Medidata Rave®

Electronic Data Capture (EDC) Training Manual

Document Version 15.0

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Revision History

Version	Date	Changed by	Description of Changes
1.0	February 2007	*James Sugrue, Team Lead*	Original Release
2.0	April 2007	*Dana Cooperman, Instructional Designer*	5.6.1 Changes Template selection and lab selection in the audit trail Go back to Grid View link
3.0	October 2007	*Dana Cooperman, Instructional Designer* *Carrie Barent, Instructional Designer*	Miscellaneous: • Updates to screenshots and content in the Queries section • Data Entry Field Control Types: Dropdown List, Searchable Picklist 5.6.2 Updates: • Data Entry Field Control Types: Radio Buttons • CRF Attachments, updated content and screenshots • Forwarding Queries • Grid View: Performing Actions Using the Grid View • Subject “In Doubt” icon
4.0	April 2008	*Richard Raguso, Instructional Designer*	5.6.3 Updates: • Reactivating an Inactivated Log Line • System Queries • CRF Coding/Data Lock notes • Adding a New Local Lab
5.0	November 2008	*Dana Cooperman, Manager, Knowledge Development*	• Manual Queries: intro to To Cancel a Query • Responding to Queries: updated note text
6.0	June 2009	*Shari Berman, Instructional Designer*	Update lab forms section based on May patch - ability to change lab ranges and unlock previously locked data

Version	Date	Changed by	Description of Changes
7.0	October 2009	*April Chiu, Instructional Designer*	Updates to the Verification and Review and Data Lock sections: added note to reflect action across paginated pages on a landscape log form
8.0	02 August 2010	*Dana Cooperman, Sr. Manager, Knowledge Development*	5.6.4 Updates: • Updated section Opening Manual Queries for Requires Response checkbox
9.0	29 OCT 2010	*Sara Feijó,* *Instructional Designer*	New sections added: • A Sample Rave Homepage • Timeouts Updated sections: • Data Lock: added notes about freezing/locking all log lines on a log form. • Electronic Signature: added a note and updated a note about iMedidata user credentials in signatures.
10.0	06 July 2011	*Janice Quiros, Instructional Designer* *Gwen Tanner, Instructional Designer*	Updated CRF Auto-Coding section to reflect coding by way of Medidata Coder. Updated Data Lock section to show functionality for Entry Lock and Hard Lock options
11.0	02 Nov 2011	*Dana Cooperman, Sr. Senior Manager, Knowledge Manager*	Updated section: • Medidata Rave Icon Key • Medidata Rave Icon Hierarchy Overview
12.0	7 Feb 2012	*Chellie Esters, Instructional Designer*	Updated copyright information Global Patch 08 Update: • Audit Trail: updated section for display of user name • Missing Codes: updated what displays in the Audit Trail Miscellaneous grammatical updates

Version	Date	Changed by	Description of Changes
13.0	26 MAR 2012	*Chellie Esters, Instructional Designer*	Global Patch 09 Updates: • Electronic Signatures: updated section
14.0	19 NOV 2012	*Shanny Lim, Instructional Designer*	EDC 2012.1.0 Updates: • Disabling Add Events: added new section • Performing Actions Using the Grid View: updated section for Disabling Add Events
15.0	21 JUN 2013	*Chellie Esters, Senior Instructional Designer*	• Updated copyright information • Added a new section: "Completing eLearning Requirements" under the "Basic Navigation" section • Miscellaneous grammatical and formatting updates Updates for 2013.2.0 • Updated the following sections for updated eSignatures functionality: ○ *Electronic Signatures in Batch* ○ *Performing Actions Using the Grid View* ○ *Log Forms* ○ *Lab Data Entry* ○ *Using Templates Forms* ○ *Verification and Review* ○ *Subject Administration* • Added a subsection under the "Protocol Deviation" section

Disclaimer: Given that Rave allows users to translate and change text strings, the screens shown in this document are only a representation of the product and may not match the actual Rave interface you are currently using.

Table of Contents

Welcome

This manual is designed to be a useful and detailed reference for the EDC module in Medidata Rave.

Using This Manual

The layout and format of this manual is intended to be as user friendly as possible. The following legend should help differentiate aspects of the information contained in the training manual:

These bullets show a list of definitions:

-
-

These bullets show a list of options:

❑

❑

These Numbered Lists Show General Step-by-step Procedures:

1.
2.

These bullets show a list of options for a step.

➪

➪

> **Note**: Information in these gray boxes is to be noted or critical. Be sure to pay special attention to the instructions or information here.

Introduction to EDC

The electronic data capture (EDC) module is the component of Medidata Rave that provides users with a means to perform electronic data capture tasks, (that is, enter and manage clinical trial data). Display of specific pages is dependent upon the configuration of the system. Exact details of the controls on the pages are described in a later section.

The EDC module is comparable to a collection of electronic Case Report Forms (eCRF). All data related to studies, sites, and subjects collected during a clinical trial are entered and modified in the EDC module. Specific privileges can be applied to users based on their assigned roles.

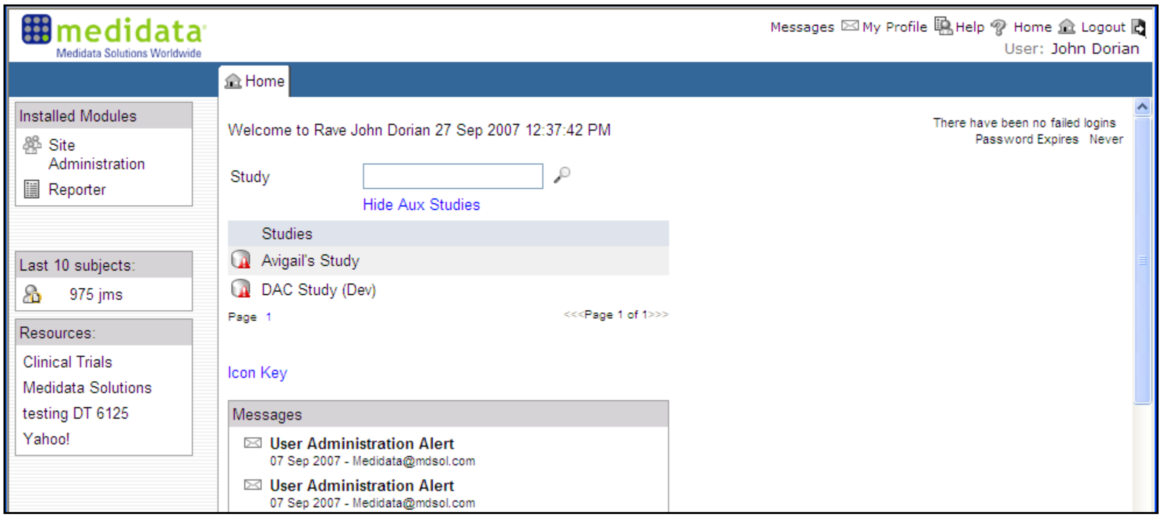
Basic Navigation

This chapter will cover the following topics:

- A Sample Rave Home Page
- Completing eLearning Requirements
- Navigation Hierarchy

A Sample Rave Home Page

This section outlines the generic layout of pages within the system. Below is an example of a sample home page. Each user's home page setup may vary, depending on the number of studies, sites, and modules of Rave to which he or she has access.



Rave offers flexibility when navigating and using the system. Rave can be configured for use with multiple studies (trials) and multiple sites (clinics or centers). The possible combinations are as follows:

Single Study → Single Site

Multiple Studies → Single Site

Single Study → Multiple Sites

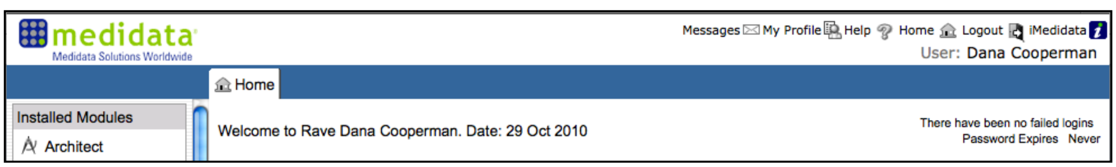
Multiple Studies → Multiple Sites

What you see may also vary depending on whether eLearning is required for any studies to which you have access. Refer to the "Completing eLearning Requirements" section in this manual for additional information.

Home Page Descriptions

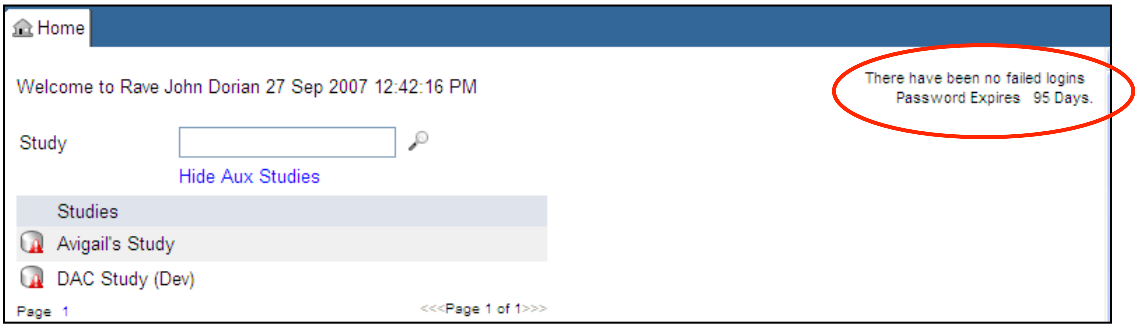
The Rave home page displays various links and pieces of information. Refer to the descriptions below for details.

- **User Name** – The user name, as registered with the system, is displayed in the upper right corner of the screen.
- **Message Icon** – Clicking the Messages icon located at the upper right corner of the screen will bring the user to the Message page, where new messages will be displayed in bold.
- **My Profile Link** – Clicking the My Profile link located in the upper right corner of the screen will bring the use to the My Profile page. On this page, the user can select a time zone, view or edit user information, and specify how many lines to be displayed per page within EDC. Not all functionality on this page is relevant for iMedidata users. Settings in the iMedidata Account Details page will override the settings on this page. See the *Getting Started in iMedidata Training Manual* for more information.
- **Help Icon** – Rave offers context-sensitive help. Clicking the Help icon located at the upper right corner of the screen loads help text that corresponds to the page currently open.
- **Home Icon** – The home page is the first page that loads when logged into the system. Clicking on the Home icon located at the upper right corner of the screen returns the user to the home page, regardless of current location in the system.
- **Logout Icon** – When finished working with the system, clicking the Logout icon located at the upper right corner of the screen clears all the Navigation tabs and loads the Logout form.

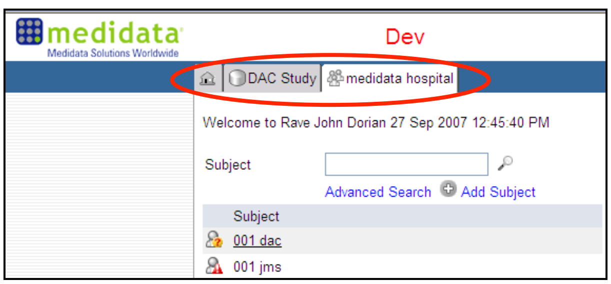


Password Expiration Message – Displays the number of days until the current password expires. This message does not apply to iMedidata users.

- **Failed Logins Message** – Displays the number of unsuccessful login attempts associated with the current user since the last successful login. This message does not apply to iMedidata users.



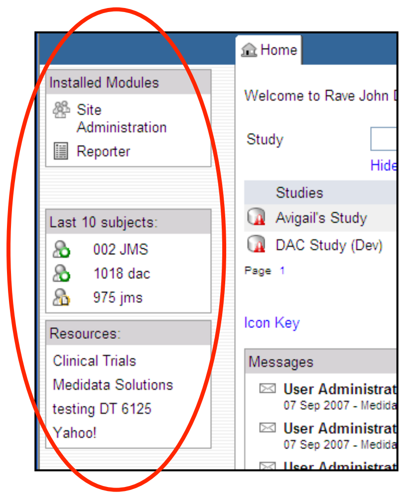
- **Navigation** –Navigation tabs and the web browser's back and forward buttons (Rave 5.6.4 and up only) are used to navigate within the system. Navigation tabs are located directly above the main area. They provide quick access to pages relevant to the page currently being viewed, as well as a means of tracking the levels of the system that have been accessed so far. Tabs are sequentially displayed from left to right in a folder style. Clicking on a tab loads the corresponding page.



Note: In Rave 5.6.3, do not use the web browser's back and forward buttons to navigate; if you do, you will be prompted to log in again. In Rave 5.6.4 and later versions, you may use the back and forward buttons.

- **Installed Modules List** – The Rave home page displays the list of installed modules to which you have access. Each module focuses on a different area of functionality in the system; for example, the Site Administration module is used to create and maintain clinical sites within the system. To access a module, simply click the module's name in the sidebar. The EDC module opens by default in the main area of the home page. Your user permissions will determine which modules within the system you can access.

- **Last 10 Subjects List** – The Rave home page displays a list of up to 10 of your most recently accessed subjects. Clicking the subject name within that list will open that subject's home page in the main area of the screen.
- **Resource Links** – The Rave home page may display a list of websites, files, or other resources that may be of interest to you. Each resource in the list is a link that, when clicked, displays that website or resource in a pop-up window. Typically, links in the Resource list may include a link to the sponsor's home page, common medical reference websites, and so on.

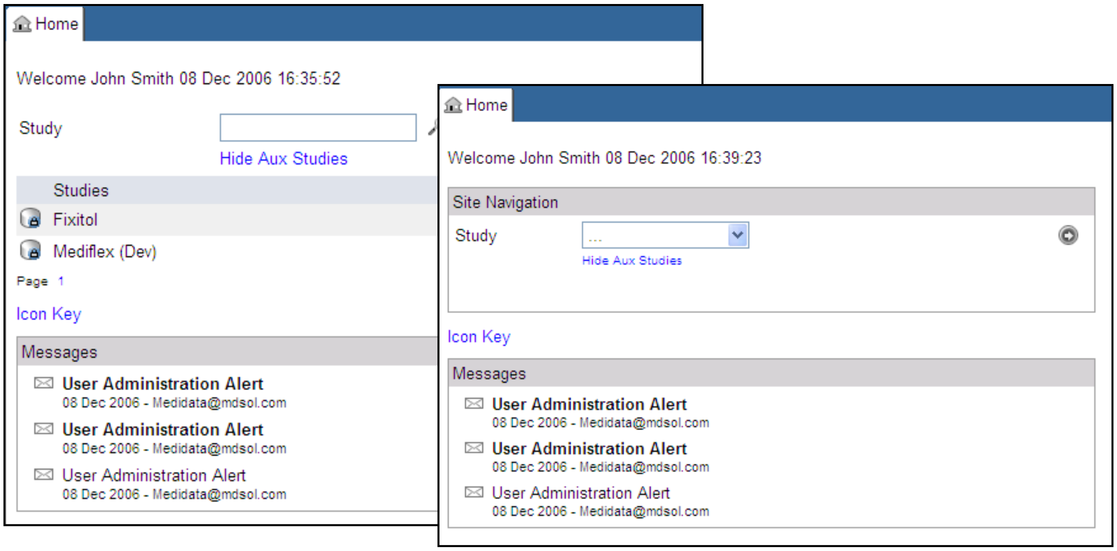


The Main Area of a Sample Home Page

The main area of the Rave system takes up most of the screen. It is the primary section of the screen where information is displayed and data is entered. Its contents are dependent on the currently selected tab or module.

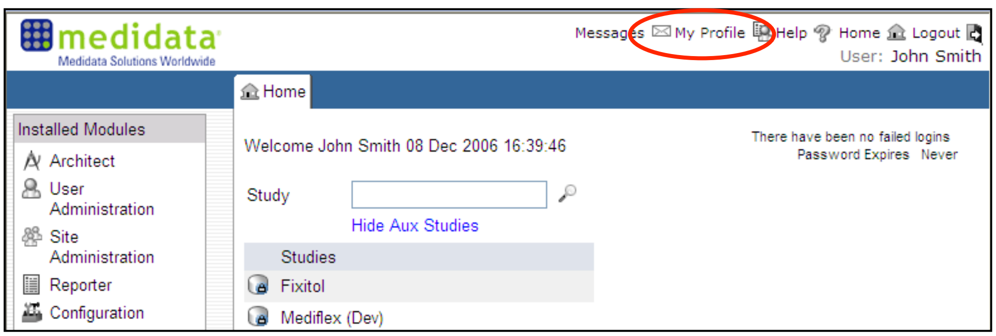
Typically, the main area of the home page displays:

- System generated welcome message
- Site navigation tools (Dropdown View or List View)
- System messages



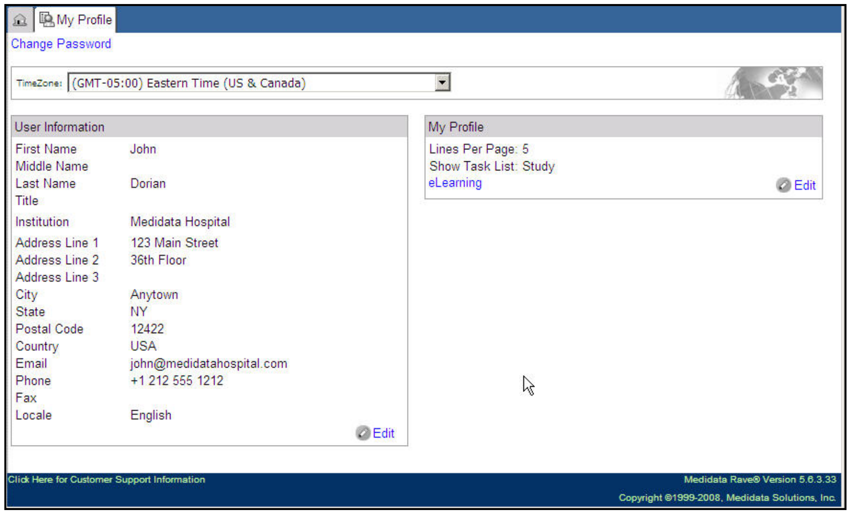
My Profile

Clicking the My Profile link located in the upper right corner of the screen of every Rave page will bring you to the My Profile Page.

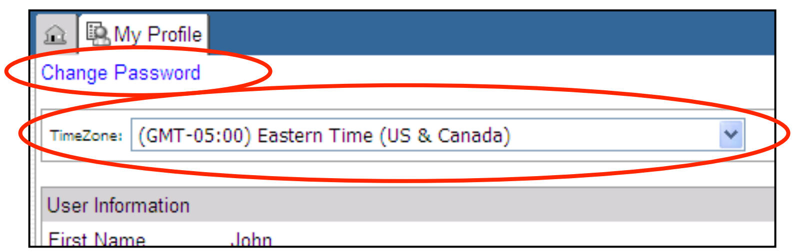


> **Note:** My Profile settings are not applicable to iMedidata users. For iMedidata users, settings in your iMedidata Account Details page override settings in other Medidata applications, such as the My Profile settings in Rave. Please see the *Getting Started in iMedidata Training Manual* for more information.

On the My Profile page, you can change your password, select a time zone, view or edit your user information, specify your preferred language for text in the system, and specify how many lines to be displayed per page within EDC.

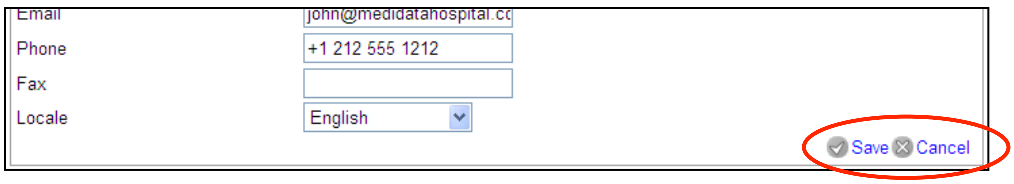


- **Change Password** – Existing passwords can be changed at any time from a link located on the home page. Refer to the "Creating Your New Rave Password" section in the "Getting Started in Rave Training Manual" for additional information.
- **Time Zone Selector** – Use the dropdown menu to select the desired time zone. The time is displayed in the EDC module in the specified time zone.

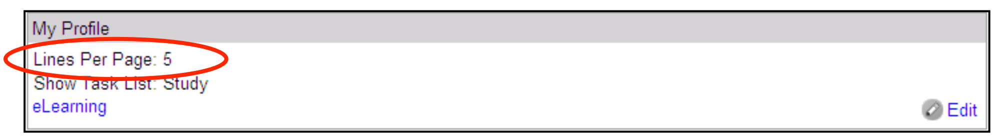


- **User Information** – User information, including name, address, phone number, and language (locale preference), is edited by clicking on the **pencil** icon or the **Edit** link in the lower right corner of the User Information table. The sponsor will determine if you have the necessary permissions to edit your user information. If you do not have the necessary permissions, the edit pencil is not displayed.

When finished making changes, click the **Save** link or **check mark** icon.

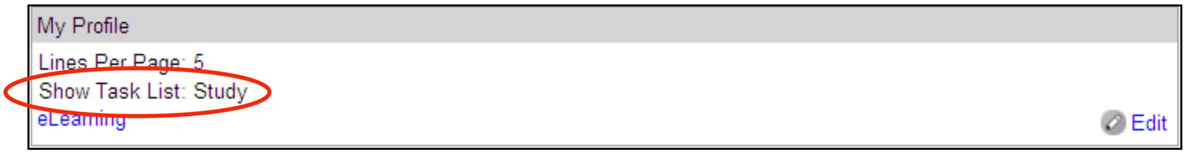


Lines per Page Preference – The Lines per Page preference indicates how many rows of information are displayed on a single page in Rave. For example, if you have specified five lines per page as your preference, you will see five subjects displayed on the Subject Listing page. If there are more than five subjects enrolled at the site, you will see multiple pages, each containing five subjects.

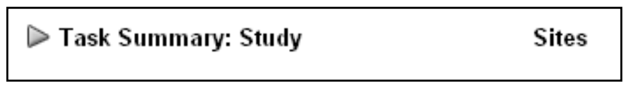


Click the **pencil** icon to change the preference. When finished making changes, click the **Save** link or **checkmark** icon.

- **Show Task List** – Show Task List preferences are edited in the same window as the Lines per Page preference, in the lower portion of the My Profile page.

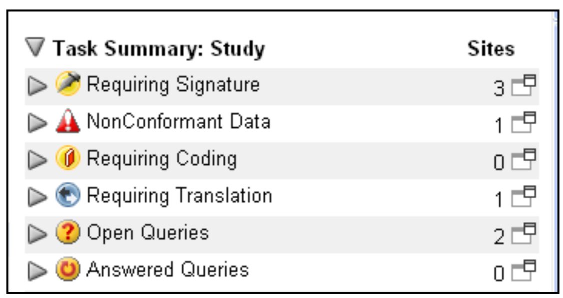


The Task List displays all pending tasks, on a user basis, in one easy-to-access location. By default, the task list is collapsed—only headings are displayed.



The Show Task List preference allows users to specify at which level in the system the Task List will be displayed in its expanded state. In the expanded state, all task categories in the list are displayed.

Depending on the system configuration, users may have the ability to select if the Task List is expanded at the study level (displaying all tasks for all sites), site level (displaying all tasks for all subjects at the selected site), or subject level (displaying all tasks for the selected subject). The sponsor may choose which level will be displayed; in that case, a message indicating the system setting is displayed.

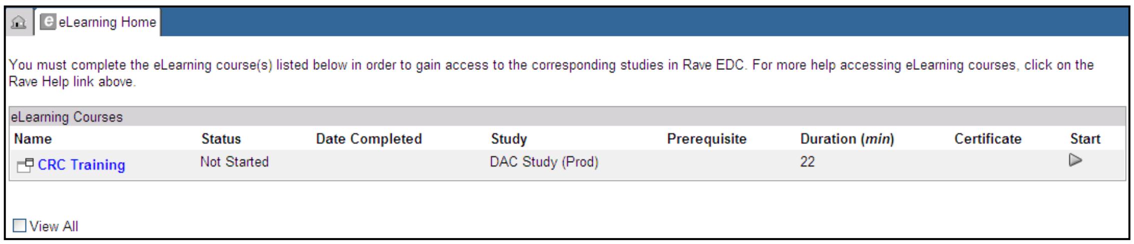


Completing eLearning Requirements

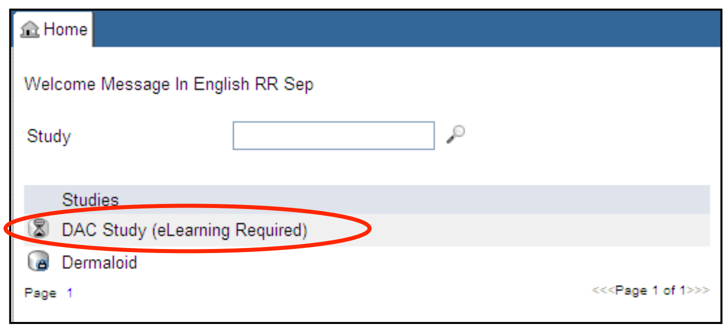
Before accessing your studies in Rave, you may be required to complete eLearning courses. What you see when you log into Rave will vary depending on your eLearning requirements.

Accessing and Completing an eLearning Course

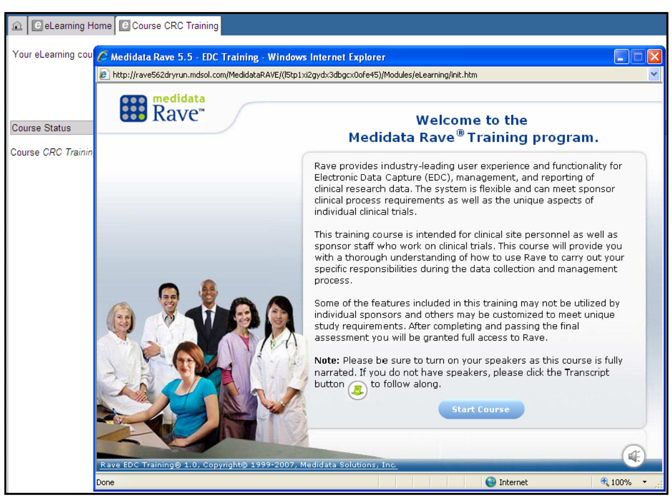
If only one study requires eLearning, and you have not taken any other training (instructor-led or eLearning), the eLearning homepage is displayed when you log into the system.



If multiple studies require eLearning courses, and/or you already have access to other studies, the Rave homepage is displayed when you log in. Any studies requiring eLearning will display the text "(eLearning Required)". If you attempt to access the study the eLearning homepage is displayed.

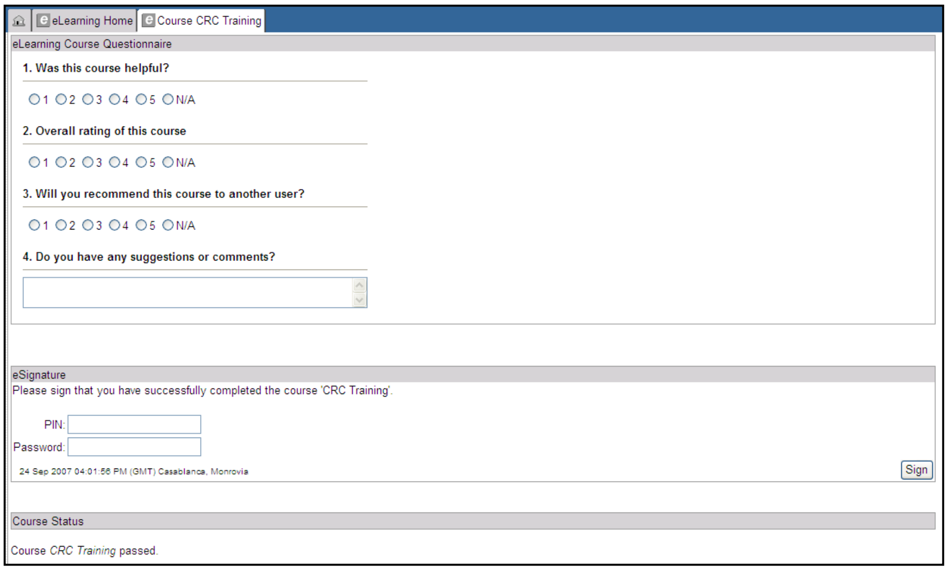


The eLearning course, when launched, will display in a pop-up window.

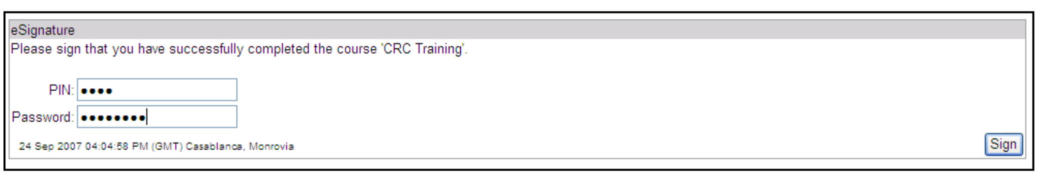


Each course includes an assessment quiz with a listed minimum score to pass in order to access the study. This score varies by course. If you score below the minimum grade, you must take the assessment again and score at or above the minimum grade.

When you pass the assessment, the signature page is displayed, and may also include an optional survey questionnaire. This survey allows you to give us feedback on your eLearning experience, so that we can improve our courses.

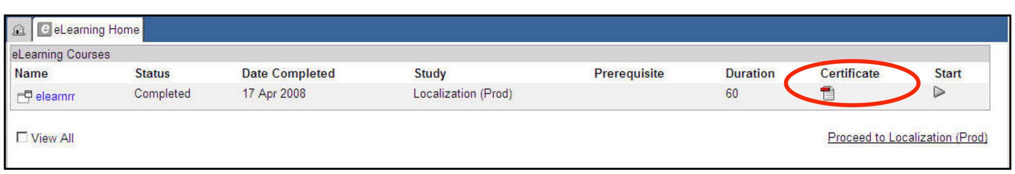


While completing the questionnaire is optional, entering your eSignature is **required** to indicate that you have completed the required training course. The eSignature is made up of you PIN or Username, and Password.

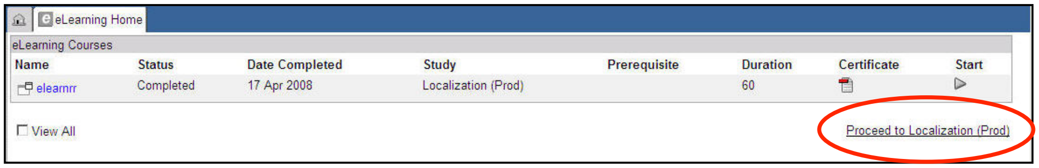


Once the eSignature has been successfully entered, if no other training is required for that study the eLearning panel closes and you are returned to the eLearning homepage, where:

- a **Certificate of Completion** is available: To view, print or save the certificate, click the **PDF icon** in the Certificate column of the eLearning homepage for the desired course.



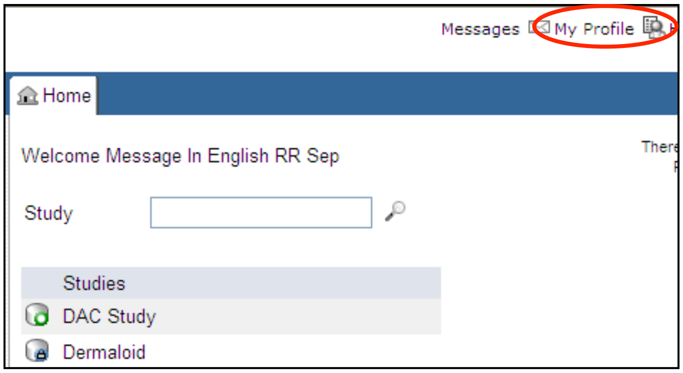
- a **Proceed to Study** link may become active below the list of eLearning courses: This link will be available if the eLearning page was accessed by clicking on a study name on the eLearning homepage, and if all required training courses for that specific study have been completed.



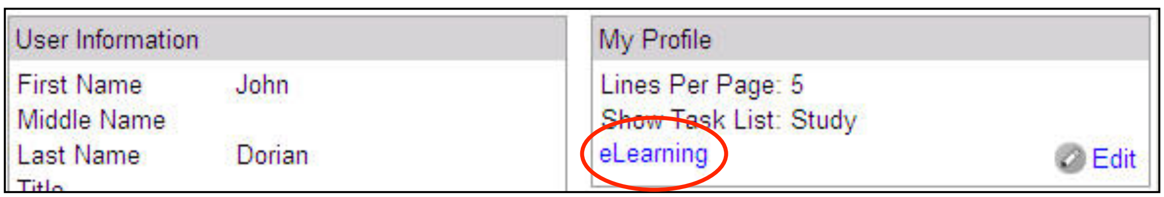
Accessing the eLearning Homepage

At any time, you can access the eLearning homepage. There, you can review completed courses and print out training certificates, as well as complete outstanding course requirements.

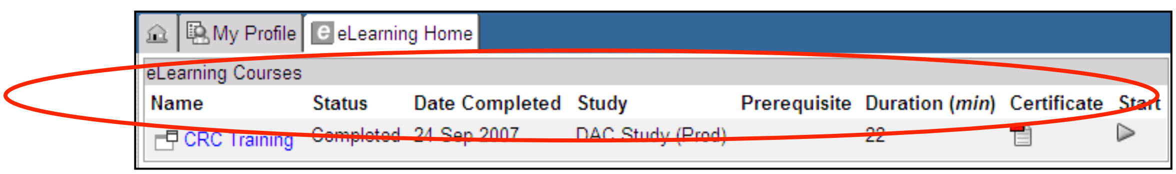
The eLearning homepage can be accessed via the My Profile link, located at the top-right of the Rave screen.



In the **My Profile** section, there is a link to the eLearning homepage.



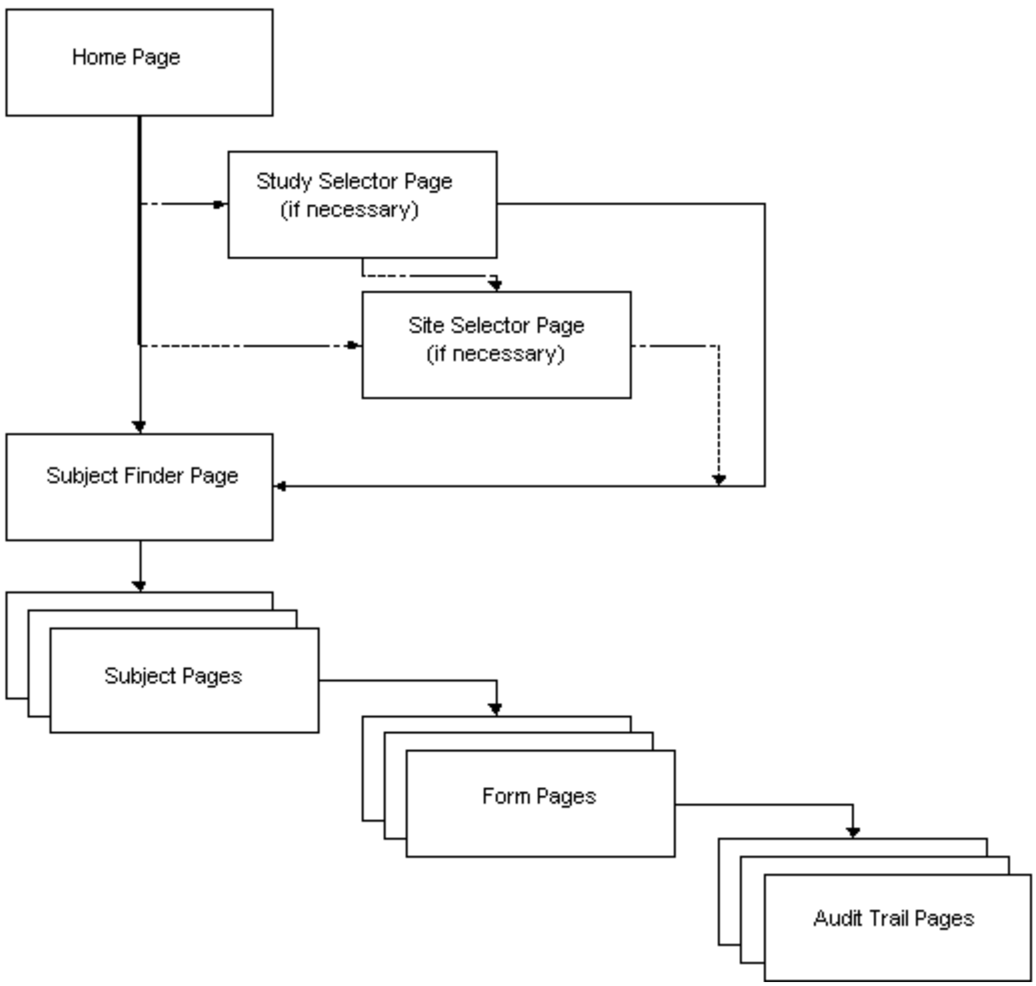
From the eLearning homepage, you can view the status of the course, review the course contents, and view and print a certificate of completion.



Navigation Hierarchy

Once logged into Rave, it is important to understand the Rave Navigation Hierarchy. For information on logging in to Rave, please refer to the *Rave Getting Started Manual*.

The Navigation Hierarchy depends upon the system configuration and user privileges. The following diagram illustrates how a user may navigate through the system:



In other terms, the study and site view ability is as follows:

Study & Site view ability		
Study	**Site**	**What is Displayed**
Single	Multiple	List of Sites
Multiple	Multiple	List of Studies. After study selection, a list of sites is displayed.
Multiple	Single	List of Studies. After study selection, a list of subject is displayed.
Single	Single	List of subjects

Each page is described in detail in its respective section in this training manual.

Using the Rave EDC Module

This chapter will cover the following topics:

- Selecting a Study
- Selecting a Site
- Icon Definitions
- Icon Progressions
- Using Task Summaries
- Understanding Data Status Roll ups
- Selecting a Subject
- Time outs

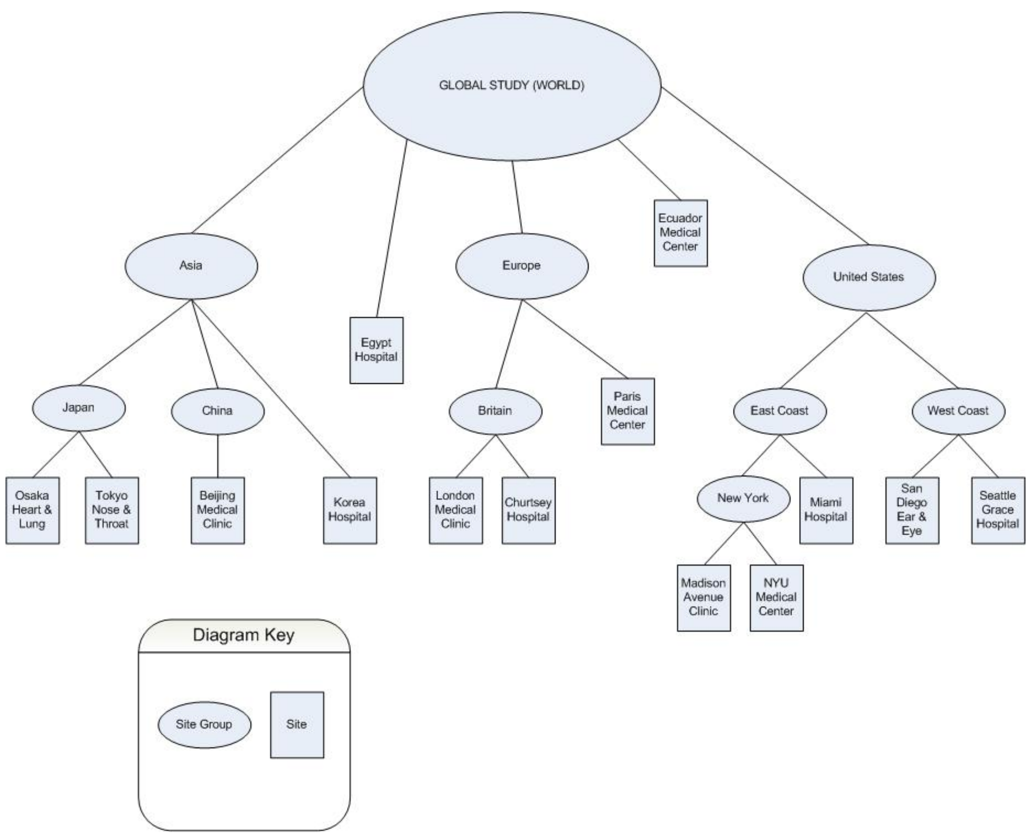
Selecting a Study

Before using site navigation tools, it is important to understand the relationships between studies, site groups, and sites.

Within each study, sites can logically be grouped into "Worlds." For example, in a global study, one world might be "Europe," and another world might be "United States." Note that worlds do not need to be based on geography, but can be grouped according to any logical association.

Within worlds, which can be considered parents, sites can be logically grouped into site groups, or children. Site groups may be based on geographical regions or any other logical association. To follow the example above, within the Europe world, site groups might include Germany, France, Spain, and Switzerland. Within the United States world, Site groups might include East Coast and West Coast.

Site groups can contain sites, or can also contain additional site groups. In the Germany site group, we might have individual sites for Berlin and Munich. In the East Coast site group, we might see another site group for Northeast, and then individual sites for Orlando and Atlanta. Within the site group Northeast, we might have a site group for New York and individual sites for Boston and Bangor. For any given study, a parent group world is assigned as the default site group. To this parent, child site groups can be assigned from the Site Administration module.

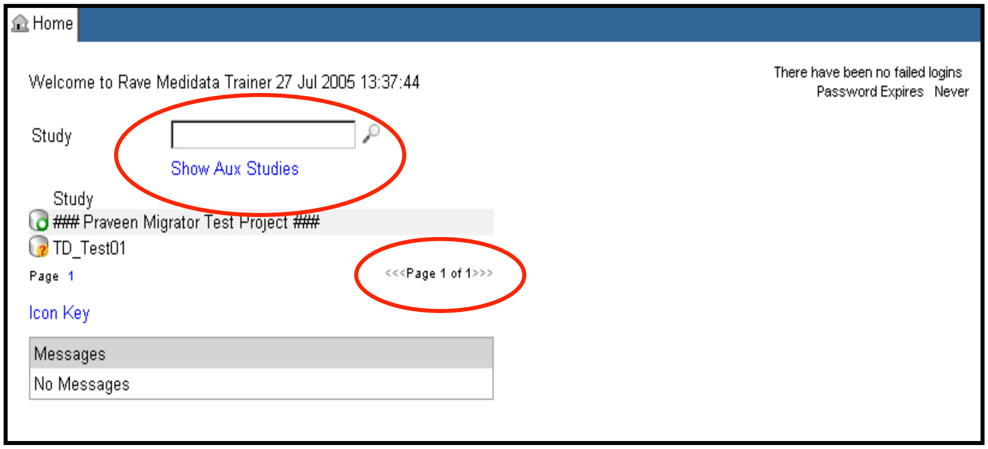


Accessing Studies from the Home Page

Logging in to the Rave system opens the home page, which displays the EDC Module. The home page appears as either Dropdown-Display or List-Display.

> **Note**: The Site Navigation tool can appear in either Dropdown-Display or List-Display. Both views are discussed in this section.

1. Upon successful login to Rave, the Study Selector page is displayed (list view is shown below).



> **Note**: If you only have access to a single study, that study automatically opens, displaying a list of sites to which you have access. If you only have access to a single site, the list of subjects for that site is displayed. Refer to the Selecting a Site/Selecting a Subject sections in this manual for additional information.

2. In the Study Selector page, users can access live and auxiliary studies, search box functionality, pagination, messages and the Icon Key.

   ➪ The Study Selector page allows selection of a specific study/environment in a multi-study configuration.

   ➪ Clicking on the study name (link) opens the Site Selector page for that study. Refer to the Selecting a Site section for further information.

   ➪ By default, there is only one live environment for each study. Additional environments can also be designed. All non-live environments are referred to as auxiliary environments. An auxiliary environment can be used for development, testing, training, and so on. Users who have access to both production (live) and auxiliary (non-live) environments can view a listing of only live environments or both live and auxiliary environments. Click the **Show Aux Studies** link to display both auxiliary and live studies.

- The pagination control (links) lists multiple pages in the study list. If there are more studies in the list than the Study area provides, a page list appears for navigation.
- Click the **Icon Key** link to display a key of graphical icons.
- The study search box filters and displays a subset of studies. Enter a value in the search box and click the magnifying glass search button to narrow down the list of studies.

Note:
Search Box – The asterisk (*) symbol can be entered as a wild card into text fields along with a search string. For example, searching for *T* will return any values that contain the letter *T*. Searching for *T** will return values that begin with the letter *T*. Searching for **T* will return results that end with the letter *T*.

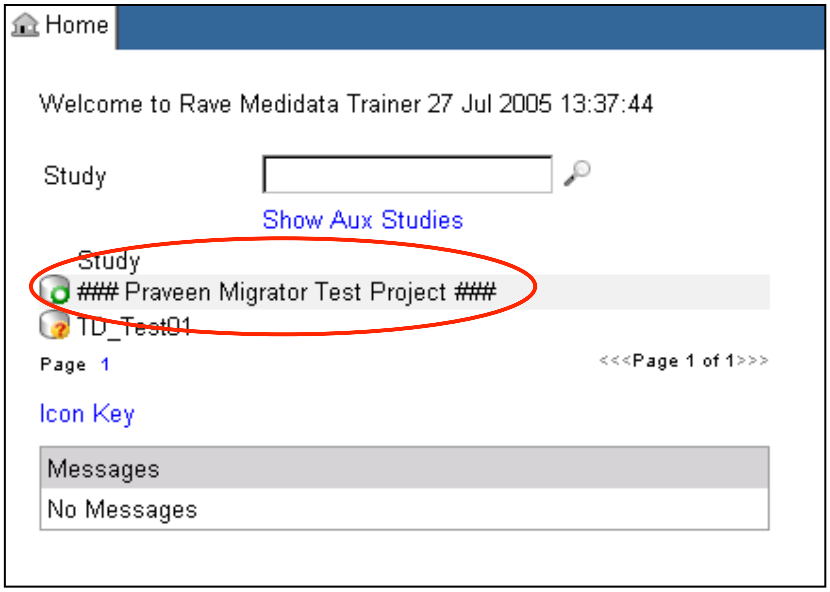
The search box functionality can be used in the same manner at the study level, the site level, and the subject level.

Pagination – The pagination functionality can be used in the same manner throughout the entire Rave application. The number of items per page is specified in the My Profile section of Rave.

Auxiliary Studies – Auxiliary studies may be hidden by clicking the **Hide Aux Studies** link. If auxiliary studies are hidden, and you are not assigned to any prod studies, a message is displayed saying “No Studies Found.” To unhide the auxiliary studies, click the **Home** navigation tab. If you are assigned to prod studies, click the **Show Aux Studies** link to unhide the auxiliary studies.

To View Studies Using List-Display Site Navigation Tools:

1. Click on the study name link to open the Site Selector page for that study.



To View Studies Using Dropdown-Display Site Navigation Tools:

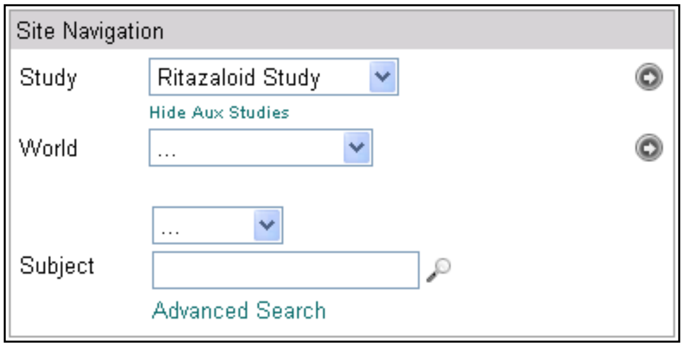
1. Select a study from the Dropdown-Display in the Site Navigation area of the home page.

   ➪ If you are assigned to more than one study, you will see a dropdown menu of alphabetically arranged studies. To omit auxiliary studies from this list, click **Hide Auxiliary Studies**.

   ➪ If you are assigned to one study, only the name of the study displays, and it is non-editable.

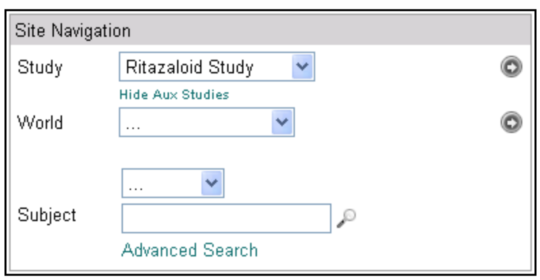
   ➪ If you are assigned to auxiliary studies only, the **Show/Hide Aux Studies** link is hidden and the study dropdown menu is populated with a list of auxiliary studies only.

2. Refine the search more by proceeding to the next step on this list or click the **Go To** icon to the right of the study selector to go directly to the Site Selector page

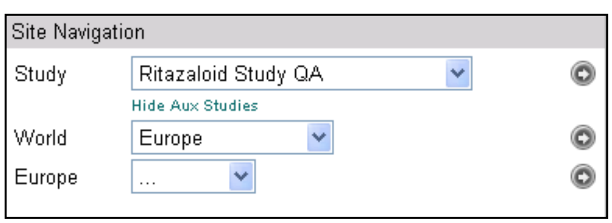


Note: To move directly to the site or subject selector at any time, click the **go to** icon to the right of the category you want to search on; for example, World, Child, Sub-Child, and so on. Refer to the Selecting a Site and/or Selecting a Subject section of this manual for additional information.

3. Once a study is selected, select the desired world, if applicable. Only those sites that are within the user's site group assignment will be displayed. Once a world is selected, a dropdown menu will appear containing only those site groups or sites associated with that world (if applicable).



4. Once a world is selected, select the desired site or site group within that world, if applicable. Once a site or site group is selected, a dropdown menu will appear containing only those sites or site groups associated with the selected site group (if applicable).



5. Continue in this manner until the search is refined to the desired level or until there are no more child groups available.

Note: There can be an unlimited number of parent/child relationships in the site navigator. These parent/child relationships enable you to narrow down your site search.

6. Click the **Go To** icon to the right of the lowest search level to access the Site or Subject Selector page.

Note: If the lowest search level is a site group, the Site Selector page for that site group will be displayed. Refer to the Selecting a Site section of this manual for additional information. If the lowest search level is a site, or if the user is only associated with one site, then the Subject Listing page will automatically open. In that case, refer to the Selecting a Subject section of this manual for additional information.

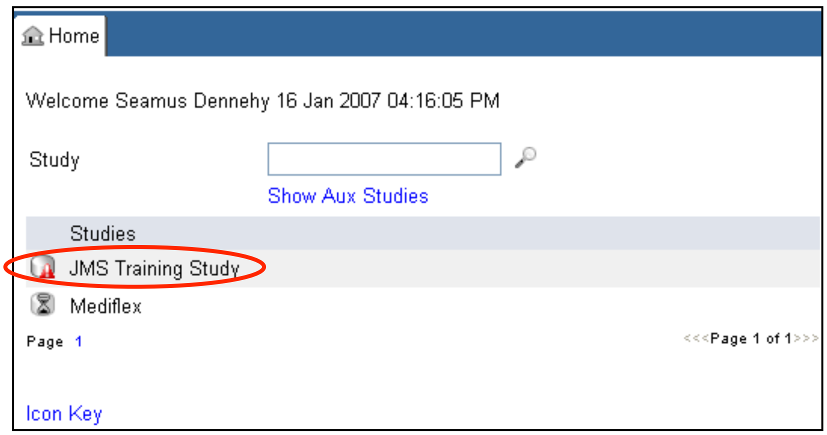
Selecting a Site

The Site Selector page allows for selection of a specific site in a multi-site configuration. The site selector has the same functionality as the study selector but allows the user to select a specific site rather than a specific study.

If a user has access to multiple sites within a study, the Site Selector page opens for site selection.

To Access a Listing of All Sites Within a Study:

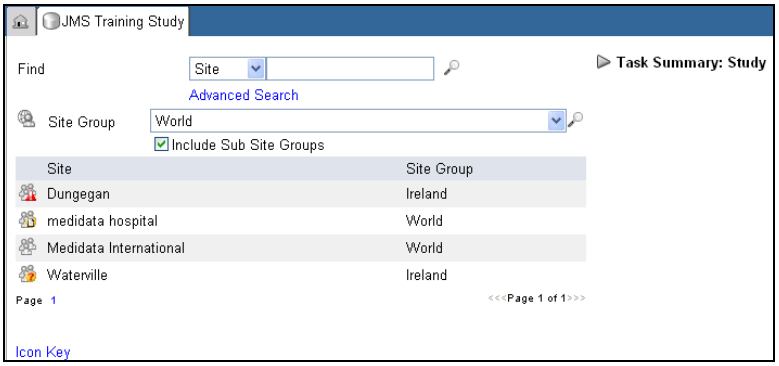
1. Click the Study link to select a study from the home page.



Note: If a user only has access to a single study, the Site page displays on the user's home page (list view) showing only those sites the user has permission to access.

2. When a study is selected, one of two pages appears:

❑ If there are multiple sites associated with the study, the Site Listing page displays.



➪ Click on a site name to display the Subject Listing page for that site.

➪ Use the Site/Subject dropdown menu to search for specific sites or subjects. Type a value or subject name in the search box and click the **magnifying glass** icon to search.

➪ Click **Advanced Search** to access the Advanced Search page.

➪ Narrow down the number of sites listed in the site area by selecting a site group from the dropdown menu.

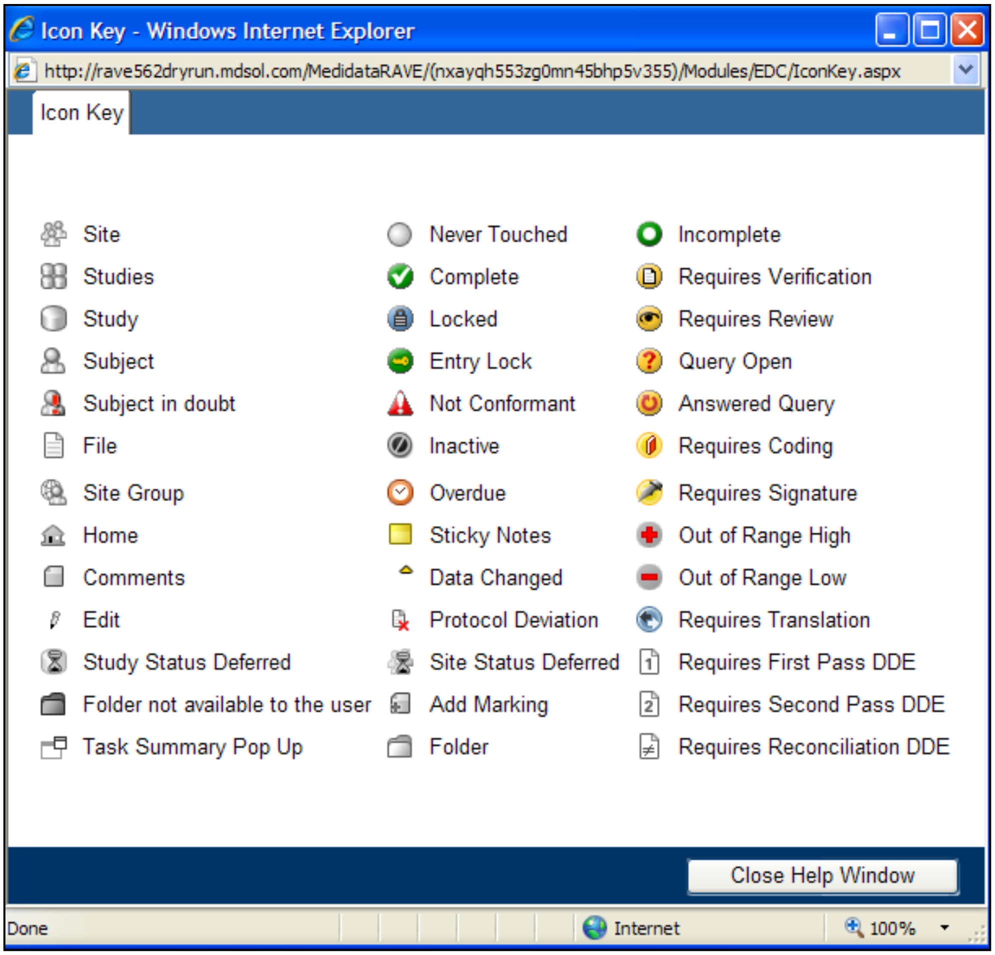
➪ Check the **Include Sub Site Groups** box to display the sites that are part of World, but also sites that are part of site groups within the World. If the box is not checked, only sites that are directly part of the World site group are displayed in the list.

❑ If there is a single site associated with the study, the Subject Listing page displays. Refer to the Accessing a Subject by way of the Subject Listing Page section in this manual for additional information.

Note: The user's ability to access sites is dependent upon which site group(s) the user belongs to and specific sites that they are given permission to access.

Icon Definitions

Within Rave, an icon key is accessible throughout the EDC module. The key contains a description and picture of the commonly used icons. Below is a screenshot of the icon key.



To Access the Icon Key:

Icon Key

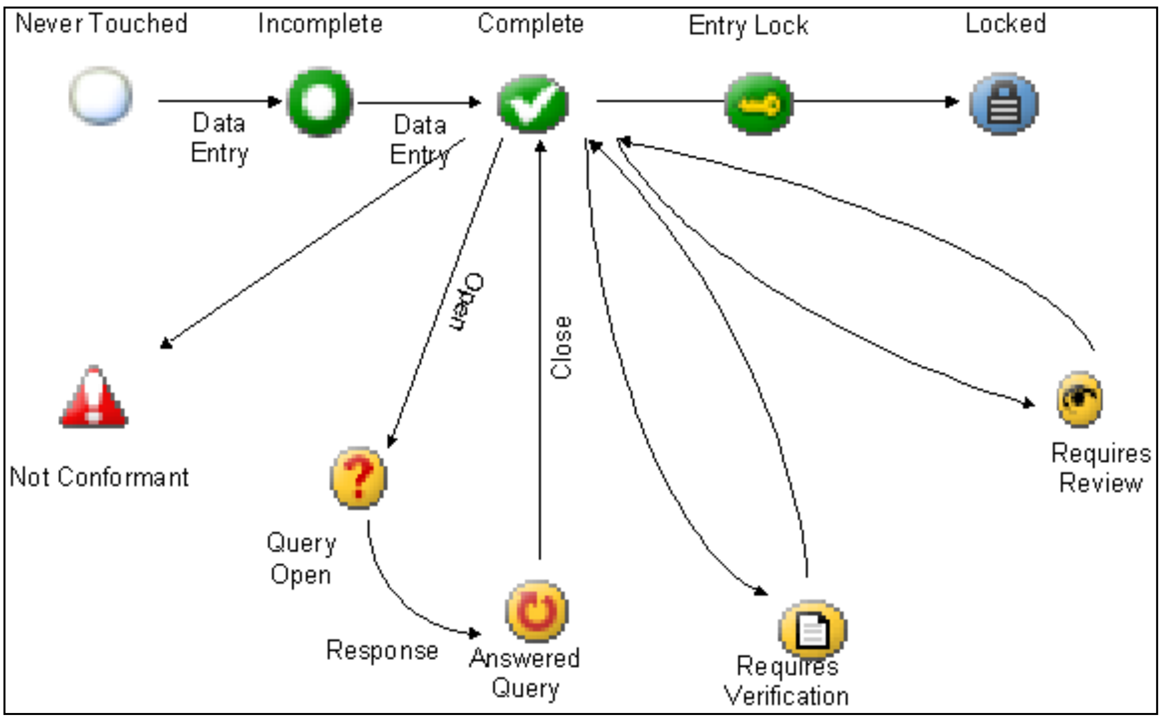
1. Click the **Icon Key** link (located throughout the EDC module).

Note: For a full listing of icons that appear throughout Rave, refer to the Appendix in this training manual.

Icon Progressions

The life cycle of subjects, folders, forms, fields, and so on follows a logical progression starting with never touched and progressing towards complete and locked. Graphical icons are used throughout the Rave system to visually denote status.

The following figure illustrates the status represented by each icon, and the progression of icons throughout the life cycle:



Using Task Summaries

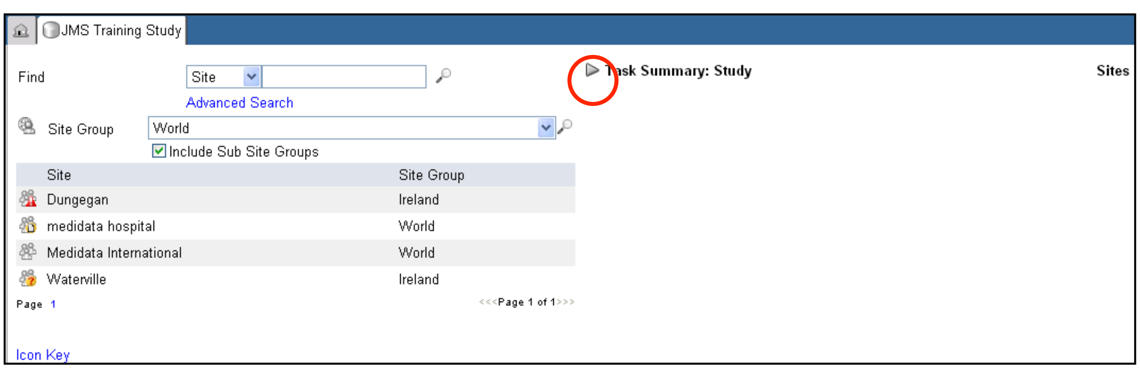
The Task Summary area displays all pending tasks for a study, on a user basis, in one easy-to-access location. The Task Summary contains high-level categories, the relevant icon for each category, and the total number of rolled-up tasks pending for the current user in that category, based on user-role and privileges.

The items listed are filtered for tasks that are one level below the current level the user is viewing. For example:

- The Task Summary on the study level displays the number of sites within that study that contains the selected item (for example, 10 sites within the study have forms that contain data that requires review). The Task Summary only lists those sites that are within the user's site group assignment. In the expanded task summary view, if a site name is clicked, that site's Subject Listing page is displayed.
- The Task Summary on a site level (also called study site) displays the number of subjects within the site that contain the selected item (for example, five subjects within the site have forms that require review). In the expanded task summary view, if a subject name is clicked, that subject's home page is displayed.
- The Task Summary on the subject level displays the number of pages (forms) within the subject that contains the selected item. (for example, three forms within the subject have data points that require review). In the expanded Task Summary view, if a form name is clicked, that form is displayed.

> **Note:** The headings in the Task Summary always indicate what is being counted; that is,, at the study site level, the word *Subjects* defines the item count.

To Expand a Task Summary Listing:

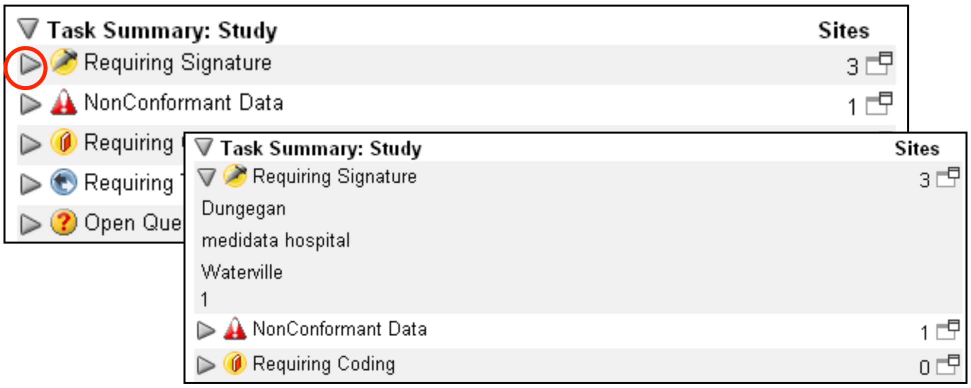


1. Go the study, site, or subject level.

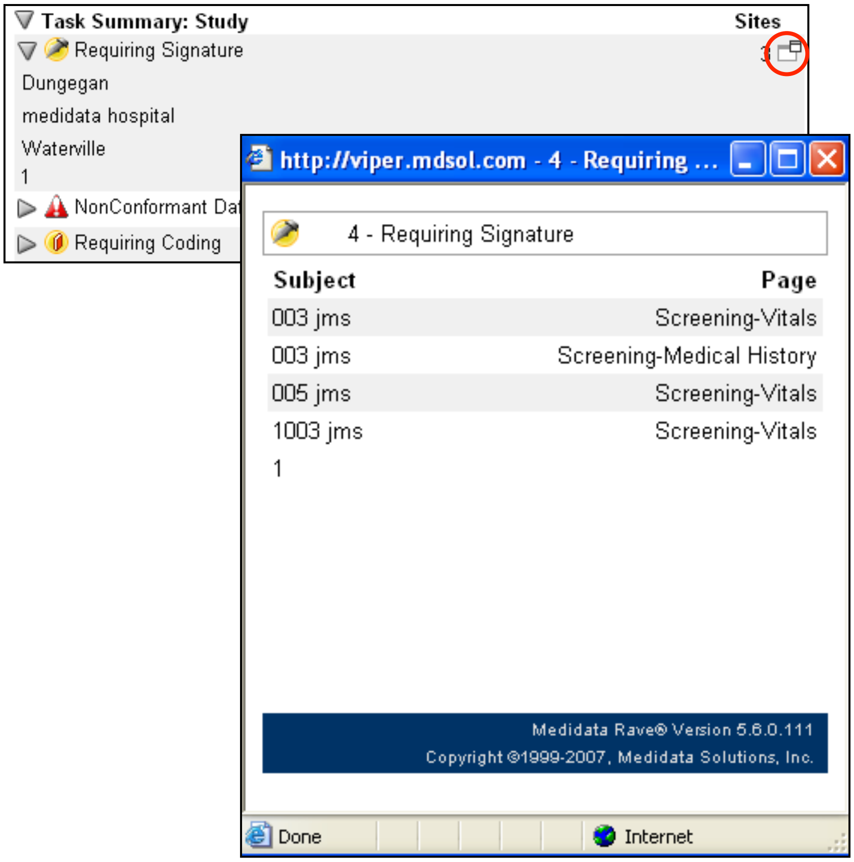
2. Click the **detail arrow** to expand the Task Summary and display a list of data for that level.

   For example, at the study level, the Requiring Signature task lists three sites, indicating that three sites have forms with open queries. When the detail arrow for Requiring Signatures is clicked, the names of the three sites appear.

3. Click the **View Details** arrow.



4. For any category, click the **pop-up** icon to view a list of all pages containing pending tasks.



In the pop-up window, clicking the **Subject Name** (link) or the eCRF **Page** link will directly open either the selected Subject home page or the eCRF page containing the task, respectively. Pagination controls are displayed for each category if the number of required tasks exceeds the number of lines displayed per page (as specified in the My Profile settings). The system can be configured to automatically expand the study, site, or subject level. The system can also be configured to allow the user to decide which level should be automatically expanded. See My Profiles in the Getting Started module.

> **Note**: The pop-up window displays the subject and page (form) regardless of the user's current navigation level.
>
> In the Task Summary area however, summary statistics are displayed based on navigation level, role, and user privileges. The heading at the top of the Task Summary area indicates the navigation level and defines what item is being counted (see screenshot above). The system's navigation tabs also indicate the user's location within the application.

Understanding Data Status Roll ups

The number of pending tasks displayed in each category of the Task Summary is calculated based on status roll ups. During a status roll up, the system reviews the data in the system against the user's role and privileges to determine the status of each data point (for example, requires review, non-conformant, and so on) and what pending tasks should be displayed in the user's Task Summary. For example:

- If a user can respond to Queries, during the status roll up, the system locates data with queries and updates the Task Summary to reflect open queries that need to be answered.
- If the same user cannot Source Data Verify data, and the system comes across data that requires verification, then that information is not displayed in the Task Summary.

If a status roll up is taking place when a user logs in at the study or site level, the Study Status Deferred or Site Status Deferred icon is displayed in the Task Summary. This indicates that the roll up is in progress. When the roll up is complete, the Study Status Deferred icon is replaced with the number of pending tasks.

While status is deferred, a Summary Rebuilding: Click for Refresh link is displayed atop the Task Summary area. This link provides the user with the ability to refresh the page they are on, thereby displaying any of the statuses that have successfully rolled up.

> **Note:** Status roll ups at the subject level and below (folder, form, and so on.) are never deferred, as the results of these lower-level roll ups are required in order for the user to make informed decisions on how to proceed. For example, a user accessing a particular subject needs to know the status of that subject's forms immediately in order to decide which forms to work on.

Subjects with the status of "In Doubt" will be ignored during a status roll up. The status that is displayed for the study-site will reflect the subjects that are not "in doubt." When an In Doubt subject is accessed, that subject's current status is determined, and its icon updated accordingly. You will only see a subject with a status of "In Doubt" in auxiliary environments, never in production.

Selecting a Subject

A user's access to subjects in Rave is restricted based on:

- The subject's status in the study.
- The user's permission to view and work with subjects of a certain status.
- The user belonging to a particular site group or site.

For example, if a subject's status in a study is set to Screened, Randomized, or Terminated, it is possible to exclude some users from seeing subjects with a Screened status, while other users could see all subjects. If a patient belongs to a site that the user does not have permission to view, the patient cannot be searched for and accessed.

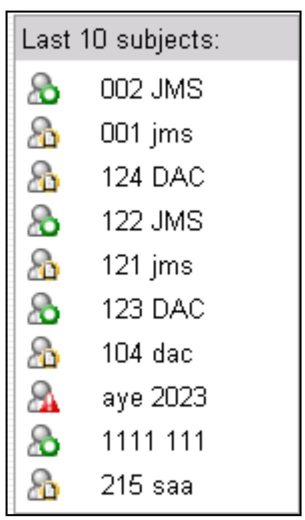
> **Note**: Subject status permissions are configured by Role in the Configuration module. Once a role is configured to view certain statuses, users with that role can only view and work with subjects of those statuses.

Subjects can be selected in multiple ways:

- Last 10 Subjects List
- Subject Listing Page
- Dropdown List Navigation
- Advanced Subject Search

Last 10 Subjects List

The Rave home page contains a Last 10 Subjects list. This list can be found in the sidebar. The list displays the names of the 10 subjects the current user has most recently accessed.



To Access a Subject Directly from the Last 10 Subjects List:

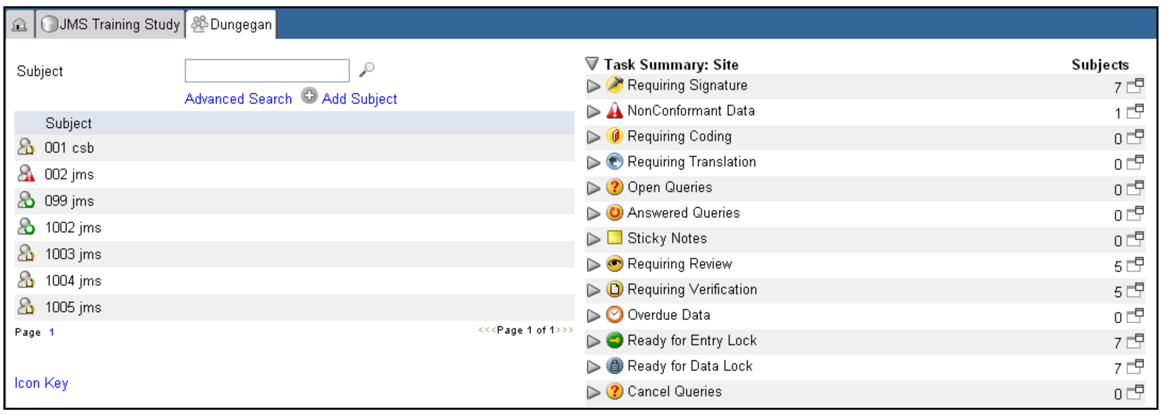
1. Go to the home page by clicking the **Home** icon in the upper right corner or the Home navigation tab.

2. Click the **Subject Name** (link) in the Last 10 Subjects list located in the sidebar.

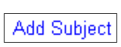
Accessing Subjects by way of the Subject Listing Page

Once a study and site are selected, the subject can be selected using the Subject Listing page within a site. The Subject page is used to select or add subjects to a specific site.

A list of all subjects associated with the study and site is displayed in the main area.



- ❑ The site-level Task Summary is displayed, containing all tasks within the current site for the current user. Refer to the Viewing Task Summaries section of this manual for additional information.
- ❑ Click a subject's name (link) to open the subject home page for that subject.



- ❑ Click the **Add Subject** link to add a subject to a study. Refer to the Adding a New Subject section of this manual for additional information.

- ❑ Click the **Advanced Search** link to open the Advanced Search page. See the Advanced Subject Search section of this manual for additional information.

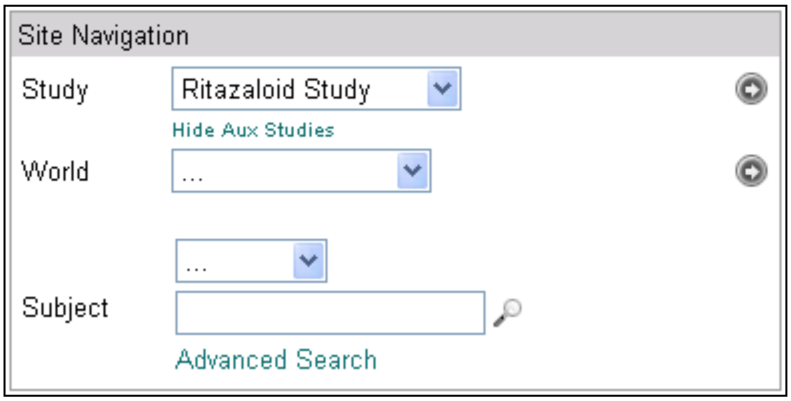
Accessing Subjects by way of the Dropdown List Navigation

The Rave home page contains search functionality within the Dropdown-Display Site Navigation area. This functionality enables users to search for subjects within a specific study. Searches can be performed on either a basic or advanced level.

> **Note**: A Rave URL can be configured to have either dropdown list navigation or list-view navigation. This setting is specified in the Configuration module.

To Access a Subject by way of the Dropdown List Navigation:

1. Select a study/site from the Site Navigator area on the home page.
2. Once a study/site is selected, the subject search field will be displayed.
3. Enter a subject name (if known) into the subject field.



Note: The Search Parameter field can be used to search on preconfigured search criteria. Select a search parameter from the dropdown menu and enter the value to search for in the Subject field.

4. Click the **Search** icon to search for subjects or values that meet the criteria entered.

   ⇨ If there is no subject enrolled that meets the criteria, a "No subject found" message will be displayed.

   ⇨ If multiple subjects are found that meet the search criteria, the list of subjects are displayed on the Advanced Subject Search page.

   ⇨ If one subject is found that meets the search criteria, the Subject home page is displayed for that specific subject.

Advanced Subject Search

Studies can be configured to contain an Advanced Search feature that enables users to search for subjects using predefined search parameters. If the Advanced Search functionality is enabled, users will see an Advanced Search link in the Site Navigation area of the home page. The Advanced Search link will appear if the user selects a study or if a basic subject search returns multiple results.

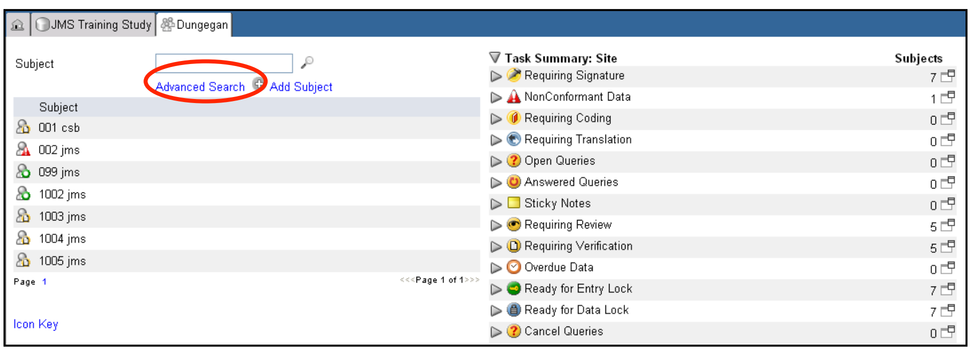
Fields commonly found in the Advanced Search include:

- ❑ Subject Name (default)
- ❑ Subject Status (default)
- ❑ Last Visit Date (default)
- ❑ Additional fields as dictated by the sponsor.

To Access Subjects using the Advanced Search Functionality:

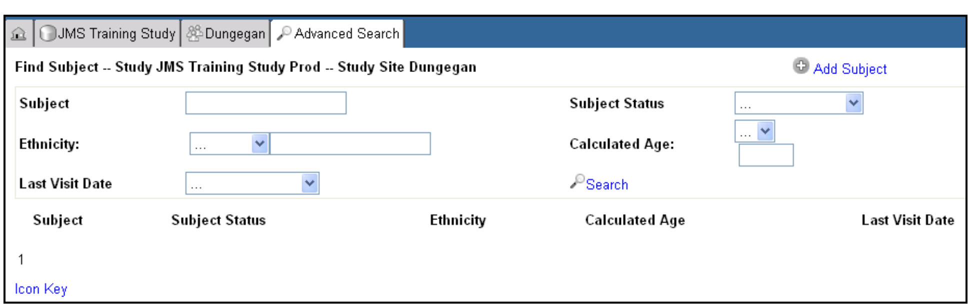
1. Select a study from the Site Navigator area on the home page.

2. Once a study is selected, the Basic Subject Search field is displayed along with a link to the Advanced Search page.



Note: The Advanced Search feature can also be accessed from the Site home page, also known as the Subject Listing Page or Subject Page.

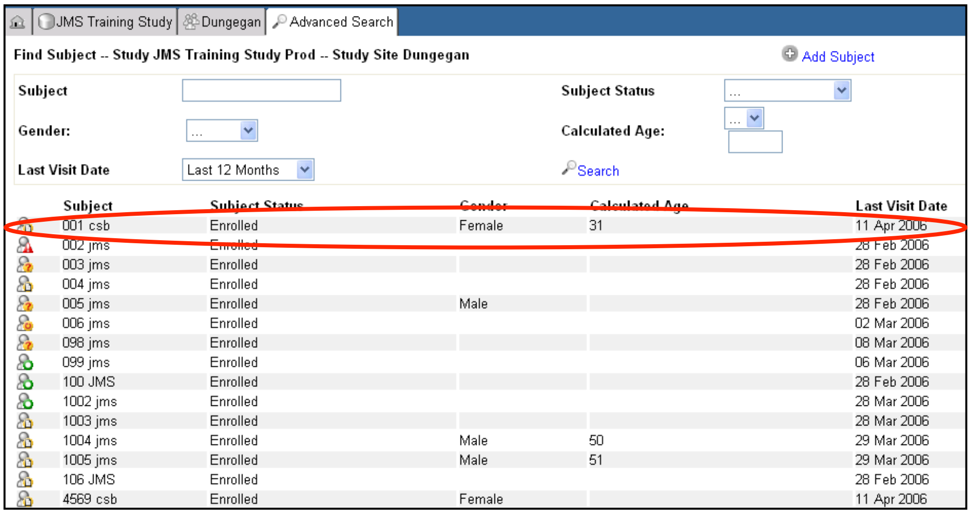
3. Click the Advanced Search link to display the Advanced Search page.



4. Enter the desired search criteria.

5. Click the **Search** icon to search for subjects who meet the specified criteria. The system returns all subject matches based on the search criteria. Certain subjects may or may not be displayed in the returned subject list based on the user's role and permissions, including which sites the user has permission to access.

6. Click the link to open the Subject home page for that subject.



Note: Click any column heading to change the sort order.

Time outs

For security purposes, Rave uses an internal timer to lock users out of the system if inactive for a certain period of time. This time period is configurable and is study-specific. There are three types of time outs:

- ❑ Password Time outs
- ❑ Interaction Time outs
- ❑ Web Session Time outs

> **Note:** For iMedidata users, there is an additional time out for iMedidata. Follow the on-screen prompts to regain system access.

Password Time outs

If logged into the system for a certain period of time (as specified by the sponsor) without interacting with the system, the user may be prompted to re-enter their password in order to continue working. A message similar to the one seen below is displayed.

When the user re-enters the password, s/he is returned to the same page that was previously accessed. Any data entered or changes made during the previous session that were not saved are lost.

Interaction Time outs

Similar to a password time out, an interaction time out occurs if a user is logged in for a certain amount of time (as specified by the sponsor) without interacting with the system. The interaction time out is typically set for a longer period of time than a password time out. When an interaction time out occurs, the next time the user attempts to interact with the system, s/he is redirected to the Rave login page. The username and password must be entered in order to access the system. This begins a new session, and the home page is displayed. Any data entered or changes made during the previous session that were not saved are lost.

> **Note:** Be sure to save all changes before leaving the application idle.

Web Session Time outs

After a certain amount of time, the web browser may need to refresh. When this occurs, the user may be prompted to re-enter the password. This setting is not configurable.

Creating Subjects

This section will cover the following topics:

- Adding a New Subject
- The Subject Home Page
- The Add Event Dropdown Menu

Adding a New Subject

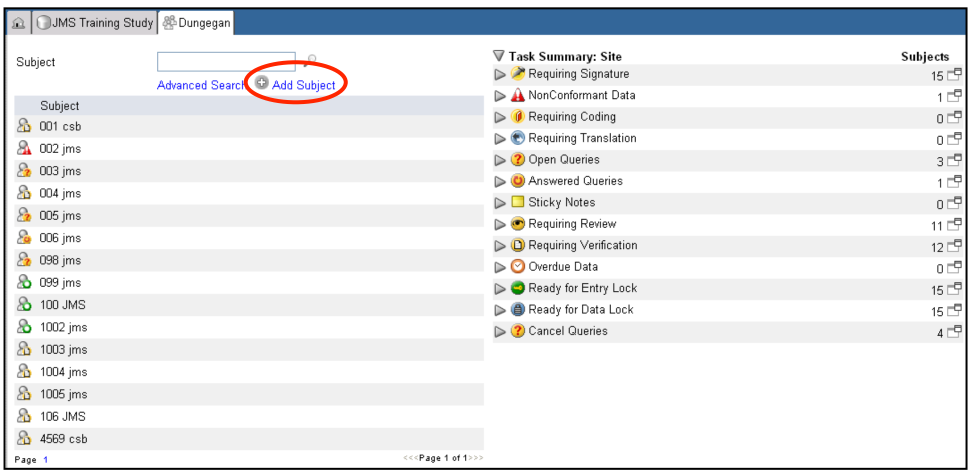
Every study has a form designated as the primary form, where data entry must be completed before a subject can be added to the system. The fields on the primary form can be used to derive the subject's name within the study. When the form is submitted, the new subject is added to the site within the study. The primary form is a required form.

> **Note**: The client defines the name & fields of the primary form.

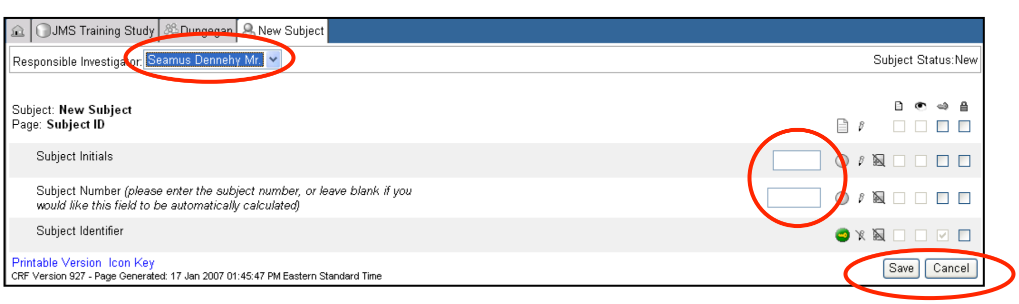
To Add a New Subject to the Study:

Add Subject

1. Click the **Add Subject** link on the Subject page.

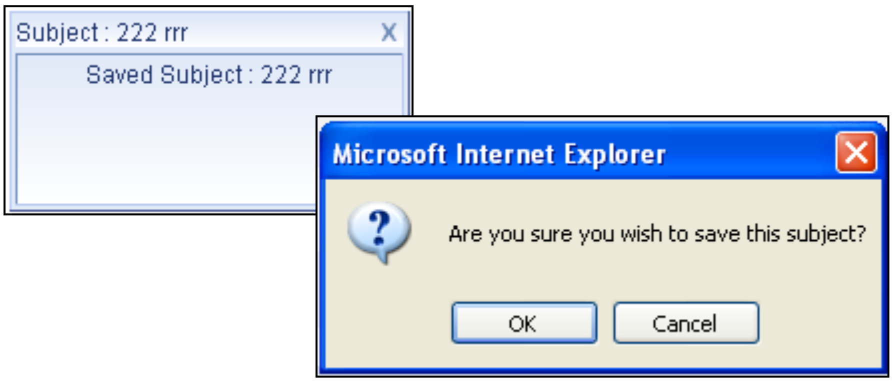


2. The primary form for the new subject is displayed:
3. If applicable, select an investigator from the dropdown menu (within the subject status bar).
4. Type in the appropriate data in the open text fields.
5. Click **Save**.



Note: A pop-up window is displayed in the lower right corner to confirm that the subject was saved in the system. No user response is required when this pop-up is displayed.

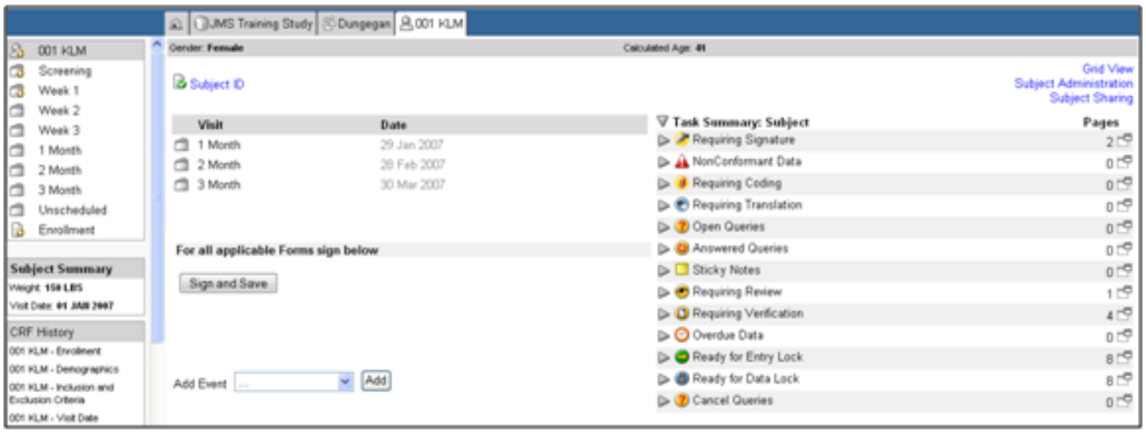
Depending on system configuration, an additional pop-up confirmation window is displayed in the center of the screen where the user must click **OK** to confirm that the subject should be created. If the user clicks **Cancel**, the subject is not created.



The Subject Home Page

Upon successfully saving the primary form, the Subject home page opens. The Subject home page summarizes the information for each subject. An example of a Subject home page appears below.

The Subject home page is made up of two main areas, each of which can contain multiple pieces of information.

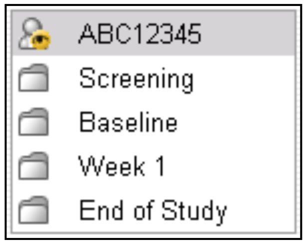


- ❑ The Sidebar
  - Subject Matrix
  - Subject Summary
  - Subject eCRF History
- ❑ The Main Area
  - Subject Schedule
  - Add Event Dropdown
  - Task Summary
  - Additional Controls

Each of these areas will be defined in detail in the upcoming sections of this manual.

Subject Matrix

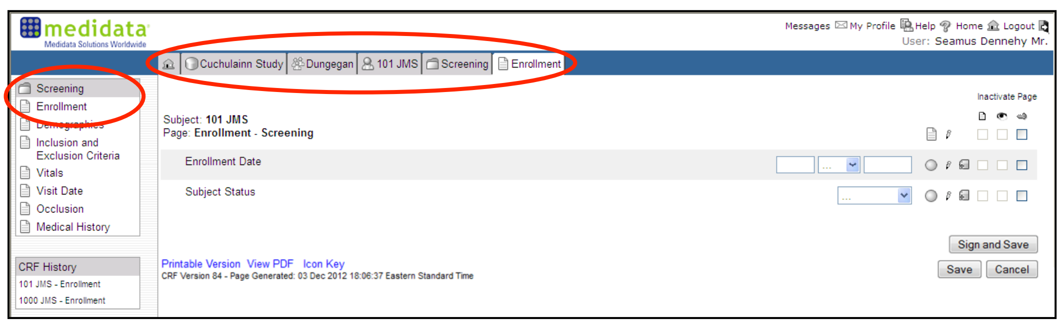
A set of forms and folders defined for the study and related to the subject is displayed in the Sidebar of the Subject home page. These forms and folders are known as the Subject Matrix. The subject name is displayed atop the Subject Matrix.



Upon subject creation, the default matrix (default set of folders and forms) for the study is assigned to the subject and is displayed in the sidebar of the Subject home page. As data is saved into the various forms in the matrix, each form displays status icons (for example, Incomplete, Complete, Query Open, and so on.)

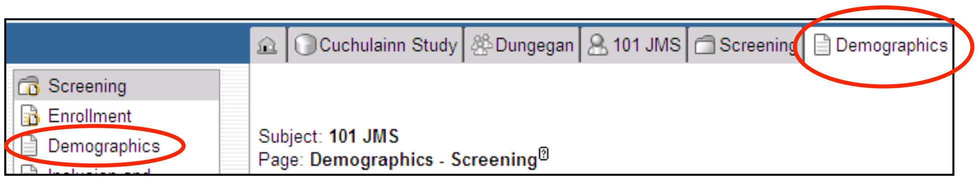
Note: Refer to the Icon Key for icon description or review the complete listing of icons located in the Appendix of this manual.

Clicking on the folder name link (for example, Screening) opens the first form inside that folder in the main area. The navigation tabs at the top of the main area are updated to reflect the user's location in the system.



Note: The navigation tabs can be used to move throughout the subject, study, and site.

For example, if the user is working in a Demographics form within the Screening folder, the tabs display in the order of Screening and then Demographics. Click the Screening tab to open the Screening folder, displaying in the sidebar all forms within the Screening folder. The first form in the list will be automatically displayed in the main area. To move to another form within the Screening folder, click the form name (link) in the sidebar.

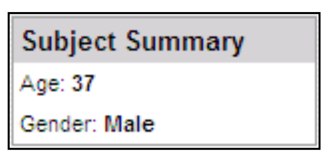


These forms and folders that make up the matrix are often required to be completed for each subject that is participating in the study. Refer to the Entering Form Data section in this manual for more information.

Subject Summary

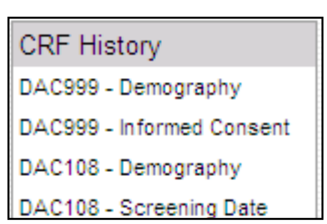
The Subject Summary contains data fields that have been configured to display in the sidebar of the Subject home page. Typically, these would include key pieces of study information such as subject name, subject number, gender, and so on. The fields displayed in the Subject Summary are dictated by the study sponsor and will appear in the sidebar of the Subject home page. The header fields are non-editable and only display fields that the user has permission to view.

The Subject Summary will display field labels whether or not data has been entered for the selected subject for that particular field. If no fields have been configured as summary fields, the summary will not be displayed.



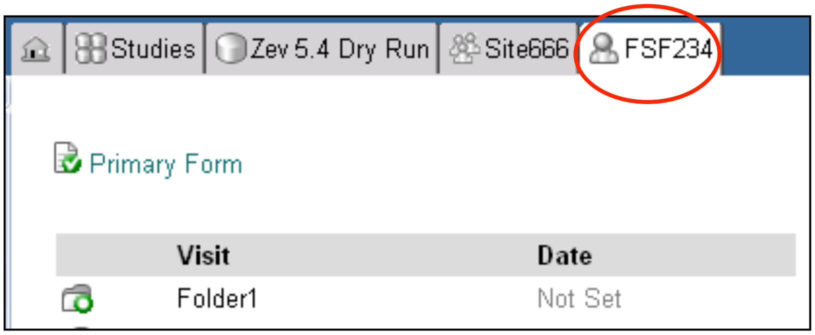
CRF History

Depending on the current navigation page and user privileges, the sidebar may also display the last 10 subjects that the user accessed in current or previous sessions. The system displays the subject name and the eCRF that was accessed for that subject. Each list item is a link that will display the specified page for the specified subject. The subjects appear on the list in reverse chronological order; the most recent subject accessed is at the top of the list.



Subject Name

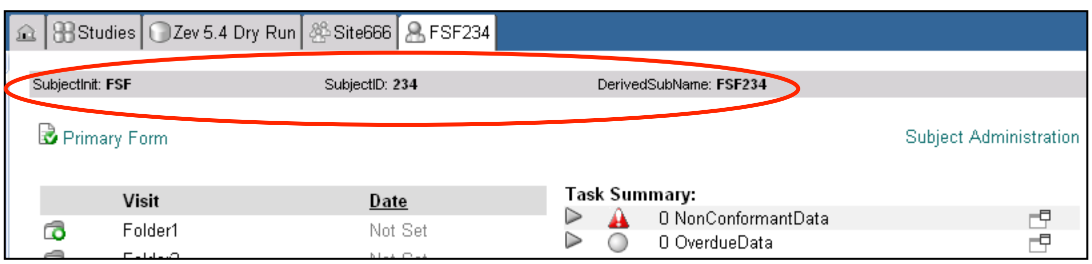
At the top of the Subject home page, the subject's name is displayed in the subject tab.



> **Note**: The new subject name is configured based on the specifications in the protocol. Often, the subject name is derived from the data entered in the primary form.

Subject Header

The Subject Header contains key pieces of subject data that are displayed at the top of the Subject home page and eCRF pages in the Subject Matrix. Typically, these would include key pieces of study information such as subject name, subject number, gender, and so on. The fields displayed in the Subject Summary are dictated by the study sponsor.



The header fields are non-editable and only display fields that the user has permission to view. The Subject Summary will display field labels whether or not data has been entered for the selected subject for that particular field.

Link to Primary Form

A link to the primary form is displayed on the Subject home page if the current user has the necessary permissions to edit the primary form.

Subject Schedule

The Subject Schedule lists visits that are required for subjects. It functions as a guide to facilitate scheduling subsequent return visits, and, depending on the role, a signature tool. The Subject Schedule is read-only and cannot be edited or deleted. The Subject Schedule can be viewed on the Subject home page.

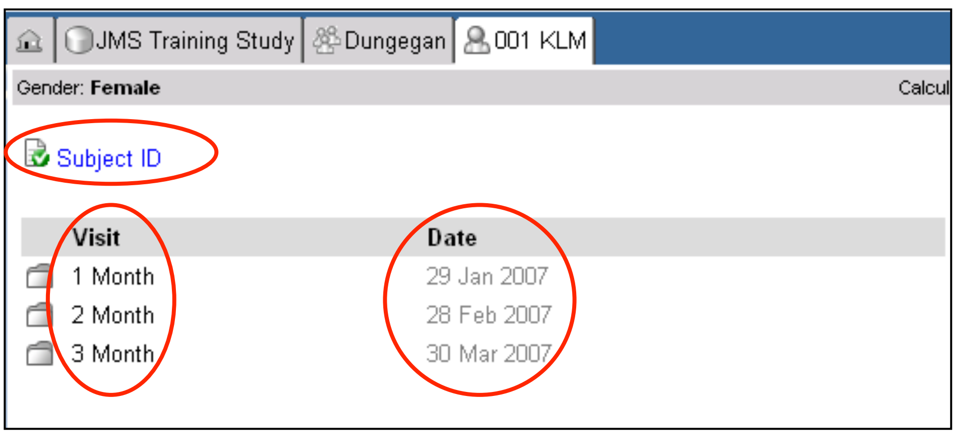
Folder Links with Status Icons

The folders listed under the Visit column heading are links that, when clicked, open the folder or form in the main area. The icon to the left of each folder name indicates the status of that folder or form; for example, complete, incomplete, locked, and so on.

Target Dates

For each visit, there is an associated target date listed in the Subject Schedule. Visits that do not currently have specified target dates display the folder or form name only.

The dates found in the Subject Schedule are calculated automatically based on data entered into the subject's eCRF. A specific date entered into an eCRF is designated as the calendar start date. The entry of the default calendar start date sets the subject calendar based on the days offset specified for each individual folder.



Note: Data entry may not be available in a folder prior to or after the reference dates specified. In this case, the folders are grayed out.

Batch Signature

Batch signing enables a user to sign off on multiple folders and forms at once for a subject. Depending on their permissions, users may be able to **batch sign** forms directly from the subject home page. Refer to the Electronic Signature section in this manual for additional information.

The Add Event Dropdown Menu

Each study has a default set of folders and forms, referred to as the "default matrix." This default matrix is assigned to each subject upon initial entry. Refer to the Subject Matrix section in this manual for further information on matrixes.

If additional forms or folders are required for a subject during a study, they can be added using the Add Event dropdown on the Subject home page:

The Add Event feature is accessible if:

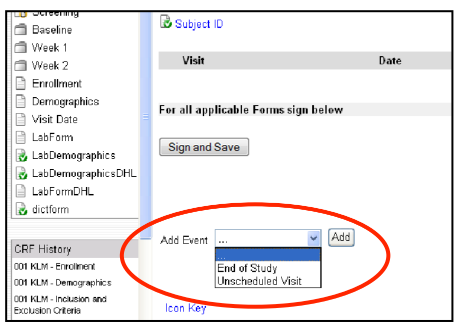
- ❑ There are additional/optional matrixes to be added to the default matrix for a study.
- ❑ A set of folder/forms is required under circumstances outside the realm of a typical study that are not contained within the default matrix; for example, an unscheduled visit.

The additional matrixes are defined by the sponsor's specifications. The number of times a matrix can be added for a subject within a study is configurable. Once the maximum number of additional matrixes is reached, the add event feature is disabled.

Note: If a user does not have Entry role action permissions, the Add Event dropdown will not display.

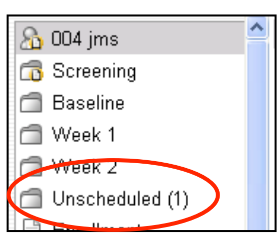
To Add an Additional Matrix:

1. Select the matrix to be added from the **Add Event** dropdown menu.



2. Click the **Add** button.

3. Upon saving, the new matrix is added to the sidebar.



Note: A number in parentheses indicates that another instance of a folder or form has been added to the subject's matrix. For example, if a folder has been added one time, it will display (1). If it is added a second time it will display (2), and so on. The new folders and forms appear in the sidebar and in the Subject Schedule as well, if applicable.

Certain folders are defined as "reusable." Reusable folders only display once in the sidebar. Reusable folders function in the Add Event matrix as follows:

- If the reusable folder is a parent folder, the first time the matrix is selected from the Add Event dropdown menu, it is added to the sidebar with all relevant folders/forms as defined within the matrix.
- If the reusable folder is a parent folder, all subsequent additions for any matrix where the folder is a parent folder uses the previously added folder. All relevant folders/forms defined within the matrix are added to the pre-existing parent folder in the sidebar.

Disable Add Events

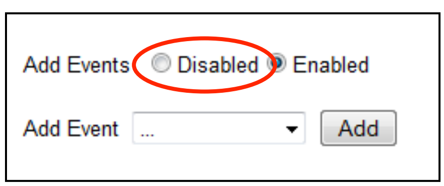
The Add Event feature can be disabled if a user has Lock role action permissions. Disabling Add Events for a particular subject prevents EDC users from using the Add Event functionality for that subject. For example, disabling Add Events may be used during the study locking period. Once the Add Event feature is disabled, it can be enabled again by a user with Unlock role action permissions.

Below is an example of how the Add Event feature displays for a user with lock, unlock and entry permissions. This display may vary depending on user role permissions.

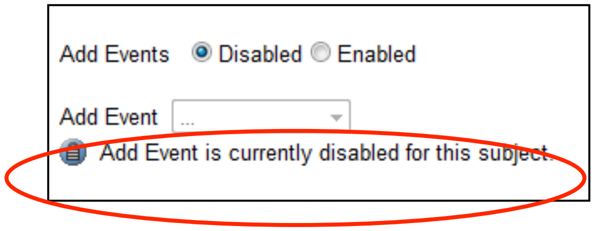
To Disable Add Events

Note: If a user only has Lock role action permissions, only the Disabled radio button will display.

1. Click the Add Events **Disabled** radio button.



2. The Add Event dropdown grays out and a lock icon with a message of "Add Event is currently disabled for this subject" are displayed.

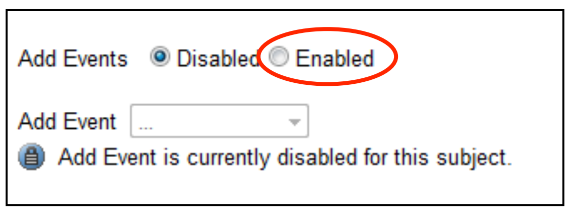


Note: A user can click either the lock icon or the message to display the audit trail.

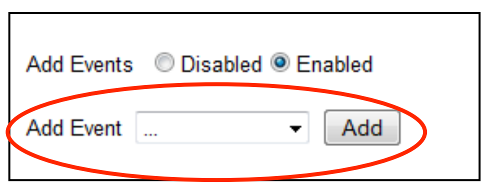
To Enable Add Events

Note: If a user only has Unlock role action permissions, only the Enabled radio button will display.

1. Click the Add Events **Enabled** radio button.



2. The Add Event dropdown is available to use.



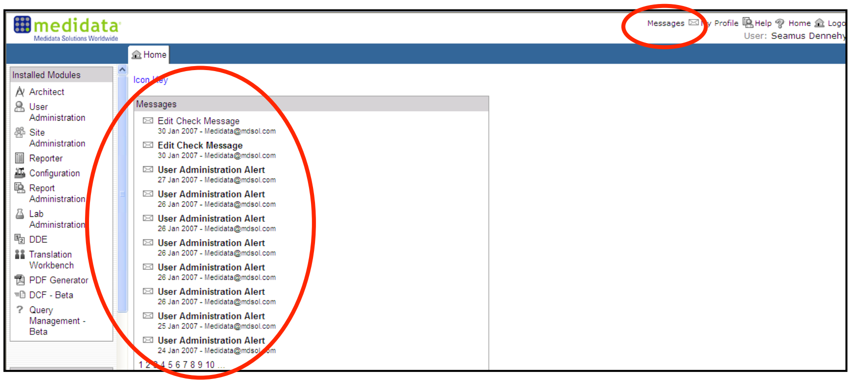
Messages

As a result of some conditions such as queries, protocol deviations, or a user being locked out of the system, an email may be sent out to a specific user or to a set of users. A copy of the message may also be displayed in the Messages section at the bottom of the Rave home page.

The user can also access messages from the Messages link on the upper right of any page in the application.

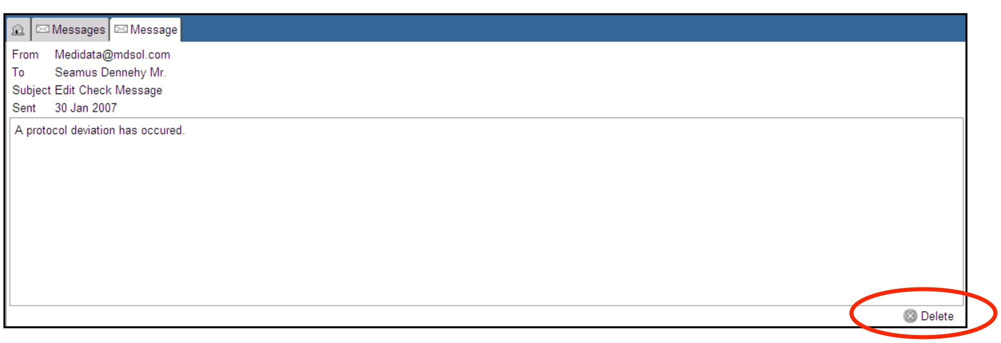
To Access Messages

1. Click on a message:



- In the Message section of the home page, or
- After clicking on the Messages link in the upper right corner of the page.

2. Click on the **Delete** button to delete the message from the list.

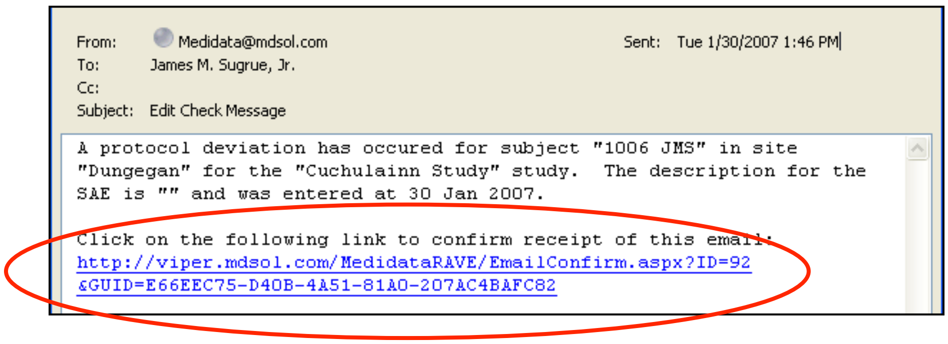


Email Confirmation

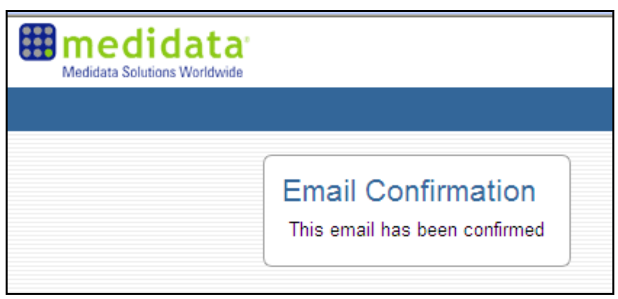
The system can be configured to send email messages and to require a confirmation that the email was read. Any email sent will continue to be re-sent at preconfigured intervals until the receiver gets a confirmation receipt. Confirmation of an email is sent through your email account, not through the Rave system.

To Confirm Receipt of an Email Message:

1. Open the email message.
2. Click on the link at the bottom of the message.



3. The Rave Email Confirmation page appears.



Note: In case the user changed any of the values in the link, an error will be displayed, indicating the email could not be confirmed.

If the user does not click on the confirmation link in the email, the system will continually resend the message.

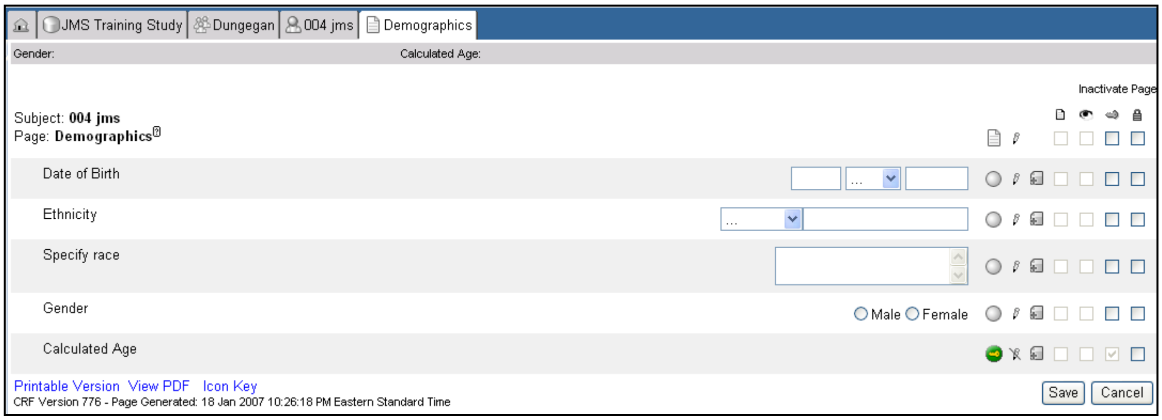
Data Entry & Maintenance Using Forms

This chapter will cover the following topics:

- Form Layout
- Entering Form Data
- Form Submission Confirmation
- Editing Data
- Audit Trail
- Log Forms
- CRF Attachments
- Missing Data Codes
- Accessing Previous Visit Data
- Using Template Forms
- Language Translation
- CRF Coding
- Lab Data Entry
- Lab Maintenance

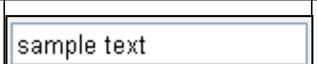
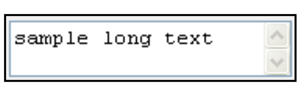
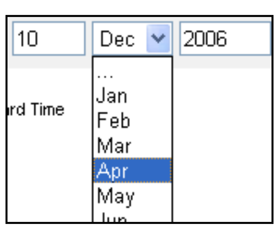
Form Layout

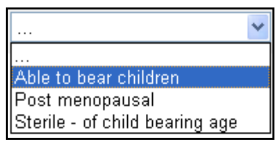
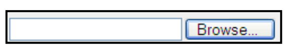
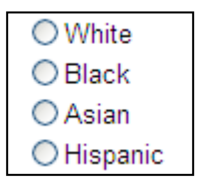
A form is used to enter data into the EDC module. A standard form consists of rows containing questions and data entry fields to answer those questions. The standard form page layout is comprised of form headings or titles, form questions, data entry fields, and additional controls (icons and links). Each area is discussed in detail in the following sections.

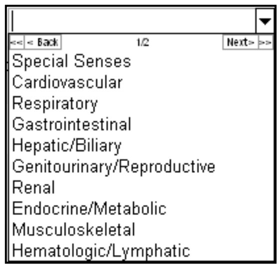


Data Entry Field Control Types

The term "control type" refers to how the data is going to be entered into the system. The data entry fields are displayed on the right side of the form and can include the following control types:

Control Type	Sample	Description
Text		Displays a horizontal text box, long enough to capture the number of characters specified in the variable format. Allows users to input alphanumeric characters.
Long Text		Displays a rectangular text box with a vertical scroll bar to accommodate a larger block of text.
Date Time		Displays text boxes for the user to enter the day, month, and year. The order of the date sections may vary according to the sponsor's specifications.

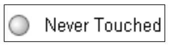
Control Type	Sample	Description
Check Box		Displays a box that the user can flag to indicate a response. For example, "Please check the box to indicate that you have read and agreed to the conditions outlined above," would display a check box for the user response.
Dropdown Menu		Displays a dropdown menu that allows users to select a single option from a list of choices. Selecting the ellipsis "…" is the equivalent of submitting the field without making a selection. If additional information is required about any entries in the list, an extra text box may be displayed to the right of the dropdown menu. This is referred to as a "specify" box.
File Upload		Displays a browse button that allows users to choose an image or file and upload it into an eCRF. Once uploaded, the file can be viewed by clicking on a link displayed on the eCRF.
Radio Button	 	Allows users to view all options from a list and select only one. Radio buttons may appear horizontally or vertically. An option is selected by clicking the radio button to the left of that option. Once an option is selected, it may be de-selected by clicking the radio button again. If additional information is required about any entries in the list, an extra text box may be displayed below the radio buttons. This is referred to as a "specify" box.
Signature		A specially formatted text box that accepts only an investigator's password.

Control Type	Sample	Description
Pick List		Displays a "smart" text field that enables users to search in their data dictionaries. For example, if the user is looking for the term "zygote," the user can type the letter z into the text box and items that start with (or contain) the letter *z* are displayed. With each additional letter the user enters, the list is narrowed down. When a user has entered enough data in a pick list field that only one value remains, that value will be auto-highlighted, allowing the user to auto-select the field by hitting the "tab" key. The search list also allows for pagination. Up to 10 values may be displayed at one time. If a search list contains more than 10 values, the list displays "Next" and "Back" navigation tools allowing the user to scroll through the pages. Double arrows navigate to the beginning or end of the list, while single arrows navigate to the next or previous page in the list. "X/Y" is displayed at the top-center of the list, where Y is the total number of pages and X is the current page. A dropdown arrow is displayed on the right side of the search list. When clicked, the first 10 entries in the list are displayed along with navigation tools to access the rest of the entries. If additional information is required about any entries in the list, an extra text box may be displayed to the right of the pick list. The text box will remain grayed out (unavailable for entry) until a selection requiring additional information is made. This is referred to as a "specify" box.

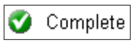
Note: Depending on a user's permissions, certain fields may be hidden from view.

Data Entry Icons

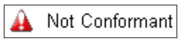
Most users may see the following icons on forms:



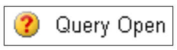
- Data has not been entered/submitted.



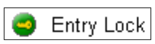
- Data has been entered/submitted.



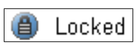
- Invalid data. Data will also be highlighted when it is not conformant.



- A query is open on the data.



- Prohibits any changes to the data.



- Prevents any changes to the data, including markings, sticky notes, and so on.

> **Note**: The display of icons or additional controls depends upon user role permissions. Refer to the Appendix of this manual for a complete listing of icons used throughout Rave. Icon definitions can also be found by clicking the **Icon Key** link on any page within the EDC module.

Entering Form Data

Once a subject is created and the primary form is complete, data can be entered for the new subject.

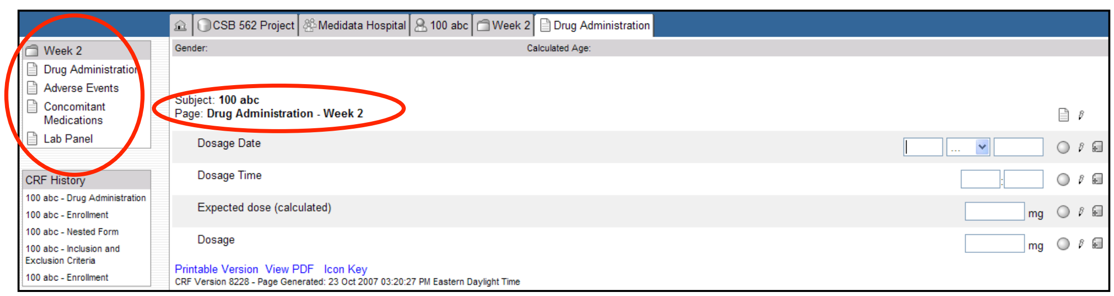
To Enter Data into an eCRF:

1. From the Subject home page, access a form by clicking on the desired folder (for example, Baseline) in the matrix (located in the sidebar).

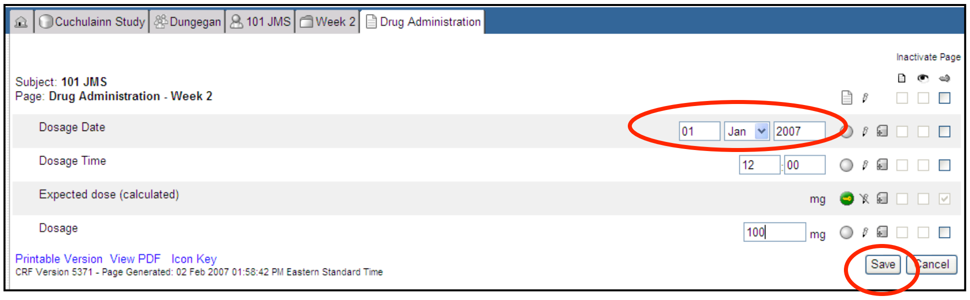
2. When the folder is selected, the first form within the folder opens in the main area with the data fields accessible for data entry.

   The subject name and current page name (including folder) are displayed as form headings above the first data collection question in the upper left of the main area.

> **Note**: To open a form other than the first form within a folder, click on the form name in the sidebar. The selected form is displayed in the main area of the screen.



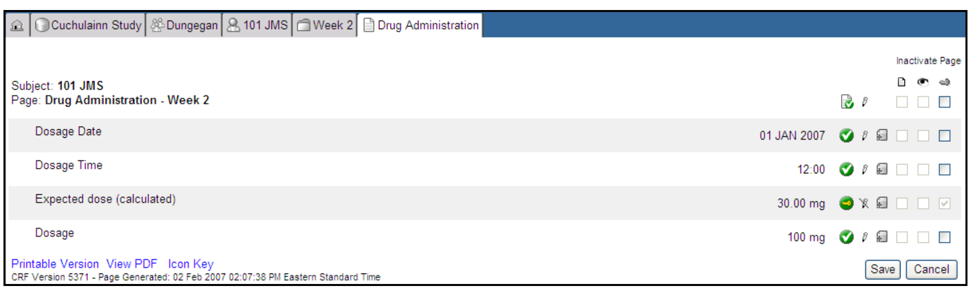
3. Enter all required data in the data entry fields using the keyboard to type data and the mouse to access dropdown menus, radio buttons, and check boxes. Move from field to field using the mouse.



4. Click **Save**.

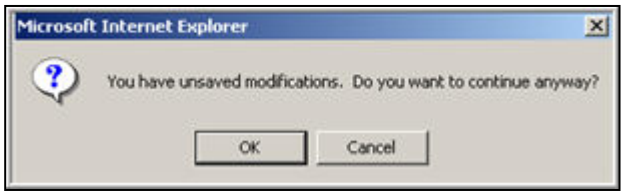
   Upon saving, the page reloads and provides immediate feedback about the validity of the data entered.

Note: The icons will remain "Never Touched" in a form until data is entered, saved, and accepted. At that point, icons appear next to the data fields to reflect their statuses. See the Icon Key located in the Appendix of this training manual for icon definitions.



Note: If you fail to save your changes, the system alerts you about navigating away from the page without submitting changes.

Upon submitting, if configured to do so, a submission confirmation message will be displayed at the top of the main area, letting the user know the form was saved successfully. Refer to the Form Submission Confirmation section of this manual for additional information.



Note: Non-conformant means that the data entered was not in the format that was expected. Take the example of entering a two-digit month: if a user enters 25, that value would be marked as non-conformant, because there is no month numbered 25. If the data entered is non-conformant when submitted, the field is highlighted and a non-conformant icon appears.

To resolve a non-conformant error, re-enter the data in the desired format and click **Save**.

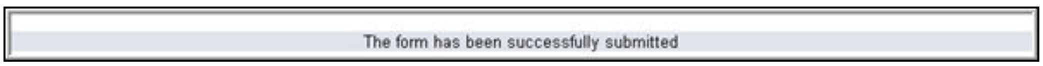
Some forms contain a help icon, which may contain information on the proper format for the data. This can be found next to the field name or form name.

Form Submission Confirmation

When a user submits an eCRF, the system displays a confirmation message, if configured to do so, in the Message area on the form. The submission confirmation message is displayed at the top of the main area of an eCRF.

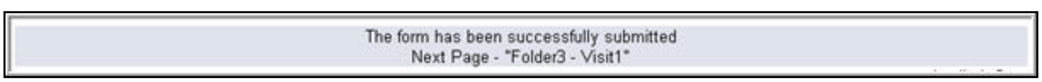
A form redirect function is associated with the confirmation message. The form redirect function lets the system know what form to display along with the confirmation message. Depending on the form redirect associated with a particular draft, the confirmation message may display:

- The submission confirmation message only (redirect is set to <none>).



- The submission confirmation message, along with a link to the next page. The user can navigate to the next form in sequence within the current folder as sequenced in the current matrix. If it is the last form in the folder, the link will not redirect the user to the next folder (redirect is set to <next>).

- The submission confirmation message, along with a link to navigate to a specific folder and form.



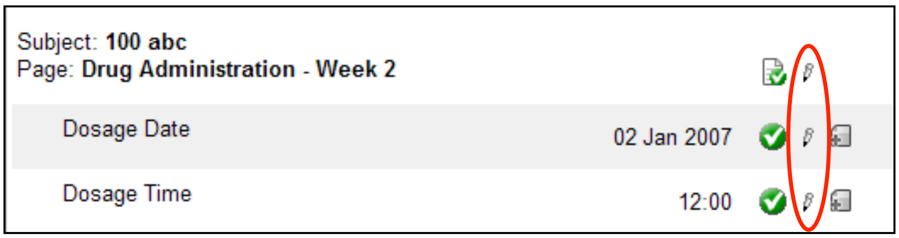
Editing Data

Data that has been submitted complete can be changed or edited.

To Edit Data:

1. Open the completed form to be edited.

2. Click on the **Pencil** icon on the far right of the data field to be edited.



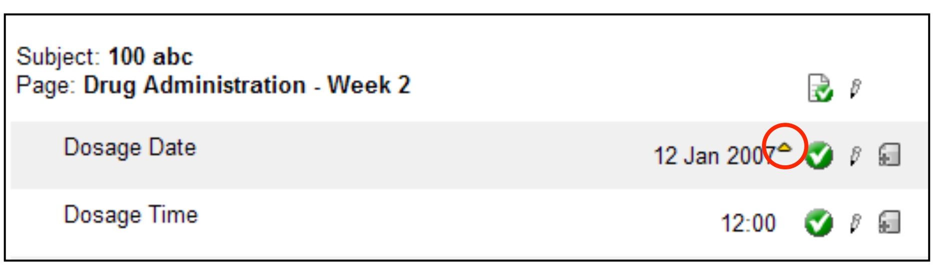
Note: To edit multiple fields in a form at the same time, select the pencil icon at the top right of the form.

3. The Form Page reloads with the data entry field open on the selected field for editing.

4. Based on study configuration, a dropdown menu containing reasons for changing data (also called "change codes") may appear. If a dropdown menu appears, select the reason for the change. This is required for the edit to be accepted.

5. Click **Save**.

6. When a field is changed after initial submission, a delta icon appears at



the data point to indicate that a change has been made.

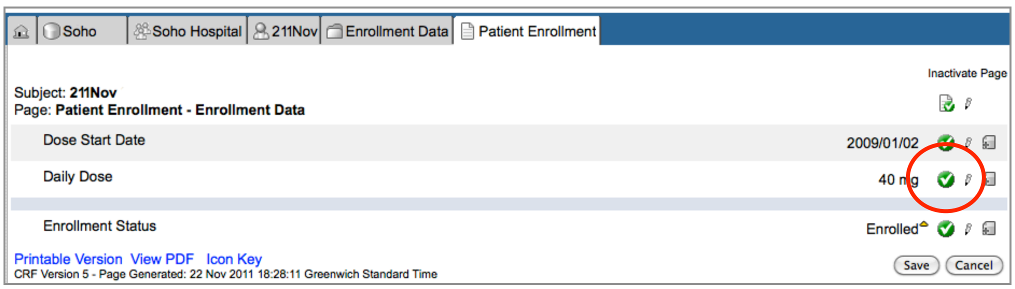
> **Note:** All changes or edits appear in the audit trail. See the Audit Trail section of this training manual for more information.

Audit Trail

All changes made to a field are tracked in an audit trail. Authorized users can view the Audit Trail.

To Access the Audit Trail:

1. Click the **Data Status** icon, located directly next to the data field. The Audit Trail is displayed when the data status icon is clicked.

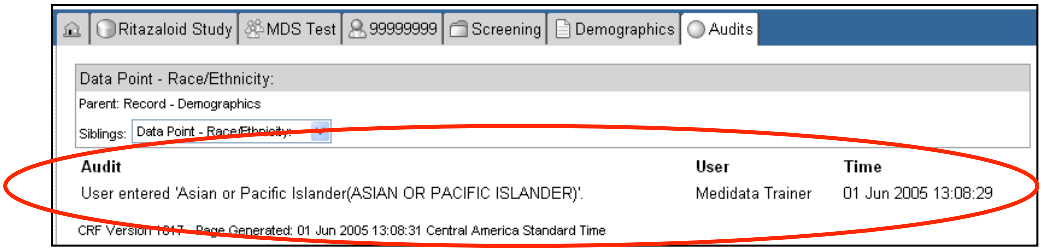


> **Note**: The Data Status displayed in the screenshot is used only as an example; it can be any of those listed in the Appendix of this manual.

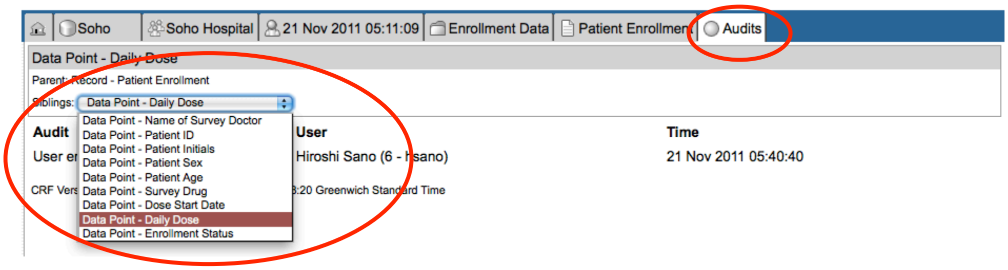
> **Note**: A user must have permission to view the Audit Trail through the Configuration module.

The Audit Trail details include the following:

- ❑ The action that was performed on the data point.
- ❑ The username (system ID - login name) that performed the action.
- ❑ The time and date of the action specified in the user's time zone.



The user viewing the Audit Trail will see the time reflected in their specified time zone. Time zone specification is done in the My Profile section of the Rave application.



> **Note**: The Audit Trail Report within Rave is always stored in Greenwich Standard Time, regardless of the user's time zone.

Other options in the Audit Trail include:

- **Audit Navigation Tab** – Indicates that you are viewing an audit trail. To return to the form the data point is on, click the form name tab.
- **Parent Record link** – Navigate quickly to the Audit Trail of the parent of the current data point. For example, the data point Ethnicity has a parent of Demographics (the form that the Ethnicity data point resides on). The Demographics form has a parent of Screening (the folder in which the Demographics form resides), and so on.
- **Sibling Dropdown** – Navigate quickly to the Audit Trail for other data points on the same form by selecting the desired data point from the sibling dropdown menu.

Log Forms

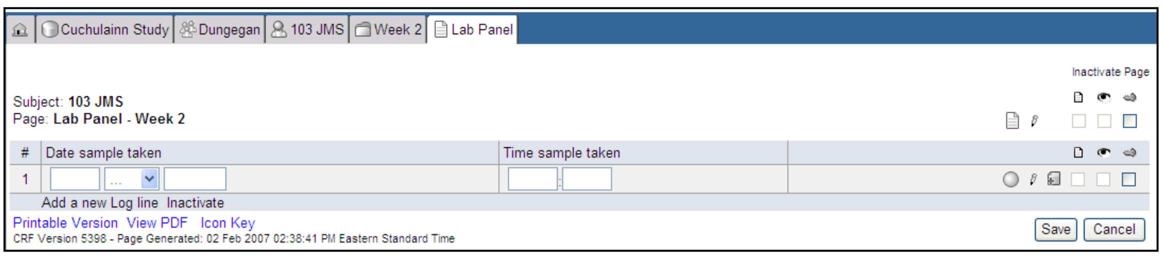
When multiple instances of the same form are needed (for example, concomitant medications or adverse events), a log form is used. The log form is used to add additional records or entries, as needed, to one form. Each entry on a log form is referred to as a log line.

> **Note**: A form can contain a non-log field and log field simultaneously, or log lines can be contained in their own form.

Log forms can appear either in portrait or landscape mode.

Landscape Mode Log Form

In landscape mode log forms, each log line is displayed in a single, horizontal row. Each row contains the details of each log line. The bottom portion of the form allows for the addition or inactivation of log lines.



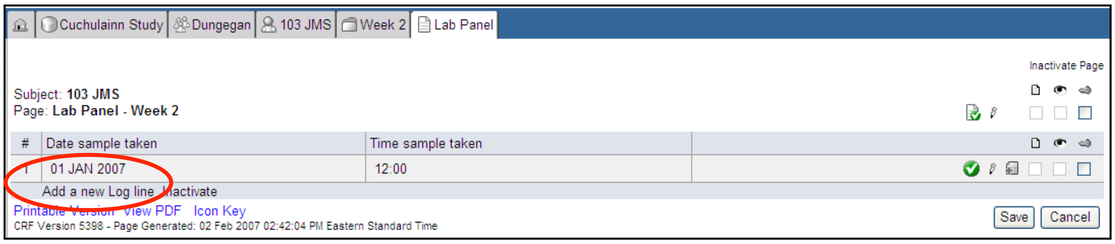
> **Note**: Adding, inactivating and reactivating log lines are disabled during the eSignature process. Refer to the "Electronic Signatures in Batch" section in this manual for more information.

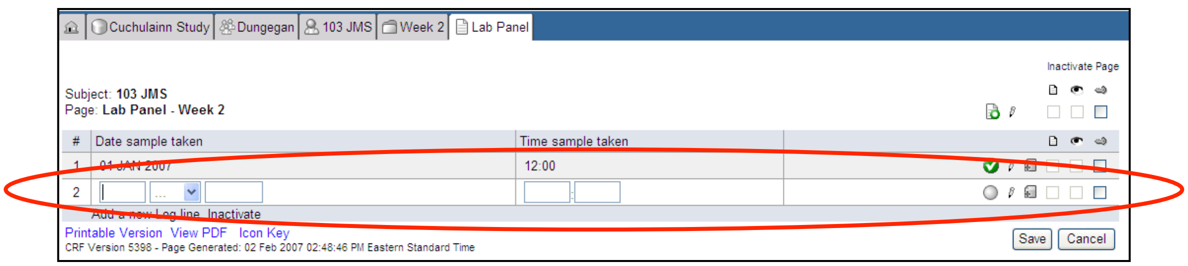
To Enter Data into a Landscape Mode Log Form:

1. Enter data as described in the Entering Form Data section.

> **Note**: Scroll the screen horizontally if necessary to view all the fields on a landscape mode log form.

2. Click the **Add a new log line** link to enter additional log lines into the form as needed.



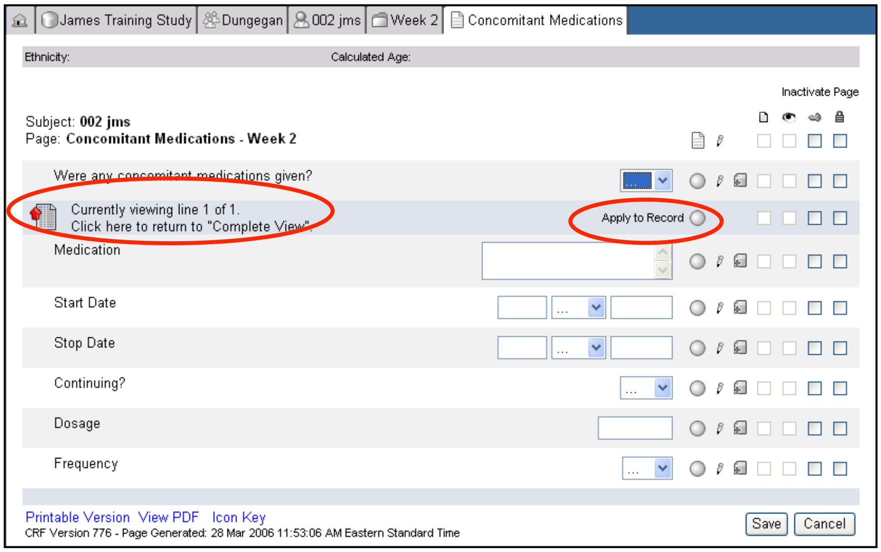


3. A new log line opens for data entry.

4. Repeat as needed.

Portrait Mode Log Form

In portrait mode log forms, data is entered for each log line on a standard vertical form.

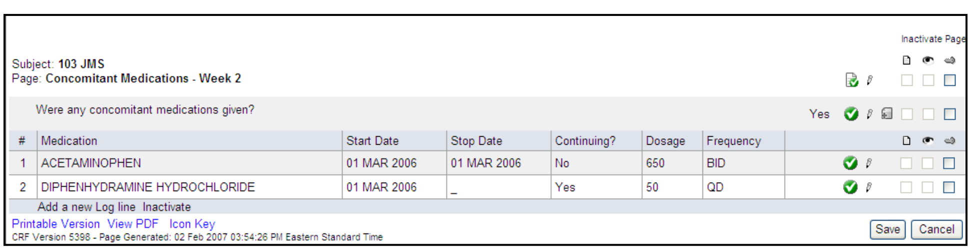


When the complete log is viewed, displaying all log lines, the layout is converted to horizontal and appears in the same manner as the landscape mode log form.

To Enter Data in a Portrait Mode Log Form:

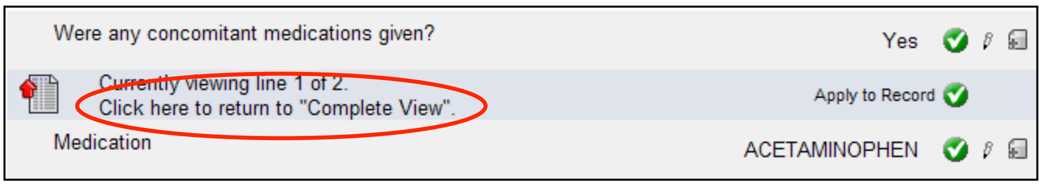
1. Enter data as described in the Entering Form Data section of this manual. When you click **Save**, the Complete View (horizontal) displays.

Note: If the Complete View is displayed and you need to enter data, click the **Add a new log line** link (located at the bottom of the log) to display the portrait data entry view.



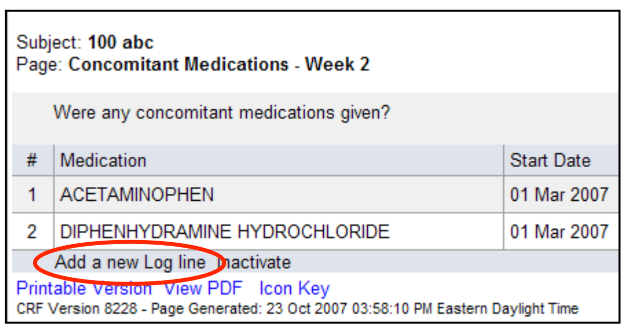
2. To view or edit a log line, click on any data value (links) to display the portrait data entry view.

3. To return to the complete view at any time, click the **Click here to return to "Complete View"** link.

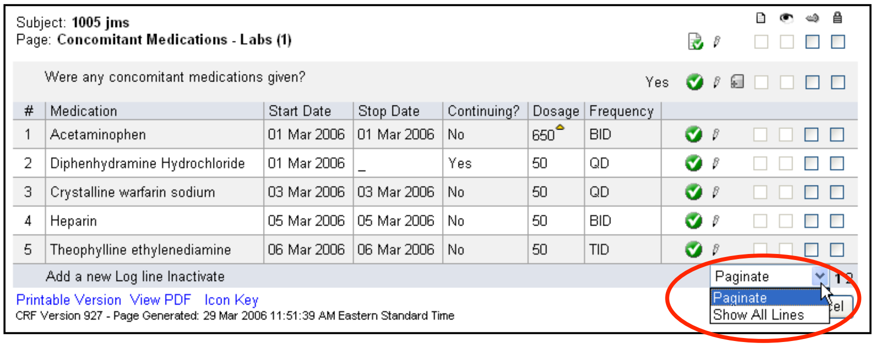


4. To enter additional log lines in the form, click the **Add a new Log line** link in the Complete View. A new, empty log form is displayed for data entry.

5. Repeat as needed.

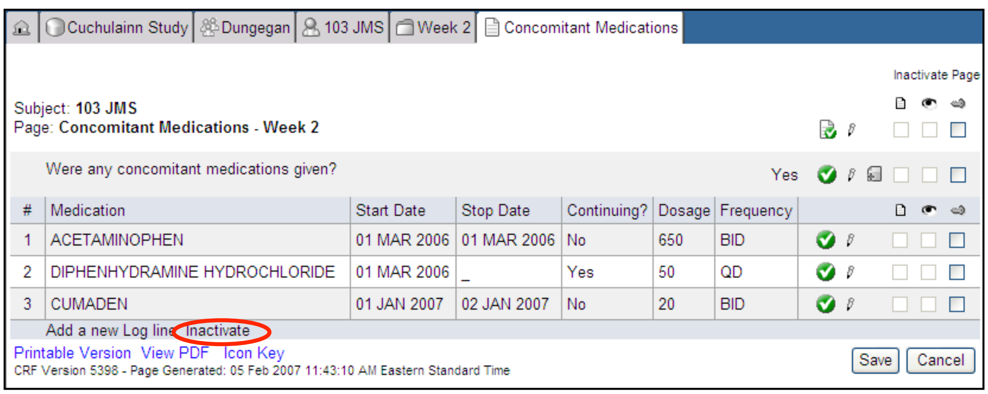


Note: If the number of lines exceeds the user's lines per page setting in My Profile, a pagination tool appears. The user has a choice of using the tool to navigate to each page of log lines or choosing the option in the dropdown menu to show all the log lines at once.



Inactivating Log Lines

After a log line is successfully saved, it can be inactivated. This may be done if a line is entered in error for a subject, among other reasons.

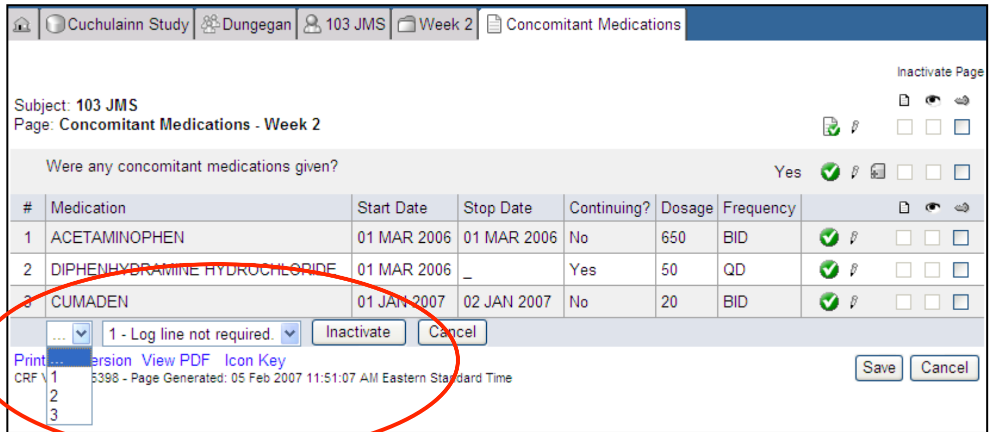


Note: Log lines cannot be deleted, they can only be inactivated.

To Inactivate an Existing Line:

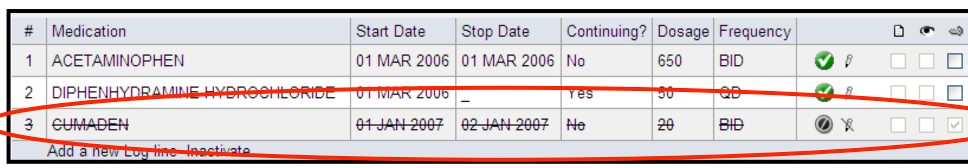
1. From the Complete View, click the **Inactivate** link.
2. The page reloads with a dropdown menu with the line numbers of existing log lines within the form, and, if configured to do so, a dropdown menu containing the possible reasons for inactivation.

3. From the dropdown lists, select the line to inactivate and (if available) the reason for the inactivation.



4. Click the **Inactivate** button.

5. Upon successful inactivation, the page reloads with a strike-through line through the inactivated log line. This line is now locked and can no longer be edited.

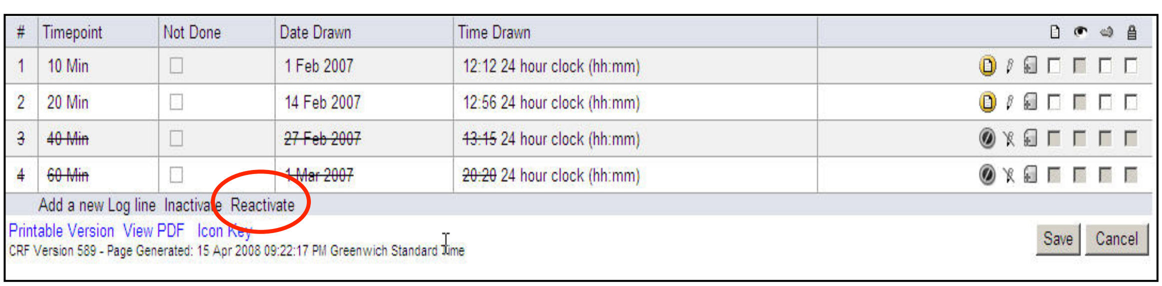


Reactivating a Log Line

If a log line was inactivated in error, it can be reactivated. When a log line is reactivated, it is returned to whatever status it displayed prior to its inactivation, and you can take action on the log line based on your permissions (for example, editing data, querying, and so on).

To Reactivate an Inactivated Line:

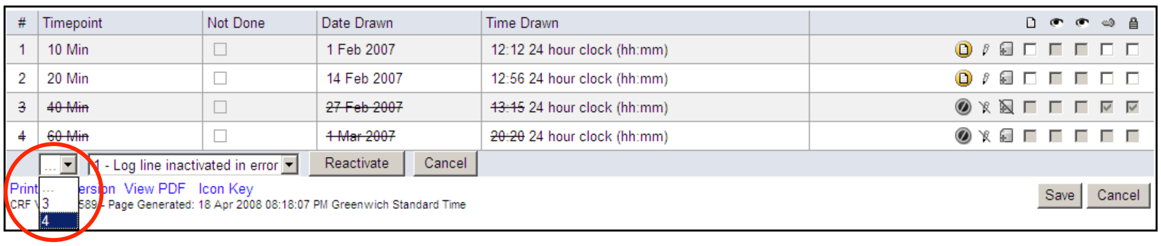
1. From the Complete View, click the **Reactivate** link.



2. The page reloads with a dropdown menu with the inactivated line numbers of existing log lines within the form.

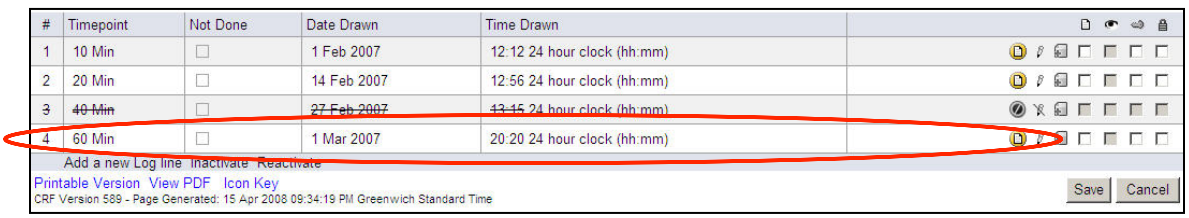
3. From the dropdown menu, select the inactivated line to reactivate and (if available) the reason for the reactivation.

4. Click the **Reactivate** button.



#	Timepoint	Not Done	Date Drawn	Time Drawn
1	10 Min		1 Feb 2007	12:12 24 hour clock (hh:mm)
2	20 Min		14 Feb 2007	12:56 24 hour clock (hh:mm)
3	~~40 Min~~		~~27 Feb 2007~~	~~13:15~~ 24 hour clock (hh:mm)
4	~~60 Min~~		~~1 Mar 2007~~	~~20:20~~ 24 hour clock (hh:mm)

5. Once successfully reactivated, the page will reload with the selected line once again active. The Inactive status icon is replaced with the line's current status.



#	Timepoint	Not Done	Date Drawn	Time Drawn
1	10 Min		1 Feb 2007	12:12 24 hour clock (hh:mm)
2	20 Min		14 Feb 2007	12:56 24 hour clock (hh:mm)
3	~~40 Min~~		~~27 Feb 2007~~	~~13:15 24 hour clock (hh:mm)~~
4	60 Min		1 Mar 2007	20:20 24 hour clock (hh:mm)

CRF Attachments

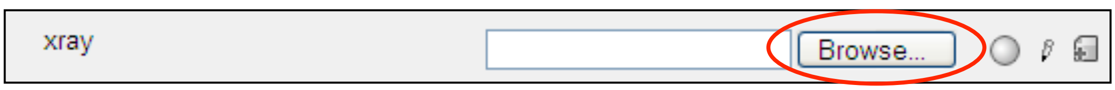
Users can upload a file or image, such as an x-ray image, into Rave and associate it with a field in an eCRF for a specific subject. The user can then click on a link in the eCRF to view the image. Only fields that have been configured for attachments will show the browse button.

Uploading a File

Files can be uploaded based on the settings defined by the sponsor. CRF attachment fields can be designed to accept file sizes between 1KB and 100MB. The sponsor will specify the maximum file size for CRF attachment fields in your Rave website. If you attempt to upload a file that falls outside the acceptable file size range, the field will be set to non-conformant and the file will not be uploaded.

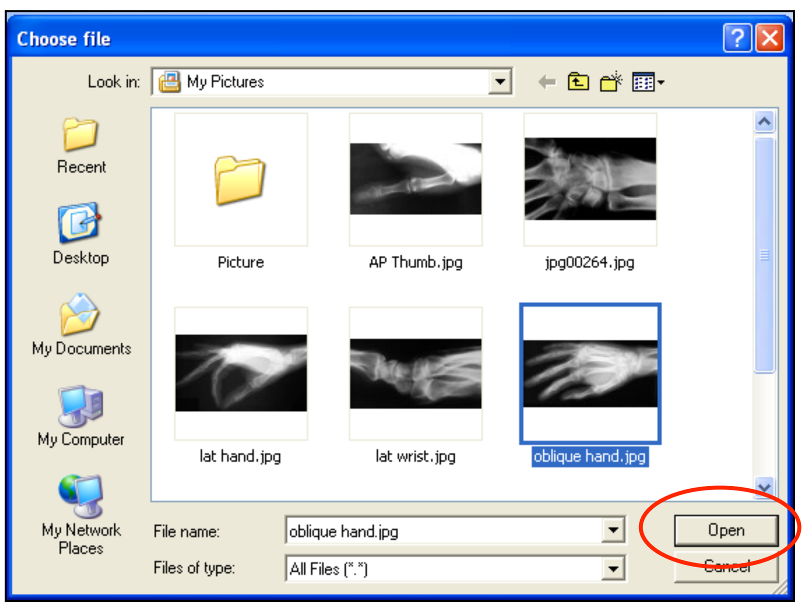
To Upload a File:

1. Click the **Browse** button.

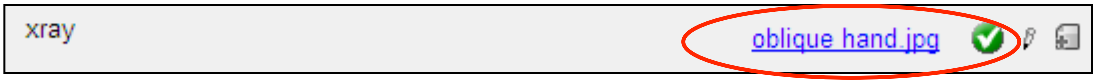


2. Select a file from the Choose file browser window.

3. Click **Open**.



4. Complete the rest of the form and click the Save button. A link to the uploaded file is displayed on the page. The filename is displayed as the



link text.

Viewing an Uploaded File

Once a file has been uploaded, it can be viewed as long as the user has the appropriate software application. For example, to view an image, the user must have Microsoft Office Picture Manager or a similar image program. If a Microsoft Excel document was uploaded, to view the file, the computer must have Microsoft Excel.

To View an Uploaded File

1. Once a file has been uploaded, it can be viewed or downloaded by clicking the file name link on the eCRF.

2. The File Download window opens. Click **Open** or **Save**.

3. Close the window to return to the eCRF.

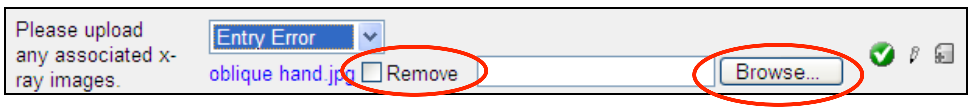
Removing or Replacing an Uploaded File

A file that was previously uploaded can be removed at any time.

To Remove/Replace an Uploaded File:

1. Click the **pencil** icon.
2. Remove or replace the file as needed:

   ➪ To replace the uploaded file with a different file, click the **Browse** button to select another image.

   ➪ To remove the uploaded file, check the **Remove** check box.

3. Click **Save**.

Missing Data Codes

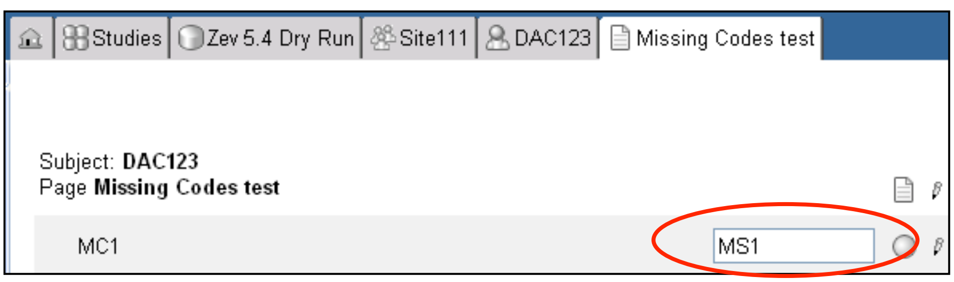
Although fields may be required, occasionally the data for those fields may be unavailable. When this occurs, a user can apply missing codes to fields that are lacking required data. The missing code replaces the actual data value to indicate that the field was left empty on purpose. If missing codes are to be used, the sponsor will let their sites know which missing codes are acceptable for their study.

When a valid missing code is submitted for a field on an eCRF:

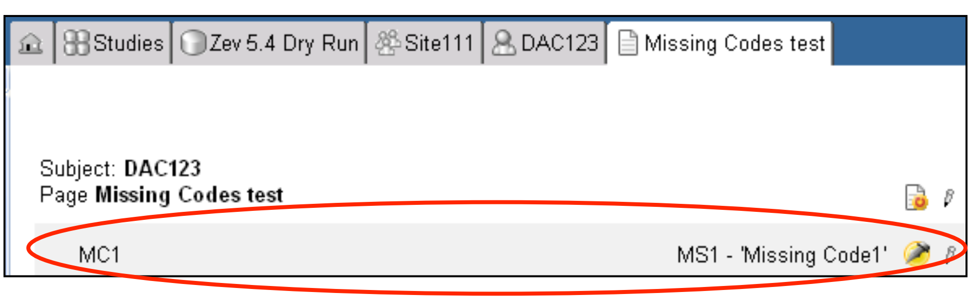
- The system accepts the data and saves the form.
- The empty field is considered not-empty even though real data has not been entered.
- The audit trail for the field displays "User entered missing code <code>, <description>." When the original data in the field is updated to a missing code, the audit trail will also display "reason for change <reason>."
- A missing code description displays for the field on the eCRF.

To Enter a Missing Code:

1. Navigate to a form that contains fields with missing code capability.
2. Enter a valid missing code into the field(s) that requires data where no data is available.

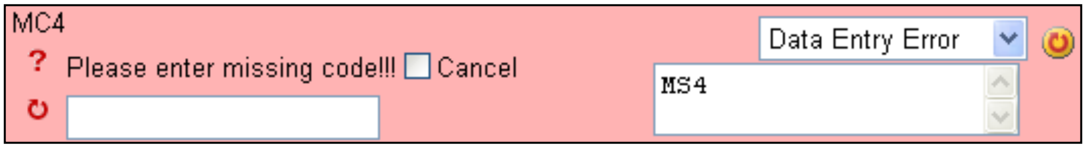


3. Click Save.



Upon successfully saving the form, the field is displayed with the missing code.

> **Note:** Missing codes can only be applied to text fields. The code can be entered into the text input. Missing codes entered in a Query response box will be recorded in the audit trail as a response, not a missing code. Refer to the Queries section of this manual for additional information.



Accessing Previous Visit Data

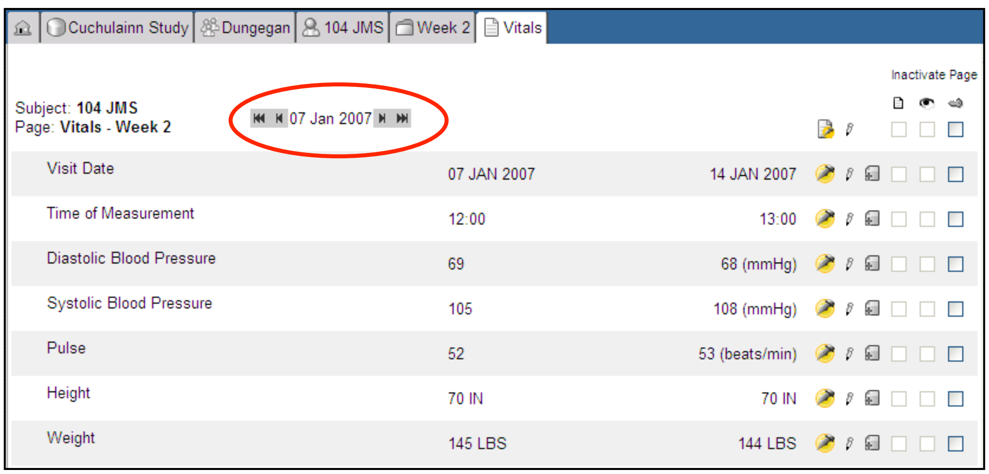
Forms can be configured to provide the user with quick access to data collected in a previous visit.

When the form is initially displayed, the current data is displayed next to the data status icon. If the form has previous visit functionality, a link to the previous visit is displayed at the top-center of the main area in the date navigation tool.

The previous visit data for each field on the form displays on the same row as the corresponding current visit data. The previous visit data is non-editable on the current form. A user can only edit data on the form for the current visit.

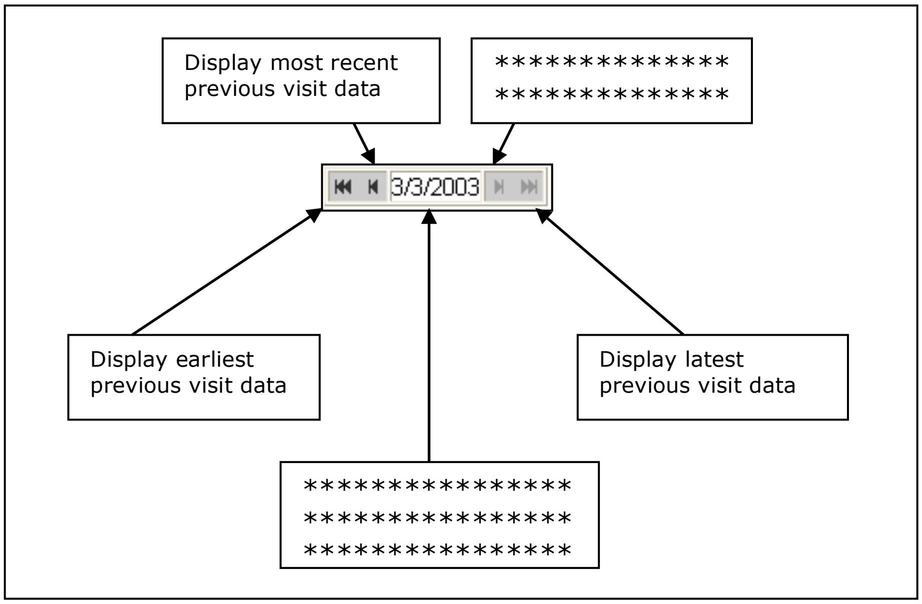
Previous visit forms are identified by the record date and time that displays on top of the data on the form. The system retrieves other active forms for the patients—that have the same form name—where the form date is prior to the current date. The forms are displayed in reverse chronological order by record date and time on the CRF form.

The screenshot below shows the previous visit date in the first column with a visit date of 07 JAN 2007. The current data is in the second column with a visit date of 14 JAN 2007.



To Display Previous Visit Data from the Current Form:

1. In the date navigation tool at the top of the main area, click on the right or left navigation arrows to display the visit data from the next or previous form.



2. The date listed in the Previous Date navigation tool is the date of the previous visit data displayed in the current form. The previous visit data is displayed in the same row as the current visit data.

3. Click the arrows in the Previous Date navigation tool to display older or newer previous visit data.

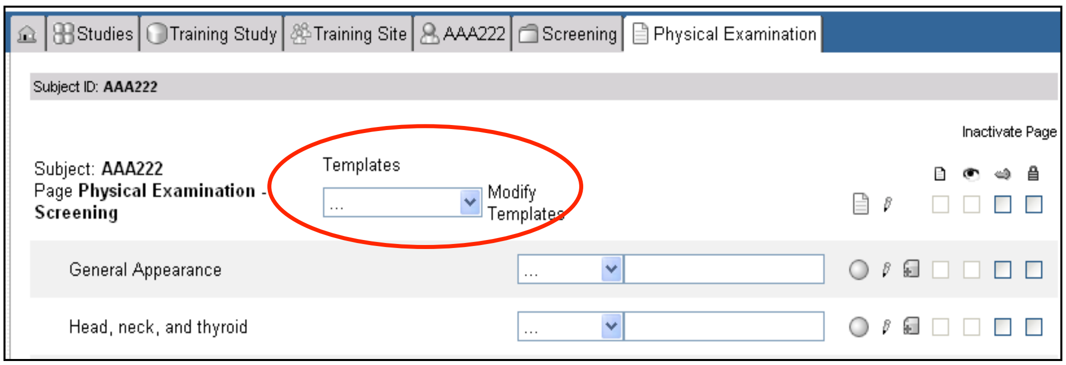
4. Click the date displayed in the Previous Date navigation tool and the form associated with that visit date will be displayed.

> **Note**: If you are already on the first form, the leftmost (|<) and the left (<) arrows are disabled. Similarly, if you are on the last previous form, then the rightmost (>|) and the right (>) arrows are disabled.

Using Template Forms

Forms can be configured as template forms. If a form is a template form, a template dropdown menu is displayed at the top of the form. The dropdown menu contains, in alphabetical order, all of the available templates for a form.

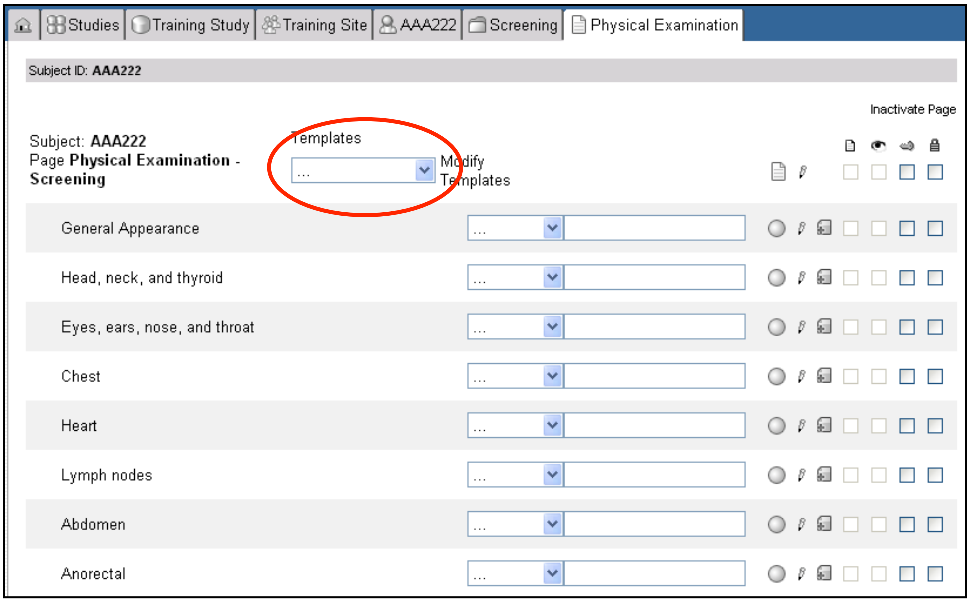
For a form that does not have templates defined or is not a template form, the CRF includes all fields that have been flagged as visible. Template forms may display only certain visible fields, but when various templates are applied to the form, additional fields may be displayed.



If a user has the necessary permissions, and a form is a template form, that user can select and apply a template from the dropdown menu of templates. Once applied, only the fields specified as visible for that specific template are displayed on the form; certain fields may be displayed, and others may be hidden. Data can be entered as usual.

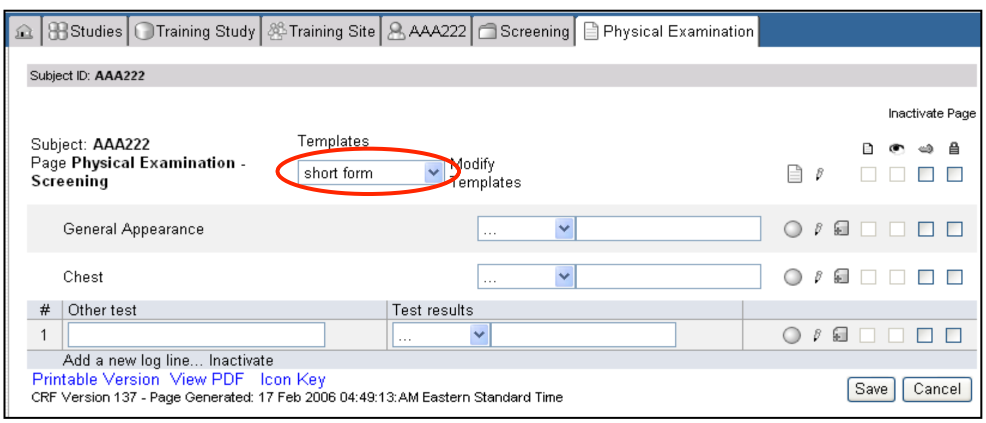
> **Note:** Templates can be applied, added, edited, or deleted based upon users' permissions. Users may have the ability to use templates, but not to create templates, and vice versa.
>
> If a template form is designated the Primary Form for the study, the template controls are not displayed.

To Apply a Template to a Template Form:



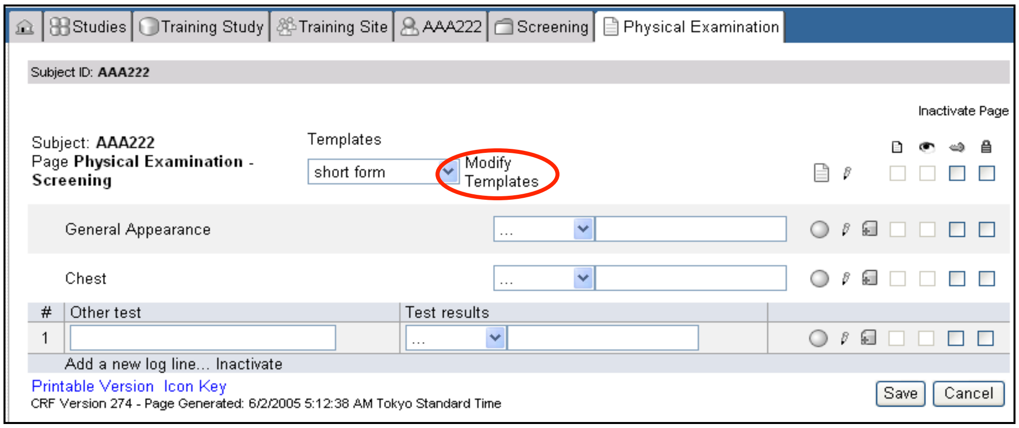
1. Select a subject and access a template form.
2. Select the desired template from the Template dropdown menu.

> **Note:** When a template is selected from the dropdown list, an entry indicating the selection is written into the audit trail.



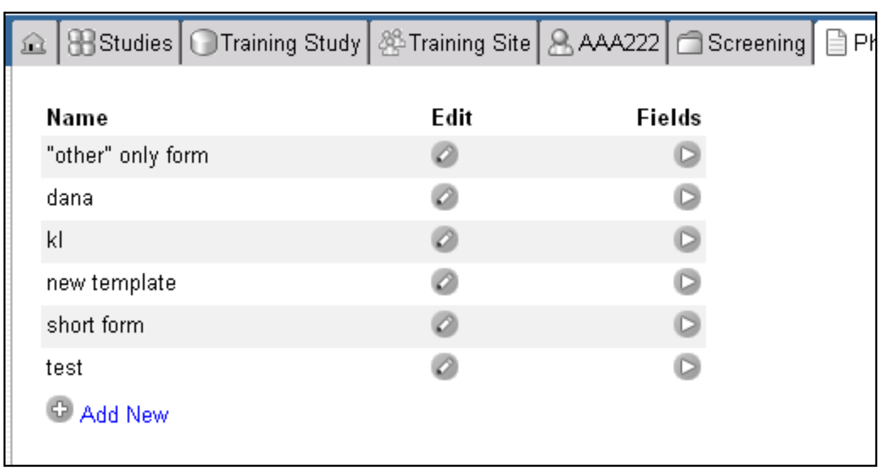
To Add a New Template Form:

1. Select a template form.
2. Click the **Modify Templates** link displayed in the top of the main area:



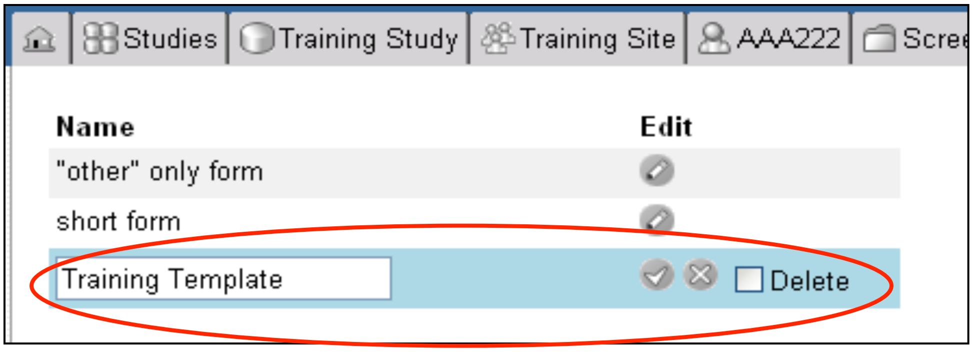
Note: If no templates have been created for the current template form, the **Modify Templates** link is displayed but the dropdown menu is hidden. The dropdown menu is displayed only when templates are created for the current form.

3. The Edit Template page opens, listing the templates that are created for the current form (if any).



4. Click the **Add New** link to create a new template.

5. Enter a template name in the template name text box. "New Template" is displayed by default.



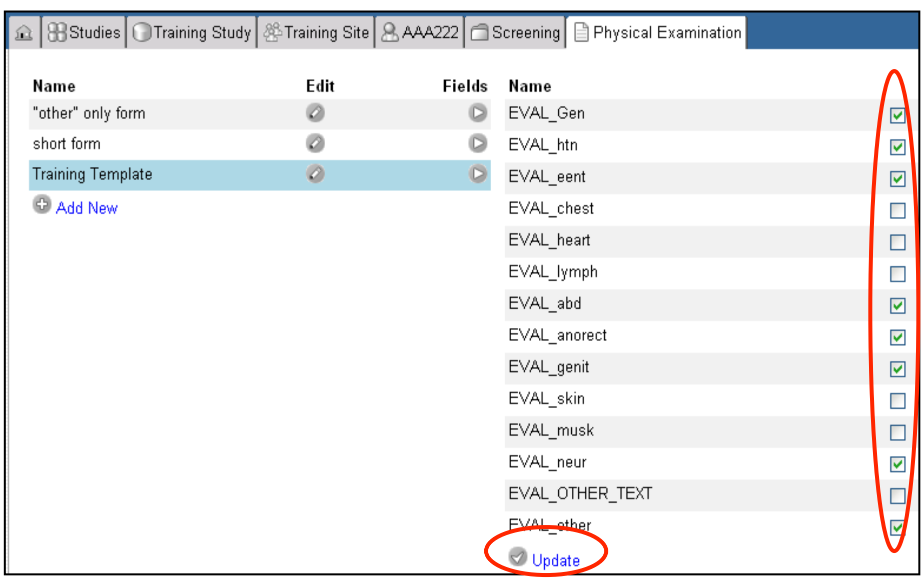
6. Click the **check mark** icon to save the new template.

7. Once saved, specify the fields to be displayed in the template form by clicking the **detail arrow** icon to the right of the template name.

Note: To edit the template name, click the **pencil**  icon.

8. In the page that opens, specify the fields to be displayed in the template by checking the box next to each field to be displayed. The fields with unchecked boxes will not be displayed in the template.

9. Click the **Update** link or **check mark** icon to save the template. The system makes the new template available in the template dropdown menu on the CRF main page.



To Edit an Existing Template:

1. Click the **Modify Templates** link displayed in the top of the main area.

2. The Modify Templates page opens, listing the templates that are created for the current form.

3. Select the template to be modified by clicking the detail arrow to the right of the template name.

4. In the page that opens, the fields displayed in the template can be modified by checking or unchecking the box next to each field name. Only fields with checked boxes will be displayed in the template.

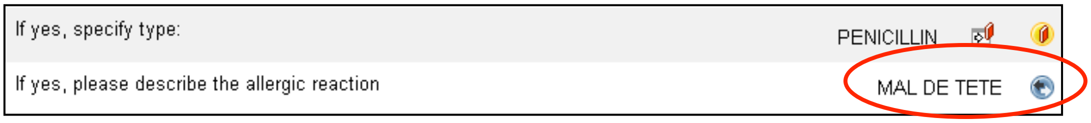
5. Click the **Update** link or **check mark** icon to save changes.

Note: The ability to Modify Templates is disabled during the eSignature process. Refer to the "Electronic Signatures in Batch" section in this manual for more information.

Language Translation

Users with Translate role action can perform translation tasks for fields on the CRF form that are flagged as Requires Translation fields. Users with See Translations role action can see translations.

When text requires translation, it is displayed with the Requires Translation icon, as seen below.



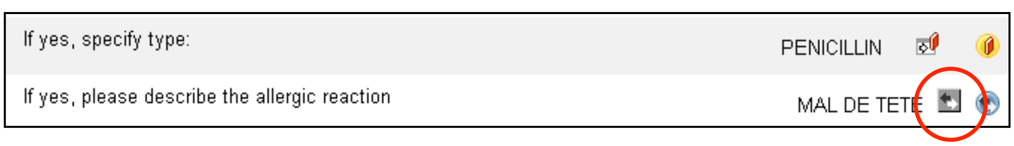
Note: In order to use the translation functionality, the initial data entry must be entered in a language other than the standard language of the study. The person doing the translating must be in the standard language of the study.

The system displays all forms requiring Translation on the Study Page Status Summary. A user may navigate to the form for the subject directly from the Task list.

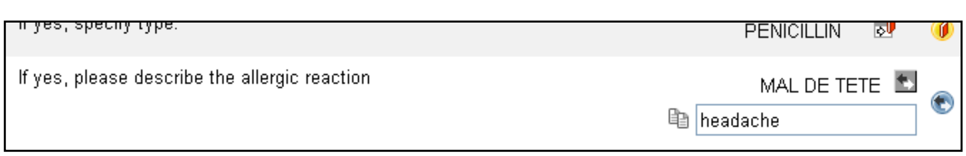
To Translate a Field on the CRF Form into Another Language:

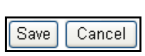
1. Navigate to a form that has been previously submitted. Any field on the form that requires translation is indicated by a Requires Translation status icon.

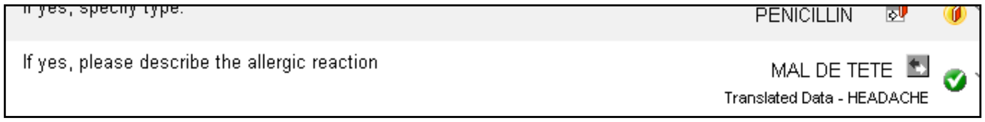
2. Click the **Translate** icon to display a text box below the field that requires translating.



3. Type the translation into the available field or click the **Copy** icon to copy the original text verbatim into the translated field text box.



4. Click **Save.** 



Note: Translations can use symbols and special characters.

CRF Coding

For regulatory purposes, medical terminology used in pharmaceutical and medical product development must adhere to standardized dictionaries.

> **Note**: If your study uses Medidata Coder, please skip to the CRF Coding with Medidata Coder section in this manual.

The CRF Coding feature in Rave EDC is a simple medical dictionary browser within the EDC module. This dictionary enables the EDC user to:

- ❑ Search for medical terms.
- ❑ Search through hierarchical terms.
- ❑ Code at the point of data entry.
- ❑ Automatically find a match for the verbatim terms in the thesaurus to be associated with medical terms within standardized dictionaries.

The CRF Coding function is available only to users with the necessary permissions. Users with this permission can manually code, recode, or modify verbatim terms entered on an eCRF and view them as displayed beneath the verbatim term on the eCRF.

Fields on the eCRF that require coding are displayed with a Requires Coding status icon.

> **Note**: If a user has access to edit coded terms or to manually code terms, the coding icon is also displayed.
>
> **Note**: A field cannot be coded if it has already been hard locked.

Users have flexibility in the CRF Coding process to use auto-coding, user coding, or both, while adhering to regulatory standards.

In auto-coding, the system automatically finds an exact match for the verbatim term in the dictionary upon form submission.

In user-coding, the user has the option to manually enter a term using specified dictionaries and versions of dictionaries.

The ability to view coded results is available only to users with the necessary permissions. The system displays the coded term and all associated information beneath the verbatim term on the eCRF.

> **Note**: Loading standard dictionaries and maintaining them is not part of the CRF coding functionality.

CRF Auto-Coding

Users in the CRF Coding process have the flexibility to use auto-coding, user coding, or both, while adhering to regulatory standards.

In Auto-coding, the system automatically attempts to find a match for the verbatim term in the loaded dictionary when a user submits a CRF that has terms that require coding. Once a match is found, the Requires Coding icon is replaced with the next logical status icon based on the user's permissions.

The coding dictionary includes five levels of hierarchy. If the automatically coded term is not the desired term, users can select a preferred term and recode all levels.

> **Note**: The system captures the coded information—the coded term, coding dictionary, version, and level—in the Audit Trail.

To Auto-code CRF Terms:

1. Navigate to a form that contains fields that require coding. Fields on the eCRF that require coding display with a Requires Coding status icon. If the user has permission to code terms, a Dictionary Coding icon is also displayed. Enter patient data into the text fields. Refer to the Entering Form Data section of this manual for additional information.

2. Click **Save**.

3. Upon a successful save, the system attempts to find a match for the verbatim term in the loaded CRF dictionary. If a match is found, the match and associated dictionary information are displayed underneath the verbatim text entered by the user. If the user has permission to edit coded terms, the Dictionary Coding icon is displayed next to the dictionary term.

> **Note**: If the system is unable to find a match, the workflow status remains Requires Coding.

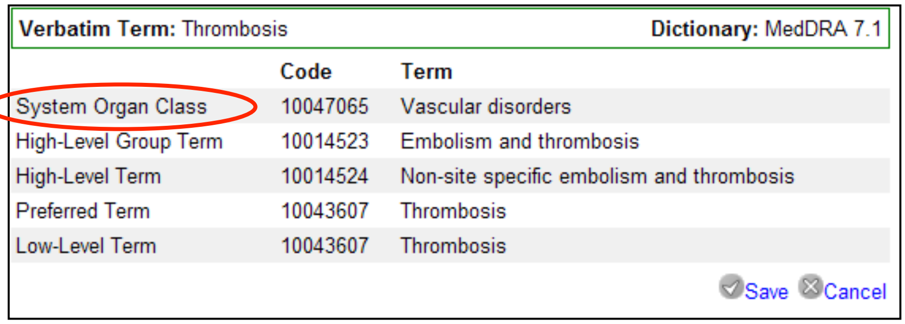
To Edit the Coding Term and Code:

1. Navigate to a form that contains a field that has coding to be edited.

2. Click the **Dictionary Coding** icon.

3. The Dictionary Coding Window displays as a pop-up window.

4. Click the **condition level** link (for the MedDRA dictionary) or the **WHO Drug Name** link (for the WHO Drug dictionary) that needs to be



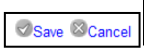
Verbatim Term: Thrombosis		Dictionary: MedDRA 7.1
	Code	**Term**
System Organ Class	10047065	Vascular disorders
High-Level Group Term	10014523	Embolism and thrombosis
High-Level Term	10014524	Non-site specific embolism and thrombosis
Preferred Term	10043607	Thrombosis
Low-Level Term	10043607	Thrombosis

edited and make the necessary changes.

5. Click **Save**.

CRF User Coding

In user-coding, the user has the option to manually enter a term using specified dictionaries and versions of dictionaries. Users must have the necessary permissions in order to manually code terms. Manual coding is performed when the system is unable to match a verbatim term entered by the user. Users can also use manual coding to override auto-coded terms.

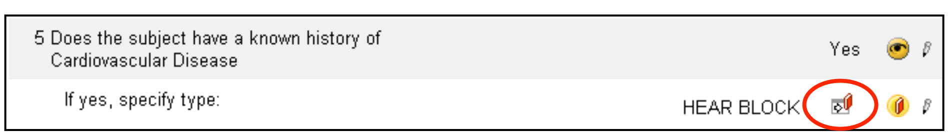


Note: Depending on the coding dictionary being used, the number of coding levels may vary.

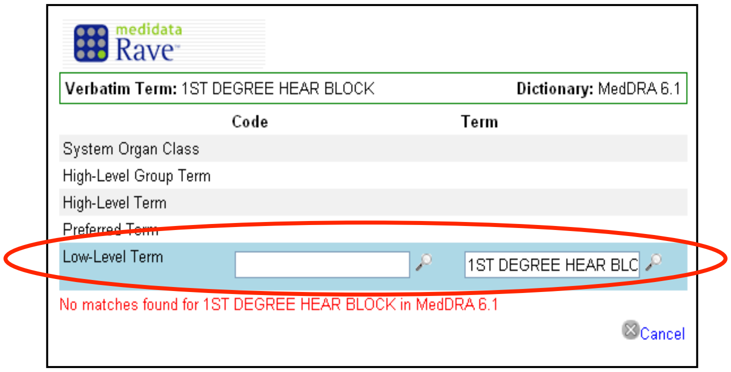
To Manually Code a Verbatim Term:

1. Navigate to a form that contains fields that require coding or to a field that has coding to be edited. Fields on the eCRF that require coding display with a Requires Coding status icon together with a Dictionary Coding icon.

2. Enter patient data into the text fields. Refer to the Entering Form Data section of this manual for additional information. Upon successfully saving the form, click the **Dictionary Coding** icon.



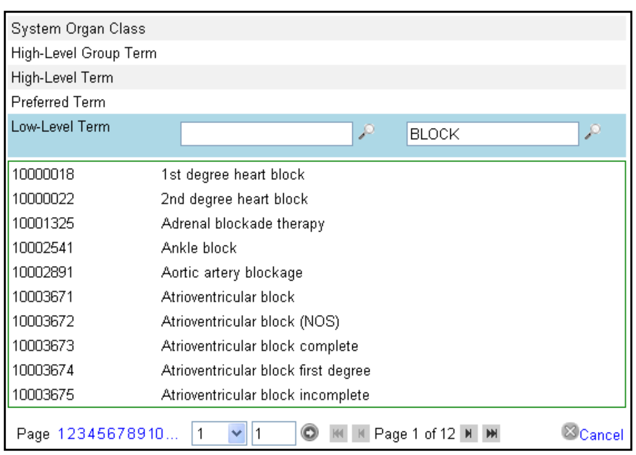
3. The Dictionary Coding window displays as a pop-up window. Terms can be coded by term name or code number. The Term field defaults to the text entered on the form by the end user.



4. Accept the verbatim term that requires coding by clicking the **magnifying glass** search icon to the right of the term or enter a new term in the Term text box. To search for the entry by way of code number rather than a term, enter a code number for the dictionary term in the Code number text box.

5. Click the **magnifying glass** search icon next to the code or term to perform the search.

6. The system returns all matched terms in the results box. If the matched terms appear on more than one page, the results box displays paginated. Use the pagination dropdown or the navigation icons to move across pages. Locate the desired term and double-click to select.

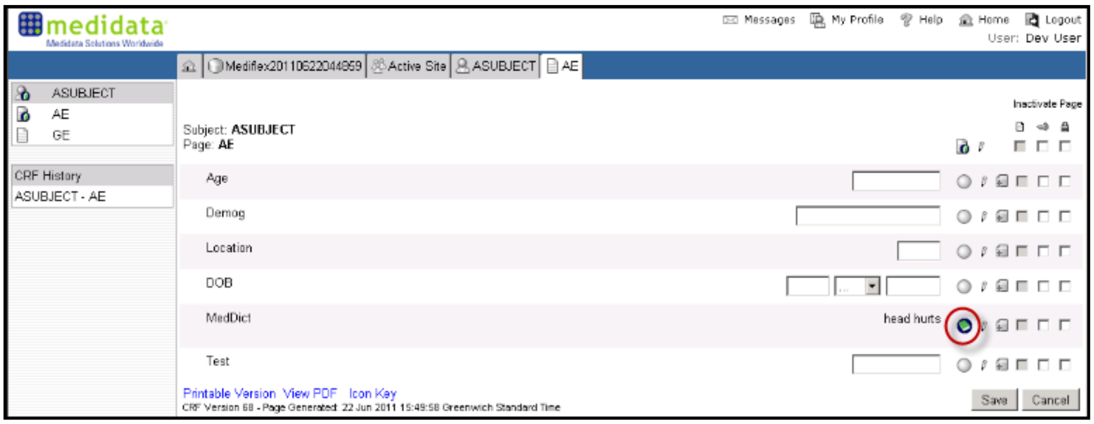


Note: The term highlighted in blue is the term level being coded. To code at a different level, click the level name (located in the top area of the screen). Once selected, the level can be coded.

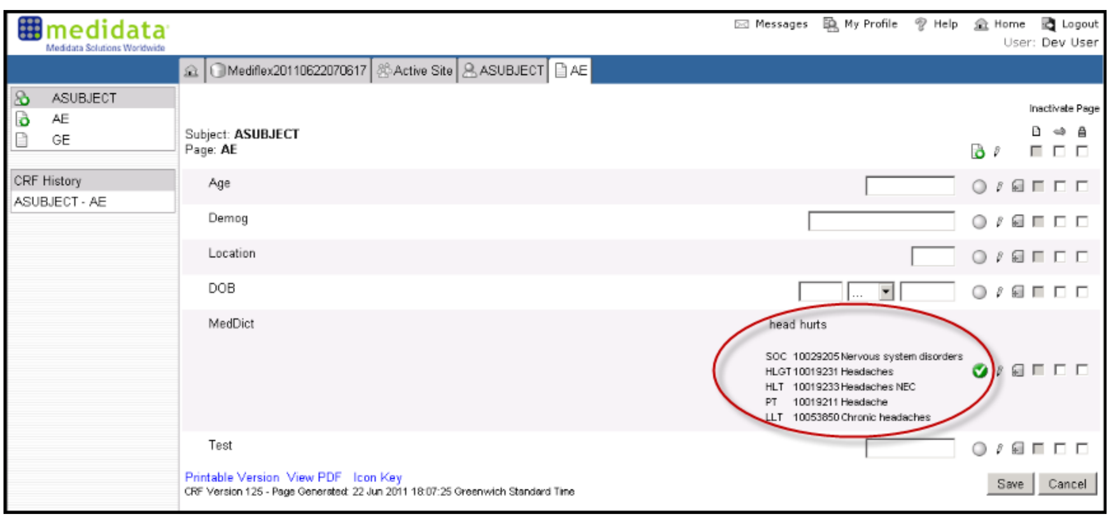
Note: Terms that were manually coded can be edited the same way as terms that were auto-coded.

CRF Coding by way of Medidata Coder

If your study uses Medidata Coder for dictionary coding, terms that require coding will display the Coder icon.



Once a term has been coded in Medidata Coder, the coding hierarchy is displayed beneath the verbatim term, and the complete icon or the next applicable status icon is displayed.



If a verbatim term is rejected by the person who is performing coding tasks in Medidata Coder, a query is displayed. Once the query is resolved, and the term is updated, the term is again ready for coding.

Lab Data Entry

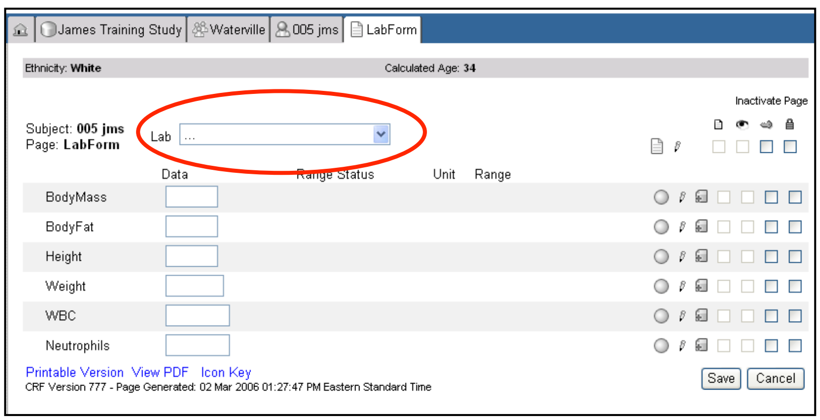
In the Rave system, lab data can be compared against local lab and alert reference ranges. When a user submits lab field values on the CRF, the system automatically performs a standard lab data range check for the entered data and looks for the following information:

- Out of range values entered for the selected analyte for a specific lab.
- Clinical significance association for the analyte.

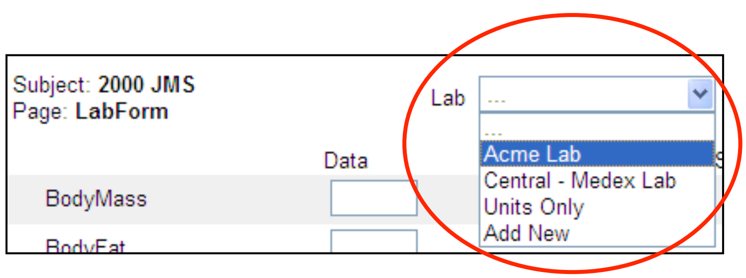
Entering Lab Data

To enter lab data:

1. Navigate to a form collecting lab data.



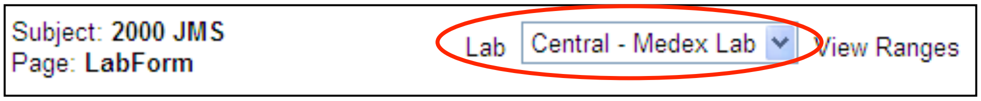
2. From the Labs dropdown menu, select the lab used to analyze the data being collected. Within the dropdown menu, a user can select from a list of predefined labs, or create a new one, if the user has the necessary permissions.



> **Note:** A lab may be selected by default, depending on the sponsor's system configuration. If a lab is selected by default, you can either keep the selection or use the dropdown menu to select another lab.

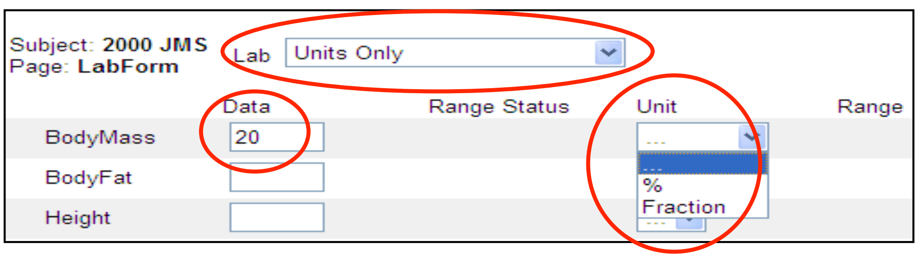
> **Note:** When a lab is selected from the dropdown menu—either automatically by the system or by an end-user—an entry indicating the selection is written into the Audit Trail.

- **Local Labs** – Can be created "on the fly" by a site and will only be applied to the site. Users with the proper permissions can create new local labs and edit local lab ranges.

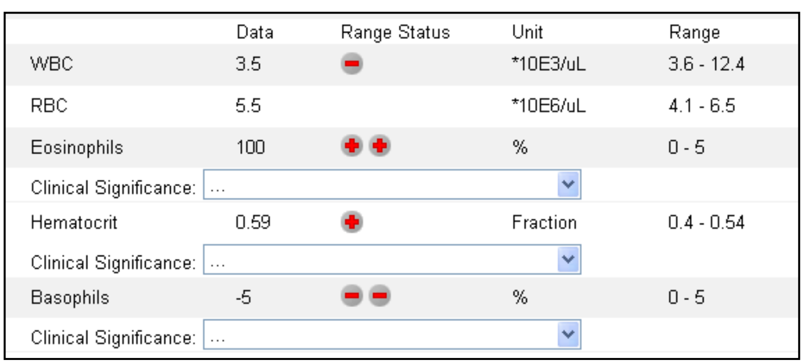


- **Central Labs** – Once created, can be applied to any site within any study. Central labs are not created or ranges edited within the EDC module. Within the dropdown menu, central labs are prefixed with the word *Central*.

- **Units Only** – If Units Only is selected, the end-user can select the unit of measure and enter each analyte value. Once entered, the values will be compared to alert ranges. Reference range values are displayed on the screen for informational purposes only.



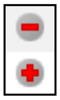
3. Enter the lab data into the applicable fields, and click **Save.**



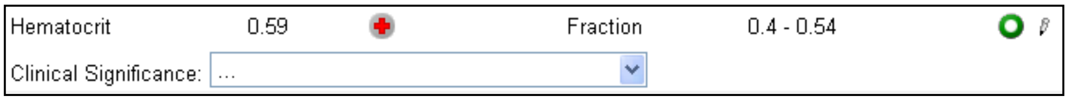
	Data	Range Status	Unit	Range
WBC	3.5		*10E3/uL	3.6 - 12.4
RBC	5.5		*10E6/uL	4.1 - 6.5
Eosinophils	100		%	0 - 5
Clinical Significance: ...				
Hematocrit	0.59		Fraction	0.4 - 0.54
Clinical Significance: ...				
Basophils	-5		%	0 - 5
Clinical Significance: ...				

On submission of lab values for a lab:

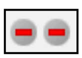
- The system compares the value entered against the high and low range values for the applied local lab range. If the values entered are within the range, the system accepts the data.



- For any field containing data that is out of the local lab range, the system displays an out of range indicator ("+" or "-").
- If the analyte field is configured for a clinical significance prompt, and the entered value are out of range, the system sets the data status to incomplete and displays a clinical significance code dropdown menu. See below for more information on how the system directs the user to respond to this scenario.



- If an alert range has been applied to the study (this is set up by a Lab Administrator), the system also compares the values entered to the high and low values defined in the alert range. For any field containing data that falls outside of the alert range, the system displays the alert out of range indicator ("++" or "--"). The alert out of range indicator overrides the local lab out of range indicator. Analyte values that fall outside of alert ranges are automatically prompted for clinical significance, whether or not the analyte is configured to do so.



> **Note**: When the mouse hovers over an alert out of range indicator, the alert range appears for the analyte.

- If no range is indicated (no lab name or range is defined for the lab) the system saves the data and sets the data status to incomplete.

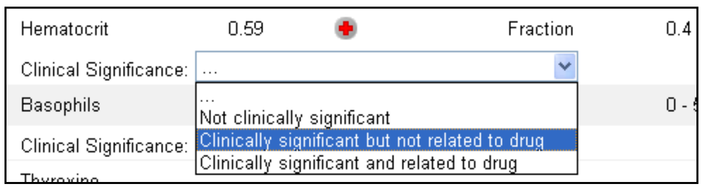
> **Note:** Fields for entering, editing and saving lab data are disabled during the eSignature process. Refer to the "Electronic Signatures in Batch" section in this manual for more information.

Responding to Clinical Significance Prompts

If data entered is out of range, the user may be prompted to enter a clinical significance. In that case, a clinical significance dropdown menu displays for a user who has the appropriate permissions.

To Respond to Clinical Significance Prompts:

1. Navigate to a lab form containing analytes prompting for clinical significance.
2. Select a preconfigured clinical significance code from the dropdown menu.

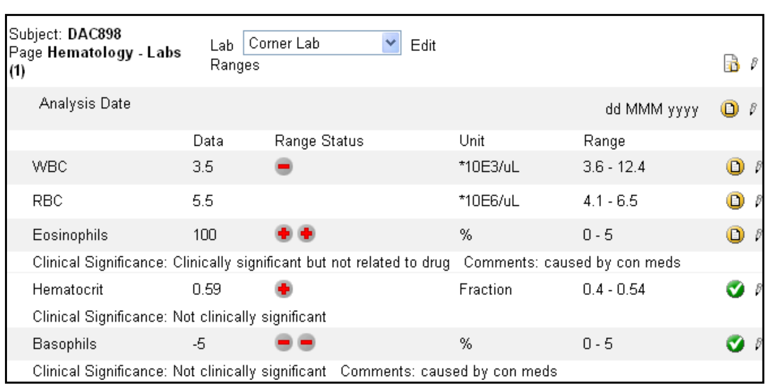


3. Once the code is selected, the user may be prompted to enter comments into a text box, to provide additional information about the significance of the out of range value. If prompted, enter comments.

Note: Clinical significance codes are created by a Lab Administrator. Upon configuration of significance codes, the Administrator can elect to have certain codes, when selected by the end user, prompt for additional comments.

If data entered by the end user falls outside of an alert range, that user will always be prompted for clinical significance and comments.

4. Click **Save**.



Lab Maintenance

Although the majority of lab setup is done by administrators using the Rave Lab Administration module, within EDC, local labs and local lab ranges can be created. Only users with the Lab Maintenance permissions can create or edit local labs and local lab ranges.

Local Labs: Definitions

The Local Labs page consists of the following information:

- **Name** – The user-defined name for the local lab. Names should be descriptive for easier maintenance. Name is required when defining a local lab.
- **Type** – Indicates that the lab is a local lab. This is not editable.
- **Description** – User-entered text that describes the local lab. Description is not required.
- **Range Type** – Indicates the range type for each local lab. In edit mode, the range type is selected from a dropdown menu. The dropdown menu is populated with all active range types defined in the Range Types section of Lab Administration.
- **Ranges Approved** – If checked, indicates that the local lab has been approved by a Lab Administrator. By default, the Ranges Approved box is checked. If the user has made any changes to a lab range, or has added a new range, the approved flag for a lab is set to unapproved (unchecked).
- **Pencil icon** – When clicked, the selected local lab is highlighted and displayed in edit mode, where the lab details may be edited as needed.

> **Note:** Once a lab has been referenced in subject data, only the Name and Description fields are editable. A local lab can be deleted only if it is not referenced in any subject data.

- **Ranges Detail Arrow** – When clicked, the ranges configured for the selected local lab are displayed in display mode.

Analyte	From Date	To Date	From Age	To Age	Sex	Low Value	High Value	Units	Dictionary	Comments	Edit	New Ver
Basophils	Jan 01 1900	Jan 01 2100	0 Years	100 Years		2	10	%				
Hematocrit	Jan 01 1900	Jan 01 2100	0 Years	100 Years		25	75	%				
Hemoglobin	Jan 01 1900	Jan 01 2100	0 Years	100 Years		12	20	mg/dl				
Neutrophils	Jan 01 1900	Jan 01 2100	0 Years	100 Years		20	50	%				
WBC	Jan 01 1900	Jan 01 2100	0 Years	100 Years		2	8	*10E6/ul				

Add New Range Copy Ranges

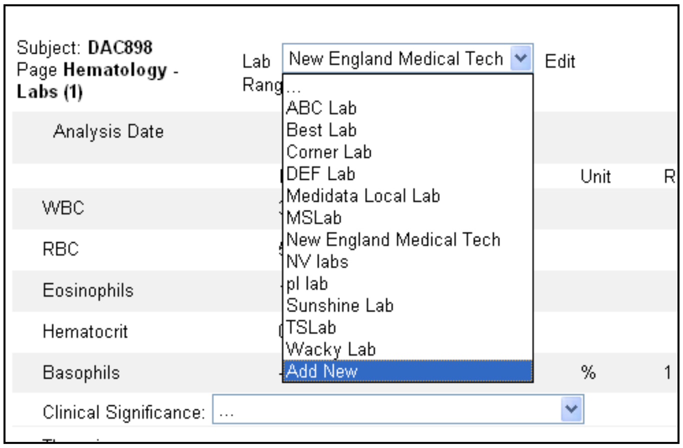
Adding a New Local Lab

Local labs can be created through the EDC module as well as by a Site Administrator. For more information on creating labs through Site Administration, refer to the *Site Administration Training Manual*.

Note: Users must have the lab maintenance permission in order to add a new lab.

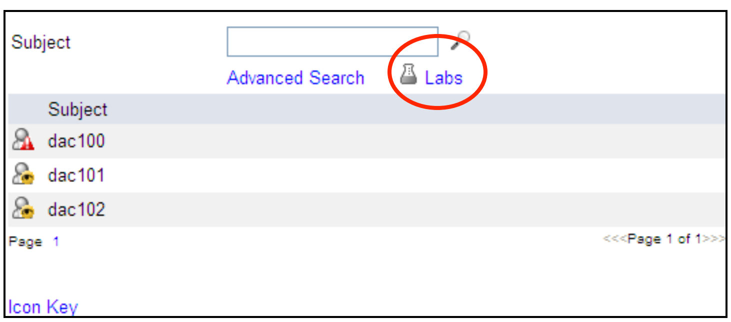
To Add a Local Lab through EDC:

1. Navigate to a form that collects lab data.



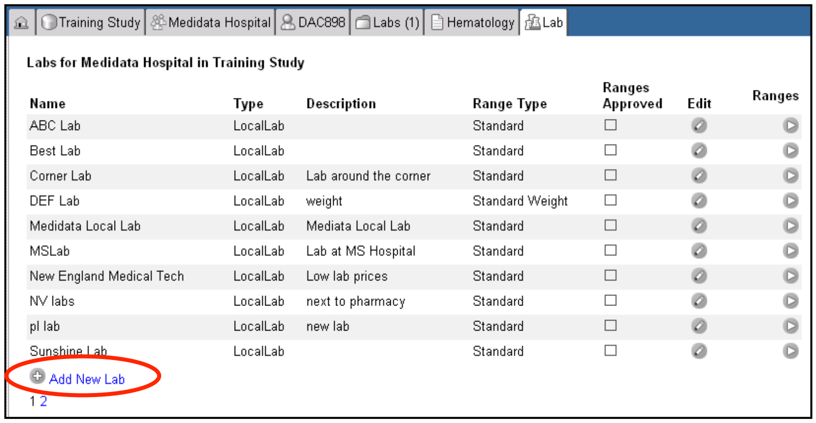
2. On the Labs dropdown menu, select **Add New**.

3. When you select Add New Lab or click the Labs link from the Site page, the Labs page is displayed, along with a Labs navigation tab.



Note: Depending on your user permissions, the Lab dropdown menu may appear grayed out. If this is the case, you may be able to access the Labs page by way of a link on the Site page, above the list of subjects (refer to screenshot below).

4. Click **Add New Lab** to create a new local lab.

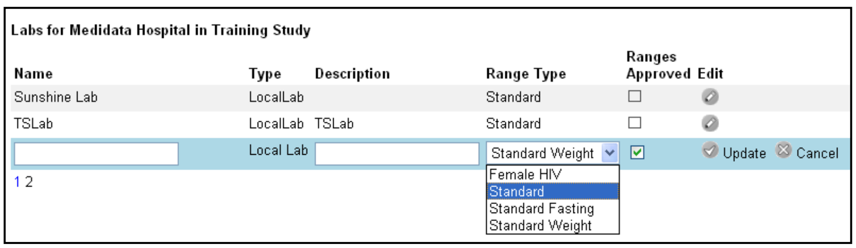


Labs for Medidata Hospital in Training Study

Name	Type	Description	Range Type	Ranges Approved	Edit	Ranges
ABC Lab	LocalLab		Standard	☐		
Best Lab	LocalLab		Standard	☐		
Corner Lab	LocalLab	Lab around the corner	Standard	☐		
DEF Lab	LocalLab	weight	Standard Weight	☐		
Medidata Local Lab	LocalLab	Mediata Local Lab	Standard	☐		
MSLab	LocalLab	Lab at MS Hospital	Standard	☐		
New England Medical Tech	LocalLab	Low lab prices	Standard	☐		
NV labs	LocalLab	next to pharmacy	Standard	☐		
pl lab	LocalLab	new lab	Standard	☐		
Sunshine Lab	LocalLab		Standard	☐		

Add New Lab
1 2

5. In the new lab line that appears, enter the local lab name, description (optional), range type, and approval flag (optional).



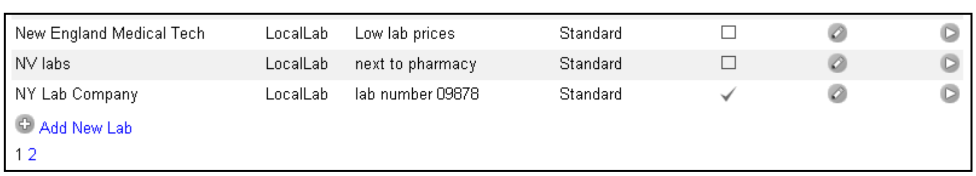
Labs for Medidata Hospital in Training Study

Name	Type	Description	Range Type	Ranges Approved	Edit
Sunshine Lab	LocalLab		Standard	☐	
TSLab	LocalLab	TSLab	Standard	☐	
	Local Lab		Standard Weight	☑	Update Cancel

1 2

Note: Range types are set up by a Lab Administrator. The range type selected for a lab indicates what variables must be assessed before a lab range can be applied to a subject. For example, the "Standard" range type might look at a subject's age and sex to determine what the low and high range values are for a particular analyte. Contact your Lab Administrator for information about your study's specific lab ranges.

6. Click **Update**.



New England Medical Tech	LocalLab	Low lab prices	Standard	☐		
NV labs	LocalLab	next to pharmacy	Standard	☐		
NY Lab Company	LocalLab	lab number 09878	Standard	✓		

Add New Lab
1 2

Note: Upon saving, labs are ordered alphabetically. If you have multiple pages of labs, use the pagination links to move through each page until you locate your lab.

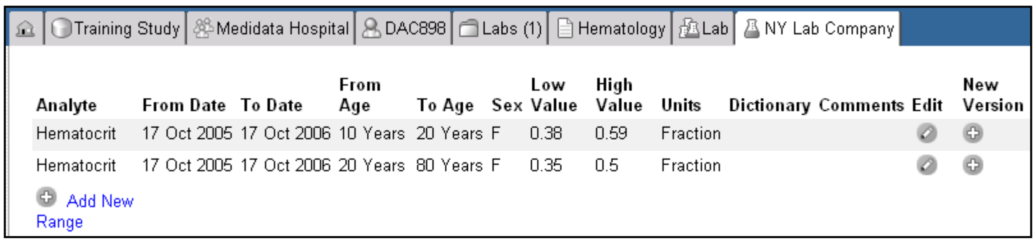
Note: To edit the lab name, description, range type, or approval flag click the **pencil** icon. To add or edit lab ranges, click the **detail** arrow. Refer to the next section for additional information.

Entering Lab Ranges for a Local Lab

Once local labs have been created, local lab ranges can be entered. lab ranges can be entered through EDC or through Site Administration. For more information on entering lab ranges through Site Administration, refer to the Site Administration module training manual.

> **Note:** Users must have the Lab Maintenance permission in order to edit lab ranges. Users who do not have this permission will be able to view the lab ranges.

Local Lab Ranges: Definitions



Analyte	From Date	To Date	From Age	To Age	Sex	Low Value	High Value	Units	Dictionary	Comments	Edit	New Version
Hematocrit	17 Oct 2005	17 Oct 2006	10 Years	20 Years	F	0.38	0.59	Fraction				
Hematocrit	17 Oct 2005	17 Oct 2006	20 Years	80 Years	F	0.35	0.5	Fraction				

Add New Range

- **Analyte** – Displays the analyte to which the range applies. In edit mode, the analyte is selected from a dropdown menu of all active analytes as defined in the Analytes section of Lab Administration. Analyte is required when configuring a lab range.
- **From Date/To Date** – The dates for which the range is valid. The date is displayed in the date format as specified in the Configuration module. The To Date cannot be before the From Date. To Date and From Date are not required.

> **Note:** When a new version of a range is saved, the system populates the To Date of the prior version with a date that is one day prior to the From Date of the new version.

- **Variable N Low and High Values/Units** – For each variable in the range type, the system creates one field if only "Low Value" is specified, or two fields if "Low" and "High" values are both specified. The column heading (for example, Age, Sex, and so on.) is taken from the variable definition as specified in the Global Variables section of Lab Administration. If the variable is assigned to a data dictionary, then in edit mode the field is displayed as a dropdown menu; otherwise, it is displayed as a text field where the content must match the format defined for the variable. Unit is only displayed if the global variable is associated with a unit dictionary
- **Low/High Value** – The minimum and maximum numeric values that fall within the range. The High Value must be greater than or equal to the Low Value. This is a required field unless a data dictionary is specified.

- **Units (Analyte Range)** – The standard unit for the range. In edit mode, the unit is selected from a dropdown menu containing the units and synonyms from the lab unit assigned to the analyte.
- **Dictionary** – The global data dictionary assigned to the range. In edit mode, the dictionary is selected from a dropdown menu containing the global data dictionaries defined in the Global Data Dictionary section of Lab Administration.
- **Comments** – Text box displaying any user-entered comments for the range.
- **Pencil icon** – When clicked, displays the selected lab range highlighted and in edit mode for modification.

Note: Audits of lab range changes are kept in the database.

- **New Version** – When clicked, the system displays a copy of the selected row, highlighted and in edit mode. The copy contains all data except for the From and To Dates. From Date is required when adding a new version. If a new version is added from the EDC module, the date is defaulted to the current subject's visit date.

Note: When a new version of a range is saved, the system populates the To Date of the prior version with a date that is one day prior to the From Date of the new version.

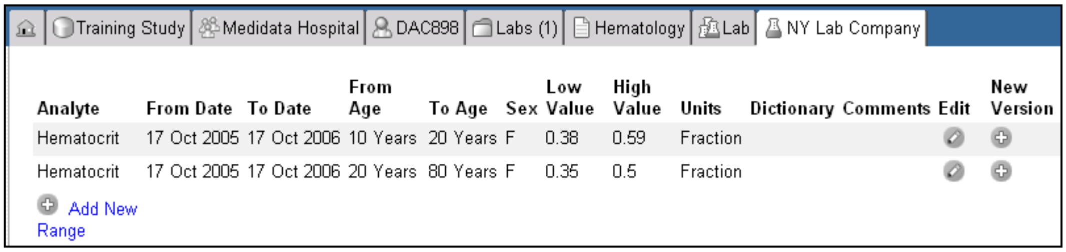
- **Add New Range** – When clicked, displays a new, blank range entry line in edit mode where a new range can be defined.

Note: The system checks for uniqueness of a lab range. A lab range has to be unique for any given analyte, any given date range, and any combination of range type values.

To Enter or Edit Lab Ranges for a Local Lab:

Refer to the definitions and screenshots on the previous pages for additional information.

1. Navigate to a form that collects lab data, and from the lab dropdown menu, select **Add New** to display the Labs page.



2. On the Labs page, use pagination tools to locate the desired lab.

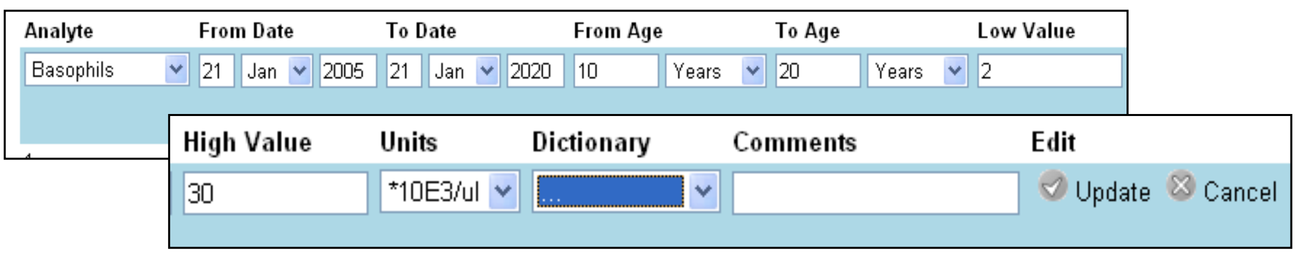
3. Click the **detail** arrow to the right of the lab to display the lab ranges page.

4. On the lab ranges page for the selected local lab, click **Add New Range** to create a new lab range, or click the **pencil** icon to edit an existing lab range.

5. Select **Analyte** name from the dropdown menu.

6. Enter **From Date** and **To Date** for the range.

7. Input data for the variables and select **Variable Units** from the dropdown menus as needed.



8. Enter **Low** and **High Values** for the range.

9. Select the **Range Units** from the Range Units dropdown menu.

10. Select a dictionary from the Dictionary dropdown menu.

11. Enter **Comments** (optional) if needed.

12. Click **Update**.

To Edit or Delete a Lab Range from a Local Lab:

Refer to the definitions and screenshots on the previous pages for additional information.

1. Click the **Ranges Detail** arrow next to the selected local lab to display the list of defined ranges for the local lab.

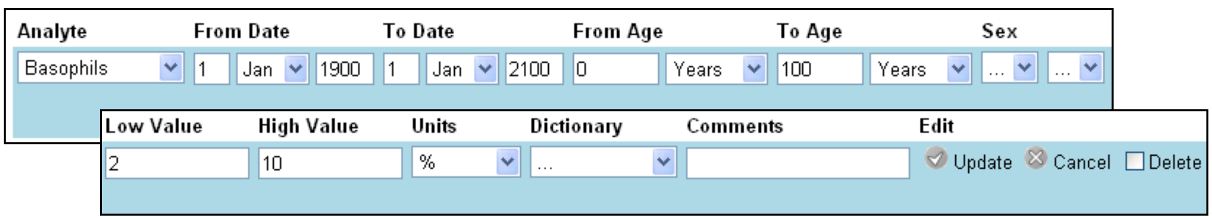
Analyte	From Date	To Date	From Age	To Age	Sex	Low Value	High Value	Units	Dictionary	Comments	Edit	New Ver
Basophils	Jan 01 1900	Jan 01 2100	0 Years	100 Years		2	10	%				
Hematocrit	Jan 01 1900	Jan 01 2100	0 Years	100 Years		25	75	%				
Hemoglobin	Jan 01 1900	Jan 01 2100	0 Years	100 Years		12	20	mg/dl				
Neutrophils	Jan 01 1900	Jan 01 2100	0 Years	100 Years		20	50	%				
WBC	Jan 01 1900	Jan 01 2100	0 Years	100 Years		2	8	*10E6/ul				

Add New Range Copy Ranges

2. Click the **Pencil** icon to display the selected lab range highlighted and in edit mode.

3. Edit the lab range as needed.

4. Click **Update.** To delete the lab range, check the **Delete** check box and click **Update**.



Note: Lab range changes trigger recalculation of any subject data based on that range.

Note: Save time when creating various ranges for the same analyte by using the **New Ver** icon to create a new version of an existing range. When clicked for a specific range, the new version icon creates a copy of the selected range, leaving the dates blank. Enter new dates for the range and click **Update**.

When a new version of a range is saved, the system populates the To Date of the prior version with a date that is one day prior to the From Date of the new version.

Altering Lab Ranges after Data has been Locked

You may find that you need to update lab ranges, such as a change to a range's values, active dates, and so on, after data referencing the same lab has been entered and locked in EDC. Depending on your Rave configuration, you may or may not be able to update lab ranges if data that references the corresponding lab has been locked.

Standard Update Behavior

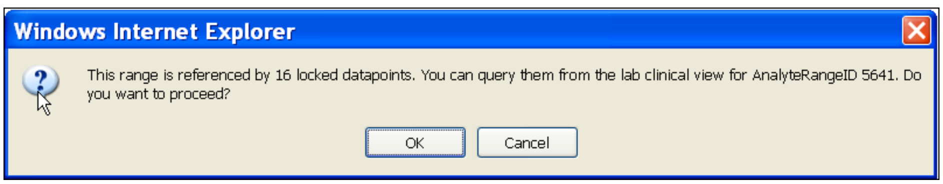
By default, if a lab is selected on an eCRF and its lab ranges are updated, the locked data will not be affected. You will be able to make the changes, assuming you have the appropriate permissions to update lab ranges (by way of the Lab Maintenance role permission).

Permissions-based Update Behavior

Your system may be configured to confirm that you have additional permissions prior to allowing you to update lab ranges that are referenced by locked data points. In that case, the system will allow you to update the lab ranges based on whether or not you can unlock locked data (by way of the Unlock role action.)

If you have the permissions to edit lab ranges and also have the permission to unlock data, when you attempt to save lab range modifications for ranges referenced by locked data, the following will occur if the changes affect the out-of-range status of the data:

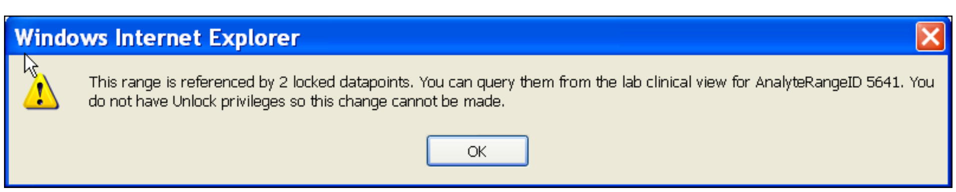
- ❑ You will receive a warning that the range is referenced by locked data. The message indicates how many locked data points reference the range and informs you that you may obtain details for which data by way of the Lab Clinical View. Typically this data can be accessed by a report or outputs specialist who works with Rave data.
- ❑ If you click **OK**, the changes will be made and the locked data points will be updated accordingly within EDC. If you click **Cancel**, no changes will be made, and the lab range modification will not be saved.



- ❑ Upon clicking **OK**, the lab range is saved, and any locked data that referenced the modified lab range will be unlocked. Any signatures applied to that data will be broken, and the data may require review, verification, freezing, and locking again, depending on the specific data’s requirements.

If you have permission to edit lab ranges, but do not have permission to unlock data, and you attempt to save edits to a lab range that is referenced by locked data, then:

- ❑ You will receive a message indicating that you cannot modify the lab range, because you do not have permission to unlock data. The message will also indicate how many locked data points reference the range and inform you that you may obtain details for which data by way of the Lab Clinical View. Typically this data can be accessed by a report or outputs specialist who works with Rave data.
- ❑ You can click **OK** to exit the message. No changes are made to the lab range or to the data status in EDC.



Utilizing Markings

This chapter will cover the following topics:

- Markings
- Protocol Deviations
- Marking Groups
- Sticky Notes
- Queries
- Annotations (Comments)

Markings

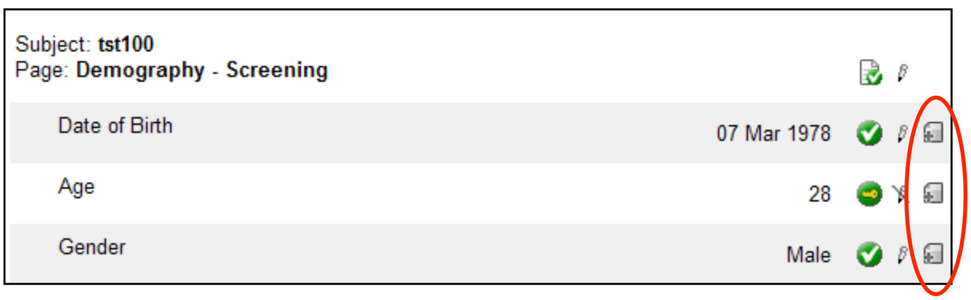
Markings are notes, remarks, or observations that can be associated with fields on a form. Permissions to markings are specified at the role level. These permissions allow user roles to create, change, respond, cancel, acknowledge, close, delete, or see the markings. Marking a form flags data for follow-up, correction, or clarification.

There are three types of markings:

- Protocol Deviations
- Sticky Notes
- Queries

Each will be explained in detail in this section of the training manual.

To Add a Marking to Any Data Entry Field:



1. Click the **marking** icon located to the right of the data entry field.

Selecting this icon opens a dropdown menu for marking type selection. These may include Open Query, Place Sticky, or Protocol Deviation based on the role permissions for the user.

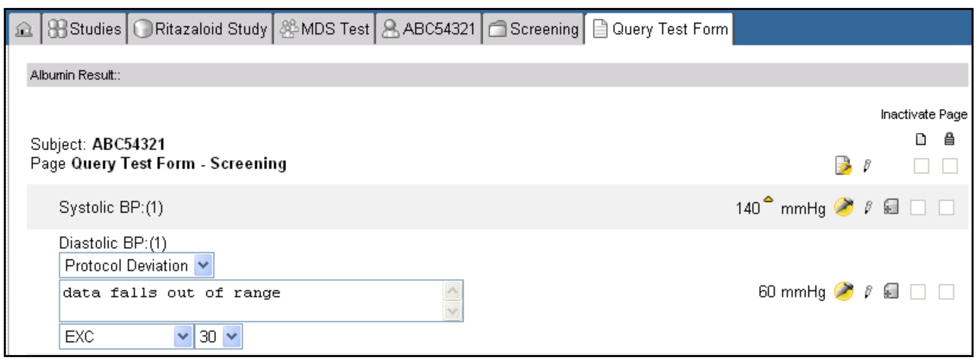
> **Note**: Dependent on role access, the marking type selection may differ. If a user has no marking privileges, the markings icon is not displayed.

Protocol Deviations

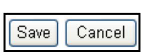
A protocol deviation is when an event or timing differs from what is stated in the protocol, (for example, a subject misses a visit and the visit occurs three days late).

To Create a Protocol Deviation:

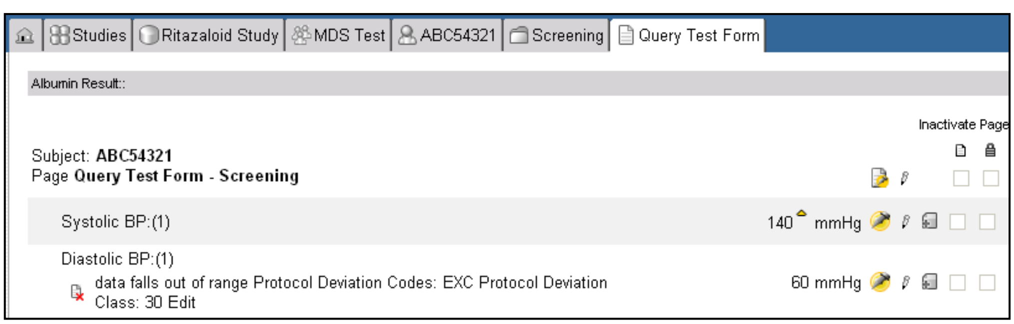
1. Add a marking.
2. Select **Protocol Deviation** from the dropdown menu.
3. Type comments in the open text box below the dropdown menu. The maximum size of the comments is specified by the sponsor.
4. Select data from the additional dropdown menus for codes and classes.



Note: A class and a code must both be selected for the form to save.



5. Click **Save**.



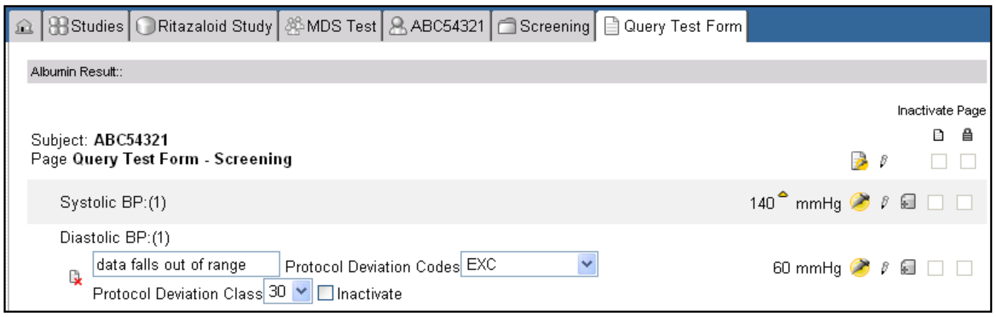
Upon successfully saving the form, the following protocol deviation appears:

Note: Even though a protocol deviation has been activated, data can still be entered into open data fields.

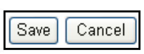
Once created, protocol deviations may be edited and/or inactivated, depending on user access.

To Edit or Inactivate a Protocol Deviation:

1. Select the **Edit** link next to the protocol deviation text to open the editable text box for the deviation, classes, and codes. The inactivate check box will also appear, depending on user permissions.



2. Enter changes or select the **Inactivate** check box.



3. Click **Save**.

Note: All protocol deviations, whether active, edited, or inactive, are recorded in the Audit Trail. The ability to add, edit, or remove a protocol deviation must be assigned to a user in the Configuration module.

More About Protocol Deviation Codes and Classes

Individual codes and classes can be inactivated in the Configuration module during the course of a study. (The sponsor determines if and when certain codes and classes become inactive.) When a code or class becomes inactive, it will no longer appear in its respective menu in EDC.

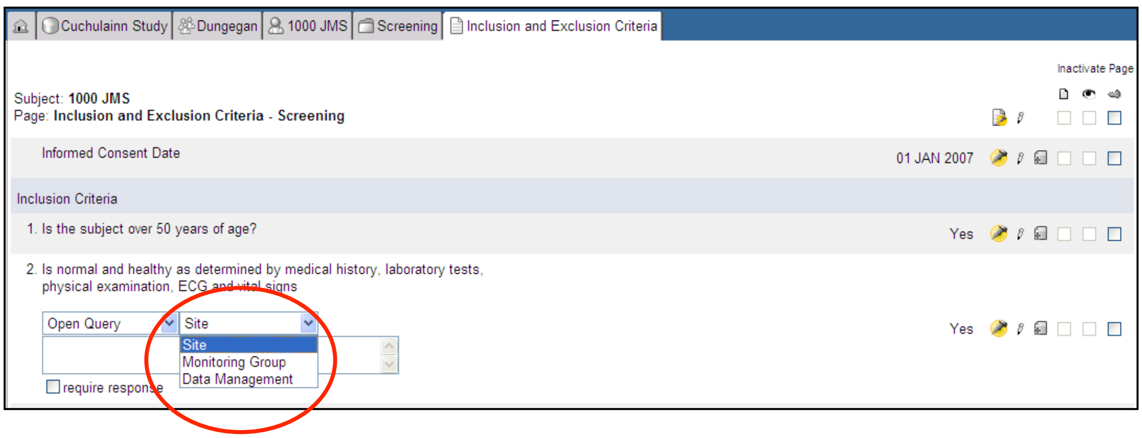
As stated above, protocol deviations appear on the line item of the datapoint. If either the code or class becomes inactive in the future, it will not affect the protocol deviation for that datapoint as long as it is not edited. Editing the datapoint itself while the code and/or class are inactive will not affect the protocol deviation.

Editing the protocol deviation after a code or class has been inactivated, however, must be done with care. Inactivated codes or classes will not appear in their respective dropdown menus if you edit any information in the protocol deviation – even if you are only editing the description. The system will automatically choose the first active code or class in their respective lists. When editing a protocol deviation, review the code and class to ensure that the same or relevant ones are applied before saving the protocol deviation.

Marking Groups

Rave allows two markings (sticky notes and queries) to be directed to specific groups. A marking created by one group can be directed to another group for response. These groups can be made up of one role or of various roles. These groups belong to a virtual communication group, similar to an email distribution group. These groups within Rave are referred to as marking groups.

Roles are assigned to a marking group by the sponsor. One role can have limited or various responsibilities or permissions within the EDC module. Due to this, there may be several marking groups created to cover the various role permissions.



Sticky Notes

Sticky notes are used for reminders and informal communication with another user. They are used the same way a sticky note would be used on a paper-based study.

To Add a Sticky Note:

1. Add a marking by clicking the **marking** icon, and select **Place Sticky**.
2. Select the appropriate marking group from the second dropdown menu. Refer to the marking group section of this manual for further information.
3. Type comments in the open text box below the dropdown menu. The maximum size for comments is dictated by the sponsor.

4. Click **Save**.

Once created, both the creator and the user receiving the sticky see the following:

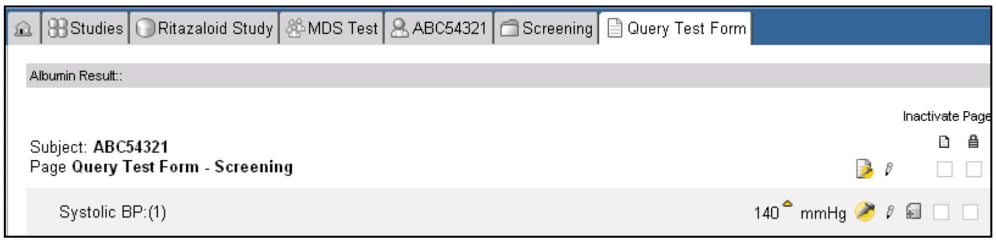
Sticky notes appear in the relevant section of the Form page. Form pages containing sticky notes are also added to the Task Summary, based upon user access, on the Subject page for appropriate follow-up.

Once read, a sticky is inactivated once acknowledged. This removes the sticky from the form as well as from the Task Summary.

To Acknowledge a Sticky:

1. Click the **Acknowledge** check box.

2. Click **Save**.



3. Upon successfully saving, the sticky is removed from the form field.

Note: Sticky notes are optionally recorded in the Audit Trail.

Queries

Within Rave, there are two types of queries:

- Manual Queries
- System Queries

Manual Queries

A manually-generated query is created in the EDC module at the data point. A user creates manual queries.

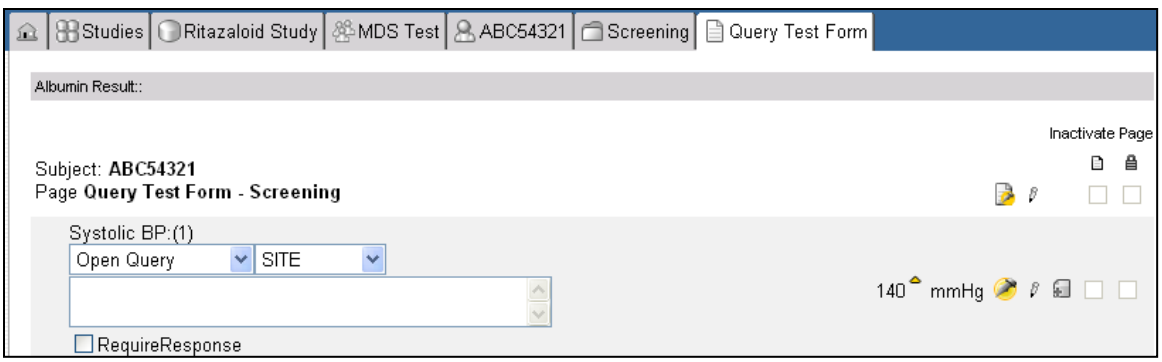
To Open a Manual Query:

1. Click the **marking** icon.

2. From the dropdown menu, select a marking type of open query.

3. Select the appropriate marking group from the second dropdown menu.

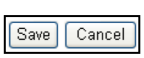
4. Type comments in the text box below the dropdown menu. The



maximum comment size is dictated by the sponsor.

5. If a response is required, select the **Require Response** check box.

Note: In Rave 5.6.3, the Require Response check box is unchecked by default. In Rave 5.6.4 and later versions, it is checked by default.



6. Click **Save**.

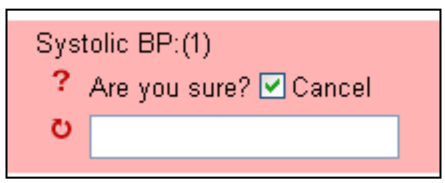
7. Upon successfully saving a manual query, the query is highlighted and reflected with a query open icon:

Note: To notify a user that a query is open for them to attend to, the Task Summary is updated to reflect the new task.

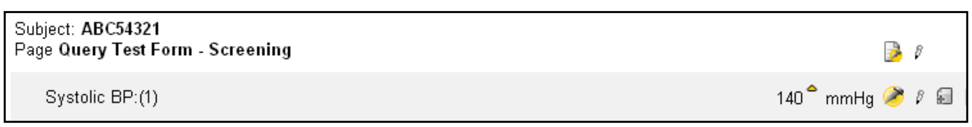
Manual queries can be cancelled. The manual query can only be cancelled if the user has the necessary permissions, and the query has not yet been answered.

To Cancel a Query:

1. Click the **Cancel** check box.



2. Click **Save**.



3. The query is canceled.

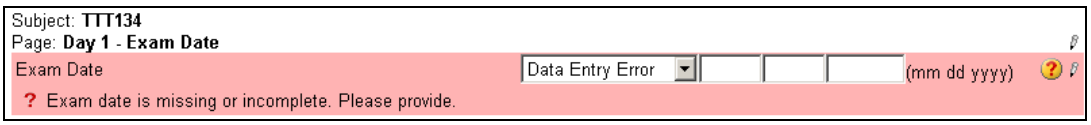
Note: Even though the query is canceled, it still shows up in the Audit Trail.

System Queries

A system query is triggered by preconfigured logic checks. If data is entered in a field that does not conform to the edit check, or a required field is left blank, a system-generated query opens. Depending on the configuration, system queries may or may not require a response. If a response is requested, a user response box opens.

The data field is highlighted and a query open icon appears. A query message is displayed with the data entry field still open for editing. The query indicates what required data is needed to clear the query.

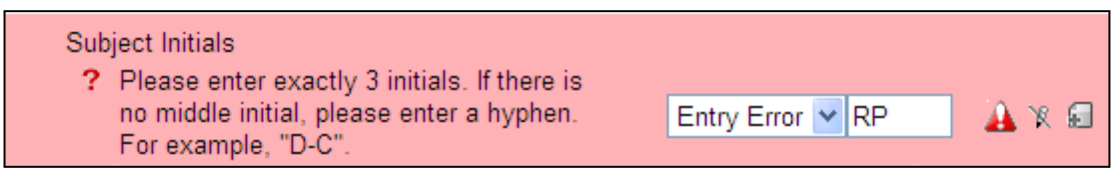
An example of a system query is seen below:



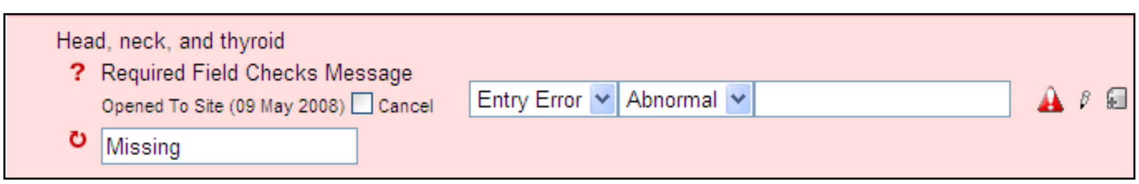
Responding to Queries

Depending on the query, different types of responses may be required.

- **Data Change Only (No Additional Response Required)** – Requires that the information in the data entry field be modified.

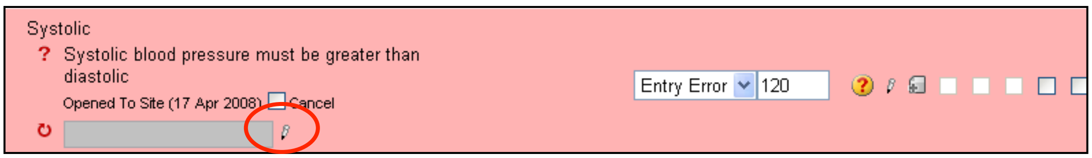


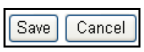
- **Additional Response Required** – Requires that the user provide additional information in a text box displayed on the left side of the screen. The user can optionally modify the data entered.



To Respond to an Open Query:

1. Open the eCRF containing the query.
2. Make changes to the data entry field as necessary. For system queries configured to require both a response and a manual close, the response box is grayed out and read only.
3. In order to enter a response, click the **edit** icon beside the field.



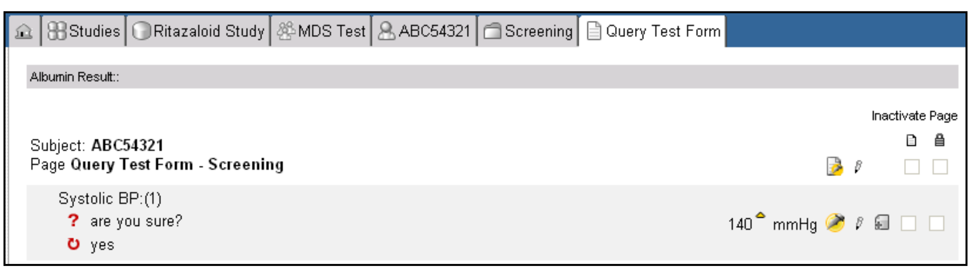


4. Click **Save**.

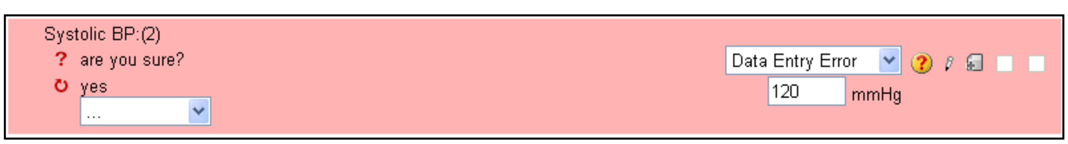
> **Note:** The response box will be open for editing until you click inside the data entry field. Afterwards, click elsewhere on the screen, and the response box will become grayed out. You can still edit the response box by clicking the **pencil** icon.

Closing Queries and/or Re-querying

To the user that has answered the query, the answered query may look like this:



Manual queries that have been resolved, or answered, are forwarded to authorized users for additional action. To those users, the answered query typically appears like this:

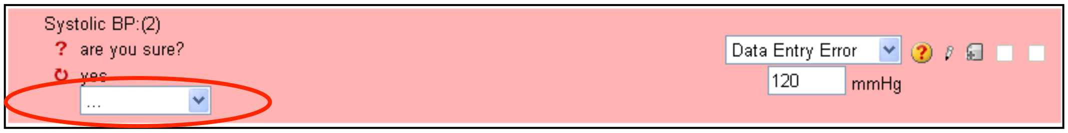


At this point, authorized users can choose to do the following with the query:

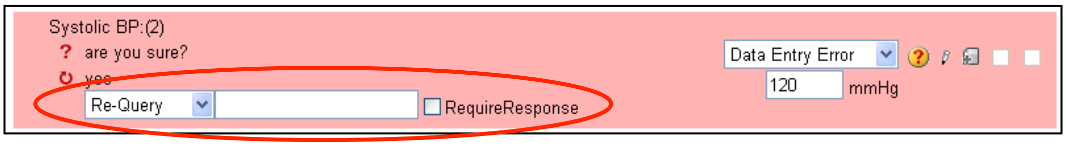
- ❑ Close the query
- ❑ Re-query

To Re-query Data:

1. Click on the dropdown menu within the answered query.



2. Select **Re-Query** from the dropdown menu.

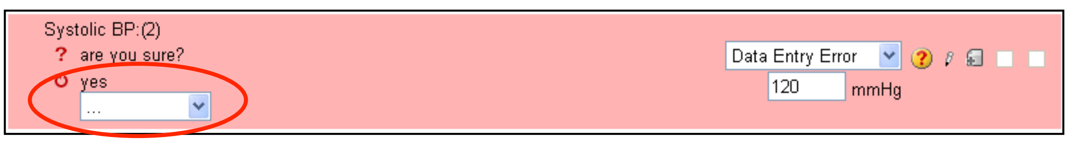


3. A text box is displayed for the text of the new query.

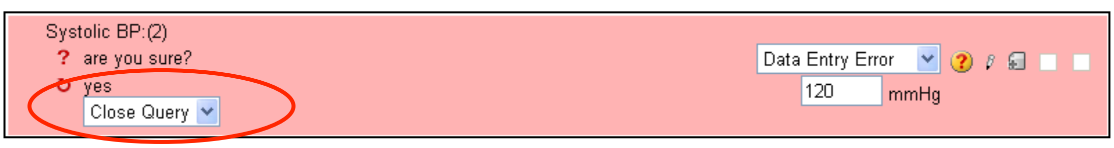
Note: From this point forward, the steps for re-querying are the same as for creating a new query: enter the query text, check the **Requires Response** box (if desired), and click **Save**.

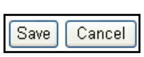
To Close a Manual Query:

1. Click on the dropdown menu within the answered query.



2. Select Close Query.





3. Click **Save**.

4. The query is closed.

Note: All queries and their responses are stored in the Audit Trail. Refer to the Audit Trail section in this manual for further information.

Forwarding Queries

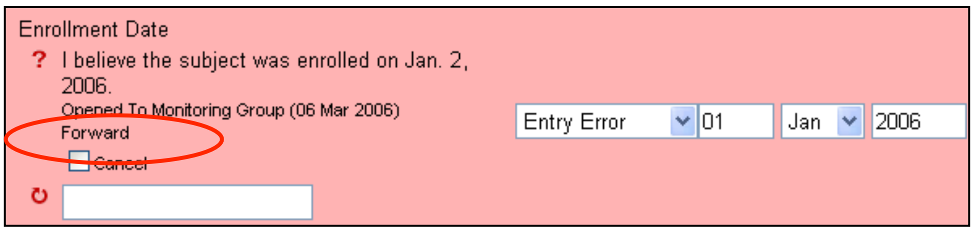
If you have the appropriate user permission, you may be able to forward open queries on to other users. Once a query is forwarded, it is just as though you had opened the query yourself.

If you have the forward query permission, you will be able to forward an open query to any marking group that you have the permission to open queries.

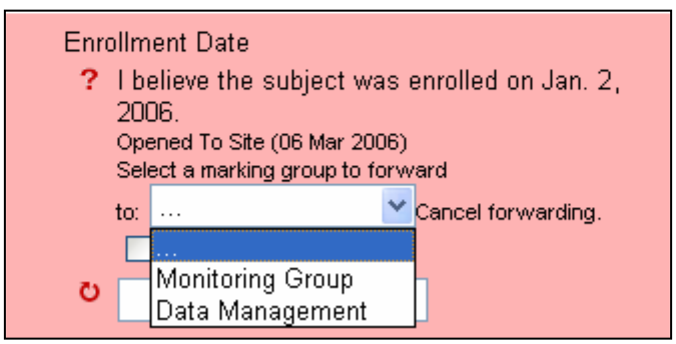
For example, suppose you are able to forward queries to the CRC marking group and the Safety marking group. If an open query is available, you will be able to forward that query to the CRC marking group and the Safety marking group.

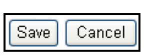
To Forward a Query:

1. Click the **Forward** link within the answered query.



2. Select from the dropdown menu the marking group that will receive the query.





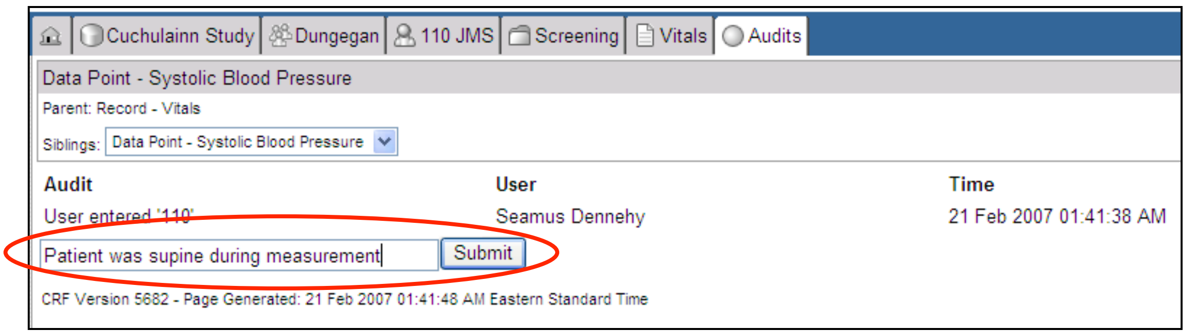
3. Click **Save**.

Annotations (Comments)

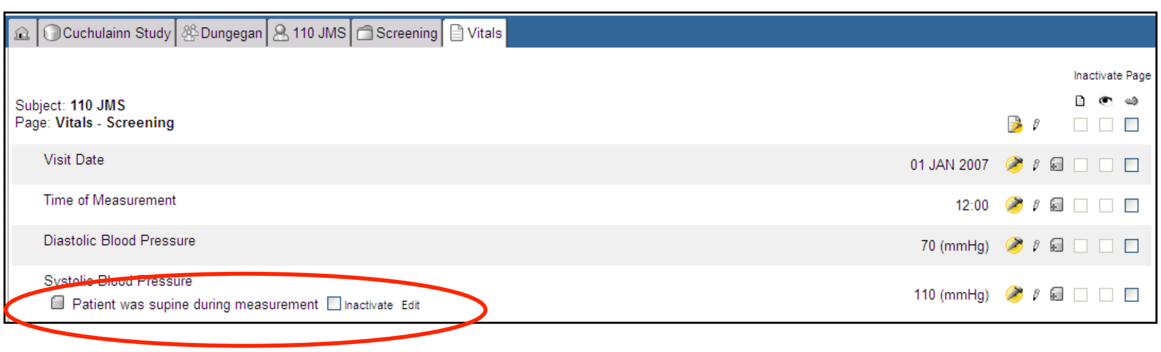
Annotations, also called comments, are used to communicate information about a particular data point. Based on role permissions, users may add, edit, or inactivate annotations. If a user has the necessary permissions, the comment entry box is displayed in the data point's audit trail.

To Add an Annotation to a Data Entry Field:

1. Access the Audit Trail for a data point to view the annotation text box.



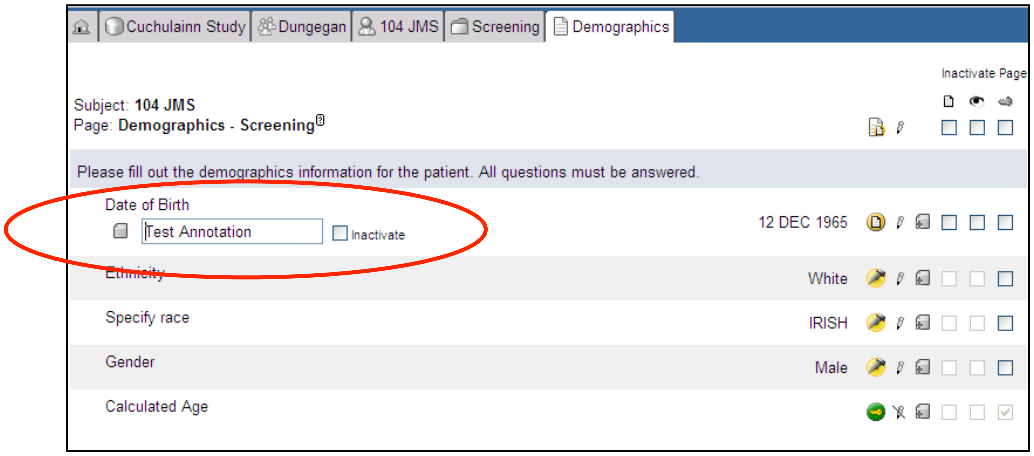
2. Type comments in the open text box.
3. Click **Submit**.
4. The annotation is added to the Audit Trail and is displayed below the field on the form.



To Edit or Inactivate the Annotation from the Form View:

1. Click the **Edit** link to open the editable comment.

2. Edit the comment in the text box, or click the **Inactivate** check box to remove the comment from the form view.



3. Click **Save**.

> **Note**: If an annotation is inactivated, it is removed from the form view but will remain in the Audit Trail.

Form and Data Administration

This chapter will cover the following topics:

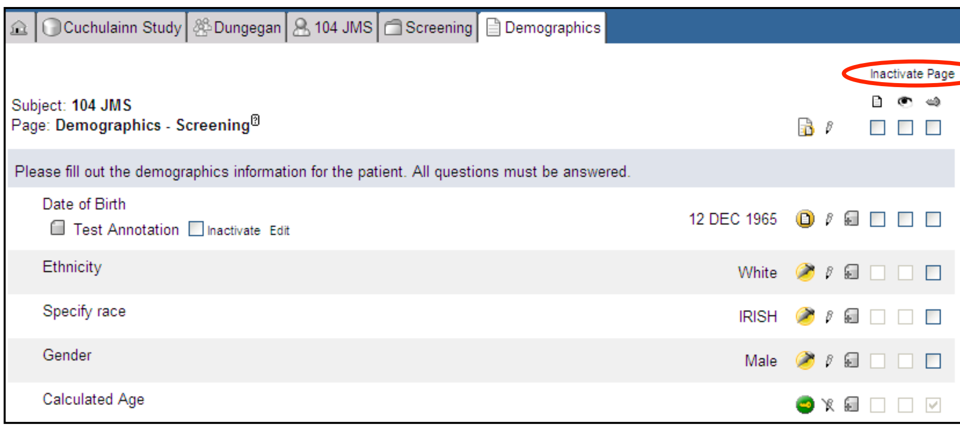
- Inactivating and Reactivating Forms
- Verification and Review
- Data Lock
- Electronic Signature
- Electronic Signature in Batch
- Printing eCRFs

Inactivating and Reactivating forms

With the exception of a subject's primary form, which is the patient's main information and background form, a user with the necessary permissions can inactivate any form for a subject. The inactivate button displays only for users with the necessary role permission. Also, depending on user permissions, forms may be reactivated.

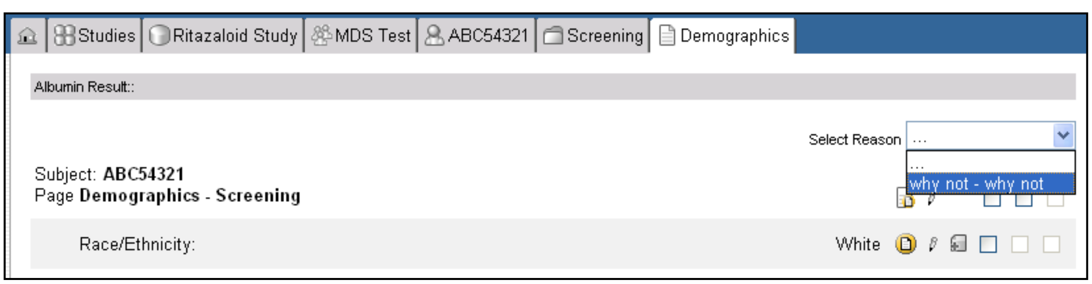
To Inactivate a CRF Form:

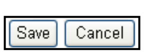
1. Select a subject and form.
2. Click the **Inactivate Page** link displayed in the upper right corner of the main area.



Note: The Inactivate Page link does not display on the subject's primary form.

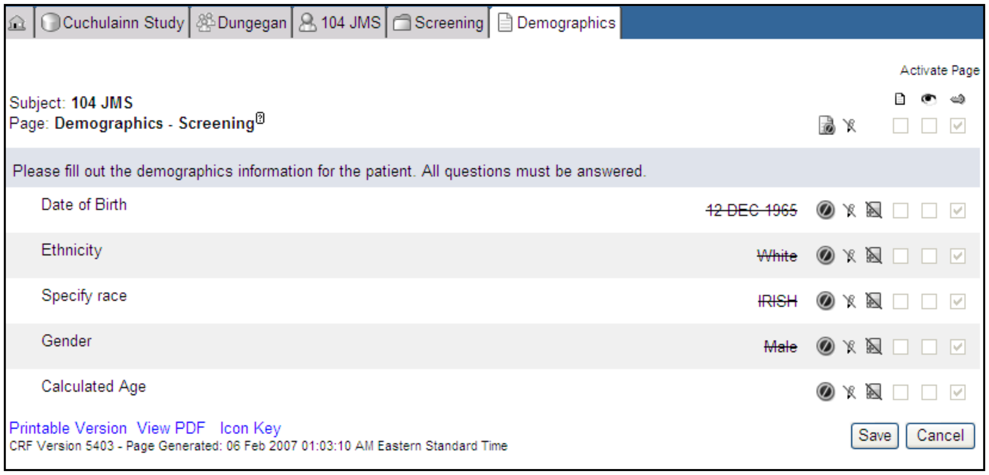
3. Select a reason for the inactivation of the form in the **Reason** dropdown list. If reasons are not configured, a Confirm Activation check box displays.





4. Click **Save**.

Upon successfully inactivating the form, the page will reload displaying all data points with strike-throughs and no-edit icons. Depending on user permissions, the Activate Page link may appear in the upper right corner of the main area:

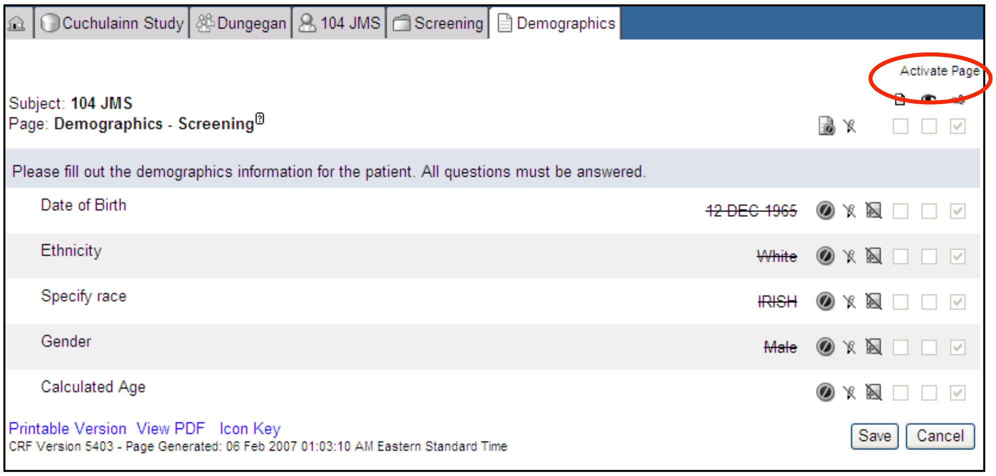


Note: Once inactivated, no further action is allowed on the form. The inactivation status is logged in the Audit Trail and displays in the Subject Task Summary with a strike-through form icon.

To Re-Activate a CRF Form:

1. Navigate to the inactivated CRF form.

2. Click the **Activate Page** link displayed in the upper right corner of the main area.



3. Select a reason for the inactivation of the form in the **Reason** dropdown list. If reasons are not configured, a Confirm Activation check box displays.

4. Click **Save**.

> **Note**: The system updates the information, and the form is restored to the status prior to inactivation. The reactivation status is logged in the Audit Trail.

Verification and Review

Source document verification is the process of confirming that data entered electronically matches the data collected first hand from the subject. This would include comparing the electronic data submitted into the Medidata system with paper forms, such as patient charts, lab reports, or even sticky notes.

Once the comparison has been made, an authorized user verifies the data in the system.

The sponsor may specify what needs to occur before and after verification and review begin; that is, data must be entered before verification begins.

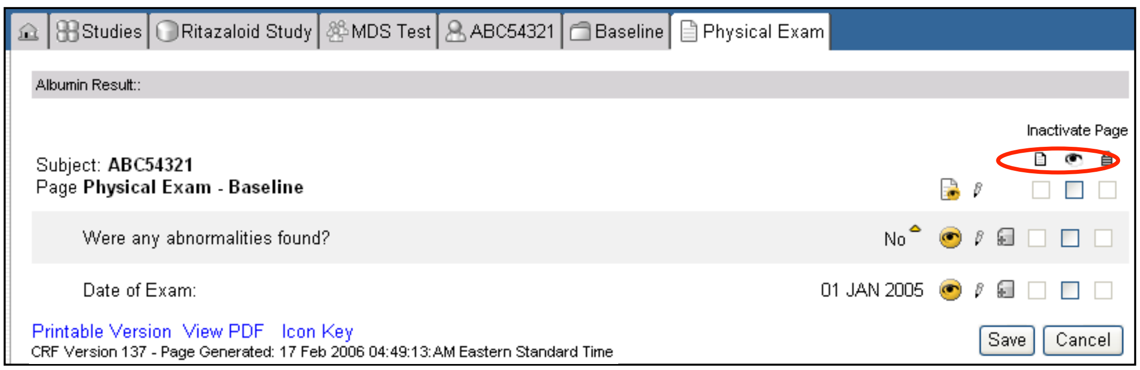
Depending upon role and user privileges, additional controls may appear next to the icons on the right side of the form.

These include:

- ❑ Verify Icon

- ❑ Review Icon

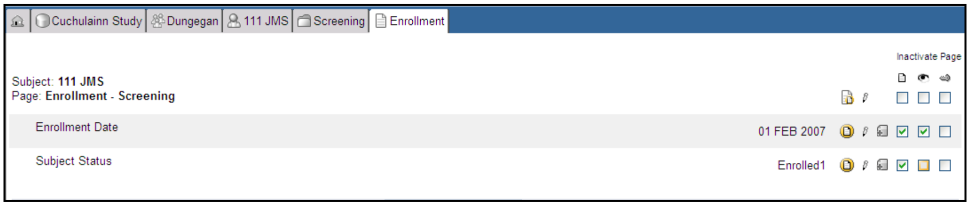
These check boxes appear next to the completed data fields that need verification and review, respectively.



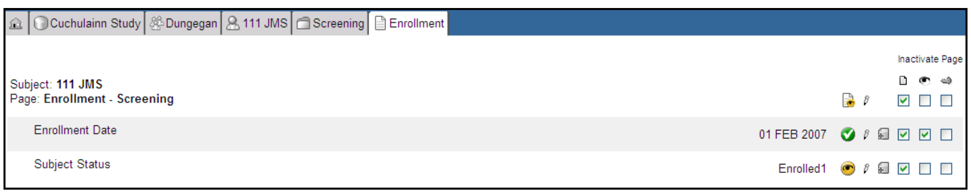
> **Note**: The sponsor determines which items in a study require verification and review. If the user hovers the mouse over the Review icon, a tool tip appears indicating which review group has been assigned to the task. The verification of data is an optional step to ensure accuracy.

To Verify or Review Data:

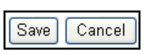
1. Click the check box or check boxes for fields requiring review and/or verification.



Note: To verify or review all the data fields in the form at once, click the check box immediately beneath the verify or review icon to select all data fields. On a landscape log form containing pagination across multiple pages, clicking the check box immediately beneath the verify or review icon on any page will verify or review all log lines on all pages at once.



2. Click **Save**.



- Upon verification and/or review, if the user has the ability to unverify or unreview, the check box can be unchecked. If the user does not have the permissions to unverify and/or unreview, the check box becomes grayed out.

- To unverify or unreview a data point, uncheck the necessary check boxes and resave the form. To unverify or unreview all data fields on one page, or all pages when using a landscape log form, clear the check box immediately below the verify or review icon.

Note: If any data is changed after it has been verified and/or reviewed, the field will become unverified and/or unreviewed. The user with the appropriate permissions will have to verify and/or review the document again.

Note: The ability to save verification and review choices is disabled during the eSignature process. Refer to the "Electronic Signatures in Batch" section in this manual for more information.

Data Lock

Depending upon role and user privileges, additional controls appear to the right side of the forms to lock data.

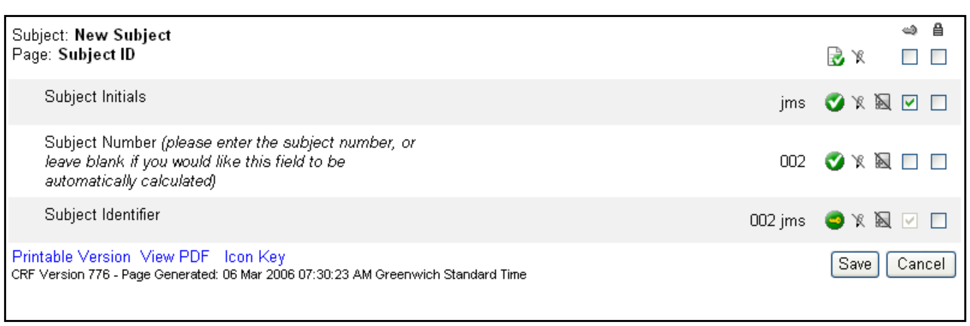
There are two ways in which to lock data:

- **Entry Lock (soft lock, freezing data)** – Prevents any future data entry or edit but allows authorized users to create and respond to markings. Also allows authorized users to perform reviews and source document verification. When data has been entry locked:
  - The Add a New Log Line and Inactivate links on log line or mixed format eCRFs will remain enabled.
  - Sites can no longer select a local lab name on local lab eCRFs.
  - Sites can only respond to queries in the response box; sites cannot change the data even if the query instructs them to do so.
  - Investigator signatures can still be applied.

- **Hard Lock** – Prevents all users from modifying the data point in any way. When data has been hard locked:
  - The Add a New Log Line and Inactivate links on log line or mixed format eCRFs are removed.
  - Sites cannot create or respond to markings.
  - If new forms or folders are required, they must be added by way of the Add Event dropdown menu on the subject home page.
  - Investigator signatures can still be applied.

To Entry Lock or Freeze Data:

1. Click the check box or check boxes (beneath the Entry Lock icon) corresponding to the appropriate data fields.



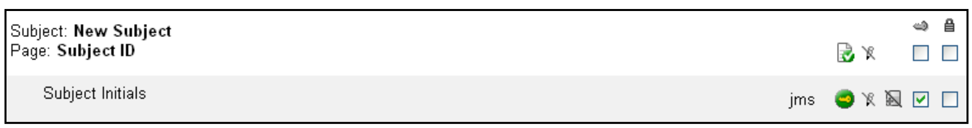
Note: To open and entry lock all the data fields in the form at once; click the check box immediately beneath the entry lock icon to select all data fields. On a landscape log form containing pagination, clicking this check box from any page will open and lock all data fields on all pages at once. Users are not able to edit frozen fields but can open a query if a data issue arises.

2. Click **Save**.

⇨ Upon entry lock of data, the status of the field is updated to the entry lock icon and the edit icon is cancelled out.

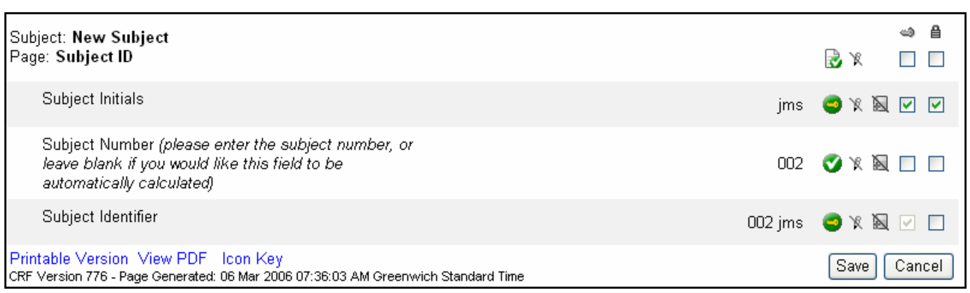
Or

⇨ If a user has access to un-entry lock data, a check mark remains in the check box. To un-entry lock a data point, click and remove the check mark from the check box. To un-entry-lock all data points on one page, or all pages when using a landscape log form, clear the check box immediately below the entry lock icon.



To Hard Lock Data:

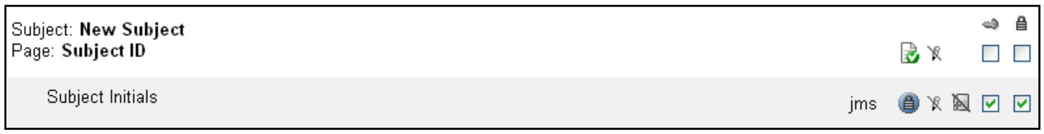
1. Click the check box or check boxes, (beneath the hard lock icon) corresponding to the appropriate data fields.



Note: To hard lock all the data fields in the form at once, click the check box immediately beneath the hard lock icon to select all data fields. On a landscape log form containing pagination, clicking this check box on any page will hard lock all data fields on all pages at once.

2. Click **Save**.

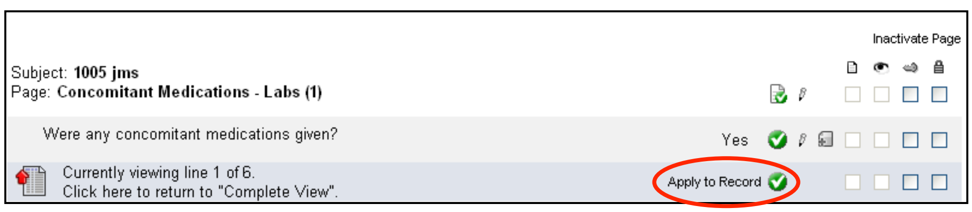
 ➪ Upon the hard lock of data, the open check box is replaced with the hard lock icon, and the edit icon is cancelled out.



Or

 ➪ If a user has access to unlock data, a checkmark remains in the check box. To unlock a data point, click and remove the check mark from the check box. To unlock all data fields on one page, or on all pages when using a landscape log form, clear the check box immediately below the hard lock icon.

> **Note**: When the verify, review, freeze and/or lock option is used on a log form on the Apply to Record row, the option is only applied to the current log line and not to the whole form.



> **Note:** The ability to save freeze and lock choices is disabled during the eSignature process. Refer to the "Electronic Signatures in Batch" section in this manual for more information.

Electronic Signature

Depending on role permissions, an electronic signature is captured to attest that data has been reviewed and deemed to be accurate. Electronic signature requirements are configurable by the sponsor; the sponsor specifies which data points require an electronic signature and if only one signature (the password) is required or an additional signature (the User ID or pin) is required.

> **Note:** iMedidata users will use their iMedidata login credentials as their electronic signature.

Electronic signatures can be obtained at three different levels:

- Subject level
- Folder level
- Form level

Electronic signatures can be applied in two ways, depending on user permissions:

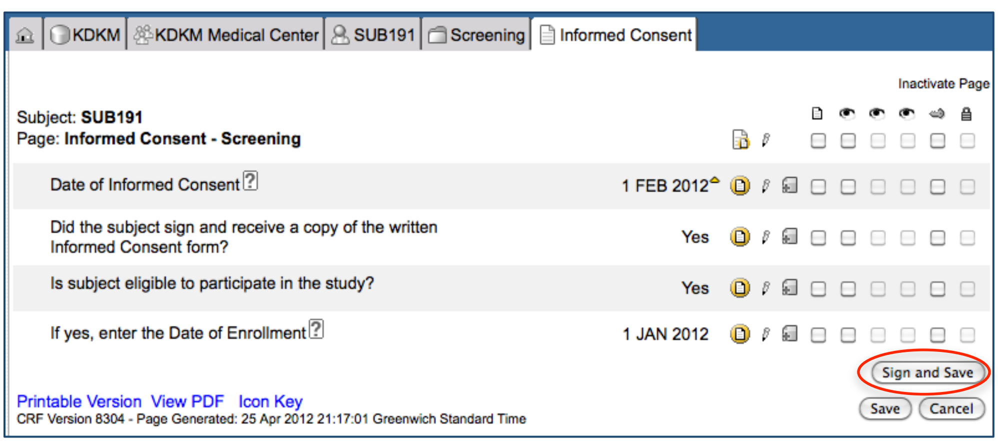
- By way of an electronic signature on a form
- By way of batch signature functionality

Electronic signature on a form

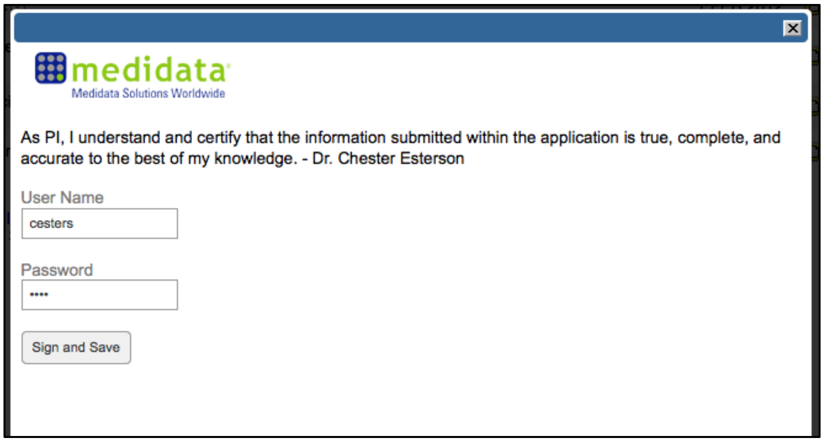
Depending on a user's permissions, a user may be able to sign off on a subject, folder, or form using the **Sign and Save** button.

To Apply an Electronic Signature to a Form:

1. Click the **Sign and** Save button located on the bottom of the eCRF.

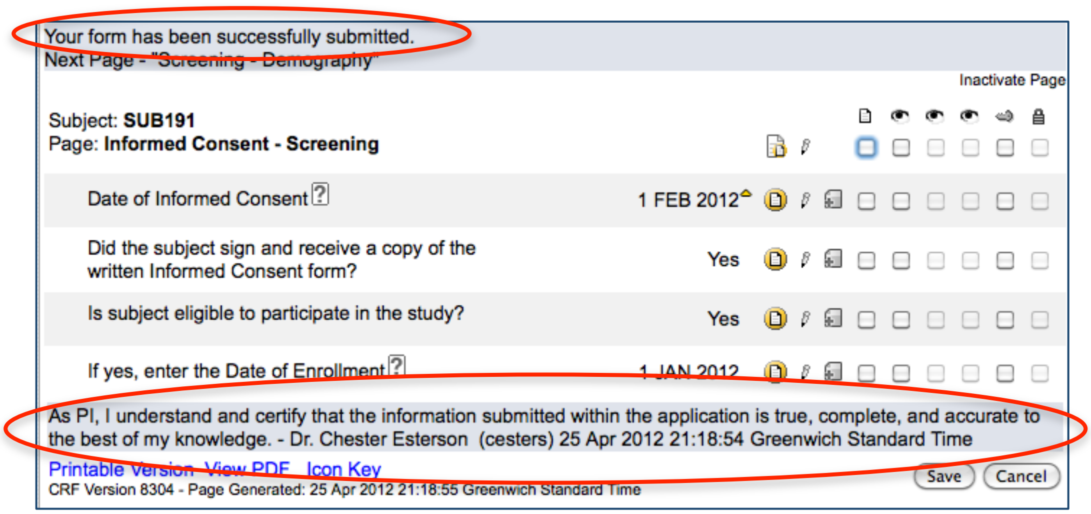


2. A popup window will appear. Read the verification message and then enter your credentials as labeled on the screen (password and User ID or PIN).

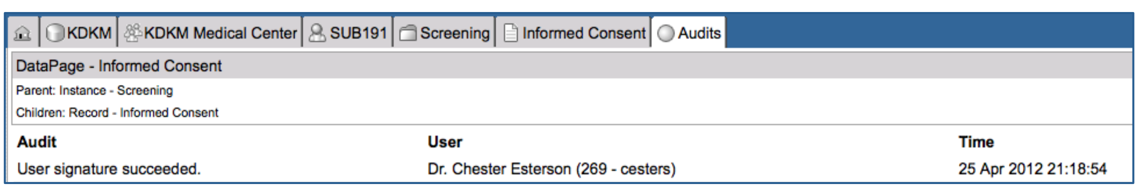


3. Click Sign and Save.

The electronic signature is captured on the eCRF, as depicted below.



The signature transaction is also saved in the Audit Trail.



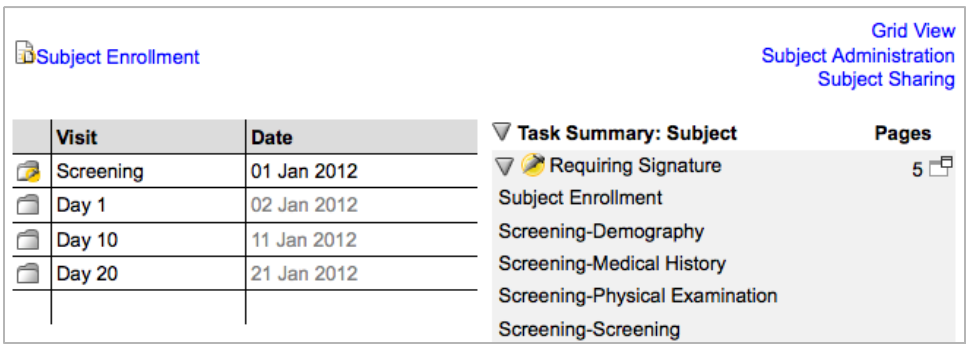
Note: If the system has been configured to require multiple parameters (for example, password and PIN or password and username), then the first time the investigator signs off on a form, they will be prompted to enter both parameters. Once this signature has been entered, a timer starts. If any additional forms are signed within a specific time period, only the password is necessary. If any additional forms are signed after the specific time period, both parameters will be required. The sponsor specifies the amount of time configured for the timer.

Electronic Signature in Batch

Depending on their permissions, users may be able to **batch sign** forms directly from either the subject home page or in Grid View. Batch signing enables a user to sign off on multiple folders and forms at once for a subject. Batch signing using the grid view will be discussed in the Grid View section.

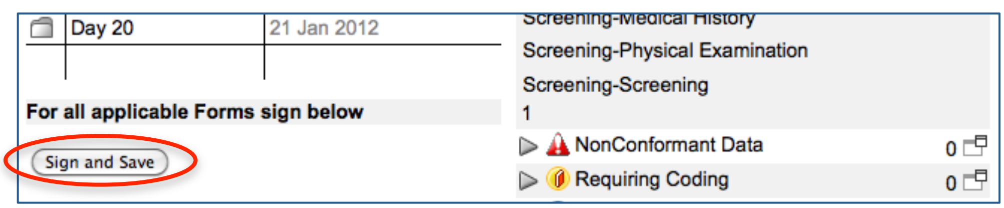
In the Subject Schedule, any folders displayed with the "Requires Signature" status icon indicate that all forms in that folder are ready to be signed. A user may see another status icon if there is at least one form in the folder that is set to a status higher than the "Requires Signature" status. (Please see the *Medidata Rave Icon Hierarchy* topic in the Appendix for more information.) Batch signing will only apply the signature to the forms in a folder that are ready to be signed.

Additionally, the Task Summary will display the forms that require signature. When users access each form, they will view the same predefined message on each page that requires the signature.



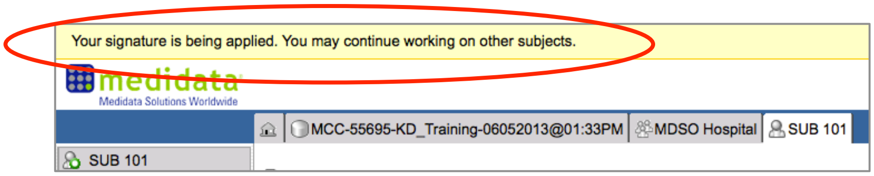
To Batch Sign Forms from the Subject Home Page:

1. Click the **Sign and Save** button.



2. Enter your credentials as displayed on the screen.

3. Click Sign and Save. A message will appear indicating that signatures are being applied to forms for the subject. The electronic signature process runs in the background, allowing you to move on to another subject to batch sign forms during this time, if necessary.



4. Refresh the page to see the updated status icons, or navigate to another page to continue working.

> **Note:** After the signature process is complete, the 'signature being applied' message will remain on the screen until the page is refreshed or you navigate to another page.

While signatures are being applied, no one can edit data, save data verification and locking choices, modify templates, or add/inactivate/reactivate log lines for the subject until the electronic signature process is complete. Users who navigate to eCRFs for the same subject will see the Save button and all edit pencils disabled until the process is complete and the page is refreshed.

As with electronic signatures for forms, individual field statuses will rollup to the next status once a folder is signed, and the audit trail will log the eSignature.

Invalid Credentials

Entering an invalid username, PIN, or password will prompt an error message to appear, indicating that the signature has failed. Re-enter the information correctly to sign the eCRFs successfully.

Rave EDC will automatically logout after continuous failed signature attempts. The user must log back into Rave with the correct credentials and navigate back to the eCRF to proceed.

Broken Signatures

The electronic signature includes the user's name and User ID, as well as the date and time the signature was applied. With the exception of changing a field's code or translating a field, any change to a form or datapoint within a previously signed folder or field will break that folder's or field's signature, and will require the user to sign the affected folders or fields again. The status of the affected datapoints will reflect these signature changes.

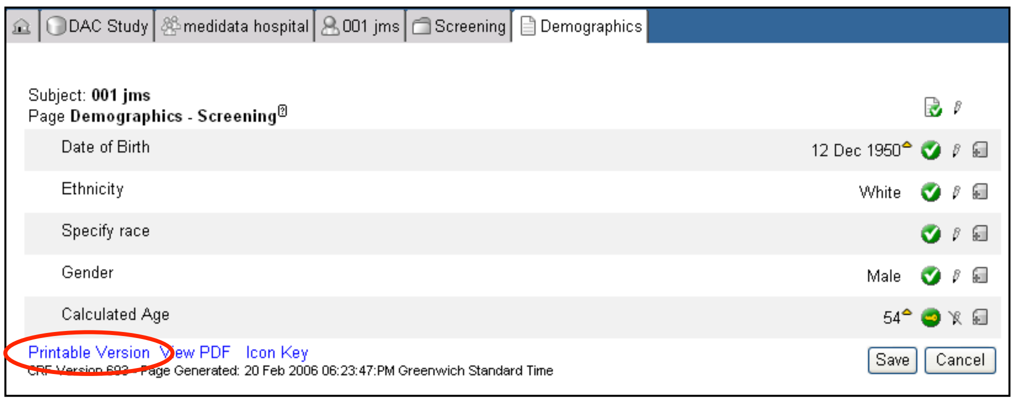
Printing eCRFs

Within the Rave user interface, eCRFs can be printed exactly as they are displayed on screen. They can be printed either before or after data has been entered. There is also an option to open the eCRF in a PDF format. The page can then be printed and stored as a PDF file. A PDF reading program must be installed to use this option.

To Print an eCRF:

1. Navigate to a form in the EDC module.

2. In the lower left of the main area, click the **Printable Version** link to display the print dialog box.

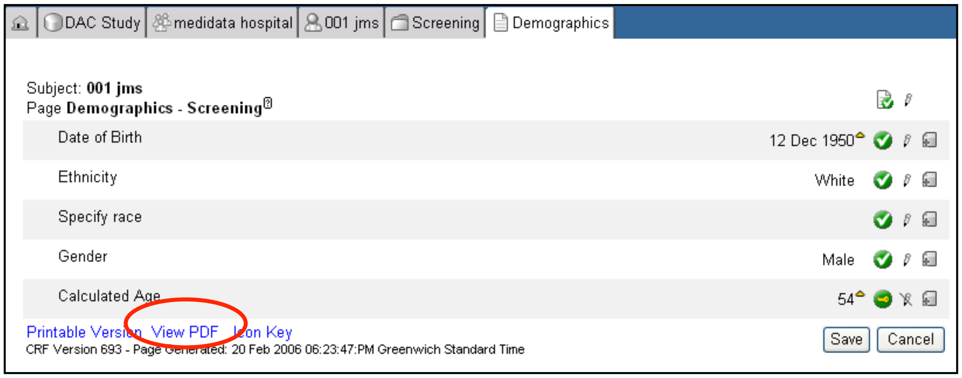


3. Select a printer, specify print options, and click **Print**.

> **Note**: Contact your IT administrator for question regarding the installation of printers, print options, and print settings.

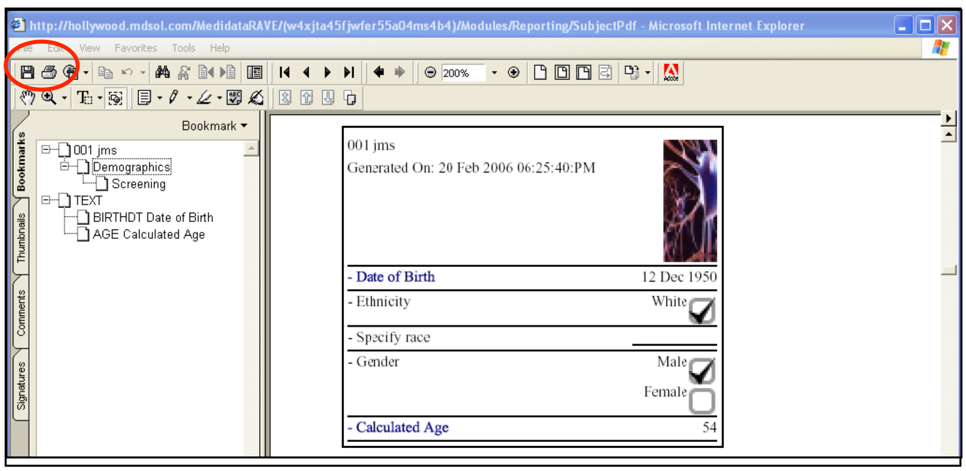
To Print a PDF:

1. Click the **View PDF** link.



2. When the PDF window opens, click the **Print** button.

3. Click the **Save** button to save the eCRF.



4. Close the PDF window to return to the Rave application.

Subject Maintenance

This chapter will cover the following topics:

- Grid View
- Subject Administration
- Subject Sharing

Grid View

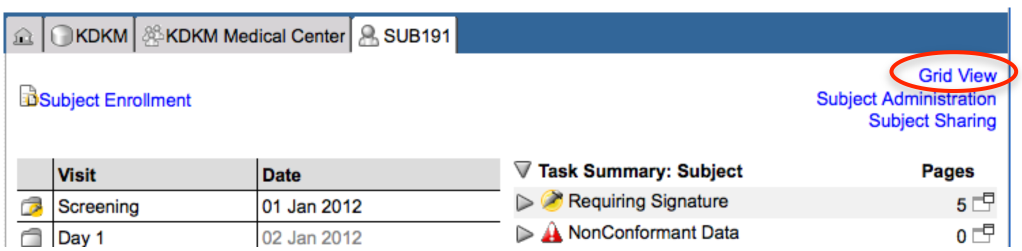
The grid view link changes the display of the subject home page such that all of the subject's top-level folders and forms appear in a grid format.

Accessing the Grid View

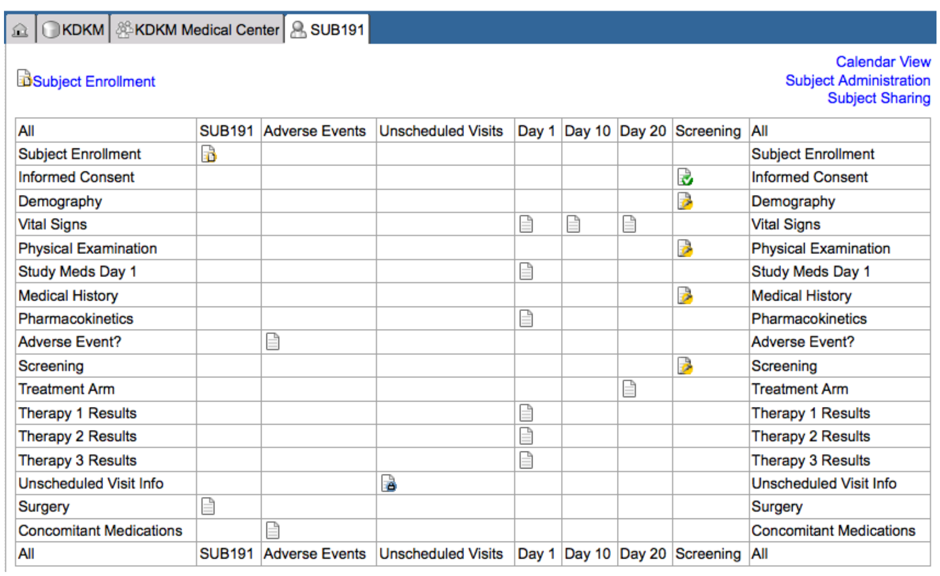
In order to access the grid view, the user must have the grid view permission set in the Configuration module.

To Access the Grid View:

1. Navigate to a subject's home page.
2. Click the **Grid View** link on the upper right corner of the page. The grid view is displayed in the main area of the screen

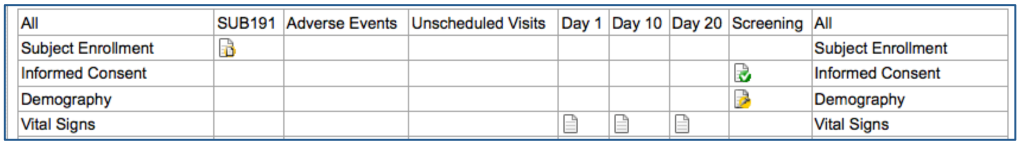


Within the Grid View

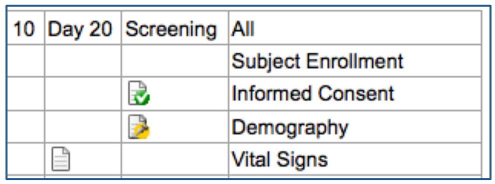


- ❑ The folders and the forms are arranged by Record Date Time.
- ❑ The folders and first level subfolders display in columns, and the forms display in rows.
- ❑ A cell showing a form icon indicates that a form is in the specified folder(s). For example, the Vital Signs form is in the Day 1, Day 10

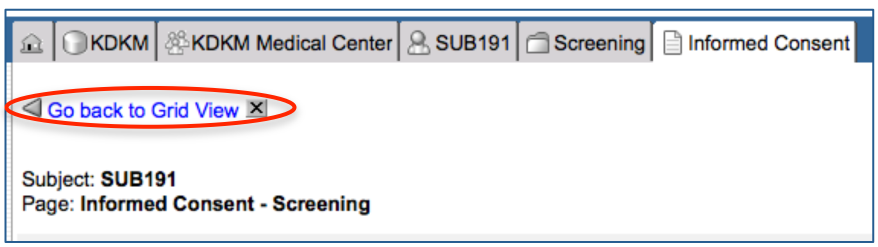
and Day 20 folder, but not in the Adverse Events folder. If there is no form, the cell will be blank.



- The form icon will also indicate the overall status icon of the form. For example, the Informed Consent form is set to the Entry Complete status, and the Demography form is set to the Requires Signature status.



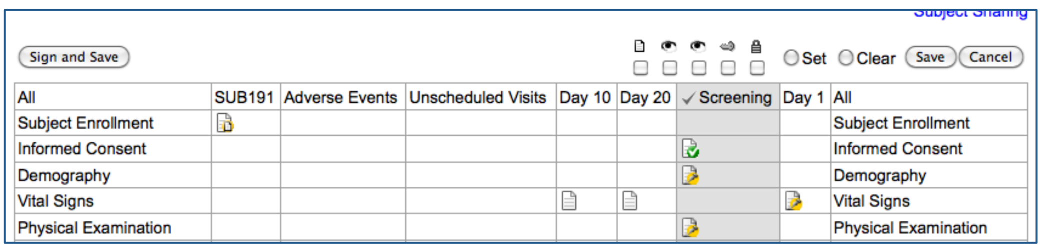
- Clicking an icon will display that form in the main area, where a user can perform normal tasks. Click the **Go back to Grid View** link at the top of the form to return to the grid. Click the **X** icon to hide that link, if desired.



Performing Actions Using the Grid View

Depending on permissions, users can verify, review, freeze, lock, or apply a batch signature to data in the grid view. A user can perform an action on all forms within a folder, for a form that spans across multiple folders, or for all forms and folders.

To select a folder, click the column header. To select a form across all folders, click the row header. Click the **All** header to select all forms and folders. Once selected, a checkmark will appear next to the header selected.



To Verify, Review, Freeze, or Lock using Grid View:

1. Click the column header, row header or All header.
2. On the top of the grid, select the desired action(s) to perform by checking the appropriate action control check boxes.

3. Select the **Set** radio button.

> **Note**: Hover your mouse pointer above the action icon to display a tooltip indicating what action the icon represents.

4. Click **Save**.

The affected icons are updated to reflect their new status.

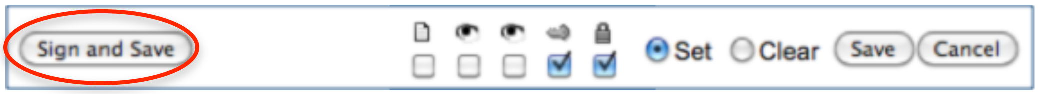
> **Note**: Setting Lock All will disable Add Events. Similarly, clearing Lock All will enable Add Events. Refer to the "Disabling Add Events" section in this manual for additional information.

To Batch Sign using the Grid View:

Note: The Sign and Save button will appear if at least one form that requires a signature is selected. If no forms that require a signature are selected, the button will not appear.

1. Click the column header, row header, or All header.

2. Click the **Sign and Save** button.



3. A popup window will appear. Read the verification message and then enter your credentials as labelled on the screen (password and User ID or PIN).

4. Click **Sign and Save**.

5. A message will appear indicating that signatures are being applied to forms for the subject. The electronic signature process runs in the background. Refer to the "Electronic Signature in Batch" section of this manual for more information.

6. The affected icons are updated to reflect their new status.

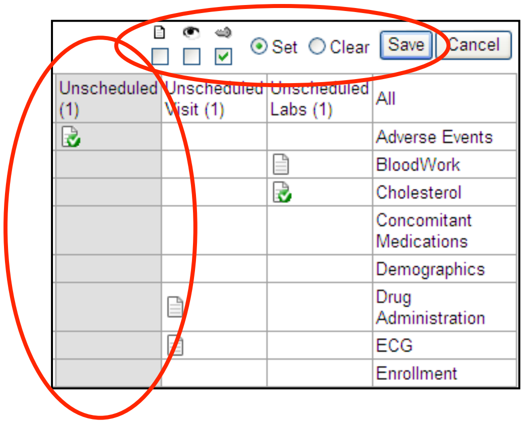
Note: Signatures cannot be undone by way of the grid view. Signatures are automatically undone, or broken, when data to which that signature is applied has been changed.

Applying Actions to Parent Folders

If a folder has subfolders, the system can be set up so that if an action is directed toward a parent folder, the same action will be propagated to the folder's subfolders.

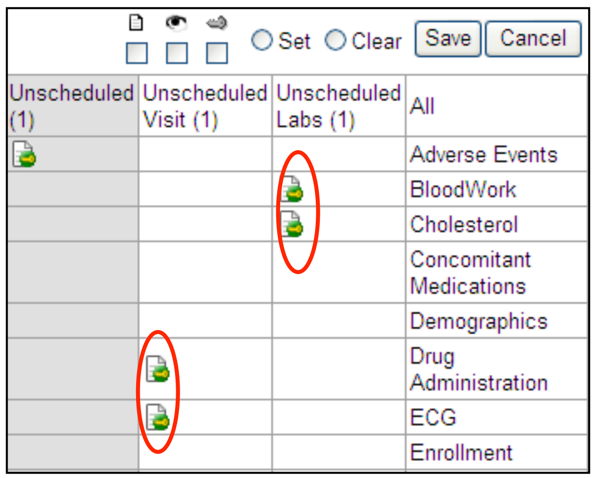
To Perform an Action across Subfolders

1. Click on a folder that has subfolders.



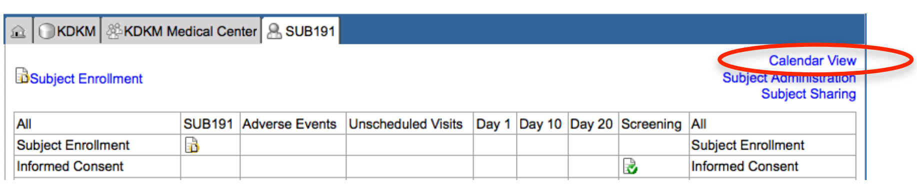
2. Click on an action, Set, and Save.

3. Review how the same action has been propagated to all subfolders.



To Return to Calendar View

Click the **Calendar View** link displayed above the grid to return to the calendar view of the subject home page.



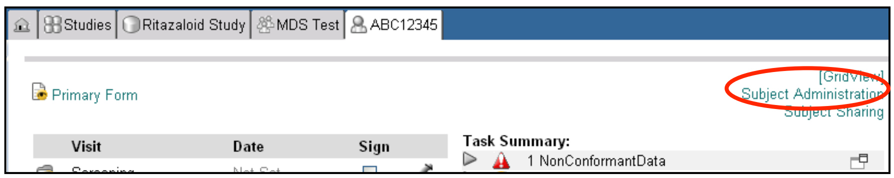
Subject Administration

The subject administration feature allows addition, activation, or inactivation of forms and folders for a particular subject by authorized users. This feature is used to customize the default matrix assigned to a subject.

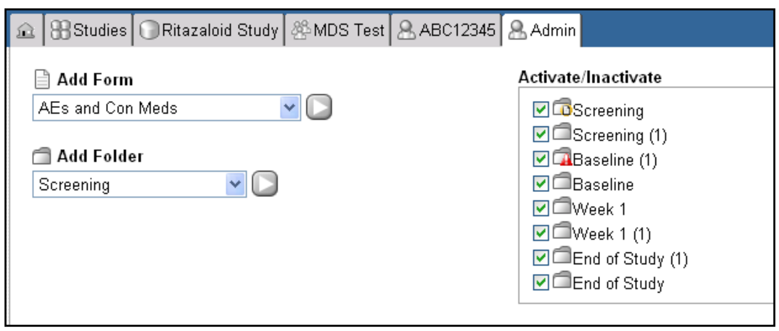
> **Note**: Access to subject administration is based upon role privilege.

To Access the Subject Administration Page:

1. Click the **Subject Administration** link on the right side of the main page:



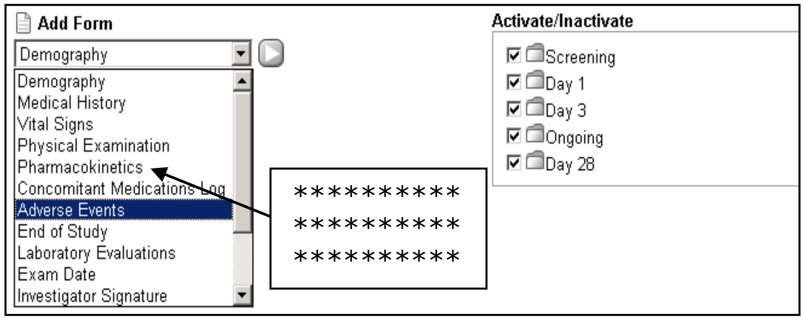
2. The Subject Administration page opens:



> **Note**: For the subsections listed below, the Activate/Inactivate checkboxes and the Save button are disabled during the eSignature process. Refer to the "Electronic Signatures in Batch" section in this manual for more information.

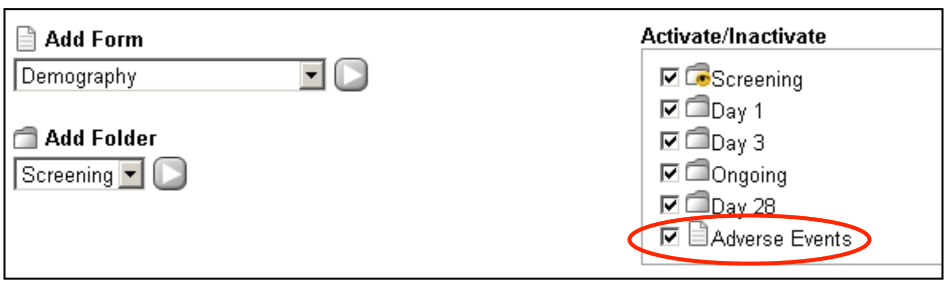
To Add a Form or Folder to the Subject Matrix:

1. Select a form from the Add Form dropdown menu or a folder from the Add Folder dropdown menu.



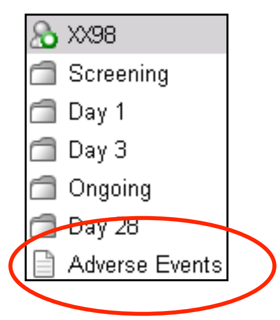
- ❑ Click the **Arrow** icon to the right of the dropdown menu.

- ❑ The form is added to the Activate/Inactivate table.



> **Note**: All forms listed with a check mark in the Activate/Inactivate table make up the subject matrix. Active folders that contain no forms are displayed with a lock icon, but when forms are added, the lock icon is no longer displayed.

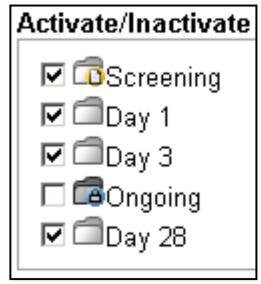
When the user returns to the subject's home page, the new form or folder is displayed in the subject matrix.



> **Note**: Click on a folder to view and inactivate/activate the forms within that folder. Exit out of the folder using the navigation tabs at the top of the main area.

To Remove a Form or Folder from the Subject Matrix:

1. Deselect the folder from the Activate/Inactivate table by deselecting the check mark associated with the folder.



2. When the check mark is removed, the folder is inactive and removed from the matrix located in the sidebar.

Note: To inactivate forms within the matrix, access the form by clicking on the folder that contains the desired form and follow the steps above.

Subject Sharing

Subjects can be shared across sites within a study. When a subject is shared, all shared sites can view and enter data for that subject. There is no limit to the number of subjects that can be shared or the number of sites that can share a subject.

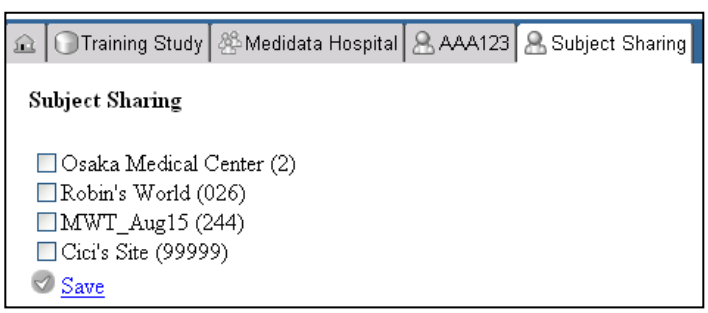
In order to share a subject, a user with subject sharing permissions can share the subject with other sites as configured within the system.

The site that initially creates the subject is the primary site. The sites that share the subject with the primary site are secondary sites. All shares must be designated by the primary site; secondary sites cannot initiate shares of a subject with other sites.

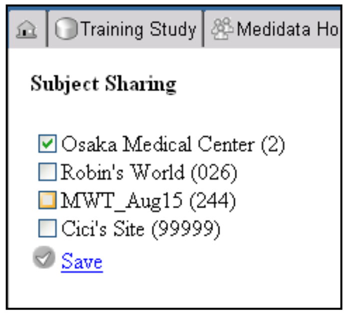
To Share a Subject from the Primary Site:

1. Select a subject in the EDC module to display the subject home page.
2. Click the **Subject Sharing** link in the upper right corner of the main area to display the Subject Sharing page.

The Subject Sharing page displays a list of sites that have established sharing relationships with the subject's primary site.



3. Check the box(es) next to the site(s) that will be secondary sites for the selected subject.



4. Click **Save**. The system updates the information and makes the subject available to the secondary site(s).

Note: If a subject that is shared is reassigned to another primary site, all previous site relationships are removed.

Appendix A: Icon Key

This section will cover the following topics:

- Medidata Rave Icon Key
- Medidata Rave Icon Hierarchy Overview

Medidata Rave Icon Key

The following icons are used throughout the Rave modules.

Status Icons			
	Never Touched		Overdue
	Answered Query		Locked
	Incomplete		Inactive
	Requires Verification		Requires Translation
	Not Conformant		Requires Coding
	Requires Review		Requires Signature
	Complete		Query Open
	Entry Lock	--	--
EDC Module Icons			
	CRF blank form – file		Site Group
	Folder		Site
	Folder not available to user		Study
	Subject		Studies
CRF Icons			
	Verify		Out of Range High
	Freeze		Alert High
	Review		Out of Range Low
	Lock		Alert Low
	Marking	?	Open Query
	Protocol Deviation		Answered Query
	Task Summary Pop-up		Edit
	Comments		Edit not available
	Sticky Notes		Data has changed

You can determine the status for each object by looking at the status icon that is displayed on that object. For example, if a subject contains non-conformant data, the subject icon will display the non-conformant icon.

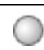
If a folder contains an open query, the folder icon will display the open query  icon.

The same logic applies for all the objects: Subject, Folder, Form, and Field. The icon displayed on each object is dependent on the status of the data within the object and the icon hierarchy. See the next section in this manual for additional information.

Medidata Rave Icon Hierarchy Overview

The icon hierarchy rules within the Medidata Rave application remain the same whether referencing a specific field, form, folder, or subject. In general, as one goes up the hierarchy (for example, field to form), the icon that is displayed depends on which status takes precedence over another as the statuses are rolled up. It should also be noted that the status icons appear in Rave based on the user's role permissions (for example, if a user does not have the Coding role action, then they should not see the Coding status icon).

The following table illustrates the icon status hierarchy in the Rave system:

Status	Icon
Non Conformant	
Locked	
Open Query	
Answered Query	
Requires Translation	
Requires Coding	
Requires Verification	
Requires Review	
Read-only Opened Query	
Read-only Answered Query	
Pending for Verification	
Is Overdue	
Pending for Review	
Entry Locked	
Untouched	
Incomplete	
Requires Signature	
Entered Complete	
Entered Empty	
Inactive	

> **Note**: The icons shown are the data status icons. They can be applied to any level of the system you are accessing. For example, if there is a non-conformant field on some form for a particular subject, and you are accessing the Subject page for the subject in question, then the icon shown is subject non-conformant.

When statuses are rolled up for a form, folder, and subject, it helps ensure that the user knows what tasks they need to complete.

Typically, the status with the highest position in the status icon hierarchy will be displayed for a given object.

For example: A form contains three fields:

- One has a status of "never touched,"
- One has a status of "requires verification," and
- One has a status of "requires review."

In this case, the form will display a status of "requires verification," because that is the highest status of those three in the hierarchy.

You can take the example further. Suppose that the form described above is in a folder with two other forms.

- One form has a status of "open query,"
- One form has a status of "requires review," and
- The form described above has a status of "requires verification."

In this case, the folder will have a status of "open query," because that is the highest status of those three in the hierarchy.

There are a few exceptions to the general behavior described above. The exceptions are fields with the following status: open query, locked, and non-conformant.

In the icon hierarchy, "non-conformant" is the highest status. If there is a "non-conformant" field on a form, regardless of what other statuses are on that form, the form will display the "non-conformant" icon, the folder containing that form will display the "non-conformant" icon, and the subject will display the "non-conformant" icon.

The next status in the hierarchy is "locked," followed by "open query" and "answered query." The roll ups of these statuses behave a little differently than the others. For the other statuses, the highest status in the hierarchy will roll up to the form, folder, or subject, as we saw in the prior examples. In the case of "open query" and "answer query," even though "locked" is higher up than they are in the hierarchy, the "locked" status will not roll up to the form, folder, or subject. The following is an example to illustrate this point.

A form contains three fields:

- One field has a status of "open query,"
- One field has a status of "locked," and
- One field has a status of "requires verification."

In this case, the form will display a status of "open query," even though "locked" is the highest status in the icon hierarchy of the three. The "open query" status displays at the form level, so that the end-user knows they have an action to take.

If the form was in a folder with two other forms, one with a status of "locked" and one with a status of "incomplete," then the folder would still display the "open query" icon, because again, even though "locked" is higher in the hierarchy, the end-user needs to know about their open queries.

If the field containing the open query is locked, the status of that field turns to "locked"; however, the status of the form remains "open query," so the end-user knows the query is there.

If the whole form is locked, the status of the form would remain "open query." If the whole folder is "locked," the status of the folder remains "open query." If the whole subject is locked, the status will finally turn to "locked." The same logic applies for the "answered query" status.