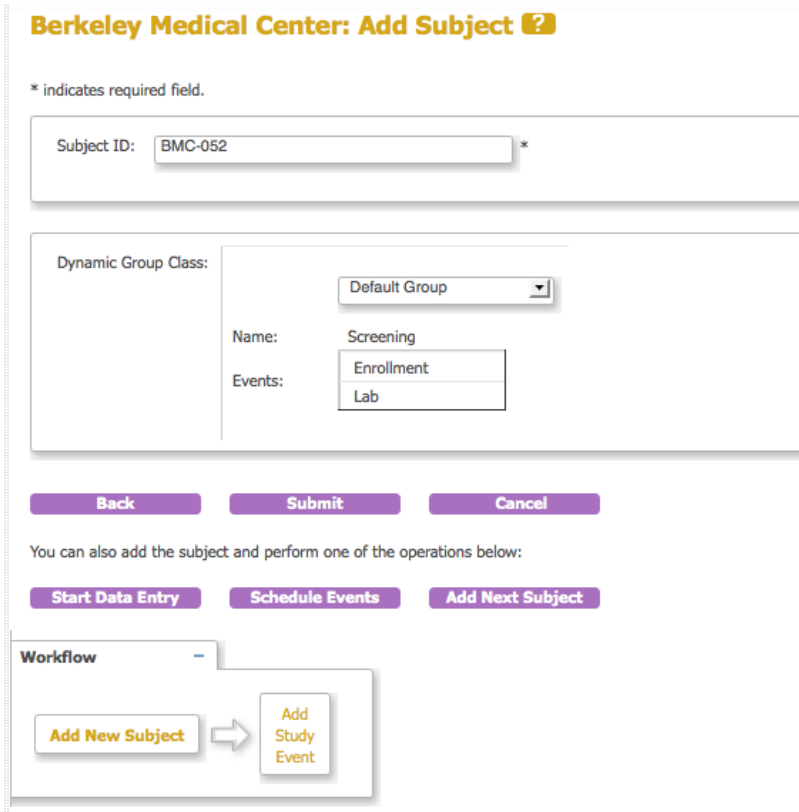
The CRC and Investigator user roles can add Subjects to their current Site, although the Study Administrator can later change the assignment.

After adding a Subject, you can edit the information in the Subject record from the Subject Matrix. See [Study Subject Record](#).

4.2.1 Add Subject from Subject Matrix

Perform the following steps to add more than one Subject and schedule them for a Study Event:

3. In the Subject Matrix, click the [Add New Subject](#) link. The *Add New Subject* page opens.



Berkeley Medical Center: Add Subject ?

* indicates required field.

Subject ID: *

Dynamic Group Class:

Name:

Events:

Enrollment
Lab

You can also add the subject and perform one of the operations below:

Workflow

```

graph LR
    A[Add New Subject] --> B[Add Study Event]
  
```

4. Complete the information on the page as described in the following steps. Some of the information might be different or optional for your Study. For a description of the terms, see the [Glossary](#).

Note: An asterisk (*) indicates a required field.

- a. Enter the **Study Subject ID**.

Depending on your Study Parameter Configurations, the Study Subject ID may be:

- Entered manually
 - Automatically generated, but you can edit it
 - Automatically generated, but you can not edit it
- b. Enter the **Secondary ID**. This is another identifier for the Subject. This field may be labeled differently or be hidden.
 - c. Enter the **Enrollment Date** in the specified format, or click the **Calendar** icon to select it. This field may be labeled differently or be hidden.
 - d. Select the **Sex**. This field may be labeled differently or be hidden.
 - e. Enter the **Date of Birth** in the specified format, or click the **Calendar** icon to select it. This field may be labeled differently or be hidden.
 - f. Select the **Group(s)** from the drop-down list, if any Subject Group Classes were defined in the Study setup.
 - g. Select the first **Study Event** from the drop-down list.
 - h. Enter the **Start Date** for the Event, or click the **Calendar** icon to select it.

The following buttons are available at the bottom of the page:

- Back:** Subject data entered is not saved and takes you back to the Home Page.
- Submit:** Saves the Subject you just created and takes you to the Subject Matrix.
- Start Data Entry:** Saves the Subject you just created and allows you to enter data for the given Study Event.
- Schedule Events:** Saves the Subject you just created and allows you to schedule the Study Events.
- Add Next Subject:** Saves the Subject you just created and opens a new *Add New Subject* page where you can add another one.
- Cancel:** Cancels the operation and takes you back to the Subject Matrix.

4.2.2 Add Subject from Tasks Menu

To add Subjects from the Task menu, select **Tasks > Add Subject**, and follow the same steps outlined in [Add Subject from Subject Matrix](#).

4.2.3 Assign or Reassign Subject to Site

When you add a Subject, the Subject is added to the current Study or Site. Typically, you set the current Site and add Subjects to that Site. However, you can add a Subject to the overall Study and later assign the Subject to a Site. You can also change a Subject's assigned Site.

The Site to which a Subject is assigned is reported in the [Study Subject Record](#). You can also see the Site assignment in the Subject Matrix. When the current Study or Site is set to the Site level, the Subject Matrix shows only the Subjects assigned to that Site, so any Subject shown in the matrix is assigned to the current Site. When the current Study or Site is set to the Study level, click the [Show More](#) link to view the Site assignments in the Subject Matrix.

A Study Administrator can assign a Subject to a Site, or reassign a Subject to a different Site from the Subject Matrix using the following steps:

1. Change your current scope to the appropriate Study, if needed.
2. Locate the Subject in the Subject Matrix.
3. In the Actions column for the Subject, click the **Reassign** icon. The *Reassign Study Subject* page opens, with the Subject's current assignment selected.

Reassign Study Subject

You choose to reassign the following subject:

Subject ID	BGH-131
Person ID	
Date Created	08-Apr-2014

Please choose a study in the following list:

- Berkeley Medical Center
- Brooklyn General Hospital (currently in)
- Image Lab

[Back](#)

[Continue](#)

4. Select the Site to which you want to assign the Subject, and click **Continue**. The *Confirm Reassign Subject* page opens.
5. Click **Submit**.

4.2.4 Add a Subject to Multiple Studies

After adding a Subject to a Study in ClinCapture, the Subject can participate in other ClinCapture Studies. Simply add the Subject to each Study, using the same Person ID. When you add a Subject to a second or subsequent Study, ClinCapture presents you with a confirmation screen, and ensures that the Sex and Date of Birth for that Subject match the values already in the database for the same Subject.

Note: A Subject cannot be added to multiple Sites within the same study.

4.3 Edit Subject

A Subject is associated with two types of information:

- Global information:** Information that is person-related and can be used across multiple studies. For example, date of birth or gender.
- Study-specific information:** Information that is specific to a study. For example, date of Study enrollment or group assignment.

You can edit both global and study-specific information.

4.3.1 Editing Global Information

Administrator users can edit the following global information from the Administration Module. For user type and role descriptions, see [User Types](#) and [User Roles](#).

- Person ID
- Sex
- Date of Birth




To edit global Subject information:

1. Click Tasks > Subjects then on the **Edit** icon for the desired Subject..

The Update Subject Details page opens.

Update Subject Details

* indicates required field.

Person ID:	<input type="text" value="XQ1-345"/>	
Date of Birth:	<input type="text" value="23-Jan-1992"/>	 (DD-MMM-YYYY)* 

2. Make the necessary changes, and click **Continue**.
3. Click **Submit** to confirm your changes.
























4.3.2 Editing Study-specific Information

The following study-specific Subject information can be edited:

- Study Subject ID:** The unique Subject ID in the Study.
- Secondary ID:** Optional secondary ID, used for example to associate Subject with a Lab ID.
- Date of Enrollment:** Date the Subject was enrolled in the Study.
- Subject Group Class:** Cohort group, such as Arm, Demographics, etc.
- Dynamic Group Class:** See [Dynamic Groups](#) for details.

To edit the Study-specific information for a Subject:

1. Open the Subject Matrix.
2. Hold your pointer over, or click on the Study Event, to display the pop-up.

			Status	Actions	X
Subject: BMC-055				   	
Event: Enrollment				  	
CRF Name	Version	Initial Data Entry			
Demographics * 	v. 1			 	
Patient Eligibility * 	v. 1			 	
Pain Scale *	<input type="text" value="v. 1.3"/>			 	
Drug Administration * 	<input type="text" value="v. 2"/>			 	

3. Click the **Edit** icon on the Subject row.

The *Update Study Subject Details* page appears.

Update Study Subject Details

Subject ID: * indicates required field.

Dynamic Group Class:

Default Group

Enrollment
Lab
TEST 22
Common
aaa
EOS
'test - 1'
SH_TEST_0095

Events:

4. Edit the necessary information, and click **Continue**.
5. Click **Submit** to confirm your changes.

4.4 Schedule Event

Study Events have a type, date, status, and associated package of CRFs. In ClinCapture, a Study Event is also referred to as an Event.

Each Event is assigned an Event Definition, for example, Registration Visit. An Event can be repeating (occurs more than once) or non-repeating (occurs only once). You can configure a Study Event in the following different ways:

- Scheduled Study Event:** When CRFs are expected for each Subject as part of the planned sequence for the Study.
- Unscheduled Study Event:** When CRFs are designed to collect data that might or might not occur for any Subject, such as early termination due to a serious adverse event.
- Common Study Event:** When CRFs are used for more than one different Event, such as a Concomitant Medications Log.

4.4.1 Scheduling a Study Event


Before you can schedule a Study Event for a Subject, the Subject must be added.

You can schedule a Study Event from the Event pop-up or the Tasks menu.

Using the Event pop-up

To schedule a Study Event using the Event pop-up:

1. Position your pointer over, or click, the Event that you want to schedule. The Event pop-up appears which allows you to schedule an Event right from the Subject Matrix.

Occurrence#1 of 1 31-Mar-2014			Status	Actions
Add Another Occurrence				
Subject: BGH-008				   
Event: 'test - 1'				  
CRF Name	Version	Initial Data Entry		
Medical Coding *	v1.0			 

2. The actions that you can take depend on the Event repeating type:
 - a. **Non-repeating Event:** Click the **Not Scheduled** icon, and follow the steps detailed in [Scheduling a Subject](#).
 - b. **Repeating Event:** Click the Event to show the number of Event occurrences that have already been scheduled or completed. To add a new Event, click the [Add Another Occurrence](#) link in the pop-up window.

Using the Tasks menu

To schedule a Study Event using the Tasks menu:


1. In the Navigation Bar, select Tasks > Schedule Event.
2. Enter the Study Subject ID. The *Schedule Study Event* page opens.



Schedule Study Event for BGH-062

* indicates required field.

Subject ID: **BGH-062**

Study Event Definition: Enrollment (non-repeating) *

Start Date/Time: 31-Mar-2014  (dd-MMM-yyyy) * 

End Date/Time:  (dd-MMM-yyyy) * 

Leave this field blank if the end date/time is not applicable.

Schedule Another Event: (optional)
 Schedule Another Event: (optional)
 Schedule Another Event: (optional)
 Schedule Another Event: (optional)

Schedule Event
Start Data Entry
View Event
Cancel

3. Enter the information in the *Schedule Study Event* page. If you need to enter dates, either type them in the field in the correct format, or click the calendar icon to select them. The End Date is optional: keep it empty if it does not apply. Keep in mind that the Event Scheduling panel may be different than shown above, as it can be configured to meet the requirements of your Study Protocol.
4. After you complete the scheduling the information, you can schedule another Event.
5. After entering information for all Events that you want to schedule, click **Start Data Entry** to proceed to the *View Event* page where you will be able to submit data.
6. If you do not want to enter data about the Event until later, click **Cancel**.

4.5 Calendared Event

A Calendared Event can be automatically scheduled when a reference visit is completed. This is typically used for follow-up events that must occur within a predefined period of time after the treatment occurred.

When a reference visit completes, Calendared Events are automatically scheduled and a **Calendar** icon appears on the subject Matrix.

Figure 23: Calendar Icon in Subject Matrix

Subject Matrix for UBCM

Show Events: 15 More 24 Hr Follow-up

Subject ID	Event Status	Event Date	Dispense	Actions
BMC				Apply Filter Clear Filter
BMC-022				
BMC-020		20-Jan-2012		
BMC-002		25-Oct-2013		
BMC-030				
BMC-003		12-May-2014		
BMC-036		30-Jan-2014		
BMC-001		25-Sep-2013		
BMC-038				
BMC-023		27-Sep-2013		
BMC-005				

Results 1 - 10 of 10.

Back

Workflow

Manage Study → Manage Subjects → View Study Subject

Click the **Calendar** icon to open a pop-up window with the scheduling details for the Calendared Events. All column headers are sortable.

Figure 24: Sample Calendared Events Parameters details

Calendared Events Parameters : BMC-003

Current Date: Mar 31, 2014

Page 1 of 1

Calendared Event Name	Min-Max Date Range	Schedule Date	User Email Date	Is Reference Event	Reference Visit for Event
Procedure	--	--	--	Yes	--
1 Month Follow-up	Apr 5, 2014 – Apr 15, 2014	Apr 9, 2014	Apr 8, 2014	No	Procedure
2 Month Follow-up	May 5, 2014 – May 15, 2014	May 7, 2014	May 1, 2014	No	Procedure
24 Hr Follow-up	Mar 11, 2014 – Mar 13, 2014	May 12, 2014	May 11, 2014	No	Procedure

Close Window

A Calendared Event must be completed within a minimum and maximum date range. In Figure 24, the 1 Month Follow-up is scheduled for 09-Apr-2014, and must be completed no sooner than 05-Apr-2014 and no later than 15-Apr-2014. If a Calendared Event is not completed as expected:

- An automatic query is generated by the system.

Start Date: Notes and Discrepancies

"Start Date" Properties:

Subject: **BMC-003** Event: **1 Month Follow-up**
 Event Date: **02-Apr-2014** CRF: **N/A**
 Current Value: **Apr 2, 2014** More:

Note Details

Event was completed earlier than expected Last updated: **31-Mar-2014** by **Abbas_admin**
 Assigned to: **Abbas Alibhoy (Abbas_admin)**

ID: **778** Type: **Query** Current Status: **New** # of Notes: **1**

Event was completed earlier than expected Status: **New** 31-Mar-2014 by **Abbas_admin**
 Assigned to: **Abbas Alibhoy (Abbas_admin)**

The 1 Month Follow -up event completed sooner than expected for subject BMC-003

Update Note **Close Note**

- The **Calendar** icon on the Subject Matrix turns red until the discrepancy is resolved.

Subject Matrix for UBCM

Show Events: 1 Month Follow-up

Subject ID	Event Status	Event Date	Follow-up Assessment	IPSS	Disease Progression	Apply Filter	Clear Filter	Actions
BGH-023		18-Dec-2013						
BGH-026								

Results 61 - 62 of 62.

Back

Workflow: Manage Study → Manage Subjects → View Study Subject

A reminder email can be sent to any user in the Study before the Calendared Event occurs. In the example above, the reminder email will be sent on 8-Apr-2014 for the 1 Month Follow-up event.

When all the Calendared Events are completed and the queries, if any, closed, the **Calendar** icon is no longer displayed in the Subject Matrix.

Note: Calendared events inside a dynamic group that is not assigned when the reference event completes will not be automatically scheduled. That is because the events inside the dynamic groups are not assigned and thus cannot be calendared.

4.6 View and Update Events

4.6.1 Viewing Events

The *View All Events* page contains information for each Event Definition that matches specific criteria. The Event name and type, and Subject status (Scheduled, Completed, and Discontinued) are shown above each table.

By default, Events in the table are sorted by date, with the most recent Event shown first. To change the sort order, click the header of the column you want to sort by. To reverse the sort order, click the column header again. An arrow indicates the order as ascending (up) or descending (down).



To find an Event within a table, type a string of characters in the find box, then click **Find**. ClinCapture finds matching strings in the Study Subject IDs or in Subject Event Status fields, and shows only those Events that match the criteria. To reset the table and show all Events, click [Clear Search Keywords](#), next to the **Find** button. You can view the details of an Event or edit the Event by clicking the **View** or **Edit** icons in the Actions column.

Yellow highlighting of a row indicates that the Event Scheduled Date has passed and data entry has not been started.

You can view information about all Events, or show only the Events that match specific criteria.



To open the *View All Events* page:

1. In the Navigation Bar, select **Tasks > View Events**. The *View All Events* page opens for the current Study or Site, presenting a filter.

View All Events in UBCM  



Filter events by:

Study Event Definition: Status:

Date Started:  (DD-MMM-YYYY) Date Ended:  (DD-MMM-YYYY)

Apply Filter

- Specify the criteria for the Events that you want to view. For example, specify Enrollment as the Study Event Definition, data entry started as the Status, and that it occurred between 01-Jan-2012 and 01-Jan-2013.
- Click **Apply Filter**. ClinCapture displays all Events that match your criteria in a series of tables, with one table of results for each Event Definition. To print the results, click the **Print** icon at the top of the page.

View All Events in UBCM  

Filter events by:











Study Event Definition: Status:

Date Started: (DD-MMM-YYYY) Date Ended: (DD-MMM-YYYY)

Apply Filter

Event Name: Enrollment
 Event Type: Scheduled, non-repeating, Category: N/A
 Subjects who scheduled: 0 (start date of first event: N/A), Completed: 0 (completion date of last event: N/A), discontinued: 0

Page 1 of 1 **Find**

Subject ID	Event Date Started	Subject Event Status	Actions
	20-Jan-2012	data entry started	 
	20-Jan-2012	data entry started	 
	20-Jan-2012	data entry started	 
	20-Jan-2012	data entry started	 
	20-Jan-2012	data entry started	 

Back


























Workflow

→

4.6.2 Updating Events

You can update information for an Event, such as the date or status. There are several ways to change Event information. The fastest way is described below:

- From the Event pop-up, click the **Edit** icon on the Event row.



			Status	Actions	X
Subject: BMC-055				   	
Event: Enrollment				  	
CRF Name	Version	Initial Data Entry			
Demographics * 	v. 1			 	
Patient Eligibility * 	v. 1			 	
Pain Scale *	v. 1.3 			 	
Drug Administration * 	v. 2 			 	



The *Update Study Event* page opens.


Update Study Event

Subject ID:

Event:

Start Date/Time:  (dd-MMM-yyyy) * 

End Date/Time:  (dd-MMM-yyyy) * 

Status: 

2. Make your changes. If you are changing the Event status, you are presented only with appropriate and allowable options, given your User role, the Study status, and the status of the CRFs for the Event. For more information, see [Event Status](#).
3. Click **Submit**.

For example, you can change the Status to Stopped, and click **Submit**. The *View Subject* page opens, showing the updated information for the Event.

UBCM (UBCM2013) | Change Study/Site Abbas_admin (Study Administrator) | Log Out

Home | Subject Matrix | Code | Notes & Discrepancies | Study Audit Log | Tasks Subject ID Go

View Subject Record: BMC-055

Study Subject Record
Events

Page 1 of 1 Find

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Enrollment	31-Mar-2014		stopped	 	Demographics * ✓ v. 1 Patient Eligibility * ✓ v. 1 Pain Scale * v. 1.3 Drug Administration * ✓ v. 2




Back Subject's Discrepancies Subject's Audit log Subject's Case Book











4.6.3 Event Status

You can manually update the Event Status as described in [Updating Events](#). ClinCapture automatically updates some conditions. There are different ways to view the Study Events status:

- Use the Event View to see all Events that match the criteria that you specify, see [Viewing Events](#).
- The Subject Matrix icon shows the status of each Event for each Subject.

These are the different Study Events status values and a description of how the status changes:

Icon	Meaning	Description
	Not Scheduled	After a Subject is added to a Study, but before an Event is scheduled. For certain Events, like Adverse Events, the Event Status might remain in this state throughout the entire Study.
	Scheduled	After a Subject has been scheduled for an Event. This is automatically set.
	Data Entry Started	<p>After a Subject is scheduled for an Event, and any CRF for that Event is opened, the Event Status is automatically set to Data Entry Started. The Data Entry Started status applies even if you did not actually enter data.</p> <p>If you inadvertently open a CRF but do not save the data, you will not be able to change the Status of the CRF or Event. To change the Status, you must delete the Event CRF, or the Event for that Subject, and restore it when you are ready to enter data.</p> <p>An Event stays in Data Entry Started until all required CRFs are completed.</p>

	Stopped	When a Subject has temporarily stopped participating in a Study.
	Skipped	When a Subject does not complete an Event.
	Completed	<p>After the Status of all required CRFs (and non-required CRFs, if data entry has started) for an Event are marked complete. This is automatically set.</p> <p>If you make any changes to a CRF after an Event has been completed, the Status of the CRF and the Event remain completed. You might need to complete a Reason For Change Discrepancy Note, depending on your system's configuration. You can manually set the Event status back to Data Entry Started, and then again back to Completed, as needed.</p>
	Initial Data Entry Completed	If the CRFs are configured for Double Data Entry or CRF Evaluation, this indicates that the CRFs have been marked complete after the initial data entry and are ready for Double Data Entry or CRF Evaluation.
	Coded	The item has been coded.
	Not Coded	The item has not been coded.
	Source Data Validated (SDV)	After all the completed CRFs with full or partial SDV requirements have been validated. This is automatically set.
	Signed	When all the CRFs for an Event have a status of Completed or Not Scheduled. When you sign the casebook for a Subject, ClinCapture automatically sets the status to Signed for all Study Events for that Subject. After an Event Status is signed, any changes to the CRF automatically change the Event Status to Completed.
	Locked	<p>When you no longer want Users to be able to enter or change data for an Event.</p> <p>Note that you can set the Status of a Study to Frozen or Locked to prevent prospective users from changing the data; however, doing so does not change the Status of any Event in the Study.</p>
	Removed	When an event has been removed.













4.6.4 Electronic Signatures

If your user role has appropriate permissions, you can sign a Study Event or an entire casebook for a Subject. The ClinCapture electronic signature process complies with the FDA Code of Federal Regulations (CFR) Title 21 Part 11.

Signing an Event

When you sign an Event, you signify your approval of all CRF data in the Event for the Subject.

1. To sign an Event, place your pointer over the Event you want to sign, and click the **Sign** icon in the pop-up.

			Status	Actions	X
Subject: BGH-009				 	
Event: CRT				  	
CRF Name	Version	Initial Data Entry			
Conventional RT Treatment Planning *	v. 1	root		 	
Conventional RT Treatment Delivery *	v. 1	root		 	

Note: You can also sign an Event by setting the Status to Signed while performing an Event update, see [Updating Events](#).

2. The *Sign Study Event* page opens and displays information on the Event, the Study Subject, and the implication of signing the Subject's record. Review the collected information as necessary.

Sign Study Event for Subject: BGH-009

Enter your user name and password below to signify agreement with the following statement:

"As the investigator or designated member of the investigator's staff, I confirm that the electronic case report forms for this subject are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."

User Full Name: Abbas Alibhoy

Date/Time: 31-Mar-2014 16:03









(The exact date and time will be recorded by the system upon submission of the signature form.)

Role: Investigator

Study Event

Subject ID	BGH-009
Study Event	CRT
Location	
Start Date	20-Jan-2012 12:01
End Date/Time	21-Jan-2012 12:01
Subject Event Status	signed
Last Updated by	Abbas_inv (31-Mar-2014 00:03)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
Conventional RT Treatment Delivery	v. 1		root	n/a	  
Conventional RT Treatment Planning	v. 1		root	n/a	  

User Name:

Password:

3. Enter your username and password in the appropriate fields.
4. Click **Sign**.

The View Subject page opens and shows the Status of the Event as signed.

Note: If, in ClinCapture Builder, a CRF within the event was defined to send an email upon signature, an email will be sent to the address specified for the CRF when the event containing the CRF is signed.

Signing a Casebook

When you sign a Subject’s casebook (complete Subject Record), you indicate your approval of all CRF data in all Study Events for the Subject.

The following requirements must be met before you can sign a casebook:

- No Events for that Subject can have a status of Scheduled or Data Entry Started.
- All CRFs that require SDV must be source data verified.
- No discrepancy or query can be opened.

The **Sign** icon appears in the Actions column in the pop-up or Subject Matrix for all Subjects that meet these requirements.

To sign a Subject casebook:

1. Click the **Sign** icon in the pop-up or Subject Matrix.

The *Sign Subject* page opens. The investigator can review the entire subject’s record by clicking the **View Subject’s Record** button. This page presents a statement about what signing the Subject Record signifies or means.

Sign Subject S001-004

Enter your user name and password below to signify agreement with the following statement:

"As the investigator or designated member of the investigator's staff, I confirm that the electronic case report forms for this subject are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."

User Full Name: Jose Castro

Date/Time: 16-Aug-2013

(The exact date and time will be recorded by the system upon submission of the signature form.)

Role: Investigator

User Name:

Password:

2. Enter your username and password in the appropriate fields.
3. Click **Sign Casebook**.

The Subject Matrix opens and shows the Status for all Events as signed.

Note: If a CRF within the event was defined to send an email upon signature, an email will be sent to the address specified for the CRF when the event containing the CRF is signed.

4.7 Entering CRF Data

In ClinCapture, users supply Event information for a given Subject using Case Report Forms (CRFs).


















ClinCapture provides the following options to enter data in a CRF:

- ❑ **Manual Data Entry:** Manual data entry using the ClinCapture web-based interface, see [Manual Data Entry](#). ClinCapture prevents multiple users from inadvertently entering data in the same CRF at the same time, by making the CRF unavailable, see [CRF Unavailable](#). An option for double data entry is available to help ensure the integrity of the data during the data entry process, see [Double Data Entry](#).
- ❑ **File Import:** Import CRF data from a file into ClinCapture for one or more Events. The import can occur once, or can be scheduled as a recurring job. See [Importing CRF Data](#) for more information.
- ❑ **Import using Web Services:** Import CRF data using SOAP Web Services. Refer to the *ClinCapture Programmer's Guide* for details.

4.7.1 Manual Data Entry




To manually enter data into a CRF:

1. Open the CRF from the Subject Matrix or *View Events* page.
 - In the Subject Matrix, place your pointer over or click on a particular Subject and Event where you want to submit data. In the pop-up, click the **Enter Data** icon for the desired CRF. This is the fastest way to enter data.













			Status	Actions	X
Subject: BMC-006				   	
Event: Enrollment				  	
CRF Name	Version	Initial Data Entry			
Demographics * 	v. 1			 	
Patient Eligibility * 	v. 1			 	
Randomization * 	v. 1			 	

- In the View Events page, click the **Enter Data** icon for the desired Event.

View Event: Enrollment for Subject SN01-015 ?

Study Subject ID	SN01-015	
Study Event	Enrollment	
Location	N/A	
Study Subject OID	SS_SN01015	
Date of Visit	17-Sep-2013	
Subject Event Status	scheduled	
Last Updated by	demo_crc (17-Sep-2013)	

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Actions
Demographics * ✓	v. 1			  
Patient Eligibility * ✓	v. 1			  
Randomization * ✓	v. 1			  

[Back](#)

[View Subject's Record](#)

[Schedule Event](#)

The *View Events* page can be opened in the following three ways:

- After you schedule an Event, click the **Submit** button on the *Schedule Study Event* page.
- Open the pop-up for an unscheduled Event on the Subject matrix, and click **Proceed to Enter Data**.
- Click Tasks > View Events. If needed, apply a filter to target the Study Events, and click the **View** icon for the desired Subject.

The orange asterisk (*) at the end of a CRF name indicates that data must be submitted to the CRF. The green check mark (✓) indicates that a full or partial SDV must be performed after data collection has been completed.

2. If multiple versions of the CRF exist, select the one you want from the drop-down list in the Version column before clicking on any action icons (**Edit**, **View** or **Print**).
3. If you want to print the CRF, click the **Print** icon for that CRF. The printout includes all data that has already been entered in the CRF. To view a read-only version of the CRF, click the **View** icon.

Note: When a CRF is viewed or printed in this manner, the skip logic cannot be triggered, and therefore, all hidden fields appear.

4. The first page of the CRF opens. In the example below, the CRF page is: **Inclusion / Exclusion**.

Eligibility Criteria v.1

Subject ID: S01-111

Event: Screening (23-Dec-2014) Site: Brooklyn Medical Center


Study: Demo Study


[▼ More Info](#)

CRF Shortcuts: 			
New Discrepancies	Updated Discrepancies	Closed Discrepancies	Annotations
2	2	0	0






Inclusion / Exclusion (0/11)

Title: Inclusion / Exclusion






Subtitle: 


Page: [Save](#) [Exit](#) 


Inclusion criterias

1. Yes No*  The patient must be over the age of 6 years.
2. Yes No*  The patient has a life expectancy of > 10 years.
3. Yes No*  Histologically confirmed, locally confined adenocarcinoma of the prostate.
4. Yes No*  The patient must have an ECOG/Zubrod performance status of 0 or 1.
5. Yes No*  Biopsy completed within 1 year of date of enrollment.

Exclusion criterias

1. Yes No*  Excluding the primary cancer targeted for this treatment the patient has a prior history of cancer (within the last 5 years) or concurrent cancer other than basal cell or squamous skin cancer.
2. Yes No*  The patient's weight exceeds the tolerances of the institution's imaging and CyberKnife platform/couch.
3. Yes No*  Clinical stage T2c or greater disease.
4. Yes No*  Clinical or pathological lymph node involvement (N1).
5. Yes No*  Evidence of distant metastases (M1).

Subject is eligible for the study? * 

[Return to top](#) [Save](#) [Exit](#) 

Click the [More Info](#) link to open the CRF Header and view additional information, such as the Interviewer's Name and Interview Date, if your study is configured to collect this information.

Eligibility Criteria v.1

Subject ID: S01-111

Event: Screening (23-Dec-2014) Site: N/A

Study: Demo Study

– [More Info](#)

CRF Header Info	
Interviewer Name: <input type="text"/>	Interview Date: <input type="text"/>



CRF Shortcuts: x			
New Discrepancies	Updated Discrepancies	Closed Discrepancies	Annotations
2	2	0	0

If notes or discrepancies exist in the CRF, the **CRF Shortcuts** panel will be displayed. Sometimes CRFs are quite long and discrepancy notes may not be readily apparent. The counters in the Discrepancy Notes section of the CRF Header are shortcuts that can quickly take you to each occurrence of the item in the CRF. Click the counter once to go directly to the first occurrence. Continue to click the counter to advance to each subsequent occurrence.


For example, in the following Discrepancy Notes image, clicking the **2** in the **New Discrepancies** column will advance to the first new discrepancy in the CRF and highlight the associated field. Clicking **2** again will advance to the next new discrepancy in the CRF.

CRF Shortcuts: x			
New Discrepancies	Updated Discrepancies	Closed Discrepancies	Annotations
2	2	0	0

The title of the CRF Page is listed in a tab above the form. To select a different page, click the tab for that Page.

- Enter the information for the current Page. The icon changes from  to  indicating that the page now contains unsaved data.
- In the tab next to the Page title there are two numbers in parenthesis. The first number indicates the number of items entered in the Page. The second number indicates the total number of items in the Page. For example, (0/5) indicates that there are 5 items in the Page, and that no data has been entered in any of them yet.

Instructions for completing each item in a Page are shown at the top of the page or with each item.

If you need to enter a value that differs from what is expected, or need to annotate a data point, you can add a Discrepancy Note by clicking the **Add Discrepancy Note** () icon for the item and entering the note. For details, see [Notes and Discrepancies](#).

- After completing a CRF Page:

- a. If you don't want to save the information you entered for a Page, click **Exit** to end data entry, or click on another Page tab. The system warns you about losing your unsaved data.
- b. If you want to keep the information you entered for that Page, click **Save**.
- c. If there are problems with the data that you entered, ClinCapture does not save the data and displays messages concerning the information that is incorrect.
- d. ClinCapture checks that all required values are provided and that the values entered comply with the field validation checks and rules that are defined for the CRF.
 - A validation check message reported in red font indicates a Hard Validation Check that must be fixed or a discrepancy note must be provided before you can save the data. For example, if you entered text in a numerical field, or a date is not correctly formatted.

- **Missing data in a required field.**
- **The input you provided is not a valid date in DD-MMM-YYYY format.**

- A validation check message reported in orange font indicates a Soft Validation Check. Soft Validation Checks occur when CRF data passes the Hard Validation Checks but its content fails to follow a Rule. For example, a person's weight is expected to be less than 350 lbs.

- **Date cannot be in the future, please update or clarify.**
- **Date Informed Consent was signed cannot be before Birth Date. Please update or clarify.**
- **Age is out of expected range. Please update or confirm.**

Two options are available to process a Soft Validation Check:

- **Option 1:** Override the validation check by clicking **Save** again. The system will automatically generate a Failed Validation Check Note. For details, see [Discrepancy Note Types](#)
- **Option 2:** Annotate the discrepant data, and click **Save** again.

Correct all data entry errors or provide Discrepancy Notes for them, and click **Save**.

- e. Upon saving a Page, ClinCapture performs any necessary calculations specific for that Page, and displays the next Page in the CRF, if any.

Complete and save all Pages in the CRF.

8. In the last CRF Page:

- a. If all information has not been entered, do not select **Mark CRF Complete**; you can return to edit the CRF later to complete the information and mark the CRF Complete at that time.
- b. After all information has been entered in the CRF, select the **Mark CRF Complete** checkbox, and click **OK** in the confirmation dialog box.
- c. Click **Save** in the last Page.
 - i. If a password is required, supply your password in the dialog box that opens.

- ii. If double data entry is required for the CRF, the CRF must be re-entered by another user.
 - iii. If CRF evaluation is required for the CRF, the study evaluator will be able to evaluate the data, and change it if necessary.
- d. The *View Event* page opens, and the Status for the CRF will be:
- i. **Initial Data Entry Complete** - If the next step is double data entry or CRF evaluation and the CRF has been marked Complete.
 - ii. **Data Entry Complete** - If the data is ready to be submitted to the Monitor or Investigator and the CRF has been marked Complete.
 - iii. **Data Entry Started** - If you did not mark the CRF Complete.
- Note:** If the CRF was defined to send an email upon completion, an email will be sent to the address specified for the CRF when the CRF is marked complete.

4.7.2 Subject Randomization

ClinCapture is integrated with a randomization module from randomize.net. This module offers block randomization, which differs from simple randomization in that it's designed to randomize Subjects into groups that result in equal sample sizes. This method ensures a balance in sample size across groups over time.

To ensure privacy and security, all communication between ClinCapture and randomize.net is encrypted.

ClinCapture supports stratified randomization, which addresses the need to control and balance the influence of covariates (baseline patient characteristics). Stratified randomization balances the control and treatment groups for age or other identified covariates.

Single- and double-blinded randomization methods are supported.

Any stratification variable can be captured and controlled in the randomization CRF, including demographics and eligibility criteria.

After randomization is configured and activated by your Study Administrator, Subjects can be randomized as follows:

1. Subjects are randomized within their specific site. Make sure your current scope is set to the proper site. See [Changing the Current Scope](#) for details. Failure to set your scope properly may result in the following error.



The Site Id configured is invalid. Please contact your system administrator

OK

2. Consult your CRF Completion Guidelines to locate the randomization CRF. Open it for data entry.
3. Enter data on the randomization CRF, including the stratification variables required to randomize the subject.
4. Click the **Randomize Subject** button once. The button is greyed-out until the randomization results are displayed.
5. When the randomization result is available, it is immediately saved to the database, along with the stratification variables, even before the CRF is saved. This is to avoid losing the randomization result because the CRF is not saved. Click **OK** to dismiss the alert message.

Message Alert

Your randomization result and randomization variables were saved successfully. Click 'Save' to run rules for this CRF.

Ok

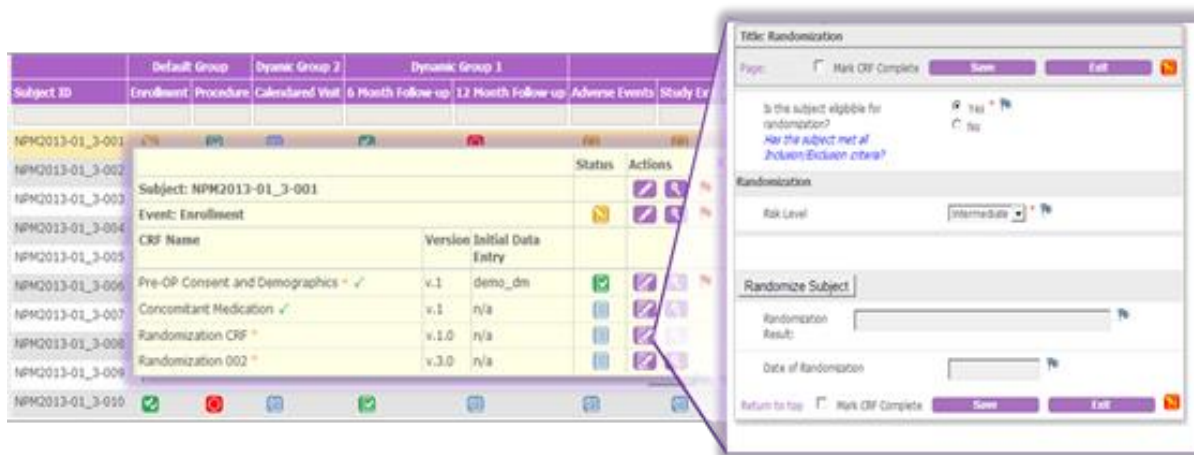
6. If the randomization result matches the name of a Dynamic Group, the Subject is automatically assigned to that Dynamic Group.
7. Check the **Mark CRF Complete** box, and click **Save** to end the randomization process and save the CRF data.

Note: Subjects can be randomized only once. If a Subject was incorrectly randomized, for example, it was randomized with incorrect stratification variables, or if the randomization CRF was deleted, you must contact your Study Administrator to correct the situation. They may have to contact randomize.net to undo the previous randomization before you can try again.

Note: Upon successful randomization, Subjects are assigned a randomization number. If the randomization parameter, **Assign Randomization Parameters to**, under Study Parameters is set to **Study Subject ID**, the randomization number becomes the Subject's Study Subject ID, replacing the existing SSID.

For example, prior to randomization, a Subject's SSID is S01-103. After this subject is randomized, the system generates a randomization number of 1048. The Subject's SSID is changed to 1048.

Figure 25: Subject Randomization CRF



4.7.3 CRF Unavailable

ClinCapture prevents multiple users from entering data in, or editing, a CRF at the same time. If you try to enter data in, or edit, a CRF that another user is already working on, ClinCapture displays a message that the CRF is unavailable for data entry. The message also indicates who is currently editing the CRF. You won't be able to edit an open CRF until the other user closes the CRF.

4.7.4 Double Data Entry

Double Data Entry requires that data intended for a particular CRF must be entered twice to ensure the integrity of the captured data. It is typically used when CRF data is first captured on paper forms, and then entered into the ClinCapture system. Double Data Entry can be classified as either optional or required, depending on the specification defined and fully described in the Study Event Definition for each CRF.

During Double Data Entry, ClinCapture detects discrepancies between the values in the initial data entry and the second data entry, and provides options for resolving the discrepancies.

There are options for who can perform the Double Data Entry, and when:

- After a user completes entering the initial CRF data, a different user can perform the double entry.
- The user who initially enters the data can also perform the double entry, provided that twelve hours have elapsed since the initial data entry was done.
- Certain user roles have permission to complete initial data entry and move directly to Double Data Entry without waiting.






Use the following process to complete CRF data entry when using Double Data Entry:



1. Perform initial data entry for the CRF, mark it complete, and click **Save**.
2. Perform Double Data Entry for the CRF, mark it complete, and click **Save**. If any values in the Double Data Entry are different from the initial data entry, an error message displays. Address the differences in one of the following ways:
 - If the value in the Double Data Entry is correct, keep that value by clicking **Save** again. The Audit Log stores the user's name, date, time, and value entered in both the initial data entry and in Double Data Entry.
 - If the value in the initial data entry is correct, change the Double Data Entry value to the correct one in the CRF field, and click **Save**. The Audit Log stores only the initial value.
 - If you want to maintain the value from the initial data entry and from the Double Data Entry for later follow-up, add a Discrepancy Note, and click **Save**.

4.7.5 CRF Status

The Status of a CRF progresses through the data entry process in the following manner.

Note: Some CRF states, such as SDV, Signed, and Removed, are not discussed here, since they are not part of the data entry process.

CRF Status	Icon	Description
Not Started		The CRF has not been opened for data entry.
Initial Data Entry		The CRF has been opened for data entry. The user might have entered some or all of the data into the CRF.
Data Entry Complete		The CRF has been marked complete. All required data has been entered and saved, and the ClinCapture edit checks have been performed. This icon appears when the CRF is not configured for Double Data Entry or CRF Evaluation. If you make changes to a CRF in this state, the Status remains complete. If the system is set up to create a Reason For Change Discrepancy Note, you must fill it out.
Initial Data Entry Complete		If the CRF is configured for Double Data Entry or CRF Evaluation, this indicates that the CRF has been marked complete after the initial data entry and is ready for Double Data Entry or CRF Evaluation.
Double Data Entry Started		A user has opened the CRF for Double Data Entry. The Status of Double Data Entry for a CRF is shown in the Enter or Validate Data page, in the CRF's table.

Double Data Entry or CRF Evaluation Complete		When the CRF has been marked complete after Double Data Entry or CRF Evaluation.
Locked		The ClinCapture system automatically sets the Status of all CRFs for an Event to locked when you set the Status of the Event to stopped, skipped, or locked. When locked, you cannot enter data or make changes to the CRF. To enter or change data in the CRF, you must change the Status of the CRF by changing the Event Status, see Updating Events .

4.7.6 Modifying a Previously Saved CRF

You can return to edit a page of a CRF that you (or someone else) had previously saved. The data entry behavior may be different under certain circumstances, as explained below.

Deletion of Previously Saved Repeating Group Rows

If your form uses repeating groups, you cannot delete previously saved rows from the grid using the **Delete** icon at the end of the row. If you need to remove a row, change all values to blank for that row. New rows can be deleted, provided they have not yet been saved.

This behavior helps ClinCapture maintain an audit trail that allows users to trace back all changes that have been made in the data and improves the integrity and traceability of the clinical data.

Administrative Editing

Another major difference in behavior is experienced after the CRF has been marked complete, and the Study has been set up to require a Reason For Change.

When you change data under Administrative Editing, for example adding new rows to a repeating group, you must enter a discrepancy note indicating the reason for change.

To facilitate changing data under Administrative Editing, the Study Administrator may have pre-configured some reasons. Contact your Study Administrator if additional reason changes are required.

4.8 Importing CRF Data

As an alternative to performing manual data entry, you can import Event CRF data from a file using the ClinCapture web interface. This import feature is useful when your Study data was captured using a system other than ClinCapture.

The following items are required to import data in ClinCapture:

- The Study exists
- Event Definitions for the data being imported exist
- Event CRFs for the data being imported must exist
- Study Subjects for the data being imported exist
- Study Subjects must be scheduled for the Study Events for which the data is being imported

The information in the file can be for one or more Subjects, for one or more Events for each Subject, and for one or more CRFs for each Event. The type of information for each Subject does not have to be the same. For example, the file can include two Events, each with a CRF for one Subject, and one Event with three CRFs for another Subject.

The imported Subject CRF data replaces any data that was already captured for that Subject and that CRF, unless a specific change is made to a study parameter that allows *skipping* existing data. The imported CRF data should contain all data required for the CRF, and should be valid. Automatic checks for imported data are limited and not as robust as when the data is entered manually in the CRF web interface. Errors trigger automatic creation of Failed Validation Discrepancy Notes. If there are no errors, the CRF is automatically marked Complete. Any subsequent changes must be done in Administrative Editing mode and require a Discrepancy Note if the CRF was set up that way. If there are any calculated value fields in the CRF, you must either supply the correct data in the import file, or open and save the CRFs manually to generate them.

The data import file must be a properly-formatted XML file. For details, see [Data File Format](#).

You can automate the data import process, which is particularly useful when you import data files on a recurring basis.

You can also import data into ClinCapture using SOAP Web Services. Refer to the *ClinCapture Programmer's Guide* for details.

4.8.1 Data Import Options

Some data import options configured during study build may affect the behavior of the system, including whether or not existing data can be replaced during data import, whether or not a CRF is marked *Complete* after data import, etc. Here is the complete list of data import options under Study Parameters:

Data Import:

- Mark imported CRF as Completed? Yes No
- Auto-schedule event during import? Yes No
- Auto-create subject during import? Yes No
- Replace existing data during import? Yes No
-

Data Import	Description
Mark imported CRF as Completed?	Select Yes to mark imported CRFs as Complete, or select No if imported CRFs should not be marked Initial Data Entry Started.
Auto-schedule event during import?	Select Yes to automatically schedule events during import, or select No if events should not be manually scheduled before the import.
Auto-create subject during import?	Select Yes to automatically create subjects during import, or select No if subjects should not be manually created before the import.
Replace existing data during import?	Select Yes to replace existing data during import, or select No if existing data should be skipped during import.

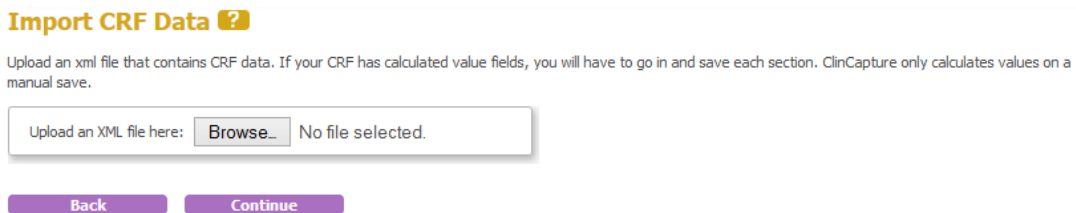
4.8.2 Data File Import

Users with proper permissions can import data from an XML file using the ClinCapture web interface. The Study or Site in the import file must be the same as the current Study or Site.

To import data from a file:

1. From the Navigation Bar, select Tasks > Import Data.

The Import CRF Data page opens.



2. Click **Browse** and locate the XML file that contains the import data, select the file, and click **Open**. The file name you selected appears on the page.

3. Click **Continue**.

ClinCapture validates the XML file. Any validation errors found appear in the Alerts and Messages section in the Side Panel. Correct the errors and retry the data file import.

When validation errors are found, ClinCapture displays a page summarizing the CRF data being imported, and the results of the Hard Validation Error Checks, including any error message. For example, an error is reported if a date format is invalid.

4. When no Hard Validation Errors are found, a page presenting the CRF data being imported, together with any Soft Validation Error Checks appears. Click **Continue**.

5. Click **OK** in the confirmation dialog box to complete the data import.

The CRF for that Subject now contains the imported data. Depending on the Study configuration, the CRF is either marked Complete, or left as Data Entry Started.

6. If the CRF contains empty fields for calculated values, manually open the CRF—under Administrative Editing if the CRF was previously marked Complete—and save each page that contains the generated values. ClinCapture only calculates the values when you save the page manually. For details, see [Entering CRF Data](#).

If you have Rules set up, you do not need to manually run them; Rules run automatically when you import data if the `Run ImportDataEntry` option is set to `true`. By default, Rules are not set to run when you import data. The `ImportDataEntry` flag must be explicitly turned on to run Rules on import.

4.8.3 Data File Format

To import Event CRF data, generate a properly formatted XML file that contains the data to be imported. The XML file must include the Subject Identifiers that ClinCapture uses to specifically identify the entities in the Study. The XML file must be compliant with the Clinical Data Interchange Standards Consortium Object Data Module (CDISC ODM), version 1.2 or 1.3.

To generate the XML file for importing data:

1. Determine the identifiers for the Subjects, Study, Event Definitions, Forms, Item Groups, and Items where you want to import data.
2. Generate the import file using the identifiers and the data.

A more detailed discussion on the data file format is available in the *ClinCapture Programmer's Guide*.

4.8.4 Data File Validation

When you import a data file, ClinCapture validates the file format and performs validity checking for the data, and displays any error messages in the Alerts and Messages in the Side Panel. Correct all errors in the file and retry the import operation again.

ClinCapture performs the following validation on the data import file:

- XML is well-formed against the ODM v1.2 or v1.3.
- The unique Study identifier in the import file matches the current Study in the ClinCapture session where you want to import the data.
- Study Subject OIDs exist for the current Study.
- Study Event Definition OIDs exist for the current Study.
- OIDs for the CRF versions exist for the Study Event Definition OID.
- Study Subject OIDs are scheduled for the Study Events.
- Data values for the Items comply with the metadata. For example, if the metadata for an Item calls for a value of 1 or 2, the data value for that Item in your import file must be 1 or 2.
- Data values are in the correct format. For example, when an integer is required, a decimal value generates an error.

If your Study is configured to flag errors in edit checks, ClinCapture performs the following edit checks on the data import file:

- Data is in the correct format. For example, a date that is not in the required DD-MMM-YYYY or yyyy-mm-dd format generates an error.
- Data values are within the limits specified for CRF Items. For example, when the CRF accepts 90 to 110 degrees for temperature, a value of 111 is not accepted.
- Data values match the acceptable criteria for CRF Items. For example, if a Yes answer is required for an Item and the value in the import file for that Item is No, a discrepancy note is required.
- Required data fields are not empty.

4.9 Notes and Discrepancies

The Notes and Discrepancies feature enables users to document, communicate, and manage the accuracy and completeness of the clinical data. In the clinical trial community, data discrepancies are typically handled using *queries*, whereas data point annotations are documented in *notes*. Whether or not Notes and Discrepancies are used in a Study depends on your Study configuration. See the *ClinCapture Study Administration Guide* for details.

There are various situations where you would use Discrepancy Notes. For example:

- When capturing or validating data in order to flag an item as incomplete or as having a value that is not expected.
- To provide an explanation about, or *annotate*, a field value in a Discrepancy Note.

ClinCapture can automatically create a Discrepancy Note under the following circumstances:

- When you save a CRF that contains unexpected data, according to an edit check rule.
- When you manually run imported edit check rules.

After a Study Monitor, Site Monitor, or Administrator creates a Discrepancy Note, another user, for example a Clinical Research Coordinator, reviews the Discrepancy Note and updates it to help resolve the issue.

The original Note is referred to as the Parent Note. Responses to the original Note are referred to as Child Notes. A single Parent Note with all the Child Notes under it are referred to as one Discrepancy Note.

A Discrepancy Note is associated with a single data element, usually a CRF Item such as a diagnosis, medication, or weight, but it can also be associated with data pertaining to the Subject record, such as sex or date of birth, or the Study Event, such as the date or the location.

After a Discrepancy Note is created, it cannot be deleted. If a Discrepancy Note is created erroneously, a common practice is to add a new Child Note with a Status of Closed.

To use Notes and Discrepancies, your browser must have:

- JavaScript enabled
- Pop-up blockers disabled

A Discrepancy Note has four key properties, which the user assigns when creating the Note:

- Note Type
- Status
- Description
- Detailed Note

After a Discrepancy Note has been created, you cannot change the Note type. To update the other properties, you add new Child Notes.

Note: If CRF masking functionality is being used, you cannot work with notes or discrepancies for CRFs that have been masked from you.

4.9.1 Discrepancy Note Types

The purpose, behavior, and workflow are different for each Note type. The Note type you can assign to an element depends on when the Note is created. ClinCapture has the following Note types:

- Failed Validation Check
- Query
- Reason For Change
- Annotation

Failed Validation Check

A Failed Validation Check Note type is for data that does not comply with the expected values, also referred to as a *Soft Validation Check*. Refer to [Manual Data Entry](#) for details on the differences between a Hard Validation Check and a Soft Validation Check. When initially created, the Status is New. The Note then requires further review to determine if the data is acceptable. ClinCapture can automatically generate this Note type when validating a field, according to its associated rules.

There are two ways to handle a Failed Validation Check:

- Before a CRF is saved.** For example, an inclusion criterion is not met and the data entry person knows that the newly entered data will not pass validation. In this case, they can annotate the field in question before a query is generated, and ClinCapture realizes that the failed validation is intentional. Thus, it will create a Failed Validation Check Parent Note and the data entry annotation as a Child Note. If this condition is met, the Failed Validation Check is considered handled, and no error message is reported when the CRF is saved.
- After a CRF is saved.** ClinCapture first displays a warning message. If the user does not change the value to one that conforms to the expected value for the Item, it automatically creates a Failed Validation Check Note.

ClinCapture also generates this Note type when imported data does not conform to the expected values.

Query

A Query Note type is used to ask a question about data provided for a CRF item. For example, a Study or Site Monitor can create a Query Note to inquire about a CRF item that seems incomplete or incorrect, even though the item has met all automated edit checks.

Below is the typical workflow:

- A Study-level user creates a Query Note. The Query Note status is New. The note originator assigns and directs the Query Note to the user who can address the issue, typically the person who entered the data.
- The user assigned to the query updates it by adding a new Child note to the Parent. The user may or may not modify the data value in conjunction with the update. The Query Note status is set to Updated.
- The note originator reviews the response and, if satisfied, marks it as Closed, or updates it with additional comments, and assigns it back to the user.

Reason For Change

A Study can be configured to force users to document any data changes made after a CRF has been marked Complete. ClinCapture automatically converts an Annotation to a Reason For Change Note

when a change is made to a completed CRF, and the data entry person enters an Annotation for the changed field. A Reason For Change Discrepancy Note always has a status of Not Applicable.





Annotation

An Annotation Discrepancy Note allows users to enter information to clarify data that cannot be adequately represented or explained in the CRF. Refer to your study's CRF completion guidelines about the appropriate use of Annotations. Annotation Notes always have a Status of Not Applicable.

4.9.2 Discrepancy Note Status

The Status for a Discrepancy Note indicates who is responsible for the next step. The Discrepancy Note type determines what status values are allowed.

The following table shows the different Discrepancy Note Status values:

Icon	Status	Description
	New	This is the initial status for a Query or Failed Validation Check Note type.
	Updated	Used when responding to a Note.
	Closed	This is the final status for a Failed Validation Check or a Query Note. When a Note has a status of Closed, it cannot be changed in any manner. Child Notes cannot be added. Only Study-level users can mark a Discrepancy Note as Closed.
	Not Applicable	This Status is reserved for Reason For Change and Annotation Note types because no further action is required. The Status of Not Applicable cannot be used for Failed Validation Check and Query Note types.

When more than one Discrepancy Note is associated with a CRF Item, the highest priority Status is shown. The following priorities are used to classify Discrepancy Notes, starting with the highest priority:

- 1- New
- 2- Updated
- 3- Closed

4.9.3 Creating Discrepancy Notes

Discrepancy Notes can be created automatically by ClinCapture, or by users.

Automatically-Created Discrepancy Notes

ClinCapture can automatically generate Discrepancy Notes under Administrative Editing, data validation checks, and data import as follows.


- ❑ When a CRF is marked Complete and you change a CRF item under Administrative Editing, ClinCapture prompts you to enter a Reason For Change if the Study configuration is set to force a Reason For Change. To avoid being prompted, you can enter a Discrepancy Note for the item changed before saving the CRF.
- ❑ When a data item entered into a CRF does not pass its Soft Validation Checks and you click **Save**, ClinCapture prompts you to provide a valid value. If you do not correct the data after being prompted and click **Save** again, ClinCapture saves the CRF and automatically creates a Discrepancy Note. For details, see [Manual Data Entry](#).
- ❑ When you import data into ClinCapture, if errors are found ClinCapture automatically generates a Failed Validation Check.



Note: In some cases, ClinCapture does not allow you to import data; for example, when Hard Validation Checks are triggered by invalid Date formats.

User-Created Discrepancy Notes















A user can generate a Note in ClinCapture during data entry or when reviewing a CRF, as follows.

1. Click the **Add Discrepancy Note** icon () next to the item.

View Event: Lab for Subject npm001-002 

Subject ID	npm001-002 
Study Event	Lab
Location	N/A 
Study Subject OID	SS_NPM00100_0000001
Subject Event Status	scheduled
Last Updated by	()

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Actions
Blood Form * 	1.2			  
Processing Form * 	1.1			  
Receipt Form *	1.1			  


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[Schedule Event](#)

Workflow

```

graph LR
    A[Study Event Overview] --> B[Data Entry]
    B --> C[Mark Event CRF Complete]
  
```

- The *Add Discrepancy Note* window opens.



Location: Add Discrepancy Note

"Location" Properties:

Subject:	npm001-002	Event:	Lab
Event Date:	28-Jul-2013	CRF:	N/A
Current Value:	N/A	More:	N/A

Add Note

Description:

Detailed Note:

Submit & Close

Note: The content of this window may look different depending on your user role.

- Complete the Description and Detailed Note fields as required.
- If your user role is Study Monitor, Site Monitor, Study Coder, or Study Administrator, select Query or Annotation as the Note type from the drop-down list. Investigators and Clinical Research Coordinators do not have the option to enter a note type; any note they enter is considered an Annotation.
- For a Query Note, select the user from the Assign to User drop-down list that can best handle the issue resolution.



Note: ClinCapture does not prevent other users from updating the Note.

To send an email to the assigned user, select the E-mail Assigned User checkbox. When an Investigator or Clinical Research Coordinator updates a Note, it is automatically assigned back to the originator.

- Click **Submit & Close**.

A message replaces the contents of the window, indicating a Note was created. The window then closes automatically.

In the CRF page, the flag icon for the Item is changed to a color that reflects the status of the Discrepancy Note.

- The flag icon color is white () if the note entered was an Annotation.
- The flag icon color is red () if the note entered was a Query.

View Event: Lab for Subject npm001-002 ?

Subject ID	npm001-002
Study Event	Lab
Location	N/A
Study Subject OID	SS_NPM00100_0000001
Subject Event Status	scheduled
Last Updated by	()

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Actions
Blood Form * ✓	1.2			
Processing Form * ✓	1.1			
Receipt Form *	1.1			

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Multiple Discrepancy Notes for a CRF Item

If a Discrepancy Note already exists for a CRF item, and you want to create a new, different Note for the item, you can do so by following these steps:

1. In the CRF, click the flag icon for the existing Discrepancy Note for that Item. ClinCapture opens the *Notes and Discrepancies* window, which contains details for the item.
2. Click **Begin New Thread**.
3. Complete the process as if adding a new Discrepancy Note.

4.9.4 Viewing a Discrepancy Note

To see a list of Discrepancy Notes or to find a Discrepancy Note, see [Viewing Discrepancy Notes](#). To view a Discrepancy Note in ClinCapture:

1. Open the CRF page that contains the Discrepancy Note.
2. Position your pointer over the flag icon for the Item with the Discrepancy Note. ClinCapture displays a pop-up window with summary information about the Discrepancy Note.
3. Click the flag icon to view the details about the Discrepancy Note. ClinCapture displays the details of the Discrepancy Note in the *Notes and Discrepancies* window. If there are multiple

Discrepancy Notes associated with the CRF Item, each Note is presented in a separate table, and has a unique Note ID.

- When you are finished viewing the Note details, click **Close Window**.

Location: Notes and Discrepancies

"Location" Properties:

Subject: **npm001-002** Event: **Lab**
 Event Date: **28-Jul-2013** CRF: **N/A**
 Current Value: More:

Note Details

<input type="checkbox"/> The location was not specified.		Last updated: 28-Jul-2013 by jose_crc Assigned to: Jose Castro (jose_crc)	
ID: 18	Type: Annotation	Current Status: Not Applicable	# of Notes: 1
The location was not specified.		Status: Not Applicable	28-Jul-2013 by jose_crc Assigned to: Jose Castro (jose_crc)
The location where the clinical research was being done was not specified in the case report form (CRF).			

[Begin New Thread](#)

Audit History

Audit Event	Date/ Time of Server	User	Value Type	Old	New
study_event_scheduled	28-Jul-2013 08:12:33	jose_crc	Status	0	1

(This item was initially entered on 28-Jul-2013.)

4.9.5 Updating a Discrepancy Note

You can update any Discrepancy Note within your current Study or Site scope, even if it is assigned to someone else.

To update a Discrepancy Note:

- Open the Discrepancy Note you want to update in one of the following ways:
 - Open the CRF with the Discrepancy Note, and click the flag icon for the item you want to change.
 - From the *Notes & Discrepancies* page, sort and filter to select the Notes and Discrepancies of interest. Click the **View** icon to display the Discrepancy Note. Click the **View Within Record** icon to display both the Discrepancy Note and the associated CRF.

Rand_Eligibility: Notes and Discrepancies

"Rand_Eligibility" Properties:

Subject: **5001-002** Event: **Enrollment**
 Event Date: **18-Jun-2013** CRF: **Randomization Form**
 Current Value: **0** More: [Data Dictionary](#)

Note Details

<input type="checkbox"/> Please verify eligibility		Last updated: 08-Jul-2013 by test_cra Assigned to: Marc Desgrouilliers (test_cra)	
ID: 12	Type: Query	Current Status: Updated	# of Notes: 3
Please verify eligibility	Status: New	08-Jul-2013 by test_cra Assigned to: Root User (root)	
Eligibility was verified	Status: Updated	08-Jul-2013 by test_pi Assigned to: Marc Desgrouilliers (test_cra)	
Monitored and closed	Status: Updated	08-Jul-2013 by test_cra Assigned to: Marc Desgrouilliers (test_cra)	
Update Note			

Begin New Thread

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
item_data_value_updated	18-Jun-2013 20:05:12	root	Rand_Eligibility		0
item_data_status_changed	17-Jul-2013 16:05:20	root	Rand_Eligibility	auto-removed	available
item_data_status_changed	17-Jul-2013 15:20:09	root	Rand_Eligibility	unavailable	auto-removed

(This item was initially entered on 18-Jun-2013.)

Close Window

- Click the **Update Note** button. A new section is displayed allowing you to enter a Description and Detailed Note for your update. These notes updates are reviewed later on by the Study Monitor, Site Monitor, or Study Administrator.

Note Details

<input type="checkbox"/> Please verify eligibility		Last updated: 08-Jul-2013 by test_cra Assigned to: Marc Desgrouilliers (test_cra)	
ID: 12	Type: Query	Current Status: Updated	# of Notes: 3
Please verify eligibility		Status: New	08-Jul-2013 by test_cra Assigned to: Root User (root)
Eligibility was verified		Status: Updated	08-Jul-2013 by test_pi Assigned to: Marc Desgrouilliers (test_cra)
Monitored and closed		Status: Updated	08-Jul-2013 by test_cra Assigned to: Marc Desgrouilliers (test_cra)
<input type="button" value="Update Note"/>			

Respond below to Update/Resolve/Close this Discrepancy Note: ✕

Description: *

Detailed Note:

3. Click **Submit** to save the updated information but keep the window open, or click **Submit and Exit** to save the updated information and close the window.

The Discrepancy Note now includes the information you provided as a new Child Note in the thread.

If you do not want to save any of the information, click the **Close Window** (✕) icon.

4. In the CRF and in the *Notes and Discrepancies* page, the color of the flag icon for that note changes to yellow (🚩) to reflect the Updated status.

Notes:

If the note is a Query or a Failed Validation Check, and your user role is Study Monitor, Site Monitor, Study Coder, or Study Administrator, you can assign the note to any user in the Study and you can select the E-mail Assigned User checkbox to send an email alert to the assigned user.

If a user changes a CRF data under Administrative Editing as a result of a query, he can update the query and does not need to enter a Reason For Change (RFC). ClinCapture will automatically process the query Update as a Reason For Change.

I_Q1: Add Discrepancy Note

"I_Q1" Properties:

Subject:	BGH-003	Event:	Enrollment
Event Date:	18-Sep-2013	CRF:	Patient Eligibility
Current Value:	1	More:	Data Dictionary

Add Note

Description:*	<input type="text"/>
Detailed Note:	<input type="text"/>
Type:*	Query <input type="button" value="v"/>
Assign to User:	Investigator, Principal (demo_pi) <input type="button" value="v"/>
Email Assigned User:	<input type="checkbox"/>
<input type="button" value="Submit"/>	

4.9.6 Managing Discrepancy Notes

The *Notes and Discrepancies* page provides a summary of Notes and Discrepancies related to your current scope: Study or Site. The notes accessible to you also depends on your role. Study Coder and Study Evaluator only see the Notes and Discrepancies associated with their tasks.

Figure 26: Notes and Discrepancies page

Notes and Discrepancies ?

Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	--	--	--	--	--
Updated	1	--	--	--	1
Resolution Proposed	--	--	--	--	--
Closed	3	--	--	--	3
Not Applicable	--	--	--	2	2
Total	4	--	--	2	6

Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User
S02-006	Query	Closed	npm001	0		30 Day Follow-up		Start Date	2013-06-27 00:00:00.0	Event was completed earlier than expected.	Marc Desgrouillier (test_dm)
S001-001	Query	Closed	npm001	0		30 Day Follow-up		Start Date	2013-06-20 12:00:00.0	Event was completed earlier than expected.	Marc Desgrouillier (test_cra)
S001-002	Query	Updated	npm001	23	0	Enrollment Form	Randomization	Rand_Eligibility	0	Please verify eligibility	Marc Desgrouillier (test_cra)
npm001-002	Annotation	Not Applicable	npm001			Lab		Location		The location was not specified.	Jose Castro (jose_crc)
npm001-004	Annotation	Not Applicable	npm001			Lab		Location		The location was not specified.	Jose Castro (jose_crc)
S001-001	Query	Closed	npm001	0		30 Day Follow-up		Start Date	2013-06-18 12:00:00.0	Event was completed	Marc Desgrouillier

A quick way to access only the Notes and Discrepancies assigned to you is from the ClinCapture *Home* page. The *Home* page reports how many Notes and Discrepancies are assigned to you in the current Study or Site. Click the [Notes & Discrepancies Assigned to Me](#) link to view details about your Notes in the *Notes and Discrepancies* page.

To view the page with all Notes and Discrepancies for the current Study or Site, click [Notes & Discrepancies](#) in the Navigation Bar.





The table at the top of the page contains summarized notes and discrepancy statistics. Click a value in this summary table to filter the details table at the bottom of the page to show only those items. Figure 27 shows an example of the details table, filtered to show only two Annotations, after clicking the number 2 in the summary table.

Figure 27: Notes and Discrepancies page filter example

Notes and Discrepancies ?

Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	--	--	--	--	--
Updated	1	--	--	--	1
Resolution Proposed	--	--	--	--	--
Closed	3	--	--	--	3
Not Applicable	--	--	--	2	2
Total	4	--	--	2	6

Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
	Annotation											Apply Filter Clear Filter
npm001-002	Annotation	Not Applicable	npm001			Lab		Location		The location was not specified.	Jose Castro (jose_crc)	 
npm001-004	Annotation	Not Applicable	npm001			Lab		Location		The location was not specified.	Jose Castro (jose_crc)	 

Results 1 - 2 of 2.

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You can filter the Notes and Discrepancies details table by the following information:

- Study Subject ID
- Type: Failed Validation Check, Annotation, Query, Reason For Change
- Resolution Status: New, Updated, Closed, Not Applicable
- Site ID
- Days Open
- Days Since Updated
- Event Name
- CRF
- Entity Name. This refers to the CRF Item for which the Note is associated.
- Entity Value. The value recorded in the CRF for the Item.
- Description. The title of the Discrepancy Note.
- Assigned User. The person assigned to handle the Discrepancy Note.

Clicking [Show More](#) provides the following additional filters:

- Note ID
- Entity Type





In addition, Notes and Discrepancies can be sorted by the following:

- Note ID
- Subject ID

- Date Created
- Days Open
- Days Since Updated

Notes and Discrepancies Actions

The following actions are available on the Notes and Discrepancies page.

Icon	Meaning	Description
	Print	Print the selected item.
	View	Displays information on the item.
	View within Record	Opens the Note and its associated location (CRF, event, Subject, etc.).
	Download Notes	Download notes.

4.9.7 Finding and Organizing Discrepancy Notes

ClinCapture has the following features to help you find and organize Notes and Discrepancies. These features are similar to those used to find and organize data in the Subject Matrix.

Number of Discrepancy Notes per Page

The bottom left corner shows the total number of Discrepancy Notes relevant to you and the number currently in view. When there are more Notes than can be listed on the page, use the green arrows to scroll through the pages of Notes.

When there is only one page of Notes, the arrows are disabled (gray). To change the number of Notes shown on a page, click the drop-down list next to the arrows and select a value: 15, 25, or 50 per page.

Sort Notes by Column

To sort the Notes by a column, click the column header. Some columns do not allow sorting by, in which case, the pointer does not change shape when you position it over the column header. To reverse the sort order, click the column header again. An arrow next to the column header indicates the current sort order: up for ascending and down for descending.

For example, click the Study Subject ID column header to sort by that column, with the lowest Study Subject ID value first. Click the column header again to show the highest Study Subject ID value first. The arrow in the column header then points down.

Filter Notes to Show Only Matches for Specified Criteria

You can filter the information shown in the *Notes and Discrepancies* page to show only Notes and Discrepancies whose data match the criteria that you specify.

- For the column whose data you want to filter, click the gray field below the column header.
- What you enter in a field depends on the type of field:
 - If a drop-down list displays, select the value you want to use as the filter.
 - If no list displays, type in the string of characters you want to filter by, and press **Enter** or click [Apply Filter](#) (located to the far right of the gray fields).

You can add more filters, if necessary.

To remove filtering for a column, clear the text you entered, or from a drop-down list, select the blank (top) item.

When filtering is applied, only those Notes and Discrepancies containing the data you specified are shown. To clear all filtering and show all data, click [Clear Filter](#) (located to the far right of the gray fields).

Figure 28: Notes and Discrepancies filtered by Type

Notes and Discrepancies ?

Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	--	--	--	--	--
Updated	1	--	--	--	1
Resolution Proposed	--	--	--	--	--
Closed	3	--	--	--	3
Not Applicable	--	--	--	2	2
Total	4	--	--	2	6

Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
	<input type="text" value="Annotation"/>											Apply Filter Clear Filter
npm001-002	Annotation	Not Applicable	npm001			Lab		Location		The location was not specified.	Jose Castro (jose_crc)	
npm001-004	Annotation	Not Applicable	npm001			Lab		Location		The location was not specified.	Jose Castro (jose_crc)	

Results 1 - 2 of 2.

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Discrepancy Notes per Subject



The *View Subject Record* page includes a Notes & Discrepancies action button. Clicking it opens the *Notes and Discrepancies* page with all the notes and discrepancies for that Subject. If needed, you can further filter these Notes to find the exact information you are looking for.

Notes & Discrepancies Assigned to Me

At the top of the *Home* page, there is a [Notes & Discrepancies Assigned to Me](#) link. Clicking on it displays the *Notes and Discrepancies* page showing your assigned Notes that are either New or Updated. This is a quick way to find the Notes that you need to process.

4.9.8 Downloading Discrepancy Notes

To download Discrepancy Notes to a file:

1. Filter the Notes and Discrepancies to show only the Notes that you want to download. All data for those Notes will be downloaded—that is, all the data that appears in the [Show More](#) view.
2. Select the file format to download the data into using the PDF or CSV icons ( ).
Comma separated values (CSV) is best to use with other software, such as a spreadsheet or database. The CSV file contains one row for each Note, whether it is a Child or Parent Note.
Portable document format (PDF) creates a file that is easy to read and print. The PDF file shows a Parent Note in bold, followed by the Child Notes associated with the Parent Note in the normal font style.
3. Depending on your browser settings, you might be prompted to open or save the downloaded file.
4. Click **Close Window**.

4.9.9 Generating Discrepancy Correction Forms (DCFs)

A Discrepancy Correction Form (DCF) is a PDF version of a discrepancy that can be sent to the site electronically by FAX or email, or printed and delivered to the site.

You can generate DCFs for New or Updated discrepancies only.

The DCF generation feature is only available if Study parameter, **Allow Discrepancy Correction Forms**, is **yes**.

The following roles may have access to the DCF feature:

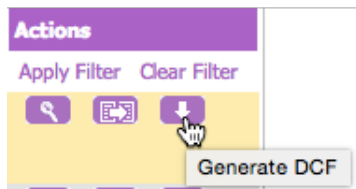
- System Administrator
- Study Administrator
- Study Monitor
- Study Coder

To generate DCFs for New discrepancies:

1. To make selection easier, filter the Notes and Discrepancies to show only New discrepancies.

2. Select one or more discrepancies for which to generate DCFs by checking the corresponding box(es) in the DCF column.

Alternatively, click the Generate DCF icon in the Actions column.



3. Click **Generate DCF**.
4. Select one or more of the following:
 - **Save the DCF** – Download the DCF in PDF format. You can then electronically FAX or email the document.
 - **Print the DCF** – Open the DCF in PDF format. You can then use your browser’s print feature to print the DCF and FAX or deliver it to the site.
 - **Email the DCF to** – Email the DCF. If you select this option, specify the email address to which it should be sent.
5. Click **Generate DCF**.

The discrepancy status is changed to Updated, and a child note is added to indicate a DCF has been generated. The note also indicates how the DCF was generated (Saved, Printed, Emailed).

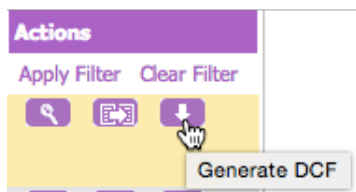
If you selected **Save the DCF**, the DCF is downloaded in PDF format. If multiple discrepancies were selected, a single PDF is generated. Line breaks separate each generated DCF.

If you selected **Print the DCF**, the DCF opens in PDF format. Use your browser’s print feature to print the DCF.

If you selected **Email the DCF**, the DCF is emailed to the address specified.

To generate DCFs for Updated discrepancies:

1. To make selection easier, filter the Notes and Discrepancies to show only Updated discrepancies.
2. Click the Generate DCF icon in the Actions column.



3. Click **Generate DCF**.
4. Select one or more of the following:

- **Save the DCF** – Download the DCF in PDF format. You can then electronically FAX or email the document.
- **Print the DCF** – Open the DCF in PDF format. You can then use your browser’s print feature to print the DCF and FAX or deliver it to the site.
- **Email the DCF to** – Email the DCF. If you select this option, specify the email address to which it should be sent.

5. Click **Generate DCF**.

The discrepancy status is changed to Updated, and a child note is added to indicate a DCF has been generated. The note also indicates how the DCF was generated (Saved, Printed, Emailed).

If you selected **Save the DCF**, the DCF is downloaded in PDF format. If multiple discrepancies were selected, a single PDF is generated. Line breaks separate each generated DCF.

If you selected **Print the DCF**, the DCF opens in PDF format. Use your browser’s print feature to print the DCF.

If you selected **Email the DCF**, the DCF is emailed to the address specified.

4.10 Special Permissions

Study Monitor, Site Monitor, and Study Coder user roles cannot access the Submit Data module. For information about features in the module, see [Submitting Data](#).

Table 3: Submit Data Permissions by feature

Feature	Task	User Role / User Type
Subject Management	Remove a Subject from a Study or Site or to restore a Study Subject.	<ul style="list-style-type: none"> ● Study Administrator ● Investigator
	Assign a Subject to another Site within the Study.	<ul style="list-style-type: none"> ● Study Administrator
	Lock/Unlock a Subject.	<ul style="list-style-type: none"> ● Study Administrator
Events and Casebooks	Sign a Study Event or a Subject Casebook.	<ul style="list-style-type: none"> ● Investigator
CRF Data and Events	Remove and restore Study Event CRFs and Study Events.	<ul style="list-style-type: none"> ● Study Administrator / Administrator
	Set Study Event Status to locked.	<ul style="list-style-type: none"> ● Study Administrator
Notes and Discrepancies	Set the status of a Discrepancy Note to closed.	<ul style="list-style-type: none"> ● Study Administrator ● Study Monitor

		<ul style="list-style-type: none">• Site Monitor• Study Coder
--	--	--------------------------------------------------------------------------------------

5 MONITOR AND MANAGE DATA

The ClinCapture Monitor and Manage Data module allows you to oversee and validate data for a Study, promoting increased productivity in clinical trials management. Access to the features in the module depends on your user role, see [ClinCapture Modules](#).

The Monitor and Manage Data module consists of the following features:

- ❑ **Source Data Verification (SDV):** Track your evaluations of data conformity reviews for CRFs and Study Subjects. This helps to ensure that the Study is complete, accurate, and verifiable.
- ❑ **Study Audit Log:** View the change history for each Study Subject in log format and use it to facilitate the Study validation process.
- ❑ **Code:** Transform verbatim term descriptions of medical diagnoses, procedures, and drugs into universal medical code numbers. This facilitates a precise tracking of diseases, thereby ensuring that these terms are used uniformly.
- ❑ **Rules:** Use Rules Studio to define edit checks, enabling you to verify the validity of data entered in a CRF for a Study. Rules Studio also allows you to manage existing rules for a Study, create new rules for a Study, or copy rules from one Study to another.
- ❑ **Subject Matrix:** View information about each Subject in the Study or Site from the Subject Matrix.
- ❑ **View Events:** View information about any Study Event.
- ❑ **Notes & Discrepancies:** Use Notes and Discrepancies for query and discrepancy management to help you verify the accuracy and completeness of data in a clinical trial.

5.1 Source Data Verification

Source Data Verification (SDV) helps you review your CRF data for conformity and track evaluations, to ensure your Study is complete, accurate, and verifiable.

When using SDV, ClinCapture presents CRFs ready for you to verify. You can perform source data verification either by Event CRF or by Subject. You can also use filters to show only the CRFs you are interested in. After you have verified the data, you can mark the CRFs as either verified individually or as a group. SDV can be done at the CRF level or at the item level, depending on the study requirement.

When CRFs are added as part of configuring the Study Event, the Study Administrator must specify whether or not SDV is required. If SDV is required, the CRF must be configured for form-level or item-level SDV. If item-level SDV is required, the specific items to be source data verified must be specified in the *View CRF Version Details* page (Tasks -> CRFs -> View -> Metadata).

Note: If CRF masking functionality is being used, users will not be able to SDV CRFs that are masked from them. Masked CRFs will not display on the SDV page.

5.1.1 Verifying Source Data

Study Monitor and Site Monitor users can verify source data in ClinCapture.

To perform CRF-level Source Data Verification:

1. Change the current Study or Site to the one where you want to perform Source Data Verification.
2. Click a completed event to open the Event pop-up
3. Click the **SDV** action icon for the Subject or Event you want to verify. The *Source Data Verification* page for the current Study or Site opens with the necessary information to filter the Subject or the Event.
4. Select Tasks > Source Data Verification.

The *Source Data Verification* page for the current Study or Site opens with unfiltered information.

Source Data Verification for PRO ?

View By Event CRF | View By Study Subject ID

15 | Show More | The table is sorted by Event Date

Select: All Shown, None

SDV Status	Subject ID	Site ID	Event Name	Event Date	CRF Name / Version	SDV Requirement	CRF Status	Actions
<input checked="" type="checkbox"/>	S001-001	npm001	Completion(1)	18-Jun-2013	Completion Form/ 1.0	100% Required	<input checked="" type="checkbox"/>	Apply Filter Clear Filter
<input type="checkbox"/>	npm001-001	npm001	Enrollment(1)	08-Jul-2013	Enrollment Form/ 1.2	100% Required	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	npm001-001	npm001	Enrollment(1)	08-Jul-2013	Randomization Form/ 1.2	100% Required	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	npm001-001	npm001	Completion(1)	17-Jul-2013	Completion Form/ 1.0	100% Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	S02-006	npm001	Completion(1)	17-Jul-2013	Completion Form/ 1.0	100% Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	S02-005	npm001	Completion(1)	17-Jul-2013	Completion Form/ 1.0	100% Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	npm001-002	npm001	Enrollment(1)	19-Jul-2013	Randomization Form/ v.1.4	100% Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	npm001-007	npm001	AE/SAE(1)	25-Jul-2013	AE Form/ 1.0	Not Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Results 1 - 8 of 8.

Back SDV All Checked

By default, the View By Event CRF tab displays, which lists only completed CRFs that are ready for Source Data Verification. Click the **CRF** status icon in the CRF Status column for the CRF you want to view.

The View By Study Subject ID tab lists all Subjects in the current Study or Site. Click the **View** icon in the Actions column for the Subject you want to view to show all Event CRFs ready for verification for that Subject. Click the **CRF** status icon for the CRF you want to view.

You can customize the view to show only those CRFs or Subjects whose data you want to verify, see [Customizing the View](#).

5. The completed CRF opens in a new window where you can review the data in the CRF.
6. If necessary, add a Query type Discrepancy Note to record a question about any Item.

7. When you have finished reviewing the data in the CRF, click the **Close** button in the CRF window.

Note: If you click **Exit** instead, the window remains open, showing the Subject details.

8. Click the **SDV** icon to mark the CRF data as verified. In the SDV status column, the checkbox is replaced by an **SDV Complete** icon (✓). The Event CRF Source Data Verification Status is logged in the Subject Audit Logs, along with the date, time, and name of the user that performed the data verification.
9. Continue viewing details and marking CRFs as verified, and changing the view as needed. You can mark multiple CRFs as verified in any of the following ways:
 - **All Eligible CRFs for a Subject:** In the Study Subject ID view, click the **SDV** button for the Subject to mark all eligible CRFs for that Subject as verified.
 - **Selected CRFs or Subjects:** In either the CRF or Subject view, select the checkbox in the SDV Status column for all CRFs or Subjects that you want to mark as verified. You can deselect a row by clicking the checkbox again, or clear all selected rows by clicking the [None](#) link (located above the column headers). Click the **SDV All Checked** button at the bottom of the page.
 - **All CRFs or Subjects Shown:** In either the CRF or Subject view, click the [All Shown](#) link (located above the column headers) to select all CRFs or Subjects on the page. You can deselect a row by clicking its checkbox, or clear all selected rows by clicking the [None](#) link (located above the column headers). Click the **SDV All Checked** button at the bottom of the page.

To perform item-level Source Data Verification:

1. Change the current Study or Site to the one where you want to perform Source Data Verification.
2. Click a completed event to open the Event pop-up
3. Click the **SDV** action icon for the Subject or Event you want to verify. The *Source Data Verification* page for the current Study or Site opens with the necessary information to filter the Subject or the Event.
4. Select Tasks > Source Data Verification.

The *Source Data Verification* page for the current Study or Site opens with unfiltered information.

Source Data Verification for PRO ?

View By Event CRF | View By Study Subject ID

15 Show More | The table is sorted by Event Date

Select: All Shown, None

SDV Status	Subject ID	Site ID	Event Name	Event Date	CRF Name / Version	SDV Requirement	CRF Status	Actions
<input checked="" type="checkbox"/>	S001-001	npm001	Completion(1)	18-Jun-2013	Completion Form/ 1.0	100% Required	<input checked="" type="checkbox"/>	Apply Filter Clear Filter
<input type="checkbox"/>	npm001-001	npm001	Enrollment(1)	08-Jul-2013	Enrollment Form/ 1.2	100% Required	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	npm001-001	npm001	Enrollment(1)	08-Jul-2013	Randomization Form/ 1.2	100% Required	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	npm001-001	npm001	Completion(1)	17-Jul-2013	Completion Form/ 1.0	100% Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	S02-006	npm001	Completion(1)	17-Jul-2013	Completion Form/ 1.0	100% Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	S02-005	npm001	Completion(1)	17-Jul-2013	Completion Form/ 1.0	100% Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	npm001-002	npm001	Enrollment(1)	19-Jul-2013	Randomization Form/ v.1.4	100% Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	npm001-007	npm001	AE/SAE(1)	25-Jul-2013	AE Form/ 1.0	Not Required	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Results 1 - 8 of 8.

Back

SDV All Checked

By default, the View By Event CRF tab displays, which lists only completed CRFs that are ready for Source Data Verification. Click the **CRF** status icon in the CRF Status column for the CRF you want to view.

The View By Study Subject ID tab lists all Subjects in the current Study or Site. Click the **View** icon in the Actions column for the Subject you want to view to show all Event CRFs ready for verification for that Subject. Click the **CRF** status icon for the CRF you want to view.

You can customize the view to show only those CRFs or Subjects whose data you want to verify, see [Customizing the View](#).

- The completed CRF opens in a new window where you can review the data in the CRF.

Demographics v.1

Subject ID: S01-102

Event: Screening (19-Dec-2014) Site: Brooklyn Medical Center

Study: Demo Study

▼ **More Info**

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

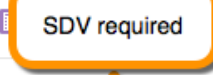











Exit

CRF Shortcuts:				
New Discrepancies	Updated Discrepancies	Closed Discrepancies	Annotations	Items to SDV
0	0	0	0	4














Informed Consent Form (6/6) Demographics (4/4)

Title: Informed Consent Form

Instructions:

1. Date of Screening:	04-May-2015	
2. Subject Initials:	AA	* 
3. Date of Birth:	04-May-1988	 *   (dd-Mmm-yyyy)
4. Age:	27	 
5. Date Informed Consent was signed:	04-May-2015	 *   (dd-Mmm-yyyy)
6. If Age is between 6 and 17, was assent to participate in the study obtained?	<input type="radio"/> Yes <input type="radio"/> No	 

- To quickly find the items that need SDV, use the CRF shortcut. Click the number link in the **Items to SDV** column. The first item on the CRF that requires SDV will be presented and highlighted in yellow.
- If necessary, add a Query type Discrepancy Note to record a question about any Item.
- When you have finished reviewing the item data, click the blue SDV required button to the right of the item to mark the item as verified.
- The SDV icon changes to a green Source Data Verified icon.

Informed Consent Form (6/6)		Demographics (4/4)	
Title: Informed Consent Form			
Instructions:			
1. Date of Screening:	04-May-2015	 *	 (dd-Mmm-yyyy)
2. Subject Initials:	AA	* 	
3. Date of Birth:	04-May-1988	 * 	 (dd-Mmm-yyyy)
4. Age:	27	 	Source Data Verified
5. Date Informed Consent was signed:	04-May-2015	 *  	(dd-Mmm-yyyy)
6. If Age is between 6 and 17, was assent to participate in the study obtained?	<input type="radio"/> Yes <input type="radio"/> No		 

10. Click the number link in the **Items to SDV** column again to jump to the next item requiring SDV.
11. Continue viewing the CRF and marking items as verified.
12. The Event CRF Source Data Verification Status is logged in the Subject Audit Logs, along with the date, time, and name of the user that performed the data verification, when all items to be source data verified have been marked SDV-ed.
13. You can mark all items on one or multiple CRFs as verified in any of the following ways:
 - **All Eligible CRFs for a Subject:** In the Study Subject ID view, click the **SDV** button for the Subject to mark all eligible CRFs for that Subject as verified.
 - **Selected CRFs or Subjects:** In either the CRF or Subject view, select the checkbox in the SDV Status column for all CRFs or Subjects that you want to mark as verified. You can deselect a row by clicking the checkbox again, or clear all selected rows by clicking the [None](#) link (located above the column headers). Click the **SDV All Checked** button at the bottom of the page.
 - **All CRFs or Subjects Shown:** In either the CRF or Subject view, click the [All Shown](#) link (located above the column headers) to select all CRFs or Subjects on the page. You can deselect a row by clicking its checkbox, or clear all selected rows by clicking the [None](#) link (located above the column headers). Click the **SDV All Checked** button at the bottom of the page.

Note: Once a CRF is source data verified, if a change is required to an item that is not to be SDV-ed, the CRF will keep its SDV status.

5.1.2 Customizing the View

You can customize the view of the *Source Data Verification* page to adapt it to your workflow. For example, you can review all CRFs for a particular Subject. Or if you use a sampling method, you can review a sample of CRFs for a Site, and then mark all CRFs for that Site as verified.

This section describes the various ways you can customize the SDV view.

SDV by CRF

Open the View By Event CRF tab. All CRFs in the current Study or Site that are eligible for Source Data Verification are shown. To be eligible, CRFs must be marked as Completed and discrepancies may or may not be opened depending on your study configuration.

CRFs are listed by Event Date, with the oldest at the top of the page. The CRF view also reports the level of Source Data Verification required for a CRF (shown in the SDV Requirement column, and specified in the CRF Event Definition). After verifying the data, you can mark one CRF or selected CRFs as verified.

SDV by Event

Open the Subject Matrix and click on a completed Event to open the Event pop-up. Click the **SDV** action icon for the Event. The *Source Data Verification* page opens and displays all eligible CRFs associated with this Event.

SDV by Subject

There are two options for performing SDV by Subject:

- Option 1:** Open the Subject Matrix, click on a Completed Event to display the pop-up, and click the **SDV** action icon for the Subject. The Source Data Verification page opens and displays the CRFs associated with this Subject.
- Option 2:** Open the View By Study Subject ID tab. All Subjects in the current scope (Study or Site) are shown, along with how many CRFs are eligible for verification and how many have already been verified, as shown in CRFs Completed and CRFs SDV columns. The view lists all Subjects, even those with no CRFs eligible for Source Data Verification, marked as SDV N/A in the Actions column.

You can mark all CRFs for one or more Subjects as verified using this view.

You can also click the **View** icon to open the SDV by CRF view to access the list of all CRFs eligible for SDV for that Subject.

5.1.3 Finding and Organizing SDV Data

Either in the CRF or Subject view, you can:

- Navigate through the pages and change the number of CRFs or Subjects shown per page
- Show more data for all rows, or hide them
- Filter the data so it shows only the CRFs or Subjects that you want to see

These features work the same as in the Subject Matrix. See [Finding and Organizing Data](#) for more information.

5.1.4 Viewing SDV Status

In the CRF view, icons in the SDV Status column indicate the CRFs that have had Source Data Verification completed and those that have not. Use the filter for the SDV Status column to show only those CRFs with SDV complete, or only those CRFs with incomplete SDV.

In the Subject view, icons in the SDV Status column indicate those Subjects that have had Source Data Verification completed and those that have not. In addition, you can see how many CRFs have had SDV completed for each Subject as shown in the CRF column.

5.1.5 Resetting SDV Status

Source Data Verification status can be reset from verified to unverified either manually by a user with appropriate permissions, or automatically by the ClinCapture software. Unverified CRFs can be verified again later on. The Study Audit Log tracks any change in Source Data Verification status for a CRF.

- Automatically:** ClinCapture automatically resets the Source Data Verification status for a CRF from verified to unverified if the CRF data changes.
- Manually:** To manually change the Source Data Verification status for any CRF in the *Source Data Verification* page, click the **SDV Complete** icon in the SDV Status column.
 - **SDV By Event View:** Click the **SDV** icon for a CRF. After you click the icon, it becomes a checkbox, and the CRF is no longer reported as verified.
 - **SDV By Subject View:** Click the **SDV** icon for a Subject to reset the SDV Status for all CRFs for that Subject. After you click the icon, it becomes a checkbox, and all CRFs for that Subject are no longer reported as verified.

5.2 Study Audit Log

Use the Study Audit Log to view the history of actions and data entered for Subjects in the current Study. Only specific user roles can access the Study Audit Log, see [ClinCapture Modules](#).
















You can access the Study Audit Log in either of the following ways:

- Click the [Study Audit Log](#) link in the Navigation Bar.
- Select Tasks > Study Audit Log.

The *View Study Log* page lists all Subjects in the Study. You can change the number of Subjects shown per page, change the sort order, and filter the table to show only the Subjects that you want to see. These features work the same as in the Subject Matrix. See [Finding and Organizing Data](#) for more information.

Figure 29: View Study Log page

View Study Log for PRO

Subject ID	Study Subject .secondary Label	Study Subject OID	Date of Birth	Person ID	Created By	Status	Actions
							Apply Filter Clear Filter
S01-001		SS_S01001			test_crc	available	
S02-004		SS_S02004			test_crc	available	
npm001-001		SS_NPM00100			test_crc	available	
S01-002		SS_S01002			test_crc	available	
S02-006		SS_S02006			test_crc	available	
npm001-005		SS_NPM00100_0000004			test_crc	available	
npm001-007		SS_NPM00100_0000006			test_crc	available	
npm001-006		SS_NPM00100_0000005			test_crc	available	
S001-003		SS_S001003			test_crc	available	
S01-003		SS_S01003			test_crc	available	
S001-002		SS_S001002			test_crc	available	
S02-001		SS_S02001			test_crc	available	
npm001-004		SS_NPM00100_0000003			test_crc	available	
S02-003		SS_S02003			test_crc	available	
npm001-003		SS_NPM00100_0000002			test_crc	available	
Results 1 - 15 of 22.							

Back

5.2.1 Viewing Audit Logs for a Subject

You can view the Study Audit Logs for a particular Subject in either of the following ways:

- Click the **View** icon in the Actions column of the *View Study Log* page.
- Click the **View** icon in the Actions column of the Subject Matrix. The *View Subject* page opens. Click the **Audit Log** button for the Subject.

The *Audit Logs* page opens, providing a detailed history of all Events for the selected Subject.

Figure 30: Audit Logs page for a Subject

BGH-002 Audit Logs

Export to Excel

Study Subject ID	Secondary ID	Date of Birth	Person ID	Created By	Status
BGH-002			S001-002	root	available

Audit Event	Date/Time of Server	User	Value Type	Old	New
Study subject created	18-Sep-2013 03:14:37	root			
Study subject status changed	18-Sep-2013 15:32:33	root	Status	auto-removed	available
Study subject status changed	18-Sep-2013 13:26:02	demo_dm	Status	available	auto-removed
Study subject value changed	18-Sep-2013 15:45:22	root	Study Subject ID	S001-002	BGH-002
Subject created	18-Sep-2013 03:14:37	root			

5.2.2 Changes Tracked in the Study Audit Logs

Table 4 lists the changes tracked in the Study Audit Logs.

Table 4: Changes tracked in Study Audit Logs

Object	Tracked Changes
Study Subject	State Changes: <ul style="list-style-type: none"> • Available • Removed • Signed <hr/> Subject ID change <hr/> Creation Date <hr/> Value change <hr/> Site assignment change <hr/> Group assignment change <hr/> Group change
Event	State Changes: Scheduled <ul style="list-style-type: none"> • Data entry started • Completed • Stopped

	<ul style="list-style-type: none"> • Skipped • Locked • Removed • Signed
	Start/End Date change
	Location change
	Creation Date
CRF	State Changes: <ul style="list-style-type: none"> • Initial data entry complete • Initial data entry completed with password • Double data entry complete • Double data entry completed with password • Marked complete • Completed with password
	Properties change
	Source data verification status changed
CRF Item	Data value updated
	Data status change
	Data deleted
	Data inserted for repeating row
	Medical Coding

The Study Audit Logs track the initial values for CRF Items provided during data entry, which are reported as updated CRF Item data values. This only occurs when a value is provided; empty or non-existent values are not tracked.

The Study Audit Logs do not track Discrepancy Notes, but you can view or download the full thread for any Discrepancy Notes. Discrepancy Notes cannot be removed and are always available.

5.2.3 Exporting Study Audit Logs for a Subject

You can export the Study Audit Logs for a Subject to an Excel file. The first worksheet contains the Subject information and the Study Event summary information. The remaining worksheets contain the audit trail for each Study Event and its associated CRFs (one Study Event occurrence per worksheet, where each occurrence is labeled from *_1* to *_n*).

Figure 31: Example Subject Study Audit Logs export

	A	B	C	D	E	F
1	Study Subject ID	Secondary Subject ID	Date of Birth	Person ID	Created By	Status
2	BGH-002				root	Available
3						
4	Audit Event	Date/Time of Server	User	Value Type	Old	New
5	study_subject_created	18-Sep-2013 03:14:37	root			
6	study_subject_status_changed	18-Sep-2013 15:32:33	root	Status	auto-removed	available
7	study_subject_status_changed	18-Sep-2013 13:26:02	demo_dm	Status	available	auto-removed
8	study_subject_value_changed	18-Sep-2013 15:45:22	root	Study Subject ID	S001-002	BGH-002
9	subject_created	18-Sep-2013 03:14:37	root			
10						
11	Study Events	Location	Date	Occurrence Number		
12	Enrollment		18-Sep-2013	1		
13						

Subject Information Enrollment_1

5.3 Medical Coding

You can use the Medical Coding feature to ensure the accuracy and consistency of documenting diseases, adverse events (AEs), or drugs during the course of a Study. This feature allows you to transform verbatim medical terms into universal medical code names and numbers.


ClinCapture supports five medical dictionaries: MedDRA, WHODrug, ICD-9-CM, ICD-10, and CTCAE. ClinCapture also allows using multiple versions of the same dictionary in a CRF.

ClinCapture retrieves medical codes from the [Bioportal](#) repository.

The Medical Coding feature is available to Study Coder, System Administrator, and Study Administrator user roles.










































The *Medical Coding* page lists all medical terms in the Study. You can access the *Medical Coding* page by clicking the [Code](#) link in the Navigation Bar, or selecting Tasks > Code.

Figure 32: Medical Coding page

Medical Coding 

Hide summary statistics

Medical Terms	Not Coded	Coded	Total
	6	14	20

Verbatim Term	Dictionary	Status	Study Subject ID	Study Event	CRF	Medical Codes	Actions
Skin rash	MedDRA	Coded	BMC-031	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="skin rash"/>	  
Nasal congestion	MedDRA	Coded	BMC-052	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Nasal congestion"/>	  
Chest pain	MedDRA	Coded	BMC-032	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Chest pain"/>	  
Headache	MedDRA	Coded	BMC-036	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Headache"/>	  
Chest pain	MedDRA	Coded	BGH-048	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="chest pain"/>	  
Abrasive skin rash	MedDRA	Coded	BMC-054	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="abrasive skin rash"/>	  
Leg pains	MedDRA	Not Coded	BMC-054	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Leg pains"/>	 
Arthritis	MedDRA	Not Coded	BMC-048	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Arthritis"/>	 
Blurred vision	MedDRA	Coded	BGH-048	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Blurred vision"/>	  
Migraine	MedDRA	Coded	BGH-048	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Migraine"/>	  
Migraine	MedDRA	Coded	BMC-051	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="migraine"/>	  
Abdominal pain	MedDRA	Coded	BGH-047	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Abdominal pain"/>	  
Nocturia	MedDRA	Not Coded	BMC-051	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Nocturia"/>	 
Skin rash	MedDRA	Not Coded	BMC-051	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Skin rash"/>	 
Abdominal pain	MedDRA	Coded	BMC-051	Common	Adverse Events w MedDRA Coding	Search: <input type="text" value="Abdominal pain"/>	  

Results 1 - 15 of 20.




[Back](#) [Auto-Code](#)

You can sort by Verbatim Term, Dictionary, Study Subject ID, Study Event, and CRF. You can filter information to display items that match specific criteria. You can also use the Summary Statistics dashboard to determine which medical terms have been coded and which have not, and filter the results by clicking the respective links.

You can customize the *Medical Coding* page similar to the Subject Matrix, see [Finding and Organizing Data](#) for more information.

When a Study is being built, the System Administrator or Study Administrator must indicate whether or not medical coding is allowed.

If configured for your Study, the Auto-Code function automatically codes all verbatim items using the coding information previously saved in a custom dictionary for similar verbatim items. Custom dictionaries can be shared between studies. Before coding a verbatim term, you can modify the search term in the Medical Codes column to allow the medical coder to correct misspelled or abbreviated terms.

A Study Coder can open the CRF where the verbatim term is located by clicking the **Open CRF** icon ( or ) in the Actions column. This allows the Study Coder to understand the context for the verbatim item and a raise query, if needed, by submitting a Discrepancy Note (.

Note: If CRF masking functionality is being used, items from CRFs that are masked from you will not be shown on the Medical Coding table.

5.3.1 Configuring Medical Coding for a Study

Only a System Administrator or Study Administrator can configure medical coding for a Study.

Note: If your study is hosted by Clinovo, we must first validate your license with your ontology provider. We will then register your account in the Bioportal virtual appliance to generate an API key to be configured for your instance. Once these steps are completed, you will be able to perform medical coding in your studies.

To configure medical coding for a Study:

1. Select Tasks > Build Study from the Navigation Bar.
2. Choose Design from the Set Study Status drop-down list, and click **Save Status**.
3. Click the **Edit** icon for the Create Study task to open the *Update Study Details* page.
4. Open the Study Parameter Configuration section, and scroll down to the Medical Coding section.

Medical Coding:

Allow medical coding Yes No

Approval Needed? Yes No

Code with context? Yes No





Auto-code Dictionary Name:

5. Set **Allow medical coding** to **Yes**.
6. Use the **Code with Context** setting to specify the amount of information displayed on the Medical Coding page. If enabled, the [Hide](#) and [Show More](#) links appear above the data table on the *Medical Coding* page.
7. Provide a name for the auto-code dictionary to enable the auto-code feature. Any name can be used. To share the auto-code dictionary between studies, enter the same name in the other studies.
8. Click **Submit**.

After you enable medical coding for a Study you can assign/add users to the Study Coder role to facilitate coding of verbatim terms.

5.3.2 Coding a Medical Term

Medical coding can be performed for CRFs in the following states:

- Data Entry Started ()
- Initial Data Entry Completed ()
- Completed ()
- Signed ()—Coding a Signed CRF, causes it to lose its Signed status.

Medical Coding cannot be performed for:

- ❑ Locked CRF (🔒)

Note: To correct a spelling issue with a Verbatim Term before coding a medical term, modify the name in the Search box in the Medical Codes column.

To code a medical term:

1. Click on the **Not Coded** icon (🔒) for the item you want to code. In this example, we are going to medical code the first item, Arthritis.

Medical Coding ?

Hide summary statistics

Medical Terms	Not Coded	Code not Found	Coded	Total
	4	1	23	28

Verbatim Term	Dictionary	Status	Study Subject ID	Study Event	CRF	Medical Codes	Actions
Arthritis	MedDRA	Not Coded	BMC-048	Common	Adverse Events w MedDRA Coding	Search: Arthritis	🔒 Apply Filter Clear Filter
Nasal congestion	MedDRA	Coded	BMC-052	Common	Adverse Events w MedDRA Coding	Search: Nasal congestion	📄 X 📄
Leg pains	MedDRA	In Process	BMC-054	Common	Adverse Events w MedDRA Coding	Search: vomiting	🔒 📄
Migraine	MedDRA	Coded	BMC-051	Common	Adverse Events w MedDRA Coding	Search: migraine	📄 X 📄
Skin rash	MedDRA	Coded	BMC-051	Common	Adverse Events w MedDRA Coding	Search: skin rash	📄 X 📄
Headache	MedDRA	Coded	BMC-036	Common	Adverse Events w MedDRA Coding	Search: Headache	📄 X 📄
Chest pain	MedDRA	Coded	BMC-032	Common	Adverse Events w MedDRA Coding	Search: Chest pain	📄 X 📄
stomach pain	MedDRA	Coded	BMC-030	Common	Adverse Events w MedDRA Coding	Search: stomach pain	📄 X 📄
Abdominal pain	MedDRA	Coded	BMC-051	Common	Adverse Events w MedDRA Coding	Search: Abdominal pain	📄 X 📄
Nocturia	MedDRA	Coded	BMC-051	Common	Adverse Events w MedDRA Coding	Search: Nocturia	📄 X 📄
Skin rash	MedDRA	Coded	BMC-030	Common	Adverse Events w MedDRA Coding	Search: Skin rash	📄 X 📄
Stomach ache	MedDRA	Code not Found	BMC-052	Common	Adverse Events w MedDRA Coding	Search: Stomach ache	🔒 📄
Skin rash	MedDRA	Not Coded	BMC-031	Common	Adverse Events w MedDRA Coding	Search: Skin rash	🔒 📄
Abrasive skin rash	MedDRA	Coded	BMC-054	Common	Adverse Events w MedDRA Coding	Search: abrasive skin rash	📄 X 📄
Migraine	MedDRA	Not Coded	BMC-032	Common	Adverse Events w MedDRA Coding	Search: Migraine	🔒 📄

Results 1 - 15 of 15.

Back Auto-Code

2. Browse through the list of results until you identify the correct code for Arthritis.

MedDRA Not Coded S01-019 Common Forms Adverse Events Search: Arthritis 🔒 📄

HTTP: <http://purl.bioontology.org/ontology/MDR/10003246>
LLT: Arthritis [Get full info](#)

HTTP: <http://purl.bioontology.org/ontology/MDR/10011503>
LLT: Crystal arthritis (excl gout) [Get full info](#)

HTTP: <http://purl.bioontology.org/ontology/MDR/10036035>
LLT: Polyarthropathy (excl rheumatoid arthritis) [Get full info](#)

HTTP: <http://purl.bioontology.org/ontology/MDR/10028902>
LLT: Neisseria gonorrhoeae arthritis [Get full info](#)

HTTP: <http://purl.bioontology.org/ontology/MDR/10060617>
LLT: Hemophilic arthritis [Get full info](#)

HTTP: <http://purl.bioontology.org/ontology/MDR/10052754>
LLT: Haemophilic arthritis [Get full info](#)

« Prev 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 Next »

If you need more information on a specific code, click the HTTP link to directly access and browse the Bioportal page for that code.

3. Click on Get Full Info to see detailed information for a specific medical code.
4. Click **Code** or **Code & Alias**. Selecting **Code & Alias** codes the item and adds an alias (synonym) in the custom dictionary, enabling the automatic coding of similar verbatim items.

5.3.3 Medical Coding Status


The Status column on the *Medical Coding* page displays the coding status of medical terms.

The following table shows the different Medical Coding Status values:

Status	Description
Not Coded	The item has not been coded.
Coded	The item has been coded.
Code Not Found	The search on a Verbatim Term yielded no coding results. This is either caused by a code not found in the Bioportal repository or a communication error. It is recommended to retry coding these items. In case of repeated coding failures, try accessing the repository directly to find the code.

5.3.4 Resetting Medical Coding Status

Medical term status can be reset from Coded to Not Coded either manually by a user with appropriate permissions, or automatically by the ClinCapture software. After resetting a medical term, it can be coded again. The Study Audit Log tracks any change in Medical Coding status for a medical term.

- Automatically:** ClinCapture automatically resets the Medical Coding status for a medical term if the verbatim item in the CRF changes.
- Manually:** To manually change the Medical Coding status for a medical term on the *Medical Coding* page, click the **Delete** icon (). This allows you to delete the Code and/or Alias, and reset the medical term to a Not Coded status.

5.4 Evaluate CRF Data

CRF Evaluation requires that data intended for a particular CRF must be reviewed by a Study Evaluator to ensure the integrity of the captured data. It is typically used for measurement-related data points.

Unlike Double Data Entry, CRF Evaluation is not blind. The Study Evaluator can see the initial CRF entry, review it or perform the measurement again, and then accept the data, or change it if necessary. If the evaluator changes the data initially entered, a Reason For Change (RFC) will be automatically generated.

Note: If CRF masking functionality is being used, you cannot evaluate CRFs that have been masked from you.

5.4.1 Study Configuration

Before you can use CRF Evaluation in your study, you must set up the required properties and user roles. The CRF Evaluation Set Up workflow is as follows:

1. Enable CRF evaluation for the study
2. Assign the role of Study Evaluator to one or more study-level users
3. Create Events and configure CRF(s) within those events

CRF Evaluation has two system-level properties:

- Allow CRF Evaluation – Allows the Evaluator to appear when defining users or changing roles of study-level users.
- Evaluate with Context – Displays additional information on the reading page, such as Subject ID and the Event Name. (The system-level properties can be overridden at the study level.)

CRF evaluation allows users with the role of Evaluator to only access the CRF(s) to be evaluated, without being able to access any other data in the study. Just like a CRC, this role is allowed to edit/view/print the CRFs to be evaluated.

When a CRF is determined to need evaluation, a setting must be turned on in the Edit Study Event Definition page. If the option, **CRF data evaluation**, is selected, the CRF appears in the CRF Evaluation page once its status is Initial Data Entry Completed; that is when the initial data is completed and submitted for evaluation.

Define Study Event - Selected CRF(s) - Select Default Version

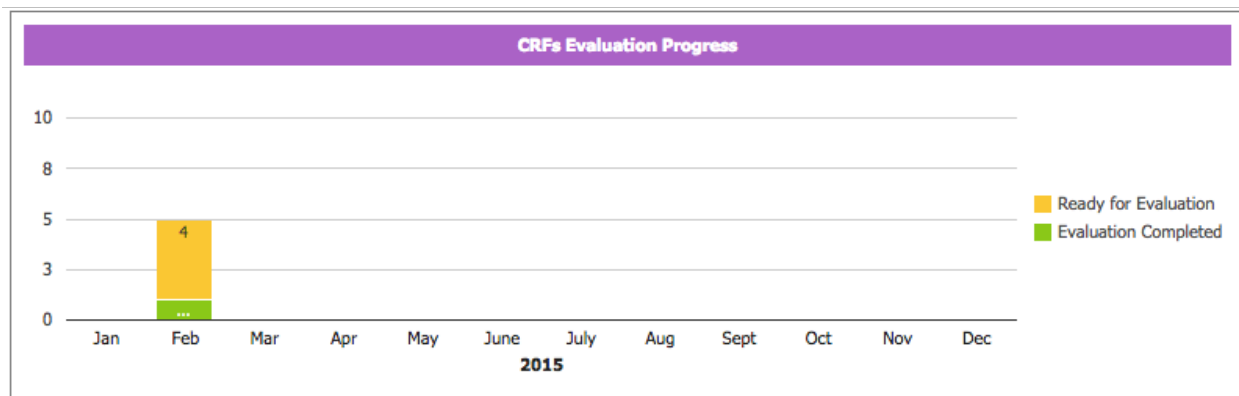
Biochemistry			
Required: <input checked="" type="checkbox"/>		Password Required: <input type="checkbox"/>	Default Version: v.1 <input type="button" value="v"/>
Hide CRF: <input type="checkbox"/>		Source Data Verification: Not Required <input type="button" value="v"/>	
Data Entry Quality: <input type="radio"/> Double Data Entry <input checked="" type="radio"/> CRF data evaluation			
Send Email when CRF is: <input type="radio"/> Complete <input type="radio"/> Sign			
Choose Null Values (What is Null Value?)			
NI <input type="checkbox"/>	NA <input type="checkbox"/>	UNK <input type="checkbox"/>	NASK <input type="checkbox"/>
ASKU <input type="checkbox"/>	NAV <input type="checkbox"/>	OTH <input type="checkbox"/>	PINF <input type="checkbox"/>
NINF <input type="checkbox"/>	MSK <input type="checkbox"/>	NP <input type="checkbox"/>	NPE <input type="checkbox"/>

Data evaluation is carried out by a Study Evaluator. This role is defined at the Study level. As a Study-level role, the Evaluator has access to all sites under a study. The Evaluator does not see any other study data, including queries, except those they generate themselves.

5.4.2 CRF Evaluation Widget

You can customize your Home Screen to display the CRF Evaluation Widget. For users with the role of Evaluator, this widget allows you to quickly see, in a graphical format, how many CRFs are ready to be evaluated and how many have already been evaluated over a period of time.

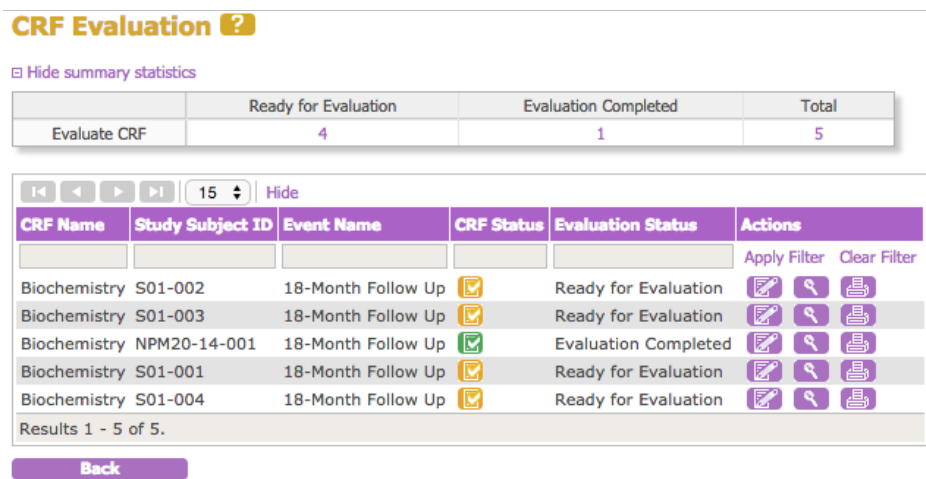
You can click a colored status section of a bar in the graph to go directly to the CRF Evaluation page. Depending on the status you clicked, the CRF Evaluation page will be filtered to show only those CRFs that are Ready for Evaluation or those that have been marked Evaluation Completed.



5.4.3 Performing CRF Evaluation

To evaluate CRF:

1. Select Tasks > Evaluate CRF to open the *CRF Evaluation* page.



CRF Evaluation ?

Hide summary statistics

	Ready for Evaluation	Evaluation Completed	Total
Evaluate CRF	4	1	5

15 Hide

CRF Name	Study Subject ID	Event Name	CRF Status	Evaluation Status	Actions
Biochemistry	S01-002	18-Month Follow Up	<input checked="" type="checkbox"/>	Ready for Evaluation	
Biochemistry	S01-003	18-Month Follow Up	<input checked="" type="checkbox"/>	Ready for Evaluation	
Biochemistry	NPM20-14-001	18-Month Follow Up	<input checked="" type="checkbox"/>	Evaluation Completed	
Biochemistry	S01-001	18-Month Follow Up	<input checked="" type="checkbox"/>	Ready for Evaluation	
Biochemistry	S01-004	18-Month Follow Up	<input checked="" type="checkbox"/>	Ready for Evaluation	

Results 1 - 5 of 5.

[Back](#)

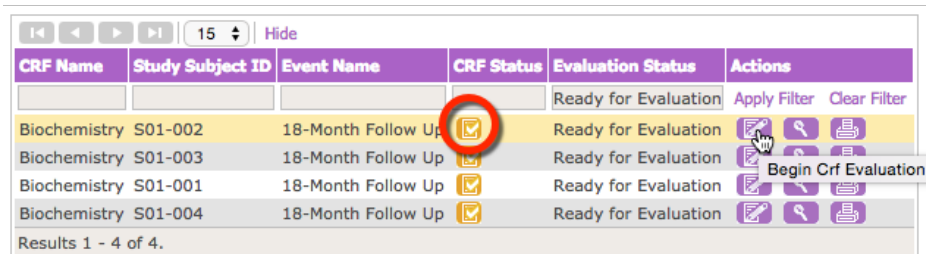
2. You can click the counters in the Summary Statistics box to filter the list to show only those CRFs with a particular evaluation status, or to show all CRFs that have been marked complete.



Hide summary statistics

	Ready for Evaluation	Evaluation Completed	Total
Evaluate CRF	4	1	5

3. CRFs with a yellow checkmark are ready for evaluation.



15 Hide

CRF Name	Study Subject ID	Event Name	CRF Status	Evaluation Status	Actions
Biochemistry	S01-002	18-Month Follow Up	<input checked="" type="checkbox"/>	Ready for Evaluation	
Biochemistry	S01-003	18-Month Follow Up	<input checked="" type="checkbox"/>	Ready for Evaluation	
Biochemistry	S01-001	18-Month Follow Up	<input checked="" type="checkbox"/>	Ready for Evaluation	
Biochemistry	S01-004	18-Month Follow Up	<input checked="" type="checkbox"/>	Ready for Evaluation	

Results 1 - 4 of 4.

4. Click the **Begin CRF Evaluation** button. The CRF opens.
5. Evaluate the data points/measurements. If necessary, make changes.
6. Check the **Mark CRF Complete** box.
7. Click **Save**.

After the CRF has been saved:

- The status of the CRF changes to Evaluation Completed.
- The CRF is now ready for SDV monitoring (if required) or e-signature.

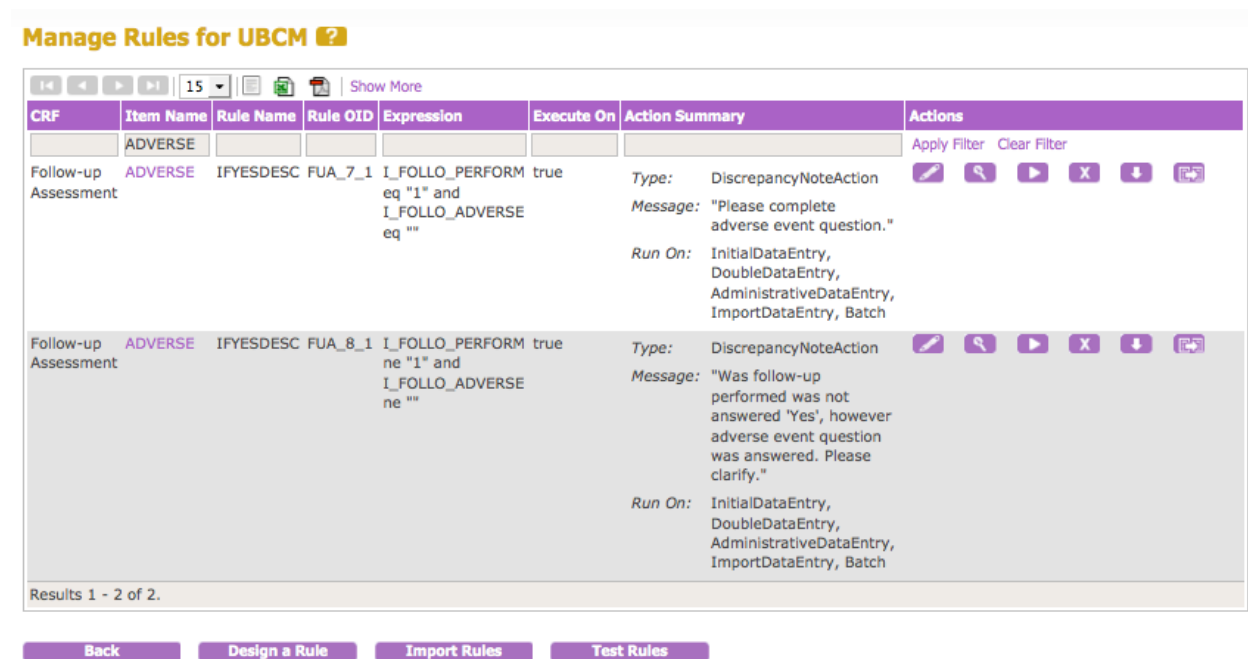
- If any change was made to a data point on the CRF, a discrepancy automatically is logged.

5.5 Rules

Edit checks, or rules, are needed to ensure the validity of the data when a Study is created.

The *Manage Rules* page lists all rules in the Study for CRFs in the Available state. You can access the *Manage Rules* page by selecting Tasks > Code.

Figure 33: Manage Rules page



CRF	Item Name	Rule Name	Rule OID	Expression	Execute On	Action Summary	Actions
Follow-up Assessment	ADVERSE	IFYESDESC FUA_7_1		I_FOLLO_PERFORM eq "1" and I_FOLLO_ADVERSE eq ""	true	Type: DiscrepancyNoteAction Message: "Please complete adverse event question." Run On: InitialDataEntry, DoubleDataEntry, AdministrativeDataEntry, ImportDataEntry, Batch	Apply Filter Clear Filter
Follow-up Assessment	ADVERSE	IFYESDESC FUA_8_1		I_FOLLO_PERFORM ne "1" and I_FOLLO_ADVERSE ne ""	true	Type: DiscrepancyNoteAction Message: "Was follow-up performed was not answered 'Yes', however adverse event question was answered. Please clarify." Run On: InitialDataEntry, DoubleDataEntry, AdministrativeDataEntry, ImportDataEntry, Batch	

Results 1 - 2 of 2.

Back Design a Rule Import Rules Test Rules

You can filter the list of Rules by CRF, Item Name, Rule Name, Expression, Execute On, and Action Summary.

You can perform the following actions from the *Manage Rules* page:

- Design a new rule for a CRF using Rules Studio
- Edit existing rules using Rules Studio
- Import rules from an XML file, which you can edit in Rules Studio
- Download a rule to an XML file
- Test rules

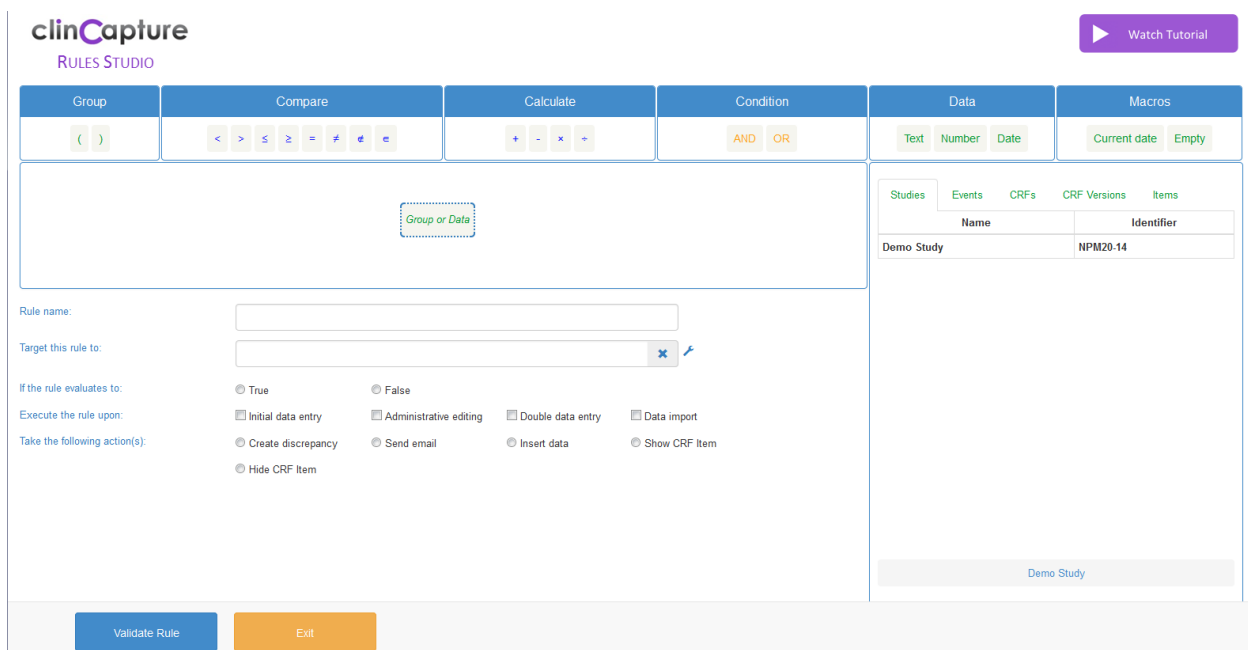
5.5.1 Rules Studio

The Rules Studio feature in ClinCapture simplifies the creation and modification of rules, allowing System Administrators and Study Administrators to implement, modify, and copy rules using an intuitive drag and drop graphical user interface.

The Rules Studio interface contains the following sections:

- Top Panel
- Data, Macros, and CRF Items Panels
- Operators Panel
- Expression Builder
- Parameters Panel
- Bottom Panel

Figure 34: Rules Studio



Top Panel

The Top Panel is the area at the top of the Rules Studio and contains the logo and a link to watch a short tutorial that shows you how to use Rules Studio.

Data, Macros, and CRF Items Panels

The **Data Panel** contains the different data field types that you can drag and drop into the Expression Builder: Text, Number, and Date.

The **Macros Panel** contains the Current date and Empty macros that you can drag and drop into the Expression Builder.

The **CRF Items Panel** is the area on the right side of the Rules Studio, just below the Data and Macros panels. From this area you can drag and drop CRF Items from a selected Study into the Expression Builder. As you navigate through the information path of a study (Study, Event, CRF, CRF version, and CRF Item), your current path appears at the bottom of the panel, as a bread crumb. Click on any part of this bread crumb to navigate back to that level in the path.

Operators Panel

The Operators Panel consists of four tool boxes: Group, Compare, Calculate, and Condition. Each tool box contains operations that you can drag into the Expression Builder. For information on entering data, see [Designing Rules](#).

Expression Builder

The Expression Builder is the area just below the Operators Panel. This is where you design or modify your rules. A rule is composed of data items, selected from the Data/Macro/CRF Items panels and various operators chosen from the Operators Panel. As you drop items into the Expression Builder, Rules Studio tries to predict your next action and displays a box with dotted lines matching the next expected item.

Parameters Panel

The Parameters Panel is the area just below the Expression Builder. This area allows you to specify the parameters for your rules, in particular, the rule description, the rule target (the CRF item to attach the rule to), and the type of action implemented in response to a rule evaluating to either true or false.

After designing a rule, you can verify the rule by clicking the **Validate Rule** button in the Bottom Panel.

Bottom Panel

The Top Panel is the area at the bottom of the Rules Studio and contains the **Validate Rule** and **Exit**. Use the Validate Rule button to verify your rules.

5.5.2 Designing Rules

To confirm the accuracy of data captured in a CRF of a Study you must design and implement rules, sometimes referred to as Soft Edit Checks. In ClinCapture, you use the Rules Studio to design rules.


To design a rule for a CRF:

8. Select **Tasks > Rules** to open the *Manage Rules* page.
9. Click **Design a Rule**. The Rules Studio interface opens.
10. Use the Expression Builder to create your rule.
11. Click **Validate Rule** to verify your rule.
12. If the rule successfully validates, click **Save** to save the rule. Otherwise, click **Back** and modify your rule as needed.

For an example on how to design a rule using Rule Studio, click the **Watch Tutorial** button in the Top Panel.

5.5.3 Editing Rules

To edit an existing rule:

1. In the *Manage Rules* page, click the **Edit** icon () in the Actions column for the rule you want to modify. The Rules Studio interface opens.
2. Use the Expression Builder to modify the rule.
3. Click **Validate Rule**.
4. If the rule successfully validates, click **Save** to save the rule. Otherwise, click **Back** and modify the rule as needed.

5.5.4 Importing Rules

You can import rules created in XML and edit them using the Rules Studio.

To import an XML rule:

1. In the *Manage Rules* page, click the **Import Rules** button. The *Import Rule* page opens.

Import Rule Data Demo Study

Upload an XML file here: No file selected.

Getting started with rules

Templates


- ▶ All actions (with comments)
- ▶ All actions (without comments)

2. Click **Browse**.

3. Select the XML file containing the rules you want to import, and click **Open**.
4. Click **Continue**.

Imported rules can be edited in Rules Studio by clicking on the **Edit** icon () in the Actions column.

5.5.5 Exporting a Rule

You can export an existing rule to an XML file. To do so, in the *Manage Rules* page, click the **Download** icon () in the Actions column for the rule you want to export.

5.5.6 Testing Rules




You should manually test your rules to ensure they function properly.

To test a Rule:

1. In the *Manage Rules* page, click the **Test** icon () for the rule you want to test.

Note: Alternatively, you can click the **Test Rules** button at the bottom of the page to type in rules and test them. In this case, be prepared to enter the target OID, expression OIDs, and action from a blank form.

Manage Rules for UBCM

CRF	Item Name	Rule Name	Rule OID	Expression	Execute On	Action Summary	Actions
Follow-up Assessment	ADVERSE	IFYESDESCI	FO_5110	F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_PERFORM true eq "1" and F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_ADVERSE eq ""	true	Type: DiscrepancyNoteAction Message: "Please complete adverse event question." Run On: InitialDataEntry, DoubleDataEntry, AdministrativeDataEntry, ImportDataEntry, Batch	Apply Filter Clear Filter      

Results 1 - 1 of 1.

[Back](#)
[Design a Rule](#)
[Import Rules](#)
[Test Rules](#)

2. The *Test Rules* page opens where, if desired, you can edit the existing target, the rule expression, and the actions to take if the expression evaluates to either true or false.

Test Rules

Step 1: Specify target, rule target, & action evaluation value

Item Name: ADVERSE ([View all rules for this item](#))

Item Description: Did any new adverse events occur since the last visit?

Target: SE_2MONTHFOLLOWUP.F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_ADVERSE

Rule Expression: F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_PERFORM eq "1" and F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_ADVERSE eq ""

Actions:

If Expression Evaluates:

Execute Action: *Type:* DiscrepancyNoteAction
Message: "Please complete adverse event question."

You can display all rules applicable to the Item Name by clicking [View all rules for this item](#). The *Manage Rules* page shows all rules for the specific item.

3. Click the **Submit** button.

Test Rules

Step 1: Specify target, rule target, & action evaluation value

Item Name: ADVERSE ([View all rules for this item](#))

Item Description: Did any new adverse events occur since the last visit?

Target: SE_2MONTHFOLLOWUP.F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_ADVERSE

Rule Expression: F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_PERFORM eq "1" and F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_ADVERSE eq ""

Actions:

If Expression Evaluates:

Execute Action: *Type:* DiscrepancyNoteAction
Message: "Please complete adverse event question."

Step 2: Specify test values for variables in your rule expression

F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_PERFORM:

F_FOLLOWUPASSESSMENT.IG_FOLLO_UNGROUPED.I_FOLLO_ADVERSE:

4. Enter the necessary test variables, and click **Submit**.

Test Rules

Step 1: Specify target, rule target, & action evaluation value

Item Name: ADVERSE ([View all rules for this item](#))

Item Description: Did any new adverse events occur since the last visit?

Target:

Rule Expression:

Actions:

If Expression Evaluates:

Execute Action: *Type:* DiscrepancyNoteAction
Message: "Please complete adverse event question."

Step 2: Specify test values for variables in your rule expression

Step 3: Verify results

Rule Validation: Valid

Expression Evaluates To: Please enter test values in Step 2 then click 'Validate & Test'

Actions Fired: Please enter test values in Step 2 then click 'Validate & Test'

Ran in: 0.015 seconds

[Back](#) [Submit](#) [Exit](#)

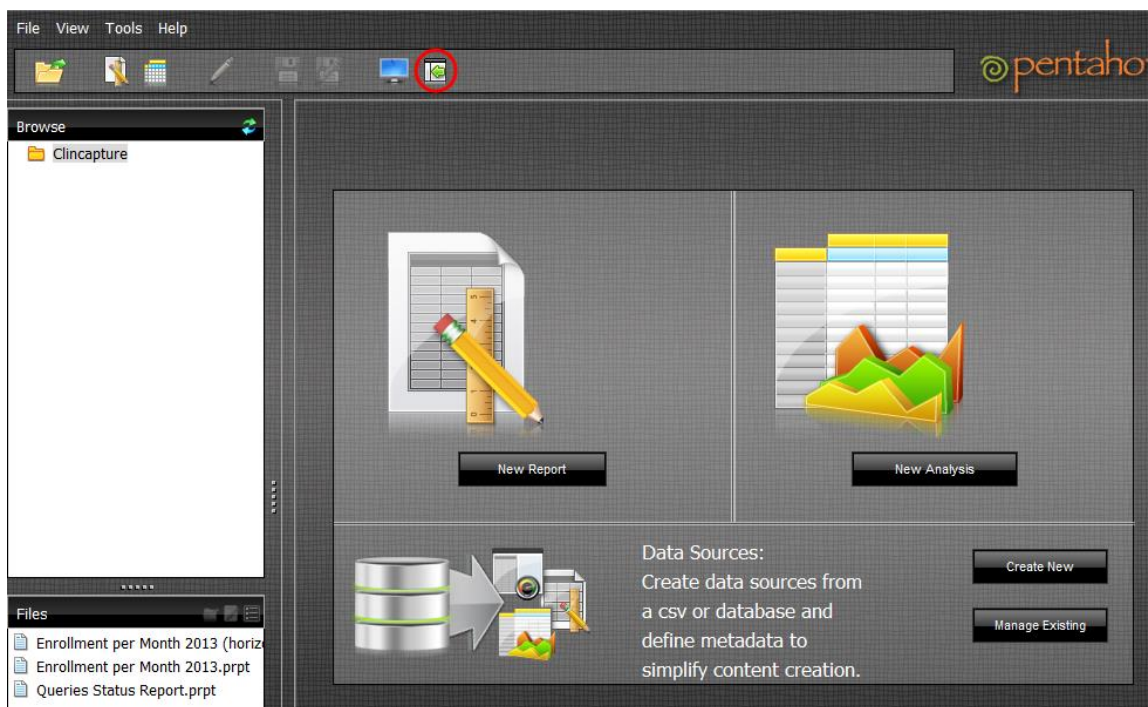
The Verify results section summarizes the results of the test, and identifies whether or not the rule is valid. If the rule is invalid, a diagnostic message appears in the Alerts & Messages panel, otherwise, the rule executes with the test parameters you supplied and the results are shown. Whether or not the specified action was triggered is indicated along with the execution time.

5.6 Reports

Using Live Reports™, Study Administrators, Study Monitors, and Site Monitors can access graphical dashboards to monitor their Studies in real time. No data extraction is required; the information is available in your reports as soon as it is available in the ClinCapture database. These reports are available through the Pentaho User Console. Please consult the *ClinCapture Programmer's Guide* for details about creating your own custom reports, or visit the [ClinCapture Community](#) for the availability of new reports.

To access the Reports feature:

1. Select Tasks > Reports. If your system is configured for this feature, it will open a new window.
2. Enter your ClinCapture username and password, and click **Login**.



3. If the navigation panel on the left is not visible, click the Toggle Browser icon in the menu bar.
4. Click the `Clincapture` folder in the navigation panel to display the reports currently available.

The following report types are available:

- Enrollment by Site—displays the enrollment dashboard by Sites.
- Enrollment by Month—shows the cumulative enrollment in metrics for all Sites, per month.
- Query Status Report—shows the total queries by status per Site, excluding annotations.

5.7 Special Permissions

System Administrator, Study Administrator, Study Monitor, Site Monitor, and Study Coder user roles can access the monitoring features in the Monitor and Manage Data module. For information about features in the module, see [ClinCapture Modules](#).

Table 5: Monitor and Manage Data Permissions by role

User Role	Task	Notes
System Administrator	Source Data Verification	No restrictions
	Study Audit Log	No restrictions
	Medical Coding	No restrictions
	Rules	No restrictions
	Group	No restrictions
	CRFs	No restrictions
	Reports	No restrictions
Study Administrator	Source Data Verification	No restrictions
	Study Audit Log	No restrictions
	Medical Coding	Study level only
	Rules	Study level only
	Group	Study level only
	CRFs	Study level only
	Reports	No restrictions
Study Monitor	Subject Matrix	Can only view. Cannot make changes to information.
	View Events	Can only view. Cannot make changes to information.
	Source Data Verification	No restrictions
	Study Audit Log	No restrictions
	Notes and Discrepancies	Can create only the Query type of Discrepancy Note. Can only update or close an existing Discrepancy Note.
	Reports	No restrictions

Site Monitor	Subject Matrix	Can only view. Cannot make changes to information.
	View Events	Can only view. Cannot make changes to information.
	Source Data Verification	No restrictions
	Study Audit Log	No restrictions
	Notes and Discrepancies	Can create only the Query type of Discrepancy Note. Can only update or close an existing Discrepancy Note.
	Reports	No restrictions
Study Coder	Medical Coding	No restrictions
	CRFs	Can only view. Cannot make changes to information.
	Notes and Discrepancies	Can only create Discrepancy Notes related to medical coding.

6 EXTRACT DATA

The ClinCapture Extract Data module allows you to define criteria for a set of data, and export it to a file for use in other applications.

You can select a standard file format to export the data to, and then download the file. You can also modify the criteria you previously defined, and create a new dataset using the revised definition. The Extract Data module also provides you with tools to help you find and organize the dataset definitions in a Study.

Only users with appropriate permissions, as defined by their user roles, can use the Extract Data module. A Study Administrator can schedule export jobs to automatically extract data from time to time.

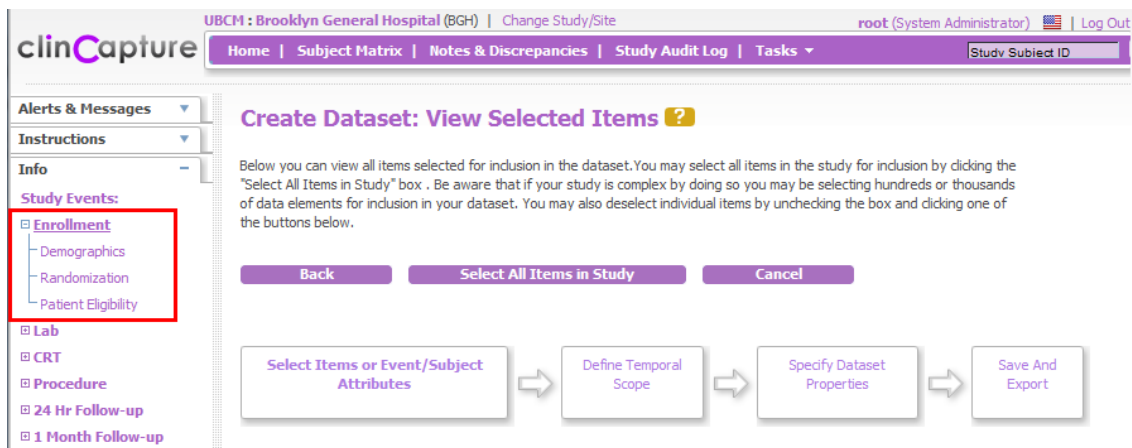
6.1 Dataset Creation

To create a dataset, you define the dataset criteria for the current Site or Study. After defining the dataset criteria, you generate and download the dataset file, extracting the data that meets your defined criteria to a file format that you select.

6.1.1 Defining a Dataset

Perform the following steps to define a dataset for the current Study or Site:

1. Select Tasks > Dataset. The *Dataset* page for the current Study or Site opens.
2. Click the **Create Dataset** button. The *Create Dataset* page opens.
3. Click **Continue**. The *Create Dataset: View Selected Items* page opens.



4. Click on a Study Event to list the associated Event CRFs in the Left Panel. For example, click on the Enrollment study event to list the following CRFs: Demographics, Randomization and Patient Eligibility.

Note: If CRF masking functionality is being used, you cannot add items to a dataset from CRFs that have been masked from you. CRFs that have been masked from you will not be displayed in the Left Panel.

Create Dataset: Select Items ?

Please select one CRF from the **left side info panel**, then select one or more items in a CRF that you would like to include to this dataset. You may select all items in the "Selected Items" (hyperlink) page and clicking "Select All".

You may also click Event Attributes/Subject Attributes to specify which event/subject attribute will be shown in the dataset.

← Use task pane on the left side to select CRFs

Event Name:	Enrollment
CRF Name:	Enrollment Form
Description:	Enrollment Form

Back

Save and Add More Items

Save and Define Scope

Cancel

Select All Items

Show the following items in this dataset:

	Name	Description	Version(s)	Section(s)	Group(s)	Data Type	Units	Response Type	Response Label	PHI	Required?	Double Data Entry
<input type="checkbox"/>	INCO01_TXT_SUBINT	Subject Initials	1.2	Criteria	Ungrouped	st		text	text	No	Yes	regexp: zA-Z]+\$

- After clicking an Event CRF, the associated CRF Items that you can include in the dataset definition are listed. Also displayed in the view is the metadata for each Item, as defined when the CRF was initially created.
- Click the checkbox for each Item to be included in the dataset definition, or click the Select All Items checkbox.

Note: If you are selecting many, but not all, items in the CRF, it might be easier to check Select All Items; then for each item that you want to exclude, click the appropriate checkbox to clear it.
- If you want to add more Event CRFs, click the **Save and Add More Items** button and repeat the steps above to select the Event CRF Items to be included in the dataset definition.
- To see the Items you have selected, click the [View Selected Items](#) link in the Info area of the Left Panel.
- If you want to select all items for all CRFs and Events, instead of selecting each Event and CRF, click [Select All Items in Study](#) in the Info area of the Left Panel.
- To select Metadata Attributes to be included in the dataset definition, such as Subject Attributes, Events Attributes, Group Attributes, etc., click its link in the Info area of the Left Panel.

For example, clicking Subject Attributes opens the *Create Dataset: Select Subject Attributes* page.

Create Dataset: Select Subject Attributes



Please select one CRF from the left side info panel, then select one or more items in a CRF that you would like to include to this dataset. You may select all items in the study by going to the "View Selected Items" (hyperlink) page and clicking "Select All".

You may also click Event Attributes/Subject Attributes to specify which event/subject attribute will be shown in the dataset.

- Date of Birth
- Subject Status
- Person ID



11. Select the checkbox for each Attribute to include.
12. If you want to include Attributes of a different type:
 - a. Click **Save and Add More Items**.
 - b. Repeat the two steps above to select additional Attributes to be included in the dataset definition.
13. To see the Attributes that have been selected, click the [View Selected Items](#) link in the Info area of the Left Panel.
14. After selecting all Items and Attributes that you want to be included in the dataset, click the **Save and Define Scope** button.

The *Create Dataset: Define Temporal Scope* page opens.

Create Dataset: Define Temporal Scope ?

Filter your data by subject enrollment date by selecting a date range below.

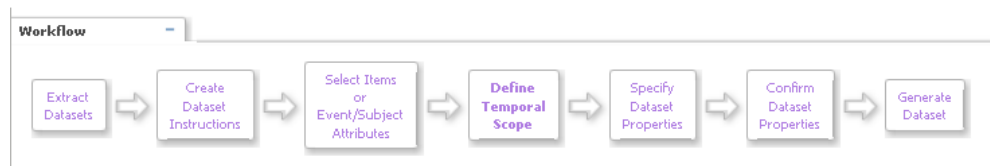
Select the event start and end dates below. To specify data from the beginning of the year, you may leave the month field blank. However, if you specify a month, you must also specify the year.

If you do not wish to filter study event data by date of subject enrollment, you may leave the date fields blank and continue.

Beginning Date:

End Date:

Save and Export your dataset now or Apply a Filter to specify additional selection criteria based on values of parameters in CRFs.



15. Set a date range for the dataset definition by following the onscreen instructions. The date you specify is the Subject enrollment date. For example, if you have selected 2011 as the year for the

Beginning Date and Ending Date, the dataset will include all Subjects enrolled in 2011. After specifying the date range, click the **Continue** button.

The *Create Dataset: Specify Dataset Properties* page opens.

Create Dataset: Specify Dataset Properties ?

Please enter the dataset properties in the fields. Be descriptive. **Name and Description fields are required.**

Name:

Description:

Item Status:

<input checked="" type="radio"/>	Data from CRFs Marked Complete
<input type="radio"/>	Data from CRFs not Marked Complete
<input type="radio"/>	Data from all Available CRFs

Meanwhile, if you choose to output your data in CDISC ODM XML format, you may like to set some properties for your CDISC ODM XML data file. Currently, the available properties include MetaDataVersion ODM ID, MetaDataVersion Name, Previous Study ODM ID and Previous MetaDataVersion ODM ID which you like to include in your ODM output file. The inputs for CDISC ODM XML format are optional. If you leave them empty, default value will be used, that is, MetaDataVersion ODM ID="v1.0.0", MetaDataVersion Name="MetaDataVersion_v1.0.0", and no include in this file. If you input previous study ODM ID, you have to input previous MetaDataVersion ODM ID, otherwise no include in you ODM output file. If you only input previous MetaDataVersion ODM ID, then current study ODM ID will be include in your ODM output file.

MetaDataVersion ODM ID:

MetaDataVersion Name:

Previous Study ODM ID:

Previous MetaDataVersion ODM ID:

16. Provide a Name and Description for the dataset definition and, if needed, change the Item Status. You can also specify the ODM ID values, which you might use if you export the dataset to an ODM file format.

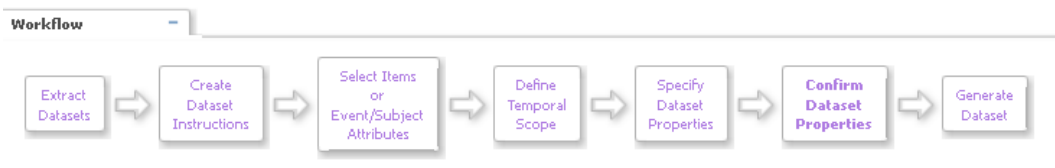
17. Click **Continue**. The *Create Dataset: Confirm Dataset Properties* page opens.

Create Dataset: Confirm Dataset Properties

Please confirm the dataset properties below, or click "Back" to return to the previous screen.

Name **INCO01_TXT_SUBINT**

Description **Subject Initials**



18. Verify the Name and Description, and click **Submit**.

A dataset definition has now been established and you can now generate and download a file containing all data that meets the specified criteria.

6.1.2 Generating Datasets

After you create, edit, or select a dataset definition you are ready to generate the dataset file. Open the *Download Data* page, and click [Run Now](#) next to the file format you want to generate. For more information about the available file formats, see [Dataset File Formats](#).

Note: If CRF masking functionality is being used, you cannot generate datasets that include CRFs that have been masked from you.

Download Data: Test2 ?

Dataset Name:	Test2
Dataset Description:	Test 2
Item Status:	Data from CRFs Marked Complete

To view or download data, select from the formats provided below. You may also select from the archived dataset files at the bottom of the page.

- CDISC ODM XML 1.3 Full with ClinCapture extensions [Run Now](#)
- CDISC ODM XML 1.3 Clinical Data with ClinCapture extensions [Run Now](#)
- CDISC ODM XML 1.3 Clinical Data [Run Now](#)
- CDISC ODM XML 1.2 Clinical Data with ClinCapture extensions [Run Now](#)
- CDISC ODM XML 1.2 Clinical Data [Run Now](#)
- View as HTML [Run Now](#)
- Excel Spreadsheet [Run Now](#)
- Tab-delimited Text [Run Now](#)
- SPSS data and syntax [Run Now](#)

Note: Large datasets may take a few minutes to generate in a pop-up window. Please disable pop-up blocking to allow the dataset to be displayed.

If you continue to have trouble, please see [Help ?](#) for additional tips on configuring your browser.

Internet Explorer users: If you are having trouble downloading files over an https connection, see [Help ?](#) for information on modifying your settings to enable https file downloads.

Archive of Exported Dataset Files:

No Pages						<input type="text"/>	Find
File Name	Run Time (Seconds)	File Size (Bytes)	Created Date	Created By	Action		
There are no rows to display.							
Back		View All Datasets					

A page appears that indicates your dataset is being extracted. ClinCapture maintains a queue of dataset extracts, including scheduled jobs and dataset extracts initiated by other users. New data extract requests are added to the end of this queue. After some time, depending on the size of the dataset and the number of requests in the queue, the dataset file becomes available.

6.1.3 Viewing and Managing Dataset Definitions








You can search, edit, download and view dataset definitions for the current Study or Site.

To view dataset definitions for the current Study or Site:

1. Select [Tasks > Datasets](#) to open the *View Datasets* page.

Datasets for: PRO ?




Page 1 of 1 Find Show only My Datasets

Dataset Name 	Description	Created By	Created Date	Status	Actions
Enrollment	Enrollment DS	test_dm	28-Jun-2013 11:47:38	available	 
INC001_TXT_SUBINT	Subject Initials	jose_investigator	17-Aug-2013 08:46:28	available	 
Lab	Lab description	zim_dm	11-Aug-2013 23:14:21	available	 
ZimDataset	ZimDataset	root	11-Aug-2013 23:10:41	removed	

Back
Create Dataset

2. Click the **View** button in the Actions column next to the dataset definition you want to view.

To manage dataset definition files, use the following actions in the Actions column:

- Click the **Export This Dataset** button to generate and download the dataset file in a format you select.
- Click the **Export** icon () to access the previously generated dataset files for the dataset definition, or generate and download the dataset to a file.
- Click the **Remove** icon () to make the dataset unavailable to other ClinCapture users.
- Click the **Restore** icon () to make a dataset available after it was previously removed.

6.2 Downloading Datasets








A dataset must be generated before you can download it, see [Generating Datasets](#) for more information.

To download a dataset for the current Study or Site:

1. Select Tasks > Datasets to open the *View Datasets* page.

Datasets for: PRO ?

Page 1 of 1 Find Show only My Datasets

Dataset Name 	Description	Created By	Created Date	Status	Actions
Enrollment	Enrollment DS	test_dm	28-Jun-2013 11:47:38	available	 
INC001_TXT_SUBINT	Subject Initials	jose_investigator	17-Aug-2013 08:46:28	available	 
Lab	Lab description	zim_dm	11-Aug-2013 23:14:21	available	 
ZimDataset	ZimDataset	root	11-Aug-2013 23:10:41	removed	

Back
Create Dataset

- Click the **Export this Dataset** button next to the dataset you want to download. The *Download Data* page opens, displaying the exported dataset files.

Download Data: Enrollment ?

Dataset Name:	Enrollment
Dataset Description:	Enrollment DS
Item Status:	Data from all Available CRFs

To view or download data, select from the formats provided below. You may also select from the archived dataset files at the bottom of the page.

- CDISC ODM XML 1.3 Full with ClinCapture extensions [Run Now](#)
- CDISC ODM XML 1.3 Clinical Data with ClinCapture extensions [Run Now](#)
- CDISC ODM XML 1.3 Clinical Data [Run Now](#)
- CDISC ODM XML 1.2 Clinical Data with ClinCapture extensions [Run Now](#)
- CDISC ODM XML 1.2 Clinical Data [Run Now](#)
- View as HTML [Run Now](#)
- Excel Spreadsheet [Run Now](#)
- Tab-delimited Text [Run Now](#)
- SPSS data and syntax [Run Now](#)

Note: Large datasets may take a few minutes to generate in a pop-up window. Please disable pop-up blocking to allow the dataset to be displayed.

If you continue to have trouble, please see [Help](#) ? for additional tips on configuring your browser.

Internet Explorer users: If you are having trouble downloading files over an https connection, see [Help](#) ? for information on modifying your settings to enable https file downloads.

Archive of Exported Dataset Files:


Page 1 of 1		<input type="text"/>	Find		
File Name	Run Time (Seconds)	File Size (Bytes)	Created Date	Created By	Action
EXCEL_Enrollment_2013-08-13-072342185.xls.zip	1.0	822	13-Aug-2013 07:25:01	dixon_admin	↓ ✖
EXCEL_Enrollment_2013-08-10-082734395.xls.zip	3.0	823	10-Aug-2013 08:27:37	root	↓ ✖

[Back](#)

[View All Datasets](#)

The file format is appended to the file name displayed in the table, along with additional details such as the file size and date the file was generated.

Note: The Archive of Exported Dataset Files table includes only one dataset file for each format for every dataset definition. When you generate a dataset file, whose format already exists in the table, the file you generate replaces the existing file in the table. If you want both files, download the existing file, and then generate the dataset and download it using a different name, or edit the dataset definition and save it using a different name and generate a new dataset for it.

- Click the **Download** icon () in the Actions column.

ClinCapture downloads the file in a `.zip` format. Extract the data using an unzip program such as WinZip or 7-Zip, and save the data file (for example, the Excel `.xls` file) to a known location on your local system.

For specific information about the file format you selected, see [Dataset File Formats](#).

ClinCapture also sends an email to you containing a link to the dataset file, providing an alternative way to access the file.

Open the file to find out if it contains the data that you expect. If not, you can edit the dataset definition in ClinCapture and generate the dataset file again, see [Editing Dataset Definitions](#). The data in the

dataset file reflects the ClinCapture database at the time the dataset file was generated, not at the time you downloaded the file. The dataset file name includes the date and time the file was generated.

6.2.1 Browser Settings for Downloading Files

It is recommended that ClinCapture be configured to work over a secure SSL internet connection. If your installation is configured this way, the URL you use to access ClinCapture begins with `https://`. To download files from ClinCapture, your web browser must be configured to use an SSL connection.

If you use Internet Explorer as your web browser, you might have difficulty downloading files over SSL. To resolve the problem, change the Internet Options for Internet Explorer:

1. In Internet Explorer, select Tools > Internet Options. The Internet Options dialog box opens.
2. Click the Advanced tab. The Advanced options page displays.
3. In the Security section, select the checkbox for *Do not save encrypted pages to disk*.
4. Click OK.

You should now be able to download ClinCapture files.

6.3 Editing Dataset Definitions

You can edit an existing dataset definition—that is, change the specified criteria—and either save the edited definition with the same name to replace the existing dataset, or with a new name to create a new copy and maintain the existing dataset definition without changes. Once you have modified the dataset definition, you can generate and download a dataset file for the new definition. The steps to edit a dataset definition are very similar to creating a new dataset definition. If you need more details than what are included in these steps, refer to [Dataset Creation](#).

Note: If CRF masking functionality is being used, editing a dataset that contains CRFs that have been masked from you will automatically be excluded from the dataset.

To edit a dataset definition:

1. Select Tasks > Datasets > View Datasets. The *View Dataset* page opens, listing all the dataset definitions for the current Study or Site.
2. For the dataset definition you want to modify, click the **Edit** icon in the Actions column.

The Edit Dataset page opens for the dataset definition you selected, listing all CRFs Items that were covered. It also lists all possible Attributes, initially marked in the checkboxes that were selected for the dataset definition.

Alerts & Messages

Instructions

Info

Study Events:

- Enrollment
- Lab
- Procedure
- CRT
- 24 Hr Follow-up
- 30 Day Follow-up
- Completion
- Common Forms
- AE/SAE

Event Attributes

Subject Attributes

CRF Attributes

Group Attributes

View Selected Items

Select All Items in Study

Dataset Name:
INC001_TXT_SUBINT

Dataset Owner:
jose_investigator

Edit Dataset: INC001_TXT_SUBINT ?

Name:	INC001_TXT_SUBINT
Description:	Subject Initials
Item Status:	Data from CRFs Marked Complete

← Use task pane on the left side to select CRFs

Show the following items in this dataset:

Back
Add or Remove Items
Continue to Define Scope

Subject Attributes

Subject Status	Person ID	Date of Birth
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Event Attributes

Event Location	Start Date	End Date	Status
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CRF Attributes

CRF Version	Interviewer Name	Interview Date	CRF Status
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Subject Group Attributes

Subject Exam Name	Subject Exam Type	Status	Subject Assignment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The Edit Dataset page lists the CRF Items in a table, with checkboxes selected for any of the Items that are already specified for the dataset.

3. To remove any of the existing criteria, clear the checkbox for the Item or Attribute, and click the **Add or Remove Items** button.
4. To add Attributes, select the checkbox for each Attribute that you want to add, and click **Add or Remove Items**.
5. To add CRF Items:
 - a. In the Info area of the Left Panel, click the Event whose CRF you want to add. The panel shows the CRFs associated with the Study Event.
 - b. Click the CRF that contains the Items you want to add.
6. Select Items from the CRF that you want to include in the dataset.
7. Click Save.
8. To continue adding CRF Items, click the **Add More Items** button and repeat the steps to add CRF items.

At any point, while you are modifying the dataset, you can click [View Selected Items](#) in the Info area of the Left Panel to see all selected Items and Attributes.

9. After changing the items contained in the dataset, click the **Save and Define Scope** button. The *Edit Dataset: Define Temporal Scope* page opens.

10. Set a date range for the dataset definition by following the onscreen instructions, and click the **Continue** button. The *Edit Dataset: Specify Dataset Properties* page opens, showing the name and description of the existing dataset definition.
11. To revise the existing dataset definition, do not change the Name and Description. To maintain the existing dataset definition and create a copy that reflects your changes, provide a new name, and click **Continue**. The *Edit Dataset: Confirm Dataset Properties* page opens.
12. Verify the Name and Description, and click **Submit**. The *Download Data* page opens. You can now generate and download a file containing all the data matching the criteria you specified in the dataset definition.

6.4 Dataset File Formats

This section provides information about the dataset file formats you can generate and download using ClinCapture.

ClinCapture's standard tabular (non-CDISC XML) data export formats are HTML, tab-delimited, Excel, and SPSS. The HTML, tab-delimited, and Excel formats each contain two tables: a header table that contains reference information about the dataset contents, and a data table. The SPSS data export format has a data table similar in structure and format to the others, but does not have a header table. Instead, it includes a separate `.sps` syntax file that describes the dataset.

The format you choose depends on how you intend to use the extracted data. The CDISC ODM formats are the most robust, including not only the data but also the metadata. HTML and Excel formats are the easiest for a person to read.

Variable names in the downloaded files use the following format:

```
ItemName_EventNumber_CRFNumber
```

6.4.1 Header Table Format

The header table includes the following information:

- Dataset name
- Dataset description
- Study name
- Protocol ID—the Study protocol ID
- Date—the date the dataset was created
- Subjects—the number of Subject records in the dataset
- Study Event Definitions—the number of Study event definitions included in the dataset
- For each of the included Study event definitions, the name of the event definition plus an identifier which is used to reference the event definition in the data table

For each of the included CRFs, the name of the CRF plus an identifier that is used to reference the CRF in the data table must be there.

6.4.2 Variable Naming Convention

To avoid duplication and confusion among the data points collected in a Study, certain identifiers and ordinal numbers must be appended to each variable name. These variable names can be used in multiple CRFs across multiple Events. These appendages help identify the Event, CRF, and Item that the value was collected in.

Identifiers are defined in the header table for tab-delimited, HTML, and Excel formats, while a separate syntax (.sps) file is used for SPSS. Identifiers use the following scheme:

- ❑ E1–The E specifies that the appendage represents an event. The 1 specifies which event the variable is from, as defined in the header table. If the event is repeating, it would be represented as E1_1, E1_2, E1_3, and so on.
- ❑ C1–The C specifies that the appendage represents a CRF. The 1 specifies which CRF the variable is from, as defined in the header table.

For repeating events and repeating groups, additional information must be provided to identify which occurrence of the event or which repeat of the group the item value comes from. This is done by appending _x, where x is the ordinal or repeat number. As an example, an item called *DEMO* appearing in the third occurrence of a repeating event, and the fifth repeat of the group is identified in the following way.

```
DEMO_E1_3_C1_5
```

For an item in a repeating event, but not part of a repeating group, the variable is identified in the following way:

```
DEMO_E1_3_C1
```

6.4.3 Supported Extract Formats

ClinCapture supports exporting data in HTML, Excel, SPSS, and CDISC ODM formats.

HTML Format

You can download and view a dataset file in HTML format (.html file).

When viewing the HTML file, you can view the metadata for an Item by clicking its column header.

Excel Spreadsheet Format

When you download to the Excel Spreadsheet Format, the dataset is an `.xls` file.

SPSS Format

When you select the SPSS format, the extracted `.zip` file contains two different files: a tab-delimited data file (`.dat`), and an SPSS data definition script file (`.sps`).

To access the data, save the `.dat` and `.sps` files to the same location, and open the `.sps` file in the IBM SPSS program. If both these files are not in the same location, change the FILE location in the `.sps` file to point to the physical location of the `.dat` file. From SPSS, select Run > All to load the data into the application.

You can preview the `.dat` file by opening it in a text editor.

CDISC ODM Formats

When you select one of the CDISC ODM formats for the dataset, ClinCapture exports the dataset to an `.xml` file that complies with the Operational Data Model (ODM) of the Clinical Data Interchange Standards Consortium (CDISC) standard. These are the different parameters for the available ODM formats:

- 1.3 or 1.2:** Refers to the version of the ODM specification.
- With extensions:** Includes ClinCapture entities that are not part of the ODM specification, such as the Subject Group Class and its attributes.
- Full:** Includes Discrepancy Notes and the Audit Log.

CDISC ODM is a vendor-neutral, platform-independent format for interchange and archive of data collected in clinical trials. The model represents Study metadata, data, and administrative data associated with a clinical trial. The ODM has been designed to be compliant with guidance and regulations published by the FDA for computer systems used in clinical trials.

The ODM model categorizes clinical Study data into several kinds of entities, including Subjects, Study Events, CRFs, Item Groups, Items, and Annotations. The Study metadata describes the types of Study events, forms, item groups, and items that are allowed in the Study. The clinical data of a Study typically has many actual entities corresponding to the definitions described in the metadata.

Like any XML file, an ODM file consists of a tree of elements that correspond to entities. Each element consists of required attributes and optional attributes. An ODM file type must be either Snapshot or Transactional. A Snapshot file shows the current state of the included data. A Transactional file shows both the latest state and (optionally) some prior states of an included entity. An ODM file has a Granularity attribute which describes the coverage information of the ODM file.

The ODM file consists of two parts: metadata followed by Subject data. The metadata provides certain identifiers for the Study, units (as defined when the CRFs were created), Event information, CRF

information including Item Groups and Items with information about validations, and user account information. The Subject data provides Subject information, Event information, CRF information, and their respective values.

For more details about the ODM specification and its use in ClinCapture, see CDISC ODM Representation in ClinCapture in the *ClinCapture Programmer's Guide* and the [ODM Final Version 1.3 for Implementation](#) at the CDISC website.

6.4.4 SAS Format via CDISC ODM

ClinCapture does not export a dataset directly into a SAS-specific format. However, you can export a dataset to the CDISC ODM 1.2 format, which can be imported into some versions of SAS.

SAS users running Release 8.2 or later can run the SAS CDISC Procedure, PROC CDISC, to load CDISC ODM 1.2 XML documents into SAS.

For more detailed instructions, see [Base SAS: PROC CDISC](#) at the SAS support website. The following papers from the Pharma SAS User Group (PharmaSUG) may also be helpful:

- Valkanova, E and Droll I, [Exploring SAS® PROC CDISC Model=ODM and Its Limitations](#), Proceedings of PharmaSUG2010.
- Valkanova, E and Droll I, [Exploring SAS® PROC CDISC Model=ODM and Its Undocumented Parameters](#), Proceedings of SESUG2009.

6.5 Special Permissions

System Administrator, Study Administrator, Study Monitor, Site Monitor, and Investigator user roles can access the Extract Data module.

Only System Administrators and Study Administrators can delete, remove, or restore Dataset Definitions they did not create.

For information about features in the module, see [Extract Data](#).

6.6 Annotated CRFs

An annotated CRF is a blank CRF that has been marked, or annotated, with the CRF item name for each item on the CRF.

To generate an annotated CRF:

1. Select Tasks > CRFs, then click the Annotate CRF icon to the right of the CRF version.

Adverse Events	09-Jun-2014	root	F_ADVERSEEVENTS	(original)		21-Jan-2013	root	available		
				v.3	F_ADVERSEEVENTS_V3	09-Jun-2014	root	available	N/A	
				v.4	F_ADVERSEEVENTS_V4	09-Jun-2014	root	available	N/A	
				v.5	F_ADVERSEEVENTS_V5	09-Jun-2014	root	available	N/A	
				v.2	F_ADVERSEEVENTS_V2	08-Jun-2014	root	available	N/A	

Alternatively, from the View CRF Details page, click the Annotate CRF icon to the right of the CRF version.

View CRF Details

Name:	Adverse Events
Description:	preview version
OID:	F_ADVERSEEVENTS

Versions

Version Name	oid	Description	Status	Revision Notes	Action
v.3	F_ADVERSEEVENTS_V3	Updated Jan-21-14	available	Added MedDRA coding - Marc D.	
v.4	F_ADVERSEEVENTS_V4	Updated Jan-21-14	available	Added MedDRA coding - Marc D.	
v.5	F_ADVERSEEVENTS_V5	Updated Jan-21-14	available	Added MedDRA coding - Marc D.	
v.2	F_ADVERSEEVENTS_V2	Updated Jan-21-14	available	Added MedDRA coding - Marc D.	

2. The annotated CRF displays.

02_Baseline Assessment v0.19

Exit

F_02_BASELINEASSESSMENT_V019

TTE and ECG (0/0) Medical History (0/0) Physical Examination (0/6) Blood Test (0/33) **Cardiac Medications (0/7)**

Title: Cardiac Medications

Instructions: List all current cardiac medications below

IG_02_BA_CARDIACMEDICATIONS

Serial Number	Generic Name	Classification	Other	Daily Dose	Units/day	Start Date dd/mmm/yyyy
		CARD_MED				
		(Please select) 1 AA : Anti-Arrhythmic 2 AI : ACE Inhibitor/AR Blocker 3 AT : Angiotensin II Antagonist 4 AC : Anti-Coagulant(e.g.Heparin) 5 AP : Anti-Platelet(e.g. ASA) 6 BB : Beta-Blocker 7 CA : Calcium Antagonist 8 DG : Digitalis 9 DU : Diuretic 10 LL : Lipid-Lowering Drug 11 NO : NO-Donor/Nitrate 12 Other				
			CARD_CLA	CARD_MED	CARD_MED	CARD_MED

Add

Each CRF field is annotated with the CRF name highlighted in yellow with green text; each table annotation is highlighted in yellow with orange text.



If Study Parameter, **SAS Name Annotation**, is answered Yes, the CRF will be annotated in SAS format. SAS field names can be eight characters long. If the CRF item name is longer than eight characters, the annotation will be truncated to display the first eight characters only.

3. If the CRF has multiple pages, you can click the page tab headings to access the annotated CRF for each page.
4. If desired, use your browser's print functionality to print the annotated CRF for your records.

7 GLOSSARY

Audit Log

A system feature that maintains a historical record of key actions related to a Study Subject made in the ClinCapture database (this is part of 21 CFR Part 11 compliance).

Calendared Event

A Calendared Event can be automatically scheduled when a *reference visit* is completed. This is typically used for follow-up events that must occur within a predefined period of time after the treatment occurred.

CRF (Case Report Form)

A form that contains Study Event information for a Study Subject. CRFs are defined using Excel spreadsheets and are presented in a web interface that is easy to complete. See also *Defined CRF*.

Dataset Definition

Criteria (metadata) specified to create a dataset.

Dataset

A collection of data and metadata from records, such as CRFs and Study Events, that match a Dataset Definition. A Dataset is exported to a file, whose format can be selected, for use in other applications.

Defined CRF

An Excel spreadsheet composed of Pages, Item Groups, and Items that you create for use in ClinCapture. A Defined CRF can have multiple versions. You assign it to one or more Study Events in one or more Studies.

Delete

A delete action completely removes the information from the ClinCapture system. Deleted information cannot be restored, although the audit log tracks the deletion action. Nearly all information in ClinCapture is removed rather than deleted because removed information can be restored. See also *Remove*.

Discrepancy Notes

A means of conveying clarifying questions about CRF Items whose value, condition, level of detail, etc., do not conform to expectations.

Dynamic Groups

In ClinCapture, specific Study Events can be associated with a Dynamic Group. For example, to create multiple treatment arms, different Dynamic Groups can be configured with different Study Events.

Enrollment

Adding a Subject to a Study. The ClinCapture Enrollment Date is when the Subject is added to a ClinCapture Study.

Event

See *Study Event*.

Group

See *Item Group* and *Subject Group Class*.

Item

Also known as a Data Item. For example, a single question in a CRF. Items have metadata attached to them. Items can have multiple Edit Checks attached to them through either metadata or Rules.

Item Group

A grouping of Items in a CRF. Item Groups can be repeating—for example, recording multiple Adverse Events on one form—or non-repeating.

Job

In ClinCapture, you can schedule Export Data Jobs and Import Data Jobs to run automatically at a specified frequency.

Module

A group of related features in ClinCapture, such as the Submit Data module. Access to a module is based on a user role and user type.

Null Values

The string that represents null values for an Event Definition—for example, N/A for Not Applicable. The string is considered as a reserved word for the CRF.

Person ID

The unique identifier for a Subject that references the Subject across all Studies in the ClinCapture system. It may be required or optional, depending on how the Study was set up.

Randomization

ClinCapture offers block randomization, which differs from simple randomization as it is designed to randomize Subjects into groups that result in equal sample sizes. This method ensures a balance in sample size across groups over time. Multi-stratification variables are supported.

Remove

A remove action makes the information unavailable in the ClinCapture system. You can restore information that has been removed to make it available again. Most information in ClinCapture is removed so that it can be restored, although, in some cases, information can be deleted. See also *Delete*.

Roles

Categories for users in ClinCapture that determine the tasks available to them in the system.

Rules

Customized methods used to trigger actions on records such as the automatic generation of a Discrepancy Note or email. Rules are stored in XML files. They can be defined in an XML file and uploaded to ClinCapture, or directly defined in ClinCapture using the Rule Studio.

Secondary ID

An optional identifier given to a Subject. It is often a legacy identifier like a patient record number used to link the Subject to another system or workflow.

Sites

Locations where the Study has taken place, although they do not have to be physical locations. You can work with ClinCapture at the Site level, which limits the view of the Study to a specific Site.

Study

In ClinCapture, a clinical trial or clinical research project, including all the metadata and data for it.

Study Event

A visit or encounter in the Study where data is captured or created. A Study Event packages one or more case report forms (CRFs). It is also referred to as an Event.

Study Event Definition

Describes a type of Study Event, and includes the CRFs to be used.

Study Level

An aggregated view of a Study with information and data for all Sites in the Study.

Study Subject

A person added to a specific Study in ClinCapture. Also referred to generally as a Subject, but keep in mind that one Subject can exist across several Studies. Therefore, we use the term Study Subject to refer to one Subject enrolled in one Study.

Subject Group Class

An optional feature used to categorize Subjects in a Study. Often, Subject Group Classes are used for different treatment arms or options. This is especially relevant for ClinCapture's Randomization and Dynamic Group features.

Study Subject ID

A unique identifier generated either manually or by the system when adding a Subject to a Study.

Subject

A person who participates in a Study.

Subject Casebook

All CRFs for all Events for a Study Subject.

**User**

The Person using the ClinCapture software. A user can have one or more Roles in one or more Studies or Sites.