DataLabs

User's Guide

v 4.6

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Preface

What's New in Version 4.6

The following enhancements have been made in DataLabs v4.6:

- **Add pre-defined events and forms to a patient's casebook**

  DataLabs 4.6 introduces the ability for DataLabs users to publish a set of pre-defined events and forms to a patient's casebook. The set(s) of events a user can publish is determined by the event cycles defined for the study in Designer.

  A user's ability to add events is controlled by security permission.

- **Edit or delete unscheduled events from a patient's casebook**

  DataLabs 4.6 introduces the ability for DataLabs users to edit the information for an unscheduled event that has been added to a patient's casebook. Users can rename the event, add or remove forms, or re-order forms for an unscheduled event. Users also have the ability to delete an unscheduled event.

  A user's ability to edit unscheduled events is controlled by security permission.

- **Blank CRF Report**

  This report is a hard copy of the electronic DataLabs patient casebook. This paper version contains a snapshot of each DataLabs system form displayed on the end-user's screen as patient data is entered.

- **Disabled event date**

  DataLabs 4.6 prohibits users from entering an event date for an event identified in the study design as having a disabled event date.

Chapter 1: Getting Started

About this Guide

This guide is intended to give you a comprehensive introduction to the DataLabs system. This guide is not intended to be an exhaustive guide on everything you may need to know about DataLabs. Instead, it is meant to be a jumping off point to get you started and introduce you to DataLabs basic functions. This guide assumes that you have a basic knowledge of and some experience with computers, but at the same time does not expect you to be a "power user."

This guide is to be used in conjunction with the instructor-led interactive demonstration and instruction. The training session is an interactive demonstration that consists of step-by-step instructions and exercises to assist you in using DataLabs for entering and reviewing patient data.

Who Should Read This Guide

This guide is designed for all study personnel who will be using the DataLabs system to enter and sign patient data as well as review and monitor patient data. All the topics covered and the examples used in this guide relate to all users except the paper data entry portal. Therefore, its intended readers include:

- System administrators

- Data managers

- Site personnel

- Primary investigators

- Field monitors

- Medical monitors

- Anyone else working in data management, the review process

How to Use This Guide

This guide uses the following conventions.

To show which steps and procedures to follow:

- Each step is numbered.

- Any text you need to type is in a typewriter font, which you must type exactly as it appears.

- Important **fields**, **buttons**, and **terms** are shown in bold text.

- Keys you press are shown in SMALL CAPS: for example, TAB, ENTER, SHIFT+F3 (hold down SHIFT and press F3).

- Notes including cautions, notes, tips, and examples:

  - **Cautions:** Alert you that failure to take or avoid a specific action might result in loss of data or hinder you from using DataLabs properly.

  - **Notes:** Emphasize or supplement information already described.

  - **Tips:** Give you shortcuts or extra information that will make what you are doing simpler, faster, or with fewer errors.

  - **Examples:** Use imaginary scenarios, case studies, or sample data to illustrate how to carry out a procedure or to illustrate a concept.

Setting up Your Desktop and Browser

Before you begin using DataLabs, make sure your desktop and browser are set up as described in the sections that follow.

Screen Resolution

DataLabs is designed for screen resolutions of **1024 x 768 or greater**. If your screen resolution is less than this, some DataLabs pages may not fit on your screen.

Multiple Browser Windows

Open DataLabs in one browser window only. When you open DataLabs, a session is created between the browser and the DataLabs database. Opening DataLabs in more than one browser window may cause DataLabs to send or receive the wrong information.

Changing the Browser Security Settings

Your browser must accept **cookies** in order to log in to DataLabs. Therefore your Privacy level can be set to no higher than Medium High in Internet Options.

To change your privacy level to accept cookies:

1   Start Internet Explorer.

2   On the Tools menu, click Internet Options. The Internet Options dialog box appears.

3   Click the Privacy tab.

4   Move the slider bar to one of the following settings:

- Medium

- Medium High

Do not select any of the following settings:

- Accept All Cookies

- Block All Cookies

5   Click **OK**.

To add the study website as a managed site:

1   Start Internet Explorer.

2   On the Tools menu, click Internet Options. The Internet Options dialog box appears.

3   Click the Privacy tab.

4   Click **Sites**. The Per Site Privacy Actions dialog box appears

5   In Address of website, enter the URL for the study.

6   Click **Allow**.

7   Click **OK**.

Disabling Script Debugging and Error Notification

Script debugging is a feature of Internet Explorer that checks a webpage for scripting errors when the page is loaded into the browser. DataLabs requires that your browser must have **script debugging** *disabled*. Also, script error notification should be enabled.

By default, Internet Explorer has the **Disable script debugging** box checked and the **Display a notification about every script error** box cleared.

To change your script debugging and Script Error notification settings:

1   Start Internet Explorer.

2   On the Tools menu, click Internet Options. The Internet Options dialog box appears.

3   Click the Advanced tab.

4   Under Settings, in the Browsing section, **check** the following boxes:

Disable script debugging

Display a notification about every script error

5   Click **OK**.

Adobe Acrobat

DataLabs supports Adobe Acrobat Reader version 7.0 and above. You can download the Adobe Acrobat Reader for free from Adobe's official website at www.adobe.com/downloads.

Getting Help

If you encounter any problems while using DataLabs, take the following steps:

1   Check this guide or the online help to see if it covers your question. For other information related to possible problems see Appendices: Troubleshooting on page 361.

2   Contact the technical support desk:

Phone: **+1 (888) 998-7941**

Email: **techsupport@clinphone.com**

Logging in to DataLabs

DataLabs is a web application. In order to log in to DataLabs, you must have the following:

- An Internet connection

- Internet Explorer 6, 7, or 8

- A DataLabs username and password

- The website address of the study you want to access

DataLabs Usernames and Passwords

Because DataLabs contains critical, sensitive, and confidential data, it is designed to be highly secure from unauthorized users who might want to explore its contents or alter information. Your username and password controls *who* has access to the DataLabs application and *what parts* of the data you have access to.

Every user must have an individual and unique username and password. Users cannot share a logon, since all activities and study data entered into DataLabs must be traced back to individual users. Keep your username and password secret so that no one else can log in to DataLabs as *you*.

Study Website Address

The DataLabs application is accessed from Internet Explorer. Since each study is identified by a unique address (assigned by the system administrator), the address you type is specific to your study. If you have been assigned to work on more than one clinical trial at a time, each study will have a different address.

Logging in to the DataLabs System

To log in to the study for your clinical trial:

1 Start Internet Explorer.

2 In the Address field at the top of your Internet Explorer window, enter the website address of the study you want to access.

3 Press ENTER. DataLabs prompts you for your username and password.

Depending on what version of Windows you are using, your logon dialog box may look different:

Windows XP   **Vista**
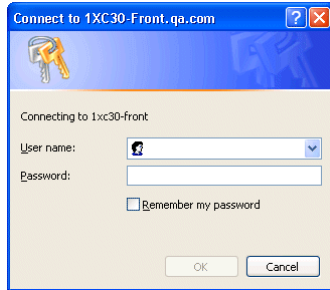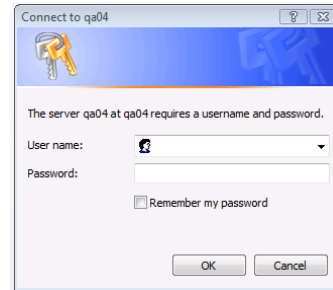
4   In the **User name** field, type **domainname\username**.

Example: For example, if the domain is "vialithival" and your Username is "Nrichards1" type both separating them with a \ (backslash): **vialithival\Nrichards1**.

---

5   In the **Password** field, type your password.

6   Clear the **Remember my password** check box.

7   Click **OK**.

DataLabs opens the Activity log. This window lists the last 10 actions you've performed in DataLabs, shows the number of items checked out to you, and shows a warning if your password will expire in 14 days or less.

Note: If you click the link to change your password, the Change Password page appears. For more information on changing your password, see Changing Your Password on page 50.

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8   Click **Close**.

Note: You must close the Activity Log before you can access the DataLabs system.

DataLabs opens with the **Patients** tab showing all sites and listing the patient count for each status.

Possible Error Messages When Logging In

Note: Your username or password can only be recovered automatically (emailed to you) if your user account is active and a unique email address is associated with your user account. The email address associated with your username is set up on the **User Preferences** page.

The username or password you entered is incorrect. Try logging in again.

You can try logging in again, request your username or reset your password.

- To try logging in again, click the **Try logging in again** link. The login dialog box appears. Enter your username and password and click **OK**.

- To request your username, click the **Forgot your username** link. The Forgot your username dialog box appears. Enter the email address associated with your username. Then, enter the word that appears in the **Security Check** box and click **Submit**.

    DataLabs sends an email to your email address. The email contains your username and a link to the study.

- Reset your password, click the **Forgot your password** link. The Forgot your password dialog box appears. Enter your username. Then, enter the word that appears in the **Security Check** box and click **Submit**.

    DataLabs sends an email to the email address associated with your username. The email contains a link that allows you to reset your password. The link expires 24 hours after the email is sent.

You are required to change your password because this is either your first time logging in to the system or because your password was reset.

Enter your current password and then enter and confirm a new password.

You are required to change your password because your password has expired.

Enter your current password and then enter and confirm a new password.

Your user account has been locked. Please try again in xx minutes and xx seconds.

Try again after the specified number of minutes and seconds. If you have forgotten your password, click the **Forgot your password** link. Enter your username. Then, enter the word that appears in the **Security Check** box and click **Submit**.

DataLabs sends an email to the email address associated with your username. The email contains a link that allows you to reset your password. The link expires 24 hours after the email was sent.

You have attempted to login with an incorrect username and/or password too many times. Your account has been temporarily locked. You may try logging in later or you may unlock your account now by resetting your password using the link below.

Try again later or click the **Forgot your password** link. Enter your username. Then, enter the word that appears in the **Security Check** box and click **Submit**.

DataLabs sends an email to the email address associated with your username. The email contains a link that allows you to reset your password. The link expires 24 hours after the email was sent.

Your user account has been locked.

You must have your account unlocked manually.

Your user account is not active. Only active users may recover passwords.

You cannot automatically recover your password through DataLabs.

Bookmarking a Study

To avoid entering the address of the study website every time you want to access it, you can bookmark the study website.

**To add the study website to your list of Favorites:**

1   Start Internet Explorer.

2   In the Address field at the top of your Internet Explorer window, enter the website address of the study you want to bookmark.

3   On the Favorites menu, click **Add to Favorites**.

4   Type a **Name** to identify the study within your list of bookmarks.

5   Click **Add**.

Logging Out of DataLabs

When you are finished using DataLabs, log out. Logging out helps keep the system secure so that no one can use the system other than authorized users.

To log out of DataLabs:

■   Click the **Log out** link at the top of the page.

DataLabs logs you out of the system and displays a logout page with the message, "You have successfully logged out of the DataLabs system."

■   Click the button on the browser window.

Inactivity Timeout

If you are logged in to DataLabs but have not taken any recent actions, DataLabs will give you a warning two minutes before automatically logging you out of DataLabs.

If you click **Reset** to acknowledge the message, you remain logged in to the DataLabs system.

If you do not click **Reset** to acknowledge the message, you are automatically logged off of the DataLabs system.

The amount of time that you must be inactive before DataLabs automatically logs you off of the system is called the user inactivity timeout setting. This setting may vary from study to study, and is set by the study administrator. For more information on the User Inactivity Timeout setting, refer to the General tab section on page 77.

Chapter 2: The DataLabs Interface

Overview

This chapter covers the following material:

- DataLabs page layout

- Basic skills

- Navigating the Patients tab

- Navigating the CRFs tab

- Navigating the DCFs tab

The DataLabs Page

In order to use DataLabs effectively, it is important that you become familiar with the DataLabs page. A sample layout is illustrated below, followed by a detailed description of each of the key areas.
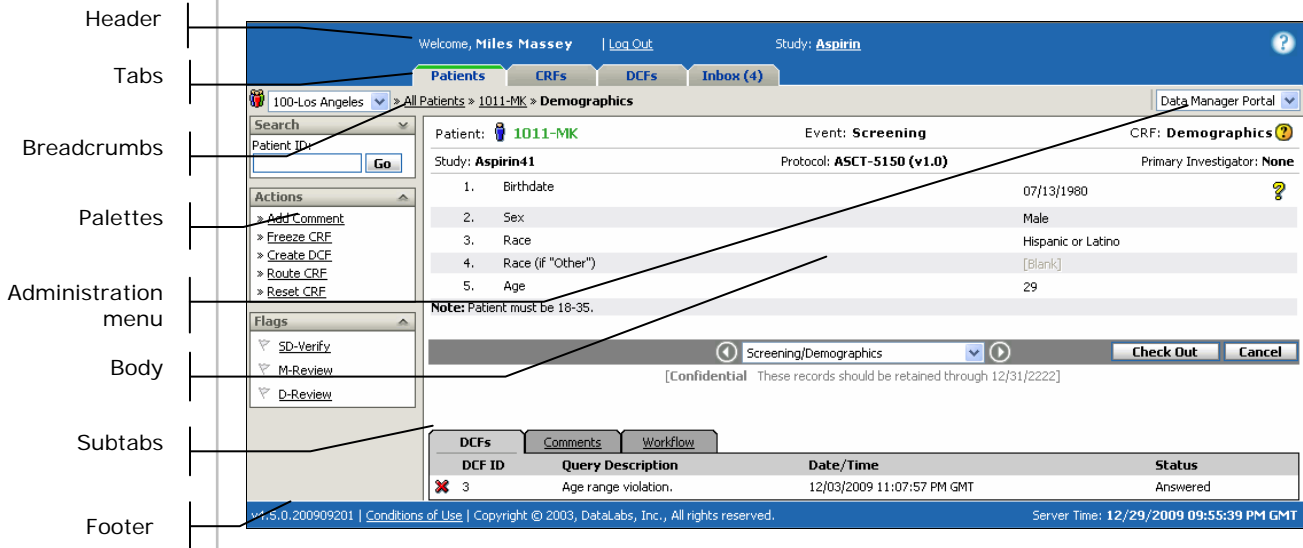
Header

Displays a logo, who is logged on, the study identifiers, and gives you access to Help.
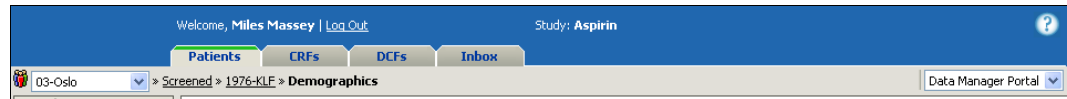
Logo: Displays a logo. This graphic can be replaced during the system setup.
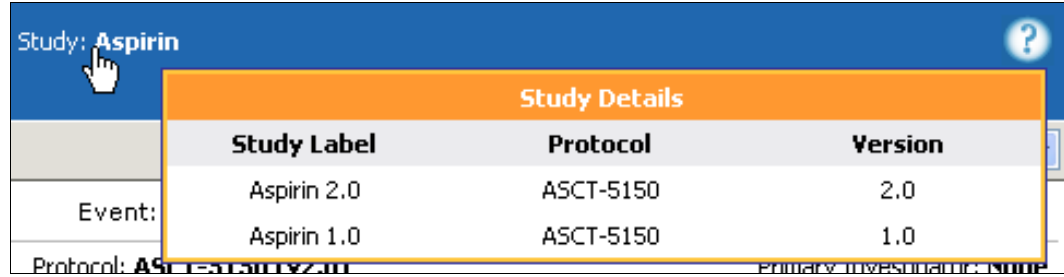
Name: Shows the Display Name of the user who is logged in.

Note: If a valid email address has not been entered for you in DataLabs, an alert icon ⚠ appears next to your display name. To enter your email address, see Changing Your User Preferences on page 47.

Log Out: Click this link to log out of DataLabs.

Study: Displays the study name. If you move your pointer over the study name, DataLabs displays more details about the study protocol and version:

Online Help

There are two kinds of Help in DataLabs: the system Help (accessible from the header by clicking the Help icon) and CRF Help (accessible from the form header). CRF Help opens a help file specifically for the CRF, which is written by the study designer.

DataLabs Help **:** Click here to open Help for the DataLabs system.

CRF Help **:** Click here to open Help for the CRF (if available).
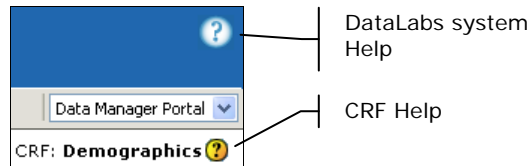
To learn how to add custom CRF Help to DataLabs, please refer to the *Installation Guide.*

Tabs

The Tabs give you access to study data from three different starting points as well as access to your DataLabs inbox:

Patients: Gives you access to the patient data in a patient-centric manner. For more information about the Patients tab, see The Patients Tab Navigation on page 27.

CRFs: Gives you access to the patient data in a CRF-centric manner. For more information about the CRFs tab, see The CRFs Tab Navigation on page 33.

DCFs: Gives you access to the patient data in a DCF-centric manner. For more information about the DCFs tab, see The DCFs Tab Navigation on page 39.

Inbox: Gives you access to the DataLabs messaging system. For more information about the Inbox tab, see Chapter 11: Inbox and Messages on page 333.

Breadcrumbs

Breadcrumbs show your current "path" in DataLabs. You can click any of the links on this bar to go back to a previous page in
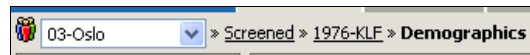
your path.

You can also click the All Patients icon (🖼) to go to the multi-patient view for the site.

Caution*: Do not* use your browser's Back button to backtrack as it may result in inaccurate data.

Administration Menu

Allows you to access user preferences, the administration features of DataLabs, the export functions, or your default portal.

```
Data Manager Portal   ▼
Data Manager Portal
-------------------
User Preferences
Study Administration
Export
Reporting
```
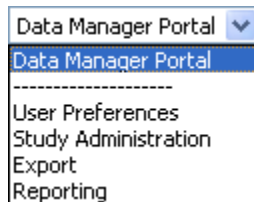
Palettes

Using the palettes on the left column of the page, you can:

■   Perform simple and complex searches.

■   Perform a variety of actions and commands.

■   View and change flag status.

■   View a summary of the data.

There are four basic kinds of palettes:

Search	Action	Flags	Summary

Search

```
Search                ▲
Patient ID:
[          ] [ Go ]
Patient Status:
[                ▼]
Signature Status:
[                ▼]
Data Status:
[                ▼]
```

Action

```
Actions               ▲
» Enroll Patient
» Fail Patient
» Add Unscheduled Event
» Request Signature
» Freeze CRFs
» M-Review CRFs
» D-Review CRFs
» SD-Verify CRFs
» Mark CRFs Not Collected
```

Flags

```
Flags                 ▲
✖ D-Review
✖ M-Review
✖ SD-Verify
```

Summary

```
Site Summary          ▲
  Screened:      44
  Failed:         1
  Enrolled:       5
  Discontinued:   0
  Completed:      0
  Signed:         0
  Frozen:         0
  Locked:         0
```

You can also collapse or expand palettes to conserve screen real estate.

To expand a palette:

■   Click the **Expand button** ⌄ at the top of the palette.
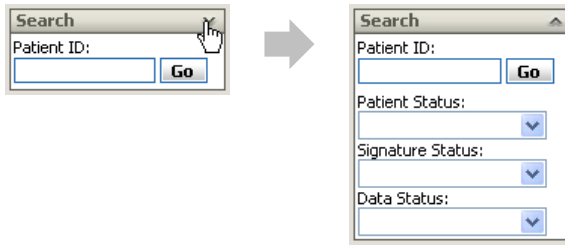
To collapse a palette:

■   Click the **Collapse button** ⌃ at the top of the palette.

Body

Allows you to list patients, CRFs or DCFs; or to display patient data. The body is your "work area." In the example below, the body contains a CRF form.

Subtabs

Allows you to view background and related information to the information contained in the body.

Here are a couple of examples of subtabs:

DCFs: Lists all DCFs generated for the CRF, including manually created and automatically generated DCFs, as well as active and closed DCFs. Clicking on the DCF opens the DCF.

	DCF ID	Query Description	Date/Time	Status
✖	1	AgeRange	11/14/2005 10:47:15 AM PST	Sent
✖	4	You selected "Other" for Race, but did not provide more detail.	11/14/2005 02:44:39 PM PST	Sent

(Tabs: DCFs | Comments | Workflow)

Comments: Lists all comments associated with the CRF, either pertaining to specific questions, or the entire form. Clicking on the comment opens it in view mode.

#	Value	Comment	Date/Time
Form	[Blank]	Patient was unsure of their father's race.	11/14/2005 02:48:26 PM PST

(Tabs: DCFs | Comments | Workflow)

Workflow: Lists each action taken for the CRF (or DCF), showing the most recent action first.

Action	Date/Time	User
Migration to ASCT-5150 (v2.0)	11/14/2005 10:54:15 AM PST	System User (system)
Submitted	11/14/2005 10:47:14 AM PST	Miles Massey (mmassey)
Published	11/14/2005 10:46:25 AM PST	Miles Massey (mmassey)

(Tabs: DCFs | Comments | Workflow)

Footer

Displays DataLabs's version number, conditions of use, copyright info and the *server's* current date and time (which may not be the same as *your* local time).

v4.6.0.200912240 | Conditions of Use | Copyright © 2003, DataLabs, Inc., All rights reserved.   Server Time: **12/30/2009 04:53:43 PM GMT**

The Patients Tab Navigation

The Patients tab allows you to work with a study in a patient-centric manner. Within the Patients tab, you can access four different pages, or views. As you progress, or "drill down," through the views you can perform various tasks.

The four views on the Patients tab are as follows:

| Patients: Multi-Site View |
| Patients: Multi-Patient View |
| Patient View |
| CRF View |
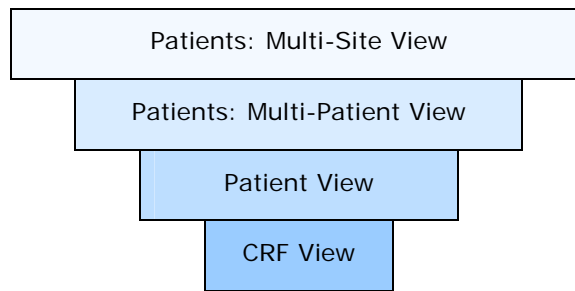
This introduction provides a high-level overview of the Patients tab. For more detailed information, see Chapter 5: Patient Workflow on page 155.

Patients Tab Navigation

Patients: Multi-Site View

Patients: Multi-Patient View

Patient View

CRF View

Click a site or a subtotal to see the Patients: Multi-Patient view.

Use the Search palette or click a patient ID to see the Patient view.

Click a CRF to see the CRF view.

Patients: Multi-Site View

The multi-site view is the main view for the Patients tab. It presents patient information at the highest level.

On this page you can see how the patients are progressing through the study by looking at the status columns. The status columns display the number of patients currently in each status.

For more information about patient statuses, see Chapter 5: Patient Workflow on page 155.

Patients: Multi-Patient View

The multi-patient view shows a list of patients and their status within the study.

There are three ways to access the multi-patient view:

- View all patients at a site.

- View patients at a site with a certain status.

- Search for patients.

On this page you can see how the patients are progressing through the study by looking at the status icons and flags. The goal is a row of green check marks (✔).

For more information about the Patients tab, see Chapter 5: Patient Workflow on page 155.

Patient View

The patient view is a summary of all events and forms associated with a patient.

There are three types of events:

Events: A patient protocol is broken out into a series of events. Each event—depending on how the study is set up—has a set of CRFs that are to be submitted.

Common: CRFs that do not correspond with one particular visit, but still contain important and necessary information regarding the patient. Common forms include patient status forms as well (screened, enrolled, etc.).

Unscheduled: Events that are not part of the original study design, but are necessary to collect patient data. For more information about adding unscheduled events, see Unscheduled Events on page 180.

On this page you can how the patient is progressing through the study events.

CRF View

The CRF view shows a single CRF for a patient.
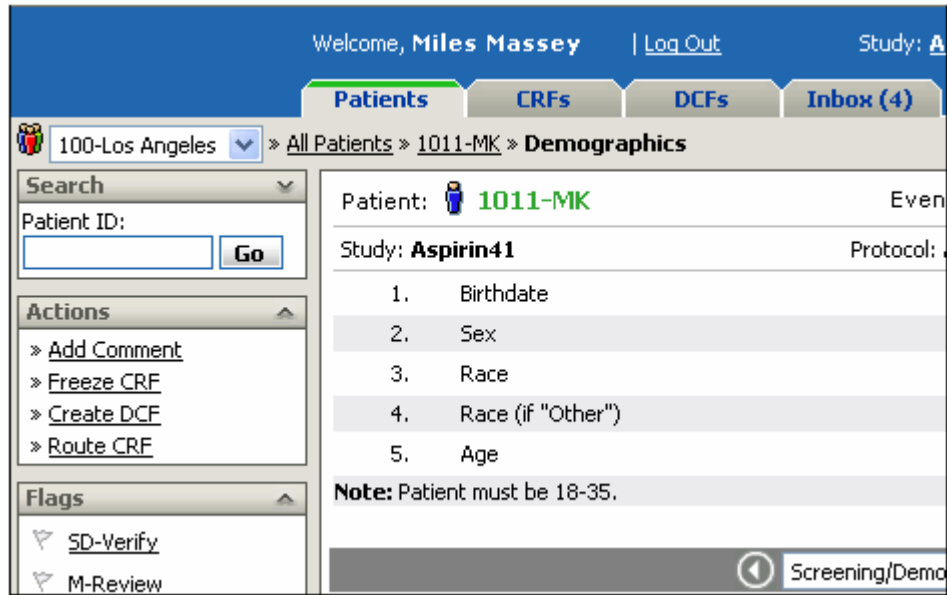
On this page you can enter patient data.

To ensure that only one user at a time is working on a CRF, DataLabs has a check in/out feature. You can check out the CRF on this page by clicking Check Out, or you can set your user preferences to automatically check out a CRF when you open it.

The CRFs Tab Navigation

The CRFs tab allows you to work with a study in a CRF-centric manner. Within the CRFs tab, you can access four different pages, or views. As you progress, or "drill down," through the views you can perform different tasks.

The four views on the CRFs tab are as follows:

This introduction provides a high-level overview of the CRFs tab. For more detailed information, see Chapter 6: Entering Patient Data (CRFs) on page 184.

CRFs Tab Navigation

CRFs: Multi-Site View

CRFs: Multi-Patient View

Multi-CRF View

CRF View

Click a site or a
subtotal to see the
CRFs: Multi-Patient
view.
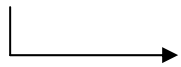
Use the Search
palette or click a
patient ID to see
the Patient view.
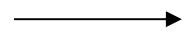
Click a CRF
to see the
CRF view.
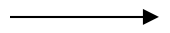
CRFs: Multi-Site View

The multi-site view is the main view for the CRFs tab. It presents CRF information at the highest level.

Welcome, **Miles Massey**	Log Out	Study: **Aspirin**

Patients	CRFs	DCFs	Inbox (4)

All Sites ▼

Sites ▲	Expected	Submitted	D-Review	DR Changed
100-Los Angeles	488	58	0	0
200 -Dublin	427	37	0	0
All Sites Totals:	**915**	**95**	**0**	**0**

On this page you can see how the sites are progressing through the study by looking at the status columns. The status columns display the number of CRFs currently in each status.

CRFs: Multi-Patient View

The multi-patient view shows a list of patients and the status of their CRFs.

There are two ways to access the multi-patient view:

- View all patients at a site.

- Search for patients.

On this page you can see how the patients are progressing through the study by looking at the CRF status subtotals.

Multi-CRF View

The multi-CRF view shows a list of CRFs for one or more patients at a site.

There are three ways to access the multi-CRF view:

- View all CRFs for a single patient at a site.

- View all CRFs with a certain status at a site.

- Search for CRFs.

On this page you can see how the patient is progressing through the study events by looking at the status icons and flags.

CRF View

The CRF view shows a single CRF for a patient.

On this page you can enter patient data.

In order to ensure that only one user at a time is working on a CRF, DataLabs has a check in/out feature. You can check out the CRF on this page by clicking Check Out, or you can set your user preferences to automatically check out a CRF when you open it.

For more information on working with CRFs, see Chapter 6: Entering Patient Data (CRFs) on page 184.

The DCFs Tab Navigation

The DCFs tab allows you to work with a study in a DCF-centric manner. Within the DCFs tab, you can access four different pages, or views. As you progress, or "drill down," through the views you can perform different tasks.

The four views on the DCFs tab are as follows:

```
┌─────────────────────────────────────────────┐
│           DCFs: Multi-Site View             │
│      ┌──────────────────────────────────┐   │
│      │     DCFs: Multi-Patient View     │   │
│      │    ┌─────────────────────────┐   │   │
│      │    │      Multi-DCF View     │   │   │
│      │    │   ┌─────────────────┐   │   │   │
│      │    │   │    DCF View     │   │   │   │
│      │    │   └─────────────────┘   │   │   │
│      │    └─────────────────────────┘   │   │
│      └──────────────────────────────────┘   │
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```
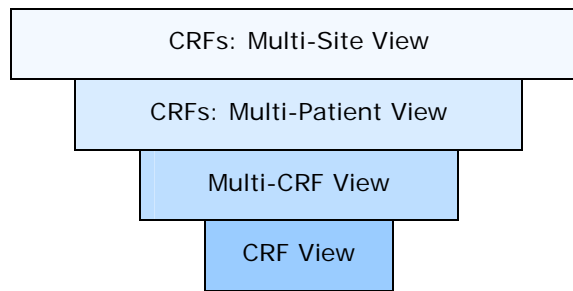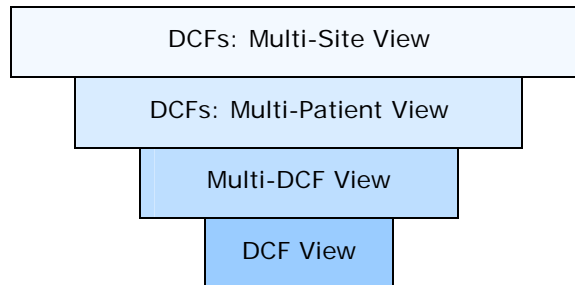
This introduction provides a high-level overview of the DCFs tab. For more detailed information, see Chapter 8: DCF Management on page 264.

DCFs Tab Navigation

DCFs: Multi-Site View

DCFs: Multi-Patient View

Click a site or a subtotal to see the DCFs: Multi-Patient view.

Multi-DCF View

Use the Search palette, click a patient ID, or click a subtotal to see the Multi-DCF view.

DCF View

Click a DCF ID to see the DCF view.

DCFs: Multi-Site View

The multi-site view is the main view for the DCF tab. It presents DCF information at the highest level.

On this page you can see how many DCFs have been created and if they are being resolved in a timely manner.

The status columns display the number of DCFs currently in each status (Draft, Sent, Viewed, Answered, Resolved, Closed).

For more information about DCF statuses, see Chapter 8: DCF Management on page 264.

DCFs: Multi-Patient View

The multi-patient view shows a list of patients and the status of their DCFs.

There are two ways to access the multi-patient view:

- View all patients at a site.

- Search for patients.

On this page you can see how the patients are progressing through the study by looking at the DCF status subtotals.

Multi-DCF View

The multi-DCF view shows a list of DCFs for one or more patients at a site.

There are three ways to access the multi-DCF view:

- View all DCFs for a single patient at a site.

- View all DCFs with a certain status at a site.

- Search for DCFs.

On this page you can see the IDs and statuses of the DCFs, along with a brief description of the issue.

DCF View

The DCF view shows a single DCF for a form.

For more information on working with DCFs, see Chapter 8: DCF Management on page 264.

Chapter 3: User Preferences

Overview

You can personalize your User Preferences for your DataLabs user account. On the top-right corner of the page is the Administration menu. By choosing User Preferences you can:

- Change your display name

- Change your email address

- Choose to forward to your external email when you receive a new email message

- Change the default portal to open when you log in

- Turn CRF auto checkout on (or off)

- Select your view options for CRF change history

- Receive notification that there are signature requests

- Receive query notification

- Set your date and time options

- View what sites you are a member of—which sites and patient-related information you can view and edit

- View your assigned permissions—which actions you are allowed to perform

- Change your password

To go to your user preferences:

1 Click the **Open List** button on the Administration menu.

2 Click **User Preferences**.

The User Preferences page appears.

Changing Your User Preferences

The User Preferences page displays the details of your user account and from it you can update some of your preferences:

Username: Displays the username you use when you log in to the study. The system administrator creates this when setting up the system—the username cannot be changed by the user within DataLabs.

Display Name: Defines your "proper name"—this is how you are identified throughout DataLabs. If the system administrator hasn't created a Display Name for you, DataLabs uses your Username by default.

Note: DataLabs identifies a user two different ways: by Display Name ("Miles Massey") or by Username ("mmassey"). Your Username is assigned in Windows Integrated Security (WIS) and cannot be changed in DataLabs. Your Display Name can be changed in your user preferences.

Email Address: Defines your current email address, which the system administrator may use to contact you.

Note: If you do not enter an email address, an alert icon appears next to the **Email Address** field on the User Preferences page and next to your display name in the header.

Email Forwarding: The Email Forwarding box is only available if an outgoing email server has been configured for DataLabs.

If cleared, new mail messages sent to your Inbox are not forwarded to your email address.

If selected, new mail messages sent to your Inbox are forwarded to your external email address. (You must enter a valid external email address to be able to forward email.)

If you select the Email Forwarding box and your DataLabs inbox already contains messages, new email messages will be forwarded to your external email, but the existing messages are not forwarded.

Portal: Determines what portal is used when you log in. Depending on your security level, you can choose one of the following portals to be your default:

Data Manager Portal – Typically used by the sponsor and CRO personnel.

Site Portal – The portal for site personnel.

Field Monitor Portal – Typically used by field monitors to verify source documents.

Medical Monitor Portal – Typically used by medical monitors to review patient medical information.

Paper Data Entry Portal – The portal for users performing double data entry (sometimes called "two pass verification") from paper CRFs.

CRF Auto Checkout: Turns auto checkout on or off.

If selected, a CRF is automatically checked out when you open it. When you "check out" a CRF, DataLabs keeps anyone else from opening it: much like checking out a library book. This keeps multiple users from editing the same form at the same time. The first user can check it out, update it, and check it in; the second user then can check out the updated form, and perform any additional updates.

If cleared, each CRF must be checked out individually.

Tip: Users who mostly enter data and update forms will want this option turned on. Reviewers and others who mostly view the data—but not update it—should have this turned off. (If a reviewer does make changes, they are prompted to "check" the form back in.)

CRF Change History: Select one of the following:

Complete Change History – View the entire change history for CRFs.

Basic Change History – View only the change history from when the CRF was "Submitted" forward.

Messaging Directory: Select one of the following:

Include – You are included in the message recipient list.

Exclude – You will not receive mail messages from other users, but will continue to receive system generated messages.

Signature Notification: If you need to monitor signature requests for a site, select this box to receive an email in your Inbox whenever you are sent a request for signature.

Query Notification: If you need to monitor query processing for a site, select this box to receive an email in your Inbox whenever a query has finished processing.

Date/Time: Selects the format to use when *displaying* dates and times in DataLabs (though not the display format on CRFs or for event dates). Time Zone selects the time zone to display. The default displays the time zone of the DataLabs server. You can also have the display time adjust automatically for Daylight Saving Time changes.

Note: The time zone list is based on the standard time zone list within the DataLabs database. If a time zone from that list is not present within the server's registry, the system will display UTC format.

Subtabs:

Sites – Lists the sites that you are allowed to access. The study administrator determines these. For more information about sites and setting them up for use, see Site Management on page 102 or User Management on page 65.

Permissions – Displays the actions you are allowed to perform. The study administrator determines what permissions are given to each group. For more information about group permissions, see Group Management on page 55.

To change your preferences:

1 From the User Preferences page make any changes to your settings.

2 Click **Save**.

Changing Your Password

If you want to create a "strong" password that is difficult for others to guess, you can use the following guidelines when creating your password:

■   Your password should not contain your username, real name, company name, or a complete dictionary word.

■   Your password should be significantly different from previous passwords. Passwords that increment (Password1, Password2, Password3...) are not strong.

■   Your password should contain at least seven characters.

■   Your password should contain at least one character from each of the following categories:

   English uppercase characters (A through Z)

   English lowercase characters (a through z)

   Base 10 digits (0 through 9)

   Non-alphabetic characters/symbols, including ` ~ ! @ # $ % ^ & * ( ) _ + - = { } | [ ] \ : " ; ' < > ? , . /

An example of a strong password is Nrechard1#.

To change your password:

1   From the User Preferences page, click **Change Password** on the Actions palette.

   The Change Password page appears.

2   Type your Current Password.

3   Type your New Password and then Retype your Password.

4   Click **Save**.

DataLabs checks:

- Whether the Current Password is correct.

- Whether the New Password and Retype Password match.

- Whether the new password meets the password length and complexity requirements (defined by the system administrator).

After changing your password, a message appears:

For security purposes, you will be logged out of the system after changing your password. You can then log back in using your new password. Click Cancel to go back, or Continue to save your new password and log out.

5 Click **Continue**.

DataLabs logs you out of the system and displays a logout page with the message, "You have successfully logged out of the DataLabs system." You must log in with your new password to continue.

Chapter 4: Study Administration

Overview

Note: This Functionality is specific to **Data Manager** portal users.

This chapter covers the following material:

- Adding and maintaining sites
- Adding and maintaining groups of users
- Adding and updating users
- Uploading a study version from Designer and testing it
- Moving a study into production
- Locking a study
- Defining the signature attestation
- Managing derived fields
- Managing queries
- Printing a Blank CRF Report

Accessing Study Administration

Study Administration gives study administrators access to the system management tools. It covers everything crucial to setting up and conducting a study.

Note: Only users who have proper permissions have access to study administration tools.

To go to study administration:

1 Click the Open List button (❯) on the Administration menu (which is near the top-right corner of the page).

2 Click **Study Administration**.

The Study Administration page appears.

Group Management

A group is a collection of users who inherit the same system permissions. System permissions are assigned to groups, and users by being members of the group receiving (or inheriting) those permissions when the group is active.

Groups must first be defined by the system administrator in WIS—including assigning individual users to groups—before the groups can be added to DataLabs.

You can use Group Management to:

- Add and edit groups.

- Set users' security permissions.

To access group management:

- From the Study Administration page, click 🔵 **Group Management**.

The Group Management page appears.
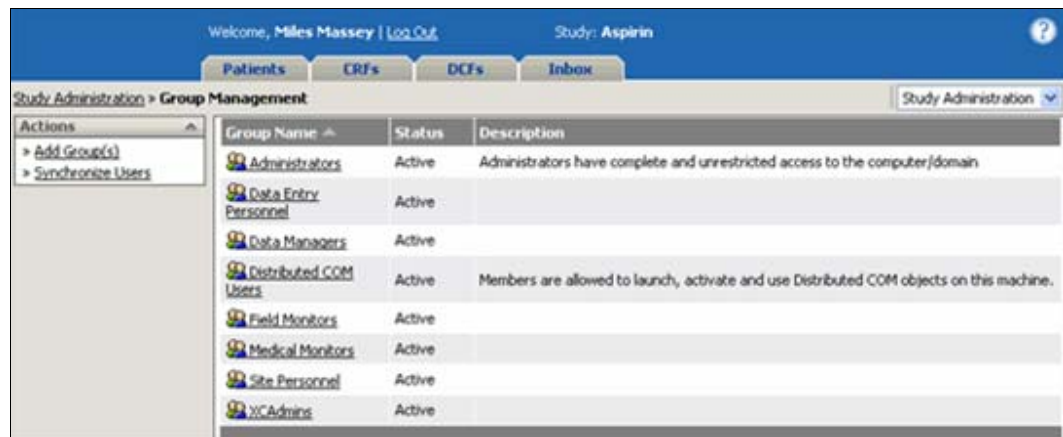
Depending on the Study Status you can perform the following actions:

Action	Production	Maintenance	Test
Add group(s)	Yes	Yes	Yes
Edit a group	Yes	Yes	Yes
View permissions	Yes	Yes	Yes
Edit permissions	Yes	Yes	Yes
Delete group(s)	No	No	Yes
Synchronize users	Yes	Yes	Yes

Each of these is detailed in the following pages.

Adding a Group

You can use the Add Group command on the Actions palette to add user groups already defined in Windows Integrated Security (WIS) to the study.

Note: Users added to a group in Windows Integrated Security after the group has been added to DataLabs will be added as "Active."

To add a group:

1 From the Group Management page, click **Add Group(s)** on the Actions palette.

The Add Group(s) page appears, listing all user groups which are defined in WIS but have not yet been added to DataLabs.
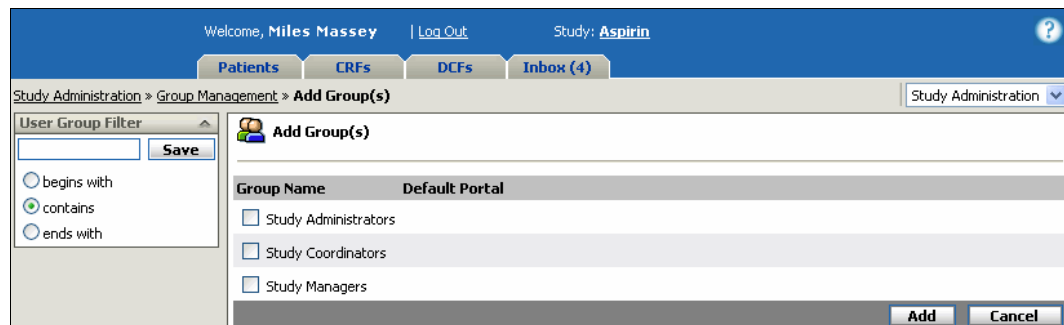
2 Select each group you want to add by selecting its check box.

When you select a group, DataLabs prompts you to supply the Default Portal.

3 From the menu, select what the group's Default Portal will be.

4 After you have selected all the groups, click **Add**.

When a group is added, all users that are members of that group in WIS are also added to DataLabs.

Caution: It is not recommended that you add groups that have administrator rights to DataLabs. If you do so, you may create an unnecessary security risk since you will be giving users the ability to reset Windows passwords from within DataLabs.

The primary example of a group with administrator rights in a domain is the Domain Admins Group; the primary example of a group with administrator rights in a local server is the Administrators Group.

Note: When a Group is added, the default Group status is Inactive and all permissions are set to either "Deny" or "Hide" while all users in the group are set to "Active." Once you have made any necessary changes to the permissions you must change the Group status to Active before the member users can log in.

IT Admin Group

The group which is created during the installation of DataLabs, the IT Admin group, is given administrative security rights (all permissions set to "Allow"). This group will have access to all features and functionalities. Due to this high level of access, special features are in place to protect this user group from changes or deletion from those users who do not have IT Admin group status. This provides an extra layer of study protection.

Note: Only members of a user group identified as **IT Admin** with the **Group Management** permissions of "Edit" or "View" will be allowed to edit other IT Admin groups or users of that particular group. Users who have the Group Management permission of "Edit" or "View" but are not assigned to the IT Admin group will be restricted from accessing the group management page for the IT Admin user group(s) or the user management page of users within the IT Admin user group(s).

After installation you can add more groups with IT Admin rights using the Installer and selecting the Configure Existing Install option. For more information about configuring existing install guide see the Install Guide: Configuring an Existing Install for more details.

Caution: It is recommended that as few groups as possible have IT Admin "super user" rights. It is a higher security risk; the more groups that can alter user and study properties.

User Group Filter

DataLabs has the ability to filter the user groups from the Add Group(s) page through the use of the User Group Filter.
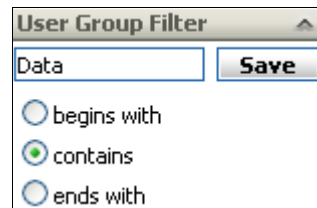
This is located in the Actions palette and allows you to filter text by one of the following three methods.

Does the Group Name:

- Begin with the filtered text

- Contain the filtered text

- End with the filtered text

Any groups which have the requested requirements will be filtered through and populate the choice of groups to be added.

Note: Only groups with IT Admin rights will have the ability to save the User Group Filter preferences.

Editing a Group

When you edit a group, you can add a description to a group, change its status, edit its permissions, or delete it.

To edit a group:

1   From the Group Management page, click the Group name.

The Edit Group page appears.

2   Make any necessary changes to the Description and Status.

3   Click **Save**.

The "Save Successful" message appears.

The Edit Group page contains the following information:

Description: Displays a short, meaningful description of the group.

Status: Selects the group status:

![] **Active** – A group currently allowed access to DataLabs.

![] **Inactive** – A group not being used by DataLabs. Users in an inactive group are not able to log in to DataLabs (unless they are a member of another active group).

Note: Users can be members of more than one group. Users that are members of multiple groups inherit the cumulative permissions of all their groups.

Subtabs: The Groups Management page has two subtabs, the Users and Permissions.

Users Tab – Lists the users that are members of this group, as defined in Windows Integrated Security; and their status, as defined in DataLabs. For more information about user groups, see User Management on page 65.

Users	Permissions	
Name	**Username**	**Status**
Carl Showalter	sshowalter	Active
G.H. Dorr	ghdorr	Active
Gus Petch	gpetch	Active
Marge Gunderson	mgunderson	Active
Miles Massey	mmassey	Active
Norville Barnes	nbarnes	Active
Ulysses Everett McGill	uemcgill	Active
Marylin Rexroth	mrexroth	Active

Name – Lists the user's Display Name.

Username – Lists the user's Windows Integrated Security (WIS) Username.

Status – Lists the user's current status.

Permissions Tab – Lists available permissions and its current setting for the group the user is a member of. To edit a group's permissions, click the Edit Permissions command on the Actions palette. For more information on editing group permissions, see Editing the Permissions for a Group on page 60.

Viewing Permissions

The Permissions subtab on the Edit group page shows you security and system permissions given to all users who are members of the group.

To view a group's permissions:

1   From the Group Management page, click the **Group name**.

2   From the Edit Group page, click the **Permissions** subtab.

Note: In the Study Permission section, the first item, "Study Administration," cannot be edited. Instead, it shows the cumulative status of the Study Administration permissions. When setting the permissions, there are six management options that are part of the Study Administration menu: Study, Site, Group, User, Query, Derivation, and Signature Management.

For example, if a user has *any one or combination* of these sections set to "View" or "Edit," then the Study Administration permission display "Allow." If *all* of these options are set to "Hide," then the Study Administration permission will be set to "Deny" and the user will not be able to access Study Administration menu page.

Editing the Permissions for a Group

A permission is a unique security right which controls a user's access to certain functions or sections of DataLabs.

You can use the Edit Permissions command on the Actions palette to update the permissions for a user group. Permissions set to "allow" give you access to portals, pages, tabs, actions and fields.

To change a group's permissions:

1   From the Group Management page, click the Group name.

2   From the Edit Group page, click the **Edit Permissions** command on the Actions palette.

The Edit Permissions page appears.

3 Make any changes to the permissions that are necessary.

4 Click **Save**.

The "Save Successful" message appears.

For each set of permissions, you can choose from two classes of settings.

Actions: Either allows or denies users in the group to perform the selected action.

Allow – Allows the users to perform this action.

Deny – Denies the users from performing this action.

Hide, View or Edit: Determines whether users are able to view or edit this category.

Hide – Hides this from the users.

View – Allows the users to view this, but not edit.

Edit – Allows the users to edit this.

Deleting a Group

Deleting a group from DataLabs removes the group from the Group Management list but does not remove the group from Windows Integrated Security.

Once a group is deleted from Windows Integrated Security, the next time a DataLabs user accesses the Study Administration Page, the deleted group will be set to Invalid and then deleted from the Group Management list. Since the group will no longer show up in Group

Administration, it will not be obvious to a DataLabs system administrator that the group was deleted from WIS.

If you delete a group in WIS it does not take effect immediately, but can take some time (sometimes up to half an hour or more) varying on how DataLabs is setup.

Deleting a group also deletes users that are members of *only* that group. Users who are members of other groups as well as the deleted one are not deleted. The historical record of the Group and the Users is never deleted.

You can use the Delete Group command on the Actions palette to delete the group you currently are editing.

Note: This command is only available if study status is "Test." For more information about how to set study status, see Study Management on page 74.

To delete more than one group:

1   From the Group Management page, click Delete Group(s) on the Actions palette.

The Delete Group(s) page appears.
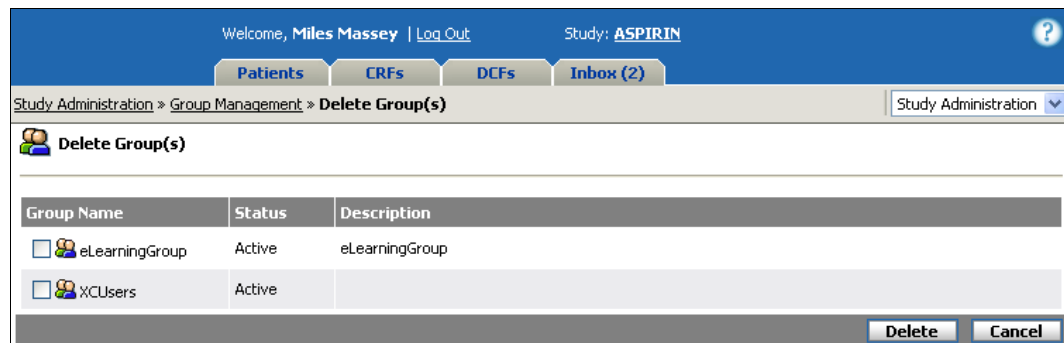
2   Select the group(s) you want to delete.

3   Click **Delete**.

The "Deleted Successfully" message appears when you are returned to the Group Management page.

To delete the current group:

1   From the Group Management page, click the Group name.

2   From the Edit Group page, click the **Delete Group** command on the Actions palette.

A warning box appears.

3   Click **Continue** to delete the group.

Note: If you delete a group, and a user belonging to the group has a form checked out, the group can still be deleted. However, the form check out is cancelled and any changes to the CRF are not saved.

A group that is renamed in Windows Integrated Security will appear to DataLabs as if the group has been deleted. The group will have to be re-added to DataLabs under the new name.

Synchronizing Users

If users are added or removed from Windows Integrated Security groups, they are not automatically updated in DataLabs's groups and users management. You can use the Synchronize Users command on the Actions palette to synchronize DataLabs with WIS.

To synchronize groups:

1   From the Group Management page, click **Synchronize Users** on the Actions palette.

A message box appears.
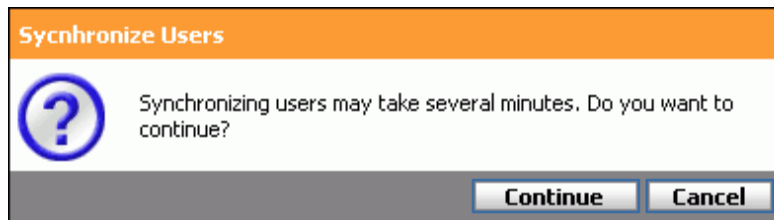
2   Click **Continue**.

The "Synchronized Users Process Started" message appears. The synchronization can be tracked in your Inbox.

3   Click the **Inbox tab**.

A "Synchronizing Users with Windows - 100% complete" message appears in the Inbox when the synchronization is complete.

To delete synchronization message:

1   Click the check box for the message(s).

2   Click **Delete**.

User Management

A user is any individual working on the study and given access to DataLabs, whether they are responsible for designing and setting up a study, managing study data, inputting patient data, editing CRFs, reviewing it, creating and responding to DCFs, signing off, or locking patients and studies. Not every user has full access to DataLabs and the data; therefore, each of these actions is determined by their group permissions. For more information about editing group permissions, see Editing the Permissions for a Group on page 60. Each of these users must be created first as a system user and have a unique and personal username and password.
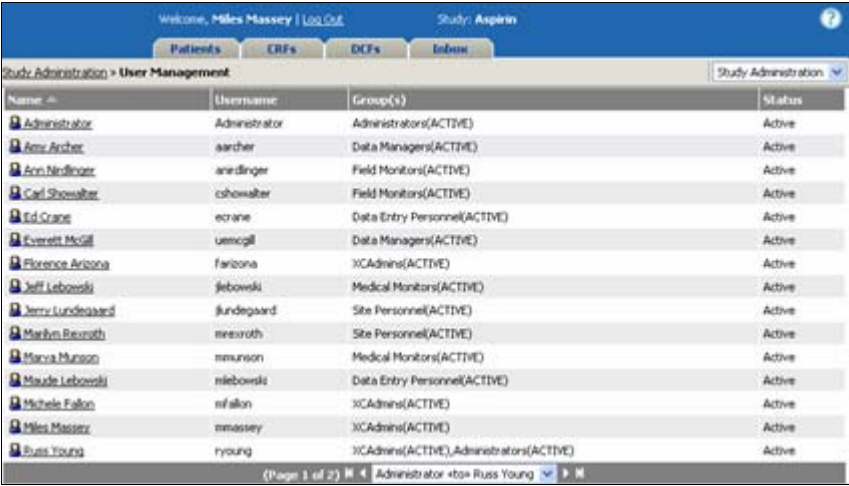
You can use User Management to:

- Edit and delete users.

- Reset users' passwords.

- Give users access to sites.

To access user management:

- From the Study Administration page, click 😃 User Management.

    The User Management page appears.

    From the User Management page you can:

    - Edit a user

    - Reset a user's password

    - Give a user access to sites

    Each of these actions is detailed in the following pages.

Updating a User

From the Edit User page you can edit a user's display name, email address, change their status, change their default portal, turn on auto-checkout, set how they view change history, set date & time view option, reset their password, and give them access to sites.

To update a user:

1   From the User Management page, click the user's name.

The Edit User page appears.

2   Make any necessary changes to the user.

3   Click **Save**.

The "Save Successful" message appears.

The Edit User page contains the following information:

Username: Displays the User Logon Name from Windows Integrated Security.

Display Name: Defines the display name of a user—this is how the user is identified throughout DataLabs. This can also be changed by the user in User Preferences.

Email Address: Defines the user's current email address. This can also be changed by the user in User Preferences.

Note: If you do not enter an email address, an alert icon appears next to the **Email Address** field on the User Preferences page and next to the user's display name in the header.

Email Forwarding: If cleared, new mail messages sent to the user's Inbox are not forwarded to the user's external email address.

If checked, new mail messages sent to the user's Inbox are forwarded to the user's external email address. If you check the Email Forwarding box and the user's Inbox already contains messages, new email messages will be forwarded to the user's external email, but the existing messages are not forwarded.

In order to be able to forward email messages, you must enter a valid email address for the user's account in **Email Address**.

The **Email Forwarding** box is only available if an outgoing email server has been configured for DataLabs. For information on configuring an outgoing email server, see Mail Tab on page 85.

Status: Selects the current user status:

> **Active** – A user currently permitted to access DataLabs.

> **Inactive** – A user currently not permitted to access DataLabs. The user cannot log in, regardless of what groups the user belongs to. The Inactive status overrides any group statuses.

Note: From within DataLabs, there are two ways to prohibit a user's ability to log in to DataLabs: by setting an individual user's status to Inactive, or by setting the group's status to Inactive.

Caution: If a user is deleted in Windows Integrated Security, they will not be permitted to log in to DataLabs, but the user's status in DataLabs will still appear as "Active"—until a Synchronize Users is executed on the system. Once users are synchronized, the deleted user is removed from DataLabs.

Note: The "Invalid" status is controlled exclusively by DataLabs. A user is assigned "Invalid" status if user is deleted, disabled or password expires in NT Security. When a user's status is "Invalid," they are no longer displayed in DataLabs though they are not completely removed from the system. If the account is resolved within NT Security, the system automatically changes the status to "Active" and you now have the ability to change their status.

Portal: Determines what portal is used when the user logs in. Depending on the user's security level, you can select one of the following portals:

> **Data Manager Portal** – Typically used by the sponsor and CRO personnel.

> **Site Portal** – The portal for site personnel.

> **Field Monitor Portal** – Typically used by field monitors, and focuses on the source document verify.

> **Medical Monitor Portal** – Typically used by medical monitors, and focuses on the medical review flag.

> **Paper Data Entry Portal** – The portal for users performing double data entry (sometimes called "A/B entry") from paper CRFs. For more information about the paper data entry portal, see the PDE Guide.

CRF Auto Checkout: Turns auto checkout on or off. This is set to "Off" by default.

Tip: Users who mostly enter data and update forms will want this option turned on. Reviewers and others who mostly view the data—but not update it—should have this turned off. (If a reviewer does make changes, they are prompted to "check" the form back in.)

CRF Change History: Select to view entire change history for CRFs, or only the change history from when the CRF was "Submitted" forward. The default is "Submitted forward."

Messaging Directory: Select one of the following:

> **Include** – Add the user to the message recipient list.

> **Exclude –** The user should not receive mail messages from other users, but should receive system generated messages.

Signature Notify: If the user is to monitor signature requests for a site, checking this box has DataLabs send a notice to their Inbox whenever the user is sent a request for signature. For more information about signature notify, see Signature Process on page 308 or Signature Request Inbox Messages on page 315.

Query Notification: If the user is to monitor query processing for a site, select this box to send an email to the user's Inbox whenever query processing is complete. For more information about query processing, see Running Selected Queries on page 131.

Date/Time Format: Selects the format to use when *displaying* dates and times in DataLabs (though not the display format on CRFs or for event dates).

Time Zone: Selects the time zone to display. The default displays the time zone of the DataLabs server. You can also have the display time adjust automatically for Daylight Saving Time changes.

Subtabs: The User Management page has three subtabs: Sites, Groups and Permissions.

Sites subtab – Lists the sites that the user is allowed to access.

Sites	Groups	Permissions	
Site ID	**Site Name**		**Site Status**
01	Copenhagen		Active
03	Oslo		Active
05	Riga		Active
07	Tallin		Active

Groups subtab – Lists the groups the user is a member of.

Sites	Groups	Permissions	
Group Name		**Status**	**Description**
Data Managers		Active	

Permissions subtab – Lists what actions the user is allowed to perform, as defined by the group(s) the user is a member of. This is a cumulative view of all their rights, based on all the groups the user is a member of. For more information about a group's permissions, see Group Management on page 55.

Sites	Groups	Permissions
Study Permissions		
Study Administration	Allow	
Study Management	Edit	
Manage Version(s)	Allow	
Lock Study	Allow	
Reset Study	Allow	
Unlock Study	Allow	
Upload Study File	Allow	
Delete Study File	Allow	
Stage/Publish Study	Allow	
Recall Study	Allow	
Site Permissions		
Site Management	Edit	
Add Site(s)	Allow	
Manage Users	Allow	
Migrate Patient(s)	Allow	
Manage Versions	Allow	
Group Permissions		
Group Management	Edit	
Add Group(s)	Allow	
Delete Group(s)	Allow	
Edit Permissions	Allow	
Synchronize Users	Allow	
User Permissions		
User Management	Edit	
Manage Sites	Allow	
Reset Password	Allow	
Derivation Permissions		
Derivation Management	Edit	

Resetting a User's Password

You can use the Reset Password command to reset a user's password. You may need to reset a password if a user forgets his password to deny a user access to DataLabs.

Note: If you reset a user's password and the user is currently logged in to DataLabs, the user will be disconnected from DataLabs.

Resetting a password changes the current password to a temporary and random "strong" password, which can then be emailed to the user.

The strong password generated by DataLabs meets the following complexity requirements:

- Does not contain all or part of the user's account name

- Contains at least twelve characters

- Contains at least one character from each of the following categories:

  English uppercase characters (A through Z)

  English lowercase characters (a through z)

  Base 10 digits (0 through 9)

  Non-alphabetic characters/symbols, including ` ~ ! @ # $ % ^ & * ( ) _ + - = { } | [ ] \ : " ; ' < > ? , . /

To reset a user's password:

1   From the User Management page, click the user whose password you want to change.

    The Edit User page for that user appears.

2   Click **Reset Password** on the Actions palette.

    The Reset Password page appears.

3   Click **Reset**.

    DataLabs resets the password and displays the temporary password.

4   Click the **user's email address** to send them their temporary password.

    Your email program opens a new message, complete with the temporary password.
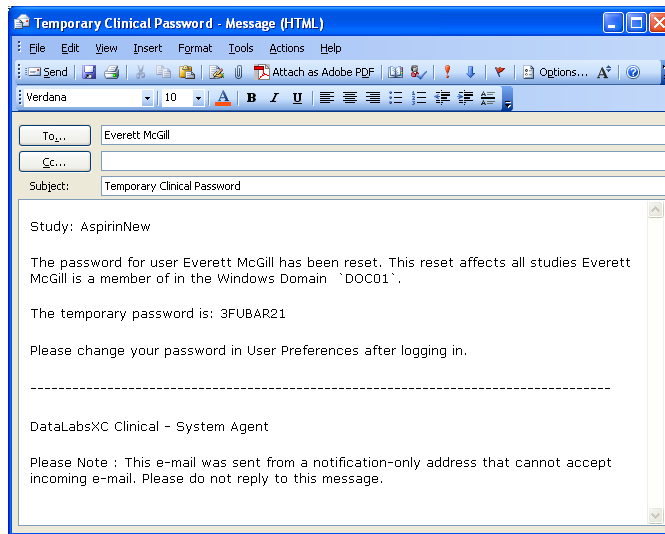
5 Add any additional comments to the user, and click **Send**.

6 On the Reset Password page, click **Done**.

You are returned to the Edit User page.

Giving a User Access to Sites

While you are working with users, you can use the Manage Sites command to give a user access to sites.

Tip: You may need to add sites to DataLabs before taking this step. For more information on how to add sites, see Site Management on page 102.

To give a user access to one or more sites:

1 From the User Management page, click the user's **Display Name**.

The Edit User page appears.

2 Click **Manage Sites** on the Actions palette.

The Manage Sites page appears, containing two lists of sites:
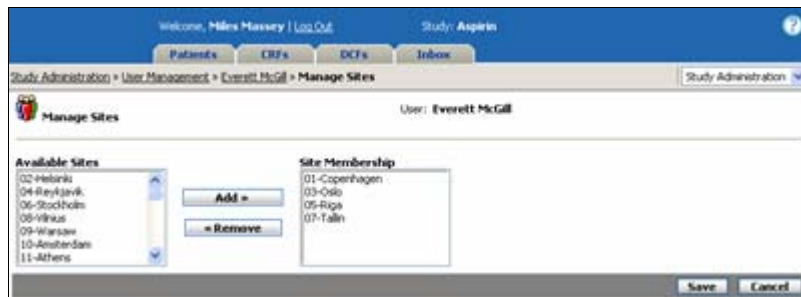
> **Available Sites:** Lists all sites that have been added to DataLabs that the user does not have permission to access.

> **Site Membership:** Lists sites the user is currently a member of.

3   From the **Available Sites** list, click the site(s) you want the user to be able to access.

> **Tip**: To select more than one site, press the CTRL key while clicking each additional site.

---

4   Click **Add**.

5   From the Site Membership list, click the site(s) that you do not want the user to access.

6   Click **Remove**.

7   Click **Save**.

The "Save Successful" message appears. DataLabs saves the changes and returns you to the Edit User page. The sites associated with the users are listed in the Sites subtab at the bottom of the page.

Deactivating a User

While DataLabs does not allow you to delete individual users, you can prevent users from logging in to DataLabs one of several ways:

- Deleting the groups that they are a member of.

- Inactivating the groups that they are a member of.

- Inactivating the individual user.

These have all been covered in the previous sections.

Tip: If you need to immediately disable a user, do the following:

In User Management in DataLabs, change the user's status from active to inactive.
Disable the user account in Windows Integrated Security.

If you disable or delete the user in WIS first it does not take effect immediately, but can take some time (sometimes up to half an hour or more) varying on how DataLabs is setup.

Note: Deleted and deactivated users can be updated *immediately* if you perform a Synchronize Groups.

Note: If a user has a CRF checked out at the time of being deactivated, the CRF will be checked back in.

Study Management

You can use Study Management to:
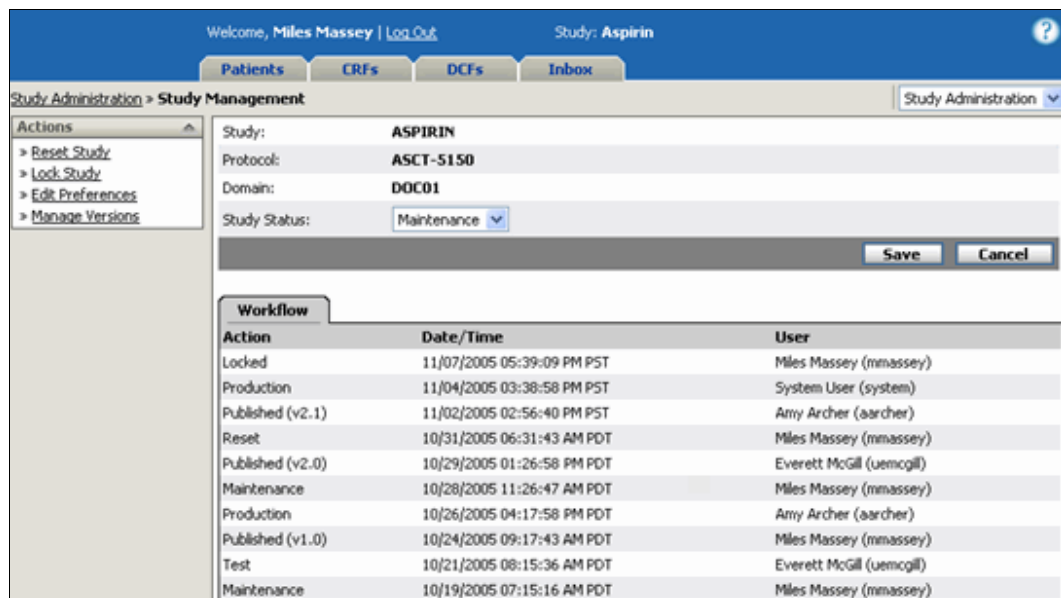
- Update study settings: status, retention end date, timeout, auto-close.

- Lock studies.

- Move studies from Test to Production Mode or Maintenance Mode.

- Set other overall study and server/security-related information.

Note: Some of these items are set within Windows Server or imported from Designer, and are mainly for your information.

To access the study status:

- From the Study Administration page, click 📘 **Study Management**.

The Study Management page appears.

The Study Management page contains the following items:

Actions: Your permissions will determine which actions are available to you on the Actions palette. For more information on permissions, see Group Management on page 55.

Reset Study – If your study has *only one* published version, this command clears all test data, republishes the study version and prepares the study to be put in production mode.

If you have *multiple* published versions, this command clears all test data that was entered for all versions, deletes all study files and versions, republishes the last published study version as version 1.0 and prepares the study to be put in production mode (see Study Status below).

When you reset a study, DataLabs lists only two actions in the workflow: Reset and Published.

Workflow		
Action	**Date/Time**	**User**
Published: v1.0 (Aspirin v1 2005-01-25)	11-May-2005 18:57:49 PDT	Miles Massey (mmassey)
Reset	06-May-2005 09:15:07 PDT	Miles Massey (mmassey)

Note: The Reset Study command appears only when the study is in "Test" or "Maintenance" mode.

Lock Study – Locks the study so that *no* data can be added or updated: the only action allowed is unlocking the study. Studies are typically locked when they are complete and the data is ready to be turned over for analysis. For more information about locking a study, see Locking a Study on page 88.

Unlock Study – Unlocks the study if it has already been locked.

Caution: Unlocking a study is an administrative challenge, since studies that have already been locked should only be unlocked with written justification and approval.

Edit Preferences – Edits the study's preferences. For more information on editing the study preferences, see Updating the Study Preferences on page 77.

Manage Versions – Uploads new versions of the study created in Designer to the server; and maintains study versions that are already in the study database. For more information on managing study versions, see Study Version Management on page 90.

Study: Displays the study name—which is contained in the XML uploaded from Designer.

Protocol: Displays the protocol name—also contained in the XML uploaded from Designer.

Note: Both the study and protocol names are determined during the design phase in Designer, and imported into the DataLabs system.

Domain: Displays the Windows network domain name. For local security, the local server name is displayed; for domain security, the domain controller is displayed.

Study Status: Selects the study's mode: test (the default), production mode or maintenance mode.

Production – Used for an actual, verified study, ready to collect real clinical trial data.

Maintenance – Used when performing maintenance tasks on a study that is in production mode.

Test – Used while the study is being set up, to test the forms and scripts that have been imported from Designer. The study should be reset before it is moved into production mode.

Workflow subtab: Shows the actions that have been performed for this study: the action, the date and time of the server at which the event occurred, and the user who initiated the event. (See the previous Actions palette commands for more information.)

Workflow		
Action	**Date/Time**	**User**
Locked	11/07/2005 05:39:09 PM PST	Miles Massey (mmassey)
Production	11/04/2005 03:38:58 PM PST	System User (system)
Published (v2.1)	11/02/2005 02:56:40 PM PST	Amy Archer (aarcher)
Reset	10/31/2005 06:31:43 AM PDT	Miles Massey (mmassey)
Published (v2.0)	10/29/2005 01:26:58 PM PDT	Everett McGill (uemcgill)
Maintenance	10/28/2005 11:26:47 AM PDT	Miles Massey (mmassey)
Production	10/26/2005 04:17:58 PM PDT	Amy Archer (aarcher)
Published (v1.0)	10/24/2005 09:17:43 AM PDT	Miles Massey (mmassey)
Test	10/21/2005 08:15:36 AM PDT	Everett McGill (uemcgill)
Maintenance	10/19/2005 07:15:16 AM PDT	Miles Massey (mmassey)

Action – Lists the name of the action taken on the study.

Maintenance – Details when the study was moved into maintenance mode—usually when patients were migrated to a newer study version.

Published (vN.N) – Details when a new study version was published, along with the study version number.

Recalled – Details when a study version was recalled.

Reset – Details when the study test data was cleared to prepare it to go from test mode to production mode.

Test – Details when the study was moved back into test mode.

Production – Details when the study was moved from test mode to production mode.

Locked – Details when the study was locked to prepare the data to be turned over for analysis.

Unlocked – Details when the locked study was unlocked.

Date/Time – Lists the date and time the action took place.

User – Lists the user who performed the action.

Updating the Study Preferences

From the Edit Preferences page you can change the study's preferences: general, CRF, DCF, script, paper data entry, date/time, and hotkey preferences.

To edit the study preferences:

1   From the Study Management page, click the **Edit Preferences** command on the Actions palette.

The Edit Preferences page appears.

2   Make any necessary changes to the preferences.

3   Click **Save**.

The "Save Successful" message appears. The Edit Preferences page has nine tabs:

General tab

Selects general study preferences:

Retention End Date: Contains the retention period during which the study data will be kept, as required by the FDA. This date appears on all CRFs in the study. (The default value is 12/31/2222.)

User Inactivity Timeout: Contains the number of minutes of inactivity before a user's session times out. A user's inactivity is based on how often a page is refreshed, not by the actions a user performs on a specific page.

The default setting is 30 minutes. This field is required.

Note: The user will receive a warning two minutes before their session will timeout. If the User Inactivity Timeout is set to three minutes (or less), users will not receive a warning.

Administrator Email: Defines the system administrator's current email address, in case they need to be contacted.

System Notification: Creates a notification banner, and defines the message that will appear in the banner. You can select the text to scroll. Maximum characters are 300.
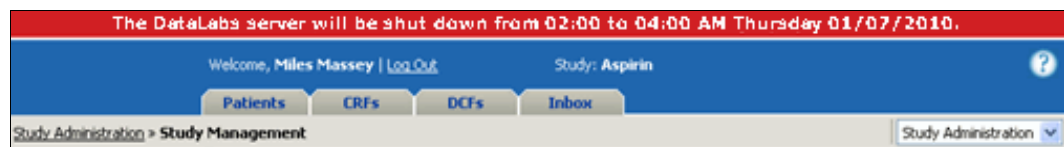
Proxy Server Host Name: Allows you to define the machine name to be used in hyperlinks that occur in emails for routing CRFs and DCFs and recovering lost usernames and passwords.

Proxy Server Host Uses SSL: Check this box if the proxy server host uses a Secure Sockets Layer (SSL). The prefix "https" will be included in hyperlinks that occur in emails for routing CRFs and DCFs and in recovering lost usernames and passwords. Clear this box if the proxy server does not use SSL. The prefix "http" will be included in hyperlinks that occur in emails for routing CRFs and DCFs and in recovering lost usernames and passwords.

Forms tab

The Forms tab allows you to select the following study preferences related to CRFs:

CRF Collection: You can enter and save data on a CRF as a whole (Form Level Submit) or enter and save part of the data on a CRF (Item Level Submit) with the ability to complete and submit at a later point.

Entry Complete Default State – If item-level data collection is used for a study, you can choose whether the Entry Complete box that appears on CRF forms is selected or cleared by default.

Unchecked. By default, the Entry Complete box on CRF forms is cleared by default. If CRFs are typically partially submitted, choosing to clear the Entry Complete box by default can help prevent users from fully submitting an incomplete CRF. After entering data for a CRF, the user must select the Entry Complete box to fully submit the form.

Checked. By default, the Entry Complete box on CRF forms is selected by default. If CRFs are typically fully submitted, choosing to select the Entry Complete box by default can help users submit CRFs more quickly. A user can fill out a CRF and press ENTER to fully submit the form. The user does not have to take the extra step of selecting the Entry Complete box.

"Question Not Answered" Values: Defines the values to be used by concurrent reporting when a question has been marked not answered. Each of these fields is required and must contain valid data for each data type. These values must be determined by your organization. (You can determine whether a user group has permission to mark questions "not answered" from the Group Management page. For more information on the group management page, see Editing the Permissions for a Group on page 60.)

Note: Sometimes questions on a CRF are purposefully skipped during data entry. Data management personnel will want to distinguish between questions intentionally not answered, and those skipped unintentionally. Mark Not Answered enables the site to mark those CRF questions that were intentionally skipped. For more information on marking an item not answered, see Marking a Question "Not Answered" on page 235.

Tip: Since the value you choose is used for data fields with various lengths and types (text, integer, float, date), you will want to select a small value that can be used by the various field types, and will not be truncated if the field length is 1.

"Code Prefix" Values: Selects whether to display the Code Prefix value in codelists as defined in Designer, in the EDC portals, the PDE portal, or both.

"Reason for Change" Values: Selects which "reasons for change" values will be available when a user updates an item in a CRF. You can click the Add New button to add additional reasons to the possible selections. For more information on adding additional reasons, see Editing a Submitted CRF on page 207.

DCFs tab

Defines the two optional DCF fields. Since some DataLabs customers—especially PDE users—may need extra fields to track custom workflow statuses, these two fields enable you to define two additional codelists:

Auto-close Resolved DCFs: When checked, automatically changes DCFs that are resolved to "Closed" status. For more information on closing a DCF, see Closing a DCF on page 288.

Turn on DCF Barcode: Includes a "scan-able" barcode on printed DCFs.

Restricted Access Forms: If checked, any DCFs that are generated by restricted forms are not visible to users if they are denied the "View/Act Upon Restricted Access Forms" Group Permission. Instead, the **DCF Description Replacement** is displayed. If unchecked, the users will see the DCF but not have access to the form. (Users with access to restricted forms will always be able to access the DCFs as well.)

Custom DCF Fields: You can define two custom DCF fields.

> **Field Label** – Defines the name of the fields as it is displayed on the DCF.

Note: You cannot use the following special characters in a Field Label: ~ ! @ # $ % ^ & * ( ) + { } | : " < > ? - = [ ] \ : ', . /.

Active/Inactive – Selects whether to display the field on DCFs.

Item list – Lists the codelist items you have added using the Add button.

Move Up/Move Down/Remove – Changes the order of a selected list item, or deletes it from the list.

Add New Item – Type the list item and click Add to add an item to the codelist.

While data saved in custom DCF fields do not record a change history, they can be used as criteria when searching for DCFs. For more information about searching for DCFs, see Searching for a DCF on page 275.

Scripts tab

Selects study preferences related to scripts (queries and derivations):

Script auto-inactivation: Turns script auto-inactivation on or off. Auto-inactivation inactivates any derivation or query script that encounters a script error (i.e., the script's syntax is invalid). The script will remain inactive until its status is changed back to Active. (The default setting is "off.")

Manual Derivation Requests: Turns polling on and off for derived fields. When manual derivations are submitted to run, they are placed in a run queue. DataLabs polls this queue every 30 seconds, and runs the next run request in the queue. When you turn off Manual Derivation Requests, DataLabs will not poll the queue, and run requests will continue to queue up. (The default setting is "on.")

Tip: This is useful to reduce server load. By turning off Manual Derivation Requests during peak system usage, you can delay run requests until the server load is lighter, running them "after hours." For more information about turning off derivation requests, see Derivation Management on page 113.

Manual Query Requests: Turns polling on and off for queries. This works similarly as Manual Derivation Requests, seen previously. For more information on turning query requests on and off, see Query Management on page 125. (The default setting is set to "on.")

Run queries on Frozen Patients: Allows queries to be run for CRFs for *patients* that have been frozen. (A patient is considered frozen if *all* their CRFs are frozen.) If this option is turned off, queries are run on all forms (including frozen ones) for patients who are not frozen; though will not run for patients who have all their CRFs frozen. (The default setting is "off.")

Note: Queries cannot be run for CRFs belonging to *locked* patients.

Paper Entry tab

Selects study preferences related to Paper Data Entry (PDE):

Note: If a PDE license key is used during the installation, the Enable Paper Data Entry box will be checked as a default, while the options below are unchecked.

Enable Paper Data Entry: Enables CRFs to go through the paper data entry process.

Restrict CRF entry via EDC after being marked Received – Locks a CRF from EDC data entry when the CRF is marked "received"—when unchecked, CRFs are not locked until they are in 1st pass entry.

Tip: If your study is not using the Received status, you should make sure this option is turned off.

Require CRFs to be marked Received prior to paper data entry – For studies that use a "Received" status, you can require that CRFs must be marked "received" in order to enter the PDE process.

Allow one user to complete both 1st and 2nd pass data entry for a CRF – Enables a single user to complete both paper data entry passes. By default, DataLabs requires 1st and 2nd pass entry to be completed by *different* users.

Display mismatches immediately after 2nd pass entry. (This will only be for users who have rights to resolve mismatches.) – If users performing 2nd pass entry also have permission to resolve mismatches, when they save the CRF, DataLabs will automatically open the CRF in Resolve Mismatches view if any mismatches are generated. If unchecked, DataLabs simply saves the CRF without displaying mismatch information (as it would for those who do not have resolve mismatches permission.

Allow users to save forms before completing entry –

Complete (default). The "1st/2nd Pass Complete" check boxes at the bottom of paper data entry CRFs are automatically checked.

Incomplete. The "1st/2nd Pass Complete" check boxes at the bottom of paper data entry CRFs are automatically unchecked. This allows users to save a CRF before it is completed, and marking its status as "Started." The user can return to the CRF later to complete it.

Auto-submit completed forms to EDC. When a CRF completes 2nd pass entry—without mismatches—it is automatically submitted to the EDC process. If there are mismatches, the CRF is automatically submitted when the mismatches are resolved.

Date/Time tab

Selects date and time study preferences:

Date/Time Format: Displays the date format (defined in Designer) to use when *displaying* dates and times in DataLabs (though not the display format on CRFs or for event dates).

Time Zone: Selects the time zone to display. The default displays the time zone of the DataLabs server. You can also have the display time adjust automatically for Daylight Saving Time changes (the Automatically adjust clock for daylight savings changes check box displays only if a time zones that recognize Daylight Saving Time).

Hotkeys Tab

This tab allows you to select the hotkey combinations for paper data entry.

To change the hotkey value, click the link, and then press the key combination you want to assign to the action.

A hotkey combination can only be defined once, and not all hotkey combinations are valid. If you assign an invalid hotkey (or a hotkey that is already assigned), DataLabs warns you.

Reports tab

If a reporting server was setup during installation, the Reports tab displays the path and access credentials for that server. If no reports server was set up during installation, the following fields will be blank. To set up a reports server, these fields can be populated and saved from this screen.

Base Url: The URL to the server being designated for reporting.

Report Folder: Folder designated for a particular study's report files.

Report Model Folder: A separate folder that is designated for ad-hoc reports.

SQL User ID: User ID which grants access to the SQL database.

SQL Password: User password which grants access to the SQL database.

Connection String: SQL Server name and Database name of the DataLabs database for this study.

Web Service Domain: Name of the Domain that the Base URL resides on.

Web Service User ID: User ID to the applicable domain.

Web Service Password: Password to the applicable domain.

If you have blank or incorrect fields in the **Reporting Administration Details** section and try to access Reporting you will receive two messages and not have access to the Reporting functionalities.

Reporting Configuration error message:
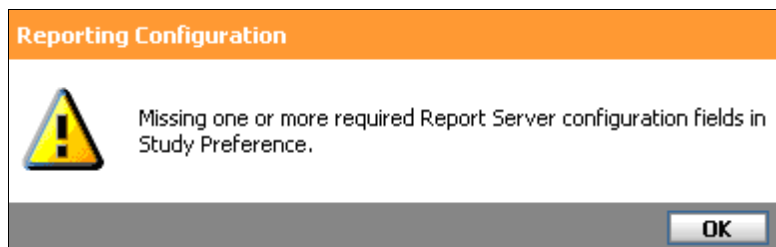
Second, a message explaining what fields are involved specific to the error.

Mail Tab

Contains the information for the email server that will be used to send emails to external email addresses, such as forwarding email from a user's inbox to an external email address or emailing a forgotten username or password requested by a user.

Enable Outgoing Email Server: When checked, the Email Forwarding feature can be used to automatically forward email from a user's inbox to an external email address. In addition, the Password Recovery feature can be used to email a forgotten username or password to a user.

When cleared, the Email Forwarding and Password Recovery features are not available.

SMTP Server: The name or IP address of the SMTP server to be used to send email from DataLabs to external email addresses.

Username: The username DataLabs can use to access the SMTP server.

Password: The password associated with the username that DataLabs can use to access the SMTP server.

SMTP Port: The port number DataLabs can use to connect to the SMTP server.

Sender Email Address: The Sender's email address that appears in emails sent to external email addresses.

Changing a Study's Workflow Status

After the study forms have been loaded from Designer into DataLabs, and you have tested them with sample data, you are ready to move the study from test mode into production mode. This is done in two steps:

- Resetting the study to clear out all test data entered or captured during testing.

- Switching the study from test mode to production mode.

Caution: Moving a study from test to production mode *does not* clear the test data. You must reset a study *before* you move it to production mode.

There are several things to note if a study has been moved to Production mode:

- The study can no longer be reset.

- A new study version cannot be published.

- A user group cannot be deleted—groups can only be inactivated.

Resetting a Study

After you have set up the study by importing the XML from Designer into DataLabs, and you have tested and verified all forms and scripts, you should purge the study of patient test data before moving it into production by using the Reset Study command.

Caution: You can only reset a study when it is in *maintenance mode*.

To reset a study:

1   From the Study Management page, click the Reset Study command on the Actions palette.

A warning box appears, asking, "Study Reset will delete all patient, CRF, and DCF data. Are you sure you want to do this?"

2   Click **Continue**.

Another message box appears, telling you, "Reset Study Successful."
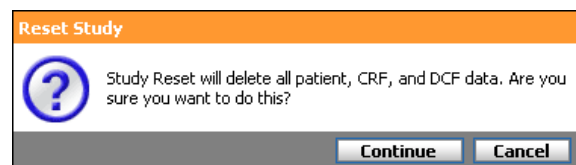
Moving from Test Mode to Production Mode

Once you have reset the test data, you can move the study into production mode to allow users to begin entering live data into DataLabs.

To switch to production mode:

1   From the Study Management page, click the Study Status list and click Production.

2   Click **Save**.

The "Save Successful" message appears.

Putting a Study in Maintenance Mode

A study that is in production mode can be put into maintenance mode to perform maintenance tasks on the study. When the study is maintenance mode, it displays a message page to non-administrator users that DataLabs is in maintenance mode and how long it is expected to last. Administrators have full access to DataLabs—except they *cannot* edit patients that are being migrated.

Note: Maintenance mode is triggered *automatically* when you migrate all patients as part of the study publishing process to the most recent study version.

To switch to maintenance mode:

1   From the Study Management page, click the Study Status list and click Maintenance.

2 Click **Save**.

The "Save Successful" message appears.

Locking a Study

At the conclusion of a study, when all CRFs are completed, encoding responses have been processed, DCFs resolved and signatures collected, and the data is complete, DataLabs enables you to lock the study.

To lock a study:

1 From the Study Management page, click the **Lock Study** command on the Actions palette.

A warning box appears, asking, "Locking this study will restrict the ability to make any changes to the study data. Are you sure you want to do this?"

2 Click **Continue**.

Another message box appears, telling you, "Lock Study Successful," and a lock icon appears to the right of the study name.
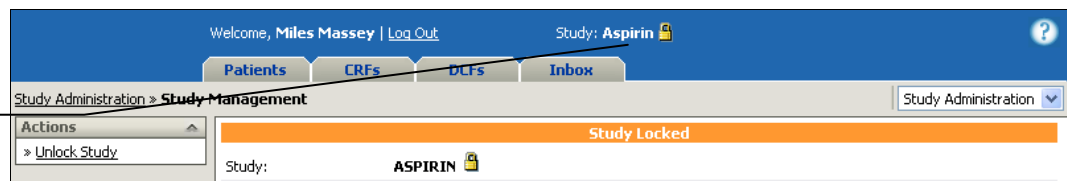
The study is locked.

Note: All patients must be frozen and locked before you can lock an entire study.

Unlocking a Study

In the event you need to unlock a study that has been locked, you can use the Unlock study command on the Actions palette.

To unlock a study:

1 From the Study Management page, click the Unlock Study command on the Actions palette.

   A warning box appears, asking, "Unlocking this study will allow the ability to make changes to the study data. Are you sure you want to do this?"

2 Click **Continue**.

   Another message box appears, telling you, "Unlock Study Successful," and the lock icon is removed from the right of study name. Locking and unlocking a study is tracked on the Workflow subtab:

Workflow		
Action	**Date/Time**	**User**
Unlocked	06/30/2005 02:35:25 AM GMT	Miles Massey (mmassey)
Locked	06/30/2005 02:33:16 AM GMT	Miles Massey (mmassey)
Published:(v2.0)	06/29/2005 11:34:24 PM GMT	Miles Massey (mmassey)
Maintenance	06/29/2005 11:34:19 PM GMT	System User (system)
Production	06/29/2005 11:15:07 PM GMT	Miles Massey (mmassey)
Published:(v1.0)	06/29/2005 10:29:17 PM GMT	Miles Massey (mmassey)

Study Version Management

Study Version Management enables you to update the study design, including the events, CRFs, queries and derivations. Put simply, you can load a new version of the study, DataLabs validates the XML, you then "publish" it so that it is available for data entry, and then "migrate" patients to it so that they use the new file. As newer files are published, older files are marked obsolete but still exist in DataLabs for historical purposes.

To access study version management:

■   From the Study Management page, click **Manage Versions** on the Actions palette.

The Study Version Management page appears.
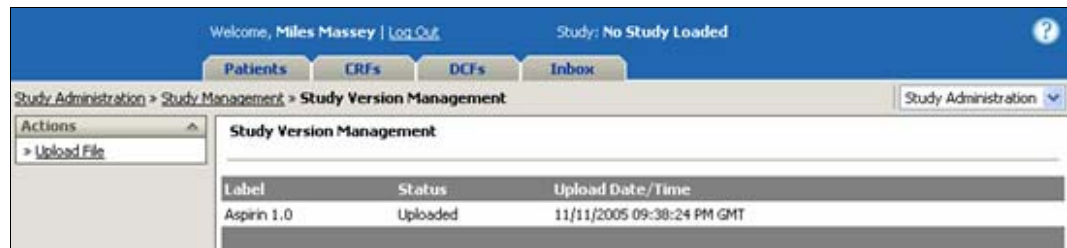
The Study Version Management page contains the following items:

Upload File: Uploads the XML files created by Designer into the DataLabs system. For more information on how to upload a file, see Uploading a Study on page 92.

Study Version Management: Lists all the files of the study that have been uploaded to server.

   Name – Displays the user-defined study version label.

   Status – Indicates the current workflow status of each file. For more information on the current workflow status, see Study Version Workflow on page 91.

   Uploaded Date/Time – Displays the date/time when file was uploaded.

Study Version Workflow

As you incorporate different versions of the study into DataLabs, it will follow a set workflow.
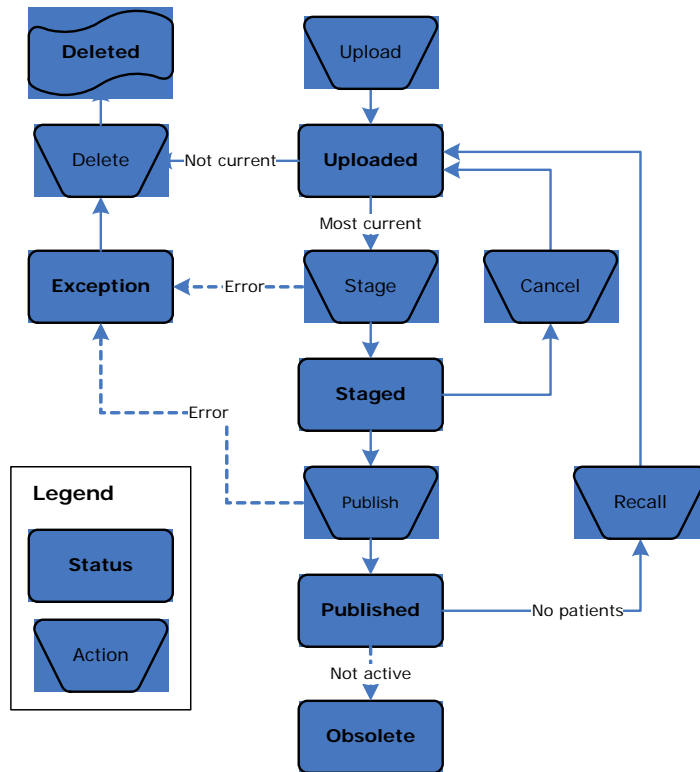
Tip: Migrating patients from the previous published file to the most recent is done either when the study is published or through Site Management. For more information about migrating patients, see Migrating Patients on page 108.

Uploaded: The study XML file created in Designer has been uploaded into the DataLabs database. For more information about how to upload an XML file, see Uploading a Study File on page 92.

Staged: The file has been staged and is ready to be published. For more information about how to stage a file, see Staging a File on page 95.

Canceled: When you cancel a staged file, its status automatically reverts back to uploaded. For more information about canceling files, see Canceling a File on page 96.

Deleted: You can delete a file from the database; if necessary. For more information about deleting a file, see Deleting a File from the Database on page 96.

Published: The file has been moved into an active version. Study data can be entered and patients can be added to it. There can only be up to two published versions at a given time; patients are assigned to one or the other.

Recalled: When you recall a published file, its status automatically reverts back to uploaded. For more information about how to recall a file, see Recalling a File on page 98.

Obsolete: Since there can only be two published files at a time, when you publish a third study, the oldest version is marked as obsolete.

Exception: While being published, the file generated an exception and could not be published. DataLabs creates an exception report. For more information about printing an exception report, see Printing an Exception Report on page 100.

Compare Report: Creates a report showing all the differences between the current study and the previously published study. For more information about printing a compare report, see Printing a Compare Report on page 99.

Download: Once a file has been uploaded to DataLabs—as long as it hasn't been deleted—you can download the XML. For more information about downloading the file's XML, see Downloading the File's XML on page 99.

Versioning

When you publish a file, DataLabs gives it a version number; the default version for the first published study is 1.0. Each subsequent published version is incremented.

	Increment	Example	Description
Major	1.0	1.0, 2.0, 3.0	Changes to the structure of the patient data (for example, form changes, patient changes, etc.).
Minor	0.1	1.1, 2.3, 3.1	Changes that do not affect the structure of the patient data (for example, queries).

If a file is published and then recalled, the version number that was assigned to it is available to be reused by the next published file.

Uploading a Study File

During the design phase, your study design team created all the forms, queries and their underlying logic using Designer. Designer exports an XML file which DataLabs uses to create the study online. You use the Upload Study action to upload the XML file into the DataLabs database. For more information about designing a study see the Study Designer's Guide.

To load a study:

1 From the Study Version Management page, click the **Upload File** command on the Actions palette.

The Upload Study page appears.

2 Click **Browse**.

A Windows Open dialog appears.

3   Select the study XML file and click **Open**.

The file name appears in the upload field in the Upload Study page.

4   Type a study **Label** so that you can distinguish this version of the file from others.

Since the file name for the XML may have the same name as the other XML files used, the version of the study you are uploading can be differentiated by assigning it a unique Label.
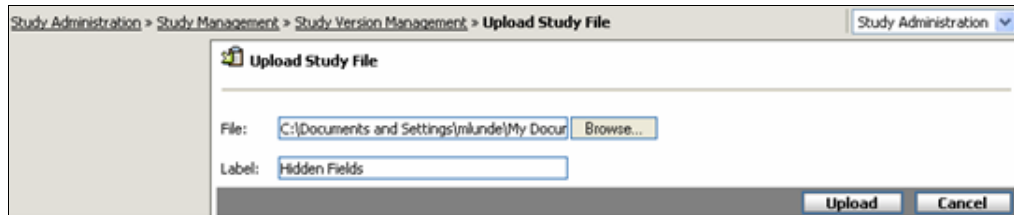
5   Click **Upload**.

At this point, DataLabs checks the XML file to validates two things:

■   That the structure of the file is valid Designer XML.

■   That the study name, protocol name and date/time format are the same as studies that already have been loaded.

If either of these validations fails, DataLabs generates an exception and the upload is cancelled.

Note: When the first study is published it will set the New Patient option to "Allow" for all existing sites. (This is for the first version only.)

When the XML file has been loaded (and stored in the DataLabs database in a compressed format), the "Study file added successfully" message appears and DataLabs returns you to the Study Version Management page.

Updating Study Version Properties

Once a file is uploaded, you can update the file's properties: change its workflow status, delete it, download it and view available reports.

To view or update a file:

■   From the Study Version Management page, click the study version Name.

The Study Version Properties page for that version appears.

Welcome, **Miles Massey** | Log Out   Study: **No Study Loaded**

| Patients | CRFs | DCFs | Inbox |

Study Administration » Study Management » Study Version Management » **Study Version Properties**   Study Administration ▾

Actions
» Cancel
» Download
» Publish

Study Name:	AspirinNew
Protocol:	ASCT-5150
Label:	Aspirin 1.0
Status:	Staged

Save   Cancel

Workflow

Action	User	Date/Time
Staged	ryoung	11/11/2005 09:40:09 PM GMT
Uploaded	ryoung	11/11/2005 09:38:24 PM GMT

The Study Version Properties page contains the following information and options:

Actions palette: Depending on the version's workflow status, the Actions palette gives you a set of commands.

Version Status ➡ Action ⬇	Uploaded	Staged	Published	Obsolete	Exception	See
Stage	✔					Staging a File on page 95
Cancel		✔				Canceling a Filee on page 96
Delete	✔				✔	Deleting a File from the Database" on page 96
Publish		✔				Publishing a File on page 97
Recall			✔			Recalling a File on page 98
Download	✔	✔	✔	✔	✔	Downloading the File's XML on page 99
Compare Report		✔	✔			Printing a Compare Report on page 99
Exception Report					✔	Printing an Exception Report on page 100

Body:

> **Study Name** – Imported from Designer.

> **Protocol** – Imported from Designer.

> **Label** – Displays the label that was entered when the study was loaded which can be edited in the text box.

> **Status** – Displays the version's current workflow status.

Workflow Tab: Actions that have been performed for this study.

Workflow		
Action	**User**	**Date/Time**
Published (v1.0)	Miles Massey	11/11/2005 04:55:12 PM PST
Staged	Miles Massey	11/11/2005 04:54:39 PM PST
Uploaded	Miles Massey	11/11/2005 04:49:58 PM PST

Action – Name of the action that took place.

User – User who initiated the action.

Date/Time – Date and time of the action.

Staging a File

A file must be staged before it can be published. The Stage command on the Actions palette stages the uploaded file, compares it to the most recently published file (if any), and creates a compare report.

To stage a file:

■   From the Study Version Properties page, click the **Stage** command on the Actions palette.

When the file has been staged, the "Study file stage successfully" message appears and DataLabs returns you to the Study Version Management page. The staged file now has a compare report attached to it. For more information about printing a compare report, see Printing a Compare Report on page 99.

When DataLabs stages a file, it checks for the following things:

- Forms without any table or question items.

- At least one event must exist.

- Each event must have at least one form.

- Verify properties of key sequence fields on autobuild tables are not changed.

- Verify tables can't be changed from non-autobuild to autobuild.

- Validate length and format of SAS and CDISC fields.

If any of these conditions generate an error, an Exception Report is created. For more information on printing an exception report, see Printing on page 100.

Note: Only *one* version of the study can be staged at any one time.

Canceling a File

The Cancel command on the Actions palette cancels a staged file, deletes its compare report and revert its status back to uploaded. Since you can have only one staged file at a time, you can cancel it if you decide instead to stage and publish a different file.

To cancel a staged file:

1 From the Study Version Properties page, click the **Cancel** command on the Actions palette.

The Cancel Study dialog box appears.
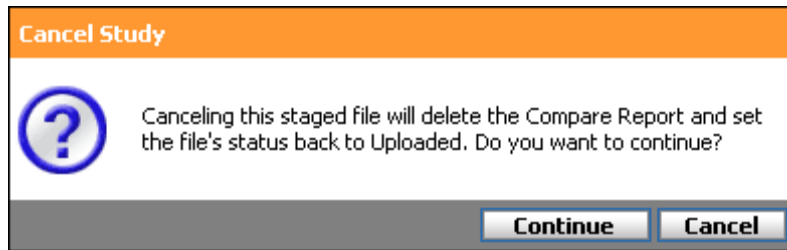
2 Click **Continue**.

Note: Only *staged* versions can be cancelled.

When the file has been cancelled, the "Study file cancelled successfully" message appears and DataLabs returns you to the Study Version Management page. The file is now in the "Uploaded" status.

Deleting a File from the Database

You can delete files that have an "Uploaded" or "Exception" from the database, if necessary.

To delete a file:

1 From the Study Version Properties page, click the **Delete** command on the Actions palette.

The Delete Study dialog box appears.
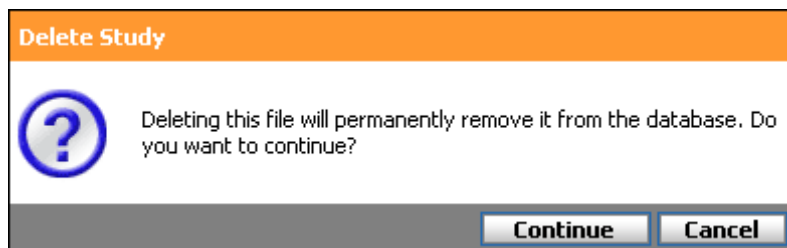
2 Click **Continue**.

When the file has been deleted from the database, the "Study file deleted successfully" message appears and DataLabs returns you to the Study Version Management page.

Note: You cannot restore a deleted study version.

Publishing a File

You can publish a staged file to set it as an active version where study data can be entered and patients can be added to it. There can be at most two published versions at a given time, and patients are assigned to one or the other.

Note: Do a back-up before publishing a study!

To publish a file:

1   From the Study Version Properties page, click the **Publish** command on the Actions palette.

The Migrate Patients dialog box appears.

2   Do one of the following:

Click **Migrate All Patients** to migrate all patients in the study to the new version. DataLabs will be switched to Maintenance Mode and all patients will be migrated to this version. By default, any new patients that are added from this point are assigned to the new version.

Click **Migrate No Patients** to retain patients in their current study version. You can use the Migrate Patients action in Site Management to migrate patients individually. For more information about migrating patients individually, see Migrating Patients on page 108.

When you publish a file, DataLabs performs a series of internal checks on the XML file. If any issues arise an exception report is create.

If any "Read-Only" parameter has changed from true to false, or vice versa, as part of a study update, then the data for these sites will remain the same (unchanged) during the migration.

Tip: Once you have published a file, you will need to go to site management to allow sites access to the new study version. For more information on site management, see Managing Study Version on page 107.

Note: Once a site is added, DataLabs will automatically set the New Patient Permissions to "Allow." This will apply only to the most recently published study. Any previously published study versions will default the New Patient permissions to "Deny."

When the file is published, the "Study file was published successfully" message appears and DataLabs returns you to the Study Version Management page. Any DataLabs users who have permission to publish a study will also receive an Inbox message that the file was published.

Obsolete Files

If there are two published files, and you publish a new file, the older version is marked obsolete.

Note: You can only publish a staged file if all patients have been migrated to the most recent published version. If you have patients in both versions of the study, you cannot publish a staged version since patients cannot belong to an obsolete study version. Migrating patients is done through site management. For more information on migrating patients, see Migrating Patients on page 108.

Recalling a File

You can recall a published file and revert it back to uploaded status if no patients have been added or migrated to the version.

To recall a published file:

1   From the Study Version Properties page, click the **Recall** command on the Actions palette.

The Recall Study dialog box appears.
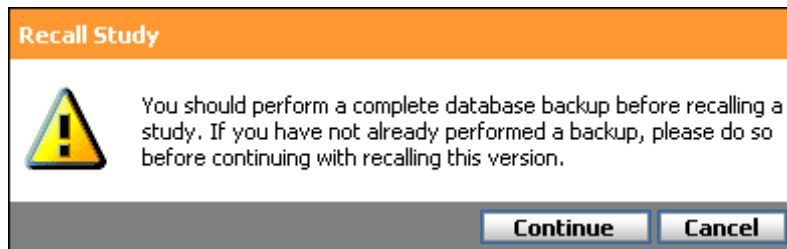
2   Click **Continue**.

When the file has been recalled, the "Study file recalled successfully" message appears and DataLabs returns you to the Study Version Management page. The file is now in the "Uploaded" status.

Note: Only the *most recent published* file can be recalled.

Note: If you recall a file, DataLabs restores the most recent obsolete file.

Downloading the File's XML

Once a file has been uploaded to DataLabs—as long as it hasn't been deleted—you can download the XML at any time, regardless of its status.

To download a file to your local computer:

1 From the Study Version Properties page, click the Download command on the Actions palette.

The File Download dialog box appears.

Caution*: Do not* uncheck the **Always ask before opening this type of file** check box. For more information about the leaving this checked, see File Download Dialog Box on page 363.

---

2 Click the **Save** button.

The Save As dialog box appears.

3 Choose the folder you want to save the ZIP file to and click **Save**.

DataLabs saves a ZIP file with the study XML into the folder you selected.

Viewing and Printing Reports

DataLabs provides two reports.

Printing a Compare Report

When a file is staged, DataLabs compares its XML with that of the most recently published version and generates a compare report. The report shows the all the differences—if any—between the two files.

Note: A compare report is only created if there is a previous version of the study loaded.

To view a compare report:

1 From the Study Version Properties page, click the Compare Report command on the Actions palette.

DataLabs opens the compare report PDF in a new browser window.

2 From the PDF, you can view, save or print the report.

An example of the report is shown below:

Study Name: Test3210   **Study Stage Compare Report**

Prev. File: TestStudy_Original.xml (Original)   Upload Date: 01/09/2006 04:47:50 PM GMT
New File: TestStudy_UpdateA.xml (Update A)   Upload Date: 01/09/2006 10:56:03 PM GMT

Change Type: **Updated**
Category: **Dictionary**
Name: **MedRA**

Property	Name	Previous Value	New Value	Action
Dictionary Version	--	2.7	7.2	Updated

Change Type: **Updated**
Category: **Domain**
Name: **Generic**

Property	Name	Previous Value	New Value	Action
CDISC SDS Variable Name	--	Gen	--	Updated
Code List Name	Select	XYN	--	Updated
SAS Field Name	T_S2Date	SASfid	--	Updated
CDISC SDS Variable Name	--	SDSfid	--	Updated
Item	NewItem_UpdateA --		NewItem_UpdateA	New
Item	NewItemB_Update -- A		NewItemB_UpdateA	New

Change Type: **Updated**
Category: **Domain**
Name: **Scripting**

Property	Name	Previous Value	New Value	Action
CDISC SDS Variable Name	--	SASDeriv	--	Updated
Item	NewItem2_Update -- A		NewItem2_UpdateA	New

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Printing an Exception Report

If a study version has generated an exception, DataLabs creates a report that details the error.

To view an exception report:

1   From the Study Version Management page, click the Exception Report command on the Actions palette.

DataLabs opens the exception report PDF in a new browser window.

2   From the PDF, you can view, save or print the report.

An example of the report is shown below:

Study Name: **Test3210**   **<u>Study Exception Report</u>**

File: **Exception_14.xml (11/14/2005 10:34:04 PM GMT)**

Details

EventEvent EventwithnoForm does not contains any forms. At least one event must be added. At least one Form must be added to the event.

Page 1 of 1

Site Management
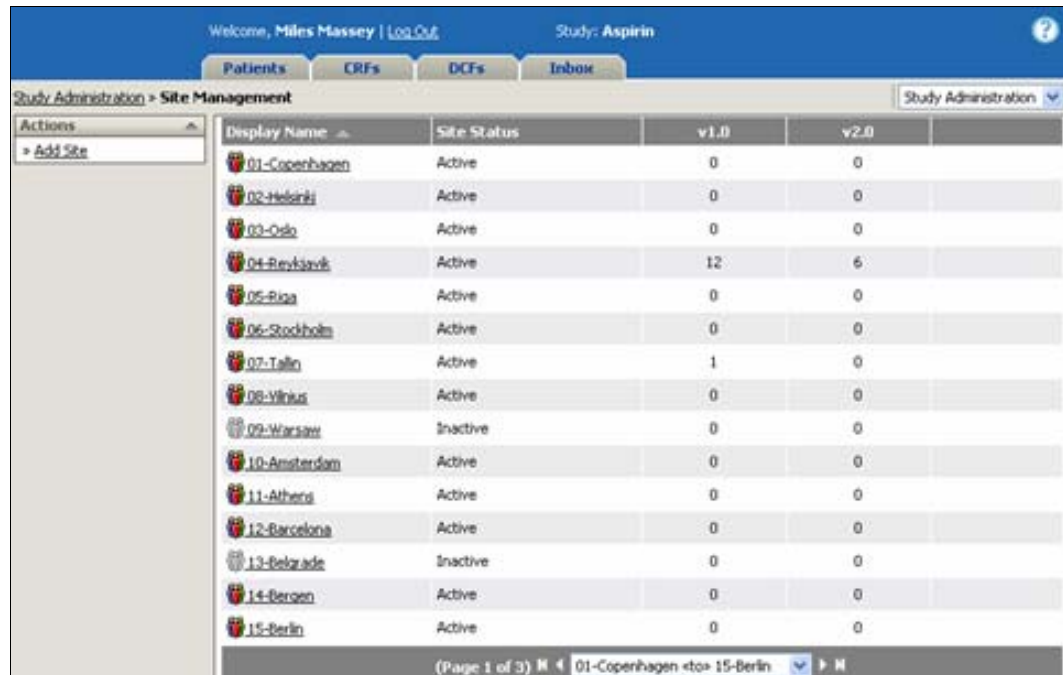
You can use Site Management to:

- ▪ Add and edit sites.

- ▪ Give users access to sites.

- ▪ Manage study versions for a site.

- ▪ Migrate patients to the newest study version.

To access Site Management:

- ◼ From the Study Administration page, click 🐞 **Site Management**.

The Site Management page appears. It lists all the sites that have been defined for this study, including their Display Names and Status, as well as how many patients belong to each published study version.

From Site Management you can:

- ◼ Add a site

- ◼ Edit a site

- ◼ Permit (or deny) users access to a site

■   Assign a PI (primary investigator)

■   Manage study versions for the site

■   Migrate patients to the most recent study version

Each of these actions is detailed in the following pages.

Adding a Site

You can use the Add Site command on the Actions palette to add sites to the study. The Add Site command is only available if the group you are a member of has the proper permissions. For more information on group permissions, see Group Management on page 55.
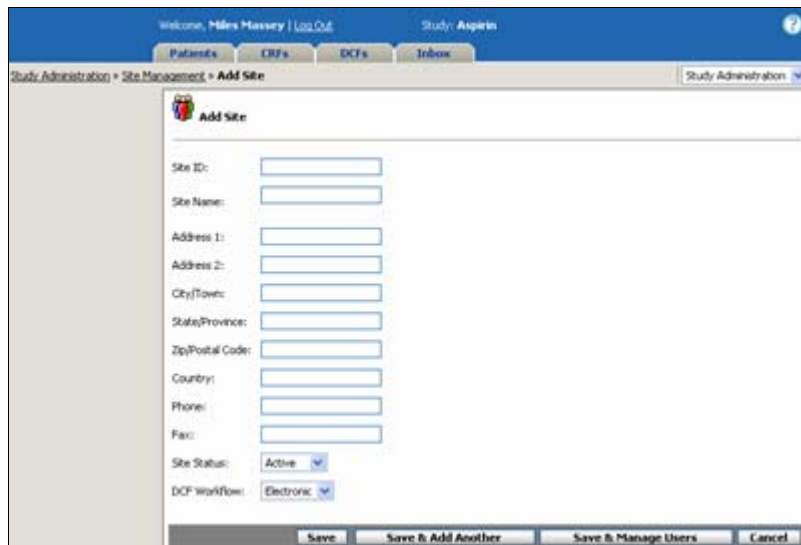
Tip: If you do not already have a naming or numbering scheme for your sites, you should define this before adding sites to DataLabs. This guarantees that you have a consistent numbering and name format.

To add a site:

1   Click **Add Site** on the Actions palette.

The Add Site page appears.

2   Fill in each field on the page with the site's information.

3   Click **Save**.

The Add Site page contains the following information:

Site ID: Defines the alphanumeric site ID that you define.

Site Name: Defines the proper site name that you define.

Note: The Display Name shown on the Site Management page is a combination of the *site ID* and *site name*. For example:

Site ID +	Site Name	=	Display Name
001 +	Los Angeles	=	001 - Los Angeles
382 +		=	382
+	Boise	=	Boise

At least one of the fields—Site ID or Site Name—must be filled in. Also, the Display Name (combination of the Site ID +Site Name) must be *unique* for the study.

Address 1 & 2: Defines the site's street address.

City/Town, State/Province, Zip/Postal Code & Country: Defines the city name, two-letter state/province abbreviation, ZIP/postal code and country name.

Phone & Fax: Defines the site's phone and fax numbers; be sure to include the area code.

Site Status: Changes the status of the site. The default is Active.

 Active – The site currently defined as active.

 Inactive – The site currently defined as inactive. While inactive sites are displayed on the Patient, CRFs or DCFs tabs, *you are only restricted from adding new patients*—you can edit CRFs and perform all other patient actions.

DCF Workflow: Selects which initial status method to apply to DCFs. When a study is created in Designer, the initial status can be selected for edit checks, range checks and queries when they fire.

	Draft	Sent
Electronic workflow	Draft	Sent
Paper workflow	Draft	New

Note: Once a site is added, DataLabs will automatically set the New Patient Permissions to "Allow." This will apply only to the most recently published study. Any previously published study versions will default the New Patient permissions to "Deny."

Editing a Site

From the Site Management page, you can click the site's Display Name to edit the site and give users access to it.

Note: It is especially important to give users access to the site—unless a user is given access to a site, they cannot edit patient data for that site, act as a PI or reviewer.

To edit the site and assign the primary investigator:

1   From the Site Management page, click the site name.

The Edit Site page appears.

2   Make any necessary changes to Site ID and Name, address and phone information.

3   Select a PI from the list of users associated to the site.

Note: It is highly recommended—though not required—that you choose a PI for each site.

4   Click **Save**.

The "Save Successful" message appears. DataLabs saves the changes you made to the site and returns you to the Site Management page.

The Edit Site page has the same options as the Add Site page (earlier), but includes some additional actions and information:

Actions palette:

Manage Users – Gives users access to the site. For more information about managing users, see Giving Users Access to a Site on page 106.

Manage Versions – Selects which study version(s) new patients added to this site can be assigned to. For more information about selecting study versions, see Managing Study Version on page 107.

Migrate Patients – Selects which patients to migrate to the latest study version. For more information about migrating patients, see Migrating Patients on page 108.

Primary Investigator: Selects the primary investigator (PI) from the list of users.

Study Versions subtab: Lists the currently published study versions (maximum two).

Study Versions	Users		
Version	**Patients**		**Default**
2.0	0		✔
1.0	0		

Version – Lists the version numbers of each published study.

Patients – Lists the number of patients assigned to each version.

Default – A check mark notes which version is the default when adding a new patient to the site.

Users subtab: Lists all the users associated to this site.

Study Versions	Users	
Name	**Group(s)**	**Primary Investigator**
Miles Massey*	XCAdmins(Active),	✔
Ed Crane	Data Entry Personnel(Active),	
Carl Showalter	Field Monitors(Active),	
Everett McGill	Data Managers(Active),	

Name – Lists the display name of user. For more information about the display name, see Chapter 3: User Preferences on page 45.

Group(s) – Lists which user group(s) the user is associated to. For more information about user group association, see Group Management on page 55.

Primary Investigator – A check mark notes which user is designated as primary investigator for the site.

Note: The PI is displayed in the header of all patient-related data pages.

Giving Users Access to a Site

Once you have added a site, you can use Manage Users to give users access to a site.

Tip: Before you give users access to a site, you need to ensure that you have added all users first. For more information about giving user groups access, see Group Management on page 55 and User Management on page 65.

To give (or deny) a user's access to a site:

1   From the Edit Site page, click **Manage Users** on the Actions palette.

The Manage Users page appears, containing two lists of users:

Available Users: Lists all users who have been added to DataLabs but are not given access to this site.

Site Users: Lists the users already given access to this site.

> **Note**: If a Primary Investigator has already been defined, an asterisk (*) appears next to the user's name.

2   From the **Available Users** list, click the user(s) you want to give access to the site.

> **Tip**: To select more than one user, press the CTRL key while clicking each additional user.

3   Click **Add**.

4   From the Site Users list, click the user(s) you want to deny access to the site.

5   Click **Remove**.

6   Click **Save**.

   The "Save Successful" message appears.

DataLabs saves the changes and returns you to the Edit Site page. The users given access to the site are listed in the Users subtab at the bottom of the page.

Managing Study Versions

The Manage Versions page selects which study version users can add new patients within this site. You can select one or both published versions. See Study Version Management on page 90.

To manage the study version for each site:

1   From the Edit Site page, click Manage Version on the Actions palette.

The Manage Versions page appears, listing only the study versions that are currently published and all obsolete versions.

2   Select whether you want to Allow or Deny users to add **New Patients** to the study version.

Note: When a site is added, DataLabs will automatically set the New Patient permissions to "Allow." This will apply only to the most recently published study. Any previously published study versions will default the New Patient permissions to "Deny."

If you set New Patients to "Allow" for both versions, you can select which version will be the **Default** when users add new patients to the site.

Note: The Default selection is only available if there are two published study versions and you allow new patients to be added to both.

3   Click **Save**.

If you migrate all patients to the most recent study version at the time that study is published, that version will be set to "Allow" for all sites in the study and will become the default. Also, the preceding study version will be automatically set to "Deny" for all sites in the study.

Note: The Manage Version action is only available if you have a published file.

Migrating Patients

The Migrate Patients command selects the patients to move from the earlier published version of the study to the most recent one. Once patients have been moved to the most recent version they cannot be moved back.

■   When a published study already exists and new study is published:

If you select Migrate Patients when you publish the study, all sites will have the New Patient permissions set to "Allow" for the newly published study. While the previous version of the study will have New Patient permissions set to "Deny."

When you select Do Not Migrate when you publish the study, all sites will have the New Patient permissions set to "Deny" for the newly published study. The old study version will not be modified.
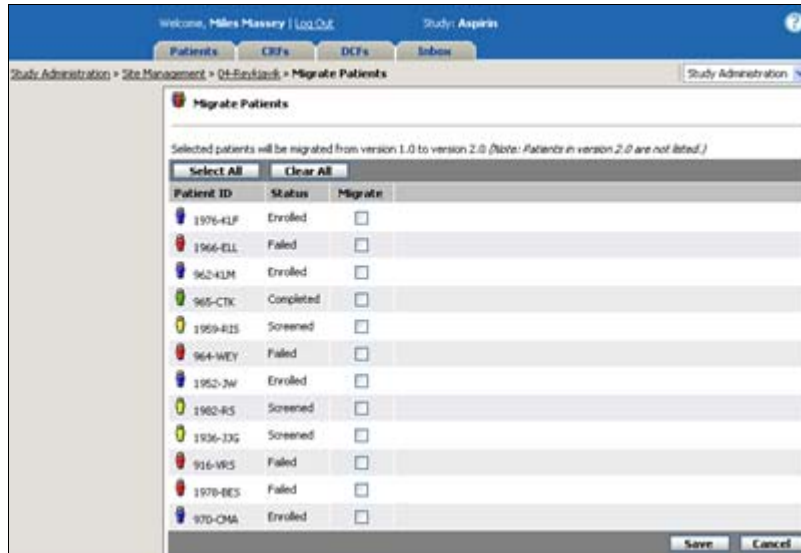
To migrate patients from the earlier study version to the most recent one:

1   From the Edit Site page, click **Migrate Patients** on the Actions palette.

The Migrate Patients page lists the patients that have not yet been migrated to the most recent study version. It contains the following information:

Patient ID: Lists the Patient ID and appropriate status icon.

Status: Lists the current workflow status of the patient.

Migrate: Selects the patients to migrate to the most recent study version.

2   Select which patients you want to Migrate to the most recent study version.

Note: If the patient is locked or any of the patient's CRFs are in the process of Paper Data Entry, the patient cannot be migrated until all forms in the process have been submitted. (If any of the patient's forms are checked out and are in electronic data entry, the CRFs checked out status are cancelled during the migration process.)

---

3   Click **Save**.

DataLabs begins migrating the patients, temporarily locking each patient as the are migrated, prohibiting users from accessing patient data; however, there is a slight delay between when the migration request is submitted and when patient CRFs are locked.

A "Migration of Site for Study file (*StudyName* v.*N*) – complete" message appears in the Jobs section of the Inbox when the patient migration is complete.
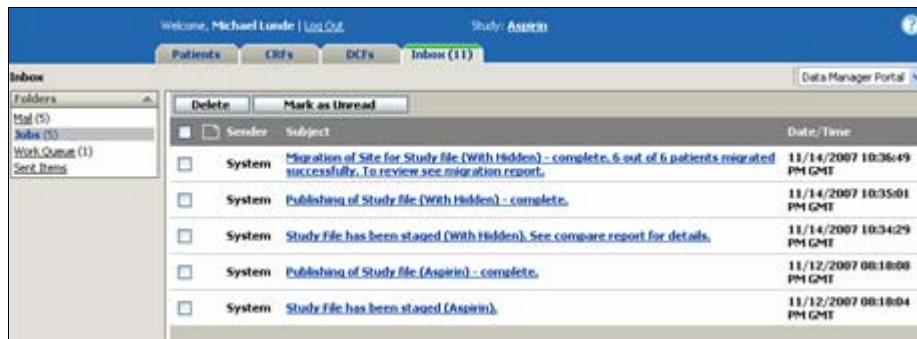
To delete the migration message:

1 Click the check box for the message(s).

2 Click **Delete**.

- The Migrate Patients command is only available if you have *two* published versions of a study.

- You can migrate frozen patients.

- All derivations and queries for the patient are run when a patient is migrated. (The exception is when a new item is added to the new study version. In this case, the query or derivation attached to it will not run until the item on the form is updated and the form is saved.)

Signature Management

The Signature Management section defines the language or text of the Primary Investigator's attestation assigned when an electronic signature is applied to a CRF.

Note: If you update the attestation during the study, any signatures up to that point will carry the previous attestation. Anything signed after the attestation has been changed will carry the new text.

To update the signature attestation page:

1   From the Study Administration page, click Signature Management.

    The Signature Management page appears in view mode.
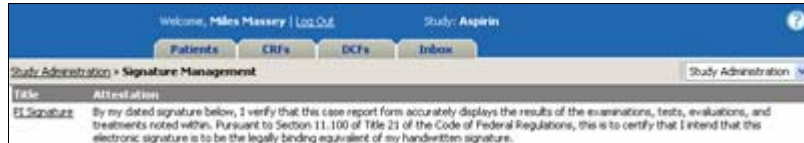
2   Click **PI Signature** to edit the attestation.

    The Signature Management Entry page appears in view mode.
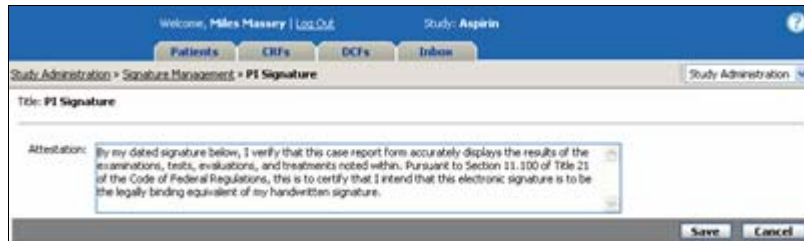
3   Edit the attestation as necessary.

4   Click **Save**.

    The "Save Successful" message appears. DataLabs saves the text you updated, and returns you to the Signature Management page.

    Note: The new text will appear on every form requiring a PI's signature (for example, the Sign Casebook page, below).

PI
Signature

Derivation Management

A derivation is a calculation based on one or more parameters—data entered into CRF fields (including external fields) and other study variables—using a user-defined derivation script.

The derivation script collects parameters, calculates a value, and stores it in a field on a CRF.

You can use the Derivation Management page to view, run and search for derivations. Derived fields, derivations and derivation scripts are created and written during the design phase in Designer.

Example: For example, a Patient_Age derivation calculates the age of the patient at the start of the study using the BirthDate and TodayDate parameters and stores it in the derived field.

Uses for Derivation Management

Derivation management is primarily useful in two cases:

- A study's derivations have been updated as part of a study update in DataLabs.

- Viewing derivations that have encountered a script error and have been inactivated. For more information about inactivated derivations, see Inactivated Derivation Scripts on page 117.

Since derivations are run automatically when parameters used by the scripts change, manually running derivations is unnecessary except in the above circumstances.

Run Methods

While all active derivations are *normally* or *automatically* run—that is, their value is calculated when a CRF is checked out, or a parameter is changed and the CRF is saved—sometimes derivations may be run *manually*.

For a derivation to run it must be triggered by a parameter changing on a CRF or elsewhere in the study. Some derivations used by a CRF are triggered when a parameter on the form itself changes, while other parameters are triggered when other CRFs or study parameters change.

Derivations are triggered three different ways:

Normal: Derivations are run when a CRF is checked out or submitted. This updates the CRF with the latest information, collecting the latest values for the derivation's parameters—whether the parameter data is on the same form, a different form, or non-form data—and calculating the new value for the derived field. This is the typical method in which a derivation is run.

Auto: Derivations on other CRFs that use parameters from the current form, are automatically run whenever the parameters are changed and the CRF has been saved.

Additionally, when non-form data changes such as event dates, signature statuses, etc., which are parameters to derivations, those derivations automatically run.

Note: Since the process of performing derivations can be intensive, auto and manual derivations are queued and run in sequence by DataLabs, spacing out the load so on-line users do not experience delays. Therefore, it may take several minutes before your derivation is queued to run.

Manual: Though all derivations are either "auto" or "normal" triggered, they can still be run manually from Derivation Management.

Tip: All derivations for the sites and patients that you select will be run, even if there is no result. In other words, if you select a site, all derivations for all patients at that site will run. To control the load on DataLabs, you should select only the derivations that need to be run.

When you run derivations manually, this is basically what happens:

1   DataLabs creates a list of derivations that will be run for each of the sites and patients selected in the derivation wizard.

2   DataLabs collects a list of forms with derived fields pointing to the selected derivations. Only published and submitted forms are included in the list.

3   DataLabs builds a master list of all instances of the derivations that need to be run.

4   DataLabs runs the instances of the derivations on the master list.

Study Versions

If your study uses multiple study versions, only derivations used by the *published* version(s) are available in derivation management. If a derivation is used by two versions of the study, each version of that derivation is listed. Derivations that have changed from the earlier version are flagged ( ). For more about study versions, see .

Note: Only the derivations associated with a patient's study version are run. For example, if a patient is in version 2.0, only the valid derivations from version 2.0 will be run for that patient.

Accessing Derivation Management

The Derivation Management page is used to view, run and search for derivations.

To access derivation management:

■   From the Study Administration page, click **Derivation Management**.

The Derivation Management page appears.
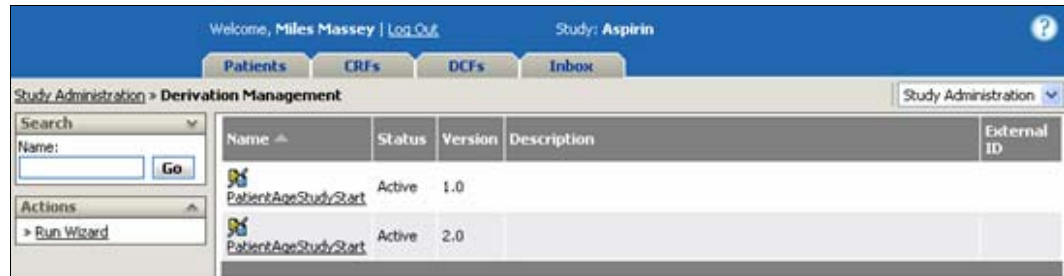
The Derivation Management page has the following information:

Search palette: See Searching for Derivations on page 119.

Actions palette:

   Run Wizard – See Running the Derivation Wizard on page 119.

Name: Displays the name of the derivation (and its status icon—see below). Click to view the derivation. If a derivation is used by two versions of the study, each version of that derivation is listed.

Status: Displays the derivation's current status: Active (⚙️), Inactive (⚙️), or Inactive with error (⚙️).

   ⚙️ **Active** – The script is currently active and has run without errors.

   ⚙️ **Inactive** – The script's status has been changed to inactive and will not run until its status is set to Active.

   ⚙️ **Inactive with error** – The script has invalid syntax and generated an exception when it last ran. See Inactivated Derivation Scripts on page 117.

Version: Lists the study version for both the earlier and later derivations. If the most recent derivation has been updated from the earlier version, it is flagged (🚩).

Description: Displays a description of the derivation script.

External ID: Displays the reference identifier for the derivation.

Viewing a Derivation

You can view a derivation by clicking on the derivation's Name. When you view a derivation you can also change its status, view a list of the forms that use it, view a list of the parameters that contribute to it, and view the derivation script itself.

To view a derivation:

■   From the Derivation Management page, click the derivation **Name**.

   The View Derivation page appears.
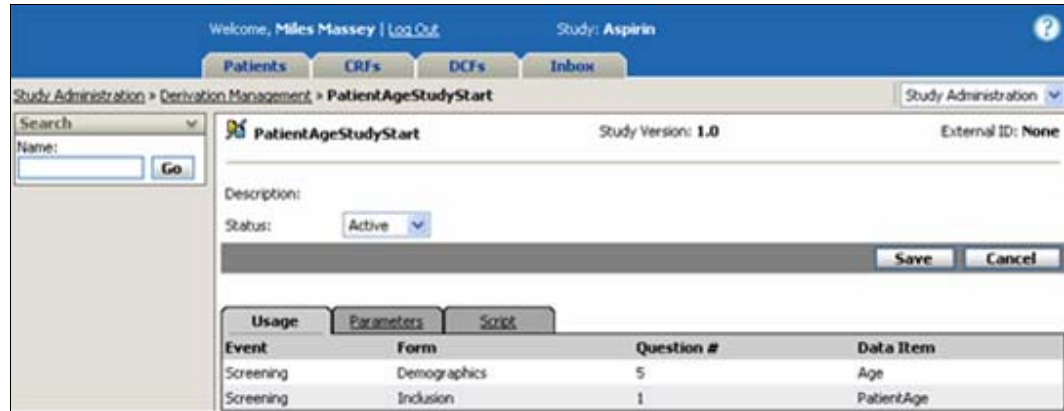
The View Derivation page has the following information:

Search palette: See Searching for Derivations on page 119.

Name: Displays the name of the derivation script and its status icon.

Study Version: Displays the version of the study that the derivation belongs to.

External ID: Displays the derivation reference ID.

Description: Displays a description of the derivation script.

Status: Changes the derivation script's status.

> By changing a scripts status to **Active**, the script can be run, either automatically or manually.

> By changing a derivation's status to **Inactive**, the script will not be run. DataLabs will not automatically fire derivations changed to inactive, nor can you manually run derivations changed to inactive.

> If a derivation has invalid syntax (this could be for a variety of reasons), DataLabs will generate errors when the script is run, and may change its status to **Inactive with errors**. See Inactivated Derivation Scripts on page 117.

Usage subtab: Lists where and how the derivation is used.

> **Event, Form, Question #** – Lists all questions that use this script, including which event and form the question is on.

> **Data Item** – Lists the specific data item on the form that is being derived.

Parameters subtab: Lists the parameters that the derivation references.

Usage	**Parameters**	Script	
Name		**Reference**	
BirthDate		Data.Screening.Demo.Birthdate.Birthdate.Value	

Name – Lists all parameters referenced for this derivation.

Reference – Lists the specific data reference for the parameter.

Script subtab: Displays the full script of the derivation. You can only edit the script in Designer.

Usage	Parameters	**Script**	
Source			

```
Function PatientAgeStudyStart(BirthDate)
PatientAgeStudyStart = DateDiff("yyyy",BirthDate,Now)
End Function
```

To change the status of a derivation:

1 From an open derivation, you can change the Status.

2 Click **Save** to keep your changes and return to the Derivation Management page.

Inactivated Derivation Scripts

If script auto-inactivation is enabled, any derivation script that encounters a script error is inactivated. The script will not run again until its status is changed to active.

Run-time errors occur when the script attempts to perform an action that cannot be processed correctly. Some examples of when this can occur are:

■ The parameter value passed to the script is in the wrong format.

■ The parameter value passed into the script is the wrong type of data, such as passing text or a date into a function that expects an integer value.

■ A text or date parameter value is passed to a function that performs arithmetic.

■ Integer parameter values are passed to a script that results in division by zero.

Syntax errors occur when the script contains a statement that violates the grammatical rules of the VBScript scripting language. Some examples of when this can occur are:

■ A statement contains typographical errors.

■ A statement is missing a symbol, such as a comma, single quote, or parenthesis.

■ For paired statements, such as Function / End Function, one of the statements is missing.

After you have identified the problem, make the appropriate corrections to the script (in Designer), update the study, and change the script's status to active.

Example: Script auto-inactivation is turned on. A derivation uses the patient's birth date, but the script uses an improper operation—(CInt(BrthDt)). Since birth date is a date-time parameter and not an integer, the script is invalid and will generate an exception when it is run, inactivating the derivation and generating a single error message. This derivation will run for no further patients until its status is changed to Active.

Note: You can turn script auto-inactivation on or off from the Study Preferences page.

Note: You can check for inactive derivation scripts and reset a derivation script's status on the Derivation Management page.

To reactivate a derivation:

1 Correct the conditions that caused the script to generate an exception.

2 From Derivation Management, click the Inactive with error (🖾) script's **Name**.

3 Change its Status from "Inactive" to "Active."

4 Click **Save**.

A confirmation box appears.

5 Click **Continue**.

Checked Out, Frozen and Locked CRFs

There are three situations that derivation scripts run atypically:

CRFs	Situation	Action
Checked out	A form on which the derived field resides is checked out.	DataLabs runs the derivation on a checked out form while leaving the form checked out.

| Frozen | A patient for which the derivation is run is frozen. | DataLabs *runs* derivations on frozen CRFs. |
| Locked | A patient for which the derivation is run is locked. | DataLabs *skips* derivations on locked CRFs. |

Searching for Derivations

Though there are usually no more than 20-30 derivations for a typical study, you may still find the Search palette useful to find derivations. For each search option you add, the more narrow your search range becomes, and the fewer results are returned.

To search for derivations:

1 Click the Expand button ⌄ at the top of the Search palette to see all the search options.

2 Enter or select your search criteria.

Tip: You can enter a partial Name or External ID.

---

3 Click **Go**.

The Search palette gives you the following options:

Name: Searches for derivations based on a Name.

Tip: The Name field considers every character you type to be included in the search criteria, so if you happen to include a [space] (even as a leading or trailing character), the search engine may not find the derivation you're looking for.

External ID: Searches for a derivation based on its External ID.

Status: Searches for a derivation based on its status (Active, Inactive or Inactive w/ errors).

Study Version: Searches for a derivation based on its study version, including newer versions that have changed.

The Derivation Management page appears with the list of derivations meeting your search criteria.

Running the Derivation Wizard

You can use the Run Wizard command on the Actions palette to run derivations for selected sites and patients. When you select a site or patients, the wizard runs all associated derivations.

To run all derivations for a selected patient or site:

1 From the Derivations Management page, click the **Run Wizard** command on the Actions palette.

The Run Wizard page appears.
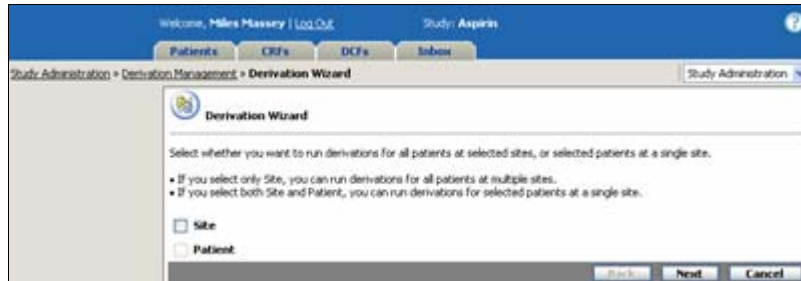
2 Select whether you want to run derivations for all patients at selected sites, or selected patients at a single site.

If you select only **Site**, you can run derivations for *all patients at multiple sites* (see below).

If you select both **Site** and **Patient**, you can run derivations for *selected patients at a single site* (see page 122).

To run derivations for all patients at multiple sites:
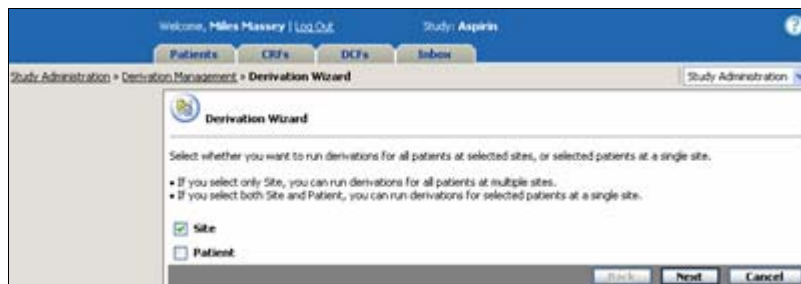
1 Select **Site**.

2 Click **Next**.

The site selection page appears. It lists only the sites that you have access to.
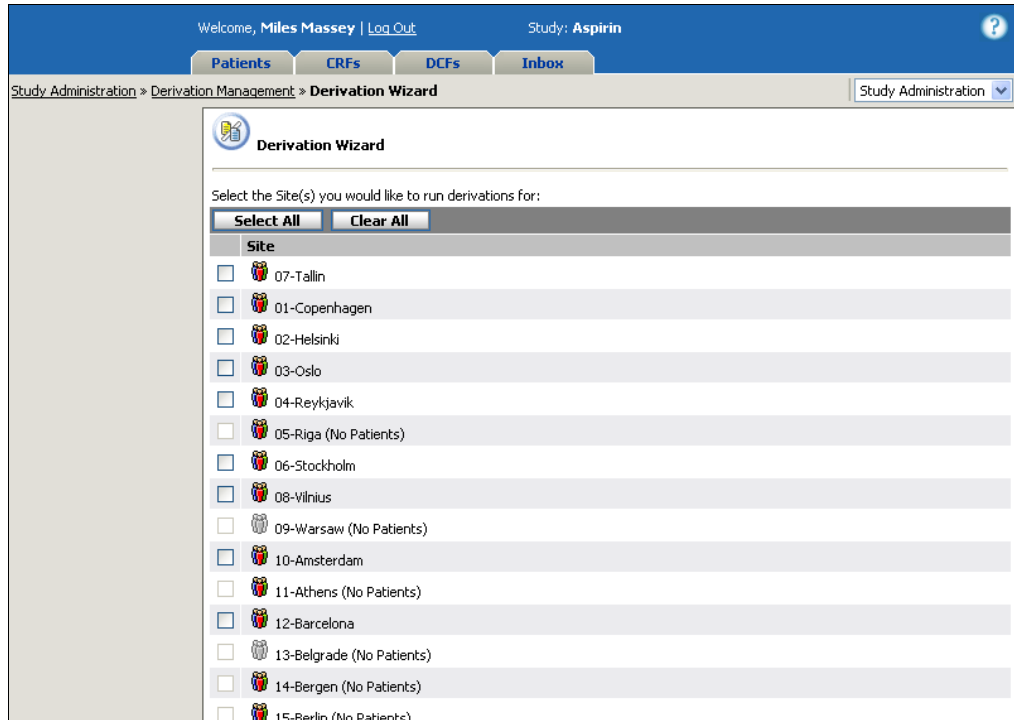
Note: This will run all derivations for every patient belonging to the selected sites.

3 Select the sites you want to run derivations for.

4 Click **Next**.

The Selection Criteria subtab shows the sites that will have derivations run.
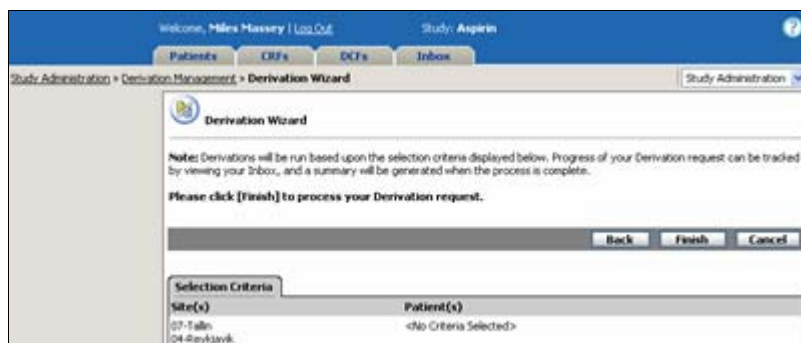
5 Click **Finish**.

DataLabs begins running the derivations, showing the progress in the Inbox. When the derivation process is complete, the Inbox lists a completion message. For more information about the derivation inbox message, see Derivation Inbox Messages on page 123.

To run derivations for selected patients at a single site:

1   Select **Site**.

The Patient check box is enabled.

2   Select **Patient**.

3   Click **Next**.

The site selection page appears. It lists only the sites that you have access to.

4   Select the site from the list.

The patient selection page appears. It lists all patients for the selected site.

Note: If a patient is locked, the check box is disabled.

5   Select the patients you want to run derivations for.

6   Click **Next**.

The Selection Criteria subtab shows the sites that will have derivations run.

7   Click **Finish**.

DataLabs begins running the derivations, showing the progress in the Inbox. When the derivation process is complete, the Inbox lists a completion message. For more information about the derivation inbox message, see Derivation Inbox Messages on page 123.

Derivation Inbox Messages

When the derivation process is complete, the Inbox lists a completion message in the jobs folder. You can click the message to view a summary of the derivation run.

The Inbox also displays a series of derivation progress messages (*#[N]* is the number of sequential derivation runs since the study was loaded):

Derivations: cancelled (queue error). The Derivation processing was started, but encountered an error.

Derivations: request is queuing. The derivation processing is waiting to start.

Note: The difference between this message and the "waiting" message: in this case, the derivations are being written but not yet in the message queue. Since this action happens so quickly, it is highly unlikely you will ever see it in the Inbox.

Derivations: #[N] - waiting. The derivation processing is waiting to start; the server checks every 20 seconds for derivation processing requests.

Note: The difference between this message and the "request is queuing" message: in this case, the derivations have been written and are in the message queue, ready to be processed.

Derivations: #[N] – running ([P]%). The derivation processing is running.

Derivations: #[N] – complete. View summary. or Derivations: #[N] – complete (with exceptions). View summary. All selected derivations are finished being run; clicking the link will open the summary of the derivation run.

To view the derivation run summary:

1   From the Inbox, click the Derivations: #[N] – complete. View report. link.

The Derivations Run Summary appears. If exceptions were generated, they are listed in the Run Summary:

2   Click Print to send the summary to a printer.

3   Click **Close**.

The Derivation Run Summary list the following information.

Total Patients Run: Lists the total number of patients for which derivations were run.

Date/Time: Lists the date and time of the derivation request.

Total Derivations: Lists the total number of derivations run.

Updated: Lists the number of derivations that were changed due to the manual derivation run.

Exception: Lists the number of the derivations that generated exceptions.

Query Management

You can use the Query Management page to view, run and search for queries. Queries are created and written during the design phase in Designer. While most queries are CRF-specific—that is, their logic and parameters check only the data in one or more CRFs—some queries check data that is outside of CRFs—for example, queries that check event dates (see the following table).

Level				Description
0-3	Form			The query checks the contents of a field or fields on a single CRF.
	0-2	Single field		The query checks the contents of the current field upon exiting the field.
		0	Required	If a required field is left unanswered, the field is marked with a ❗ icon.
		1	Format	If the answer provided does not match one of the defined data types—integer, float, text, date, etc.—the field is marked with a ❗ icon
		2	Range check; min/max length; min/max precision	The data needs to fall within a specific range: date range, numeric range, etc. If the answer provided is outside of the range—a date not in the date range, for example—the field is marked with a ❗ icon.
				The total number of characters or numbers entered in the field. For numeric fields, the decimal point is not counted in the length, so the length for "123.456" is 6.
				The number of digits to the right of the decimal for numeric fields. For example, a max precision of 3 would allow "123.456" but not "12.3456."
	3	Multi-field Custom, complex		The query checks the contents of multiple fields on a single form. These queries are run only when the CRF is submitted or checked in.
4	Event	Custom, complex		The query checks the contents of multiple fields, on multiple CRFs, for a single event. These queries are run when the CRF is submitted or checked in.
5	Patient	Custom, complex		The query checks the contents of multiple fields, on multiple CRFs, for multiple events, for a single patient. These queries are run when the CRF is submitted or checked in.

Study Versions

If your study uses multiple study versions, only queries used by the *published* version(s) are available in query management. If a query is used by two versions of the study, each version of that query is listed. Queries that have changed from the earlier version are flagged (🚩). For more information about study versions, see "Study Version Management" on page 90.

Note: Only the queries associated with a patient's study version are run. For example, if a patient is in version 2.0, only the valid queries from version 2.0 will be run for that patient.

Accessing Query Management

The Query Management page is mostly used to view and manually run queries.

To access query management:

1   From the Study Administration page, click 🔍 **Query Management**.

The Query Management page appears.

The Query Management page has the following information:

Search palette: See Searching for a Query on page 130.

Actions palette:

> **Run Queries** – See Running Selected Queries on page 131.

> **Run Wizard** – See Running the Query Wizard on page 134.

Name: Displays the query's status icon and name.

Type: Displays whether it is DCF or Notify type query.

Status: Displays the query's current parameter status:

> 🔍 **Active** – The query is currently active and has run without errors.

> 🔍 **Inactive** – The query status has been changed to inactive and will not run until its status is set to Active.

> 🔍 **Inactive with error** – The script has invalid syntax and generated an exception when it last ran. See Inactivated Query Scripts on page 129.

Version: Lists the study version for both the earlier and later queries. If the later query has been changed from the earlier version, it is flagged (🚩).

Description: Displays a description of the query.

External ID: Displays the reference identifier for the query.

Viewing a Query

You can view a query script by clicking on the query's name. When you view a script you can also change its status, view its parameters, and view the script itself.

To view a query:

1 From the Query Management page, click the **Name**.

The View Query page appears.
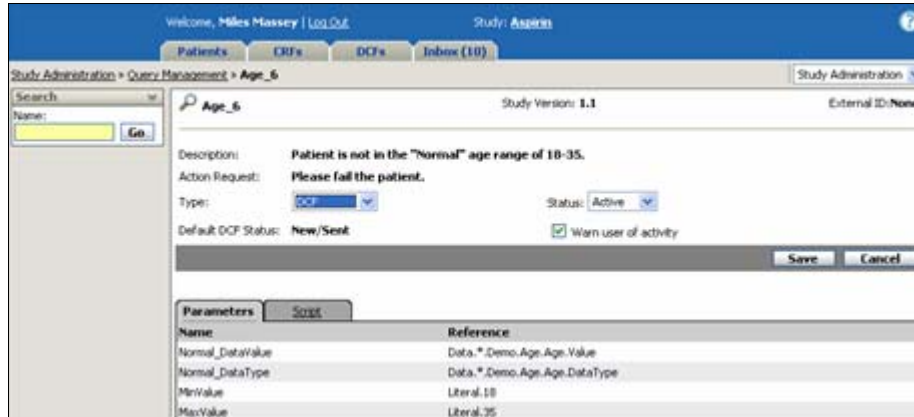
The View Query page has the following information (most of which are configured in Designer during the design phase):

Search palette: See Searching for a Query on page 130.

Name: Displays the query's status icon and query name.

Study Version: Lists the study version for the query.

External ID: Displays the query reference ID.

Description: Displays a description of the query. This text appears in the DCF.

Action Request: Displays the action requested for the query. This text appears in the DCF.

Type: Displays whether it is a DCF or Notify type query.

Default DCF Status: Displays the default status for DCF (New, Draft or Sent).

Status: Selects the query status (Active or Inactive).

By changing a query's status to **Active**, the script can be run.

By changing a query's status to **Inactive**, the script will not be run: neither automatically by DataLabs nor manually.

Note: If the query status is set to Inactive, and has DCFs associated to it, when you click Save, DataLabs prompts you with, "Would you like to close all DCFs associated with this Query?"

Warn user of activity: Select to be notified if the query fires. If this is selected, when a user saves a CRF and this query fires, they will receive a pop-up warning that a DCF will be created.

Parameters subtab: Lists the parameters checked by the query.

Parameters	Script
Name	**Reference**
Normal_DataValue	Data.*.Demo.Age.Age.Value
Normal_DataType	Data.*.Demo.Age.Age.DataType
MinValue	Literal.18
MaxValue	Literal.35

Script subtab: Displays the full script of the query. You can only edit the script in Designer.

```
Parameters    Script
Script Name   Source
Age_6
            Function Level2RangeNotValid(DataValue, DataType, MinValue, MaxValue)
                If LCase(DataValue) = "null" or DataValue = "" Then
                    Level2RangeNotValid = "False"
                ElseIf LCase(DataType) = "datetime" Then
                    If IsDate(DataValue) THEN
                        DataValue = cDate(DataValue)
                        MinValue = cDate(MinValue)
                        MaxValue = cDate(MaxValue)

                        IF (DataValue >= MinValue) and (DataValue <= MaxValue) THEN
                            Level2RangeNotValid = "False"
                        ELSE
                            Level2RangeNotValid = "True"
                        END IF
                    Else
                        Level2RangeNotValid = "True"
                    END IF
                ElseIf LCase(DataType) = "integer" Or LCase(DataType) = "float" Then
                    If IsNumeric(DataValue) THEN
                        DataValue = cDbl(DataValue)
                        MinValue = cDbl(MinValue)
                        MaxValue = cDbl(MaxValue)

                        IF (DataValue >= MinValue) and (DataValue <= MaxValue) THEN
                            Level2RangeNotValid = "False"
                        ELSE
                            Level2RangeNotValid = "True"
                        END IF
                    Else
                        Level2RangeNotValid = "True"
                    END IF
                Else
                    Level2RangeNotValid = "False"
                End If
            End Function
```

To make changes to a query:

1   From an open query, you can change three settings:

   Status: Active or Inactive.

   Type: DCF or Notify.

   Warn user of activity: On or Off.

2   Click **Save** to keep your changes and return to the Query Management page.

Inactivated Query Scripts

If script auto-inactivation is enabled, any query script that encounters a script error is inactivated. The script will not run again until its status is changed to active.

Run-time errors occur when the script attempts to perform an action that cannot be processed correctly. Some examples of when this can occur are:

■   The parameter value passed to the script is in the wrong format.

■   The parameter value passed into the script is the wrong type of data, such as passing text or a date into a function that expects an integer value.

■   A text or date parameter value is passed to a function that performs arithmetic.

■   Integer parameter values are passed to a script that results in division by zero.

Syntax errors occur when the script contains a statement that violates the grammatical rules of the VBScript scripting language. Some examples of when this can occur are:

■   A statement contains typographical errors.

■   A statement is missing a symbol, such as a comma, single quote, or parenthesis.

■   For paired statements, such as Function / End Function, one of the statements is missing.

After you have identified the problem, make the appropriate corrections to the script (in Designer), update the study, and change the script's status to active.

Example: Script auto-inactivation is turned on. A query uses the patient's birth date, but the script uses an improper operation—(CInt(BrthDt)). Since birth date is a date-time parameter and not an integer, the script is invalid and will generate an exception when it is run, inactivating the query and generating a single error message. This query will run for no further patients until its status is changed to Active.

Note: You can turn script auto-inactivation on or off from the Study Preferences page. For information on turning script auto-inactivation on or off, see Updating the Study Preferences on page 77.

Note: You can check for inactive query scripts and reset a query script's status on the Query Management page.

To reactivate a query:

1 Correct the conditions that caused the script to generate an exception.

2 From Query Management, click the Inactive with error (🔍) script's **Name**.

3 Change its **Status** from "Inactive" to "Active."

4 Click **Save**.

A confirmation box appears, asking if you want the query to be queued to run.

5 Click **Continue**.

Searching for a Query

Since there could be hundreds of queries, you can use the Search palette to find queries. For each search option you add, the more narrow your search range becomes, and the fewer results are returned.

Example: For example, you could search by query name or external ID alone; or you could select queries that have some parameters within CRFs; or only inactive queries.

To search for queries:

1 Click the Expand button ⌄ at the top of the Search palette to see all the search options.

2 Enter or select your search criteria.

3 Click **Go**.

The Search palette gives you the following options:

Name: Searches for queries based on a query name.

Tip: The Name field considers every character you type to be included in the search criteria, so if you happen to include a [space] (even as a leading or trailing character), the search engine may not find the query you're looking for.

External ID: Searches for queries based on its External ID.

Status: Searches for a query based on its status.

Study Version: Searches for a query based on its study version, including newer versions that have changed.

The Query Management page appears with the list of queries meeting your search criteria.

Running Selected Queries

You can use the Run Queries command on the Actions palette to select which individual queries to run, and to monitor their progress from the Inbox.

Caution: When queries are run automatically, they follow run rules and sequences. When you run them manually, these rules and sequences are not followed, and you could generate more DCFs—and therefore more work—for your staff and site personnel. This is especially true for level 0-2 queries.

To run selected queries:

1   From the Query Management page, perform a search for the query(ies) you want to run. For more information about searching for a query see Searching for a Query on page 130.

From the search results, you can select which queries you wish to run.

2   From the Query Management page, click the **Run Queries** command on the Actions palette.

The Run Queries page appears.
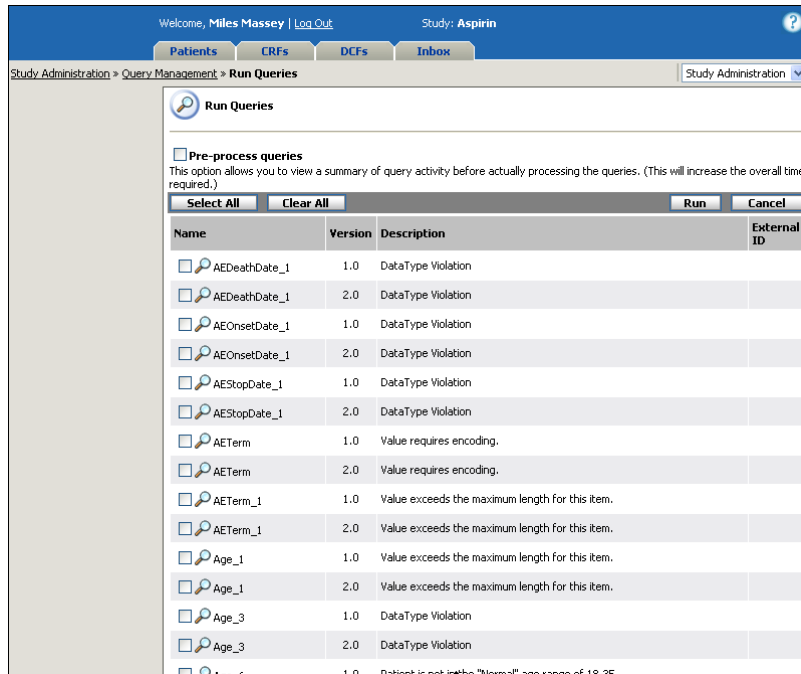
The Run Queries page has the following information:

Pre-process queries: Performs pre-processing to test the queries before actually processing data. Pre-processing does not change any data, but gives you a summary of the entire potential run process.

Tip: You will normally want to skip pre-processing since it doubles the amount of time required to run queries.

Select All button: Selects all queries listed to be run.

Clear All button: Clears all previously selected queries.

Name: Displays the query's status icon and query name.

Version: Lists the study version for the query. If the query has been updated since the other published version, it is flagged ().

External ID: Displays the external ID.

Description: Displays a description of the query.

Run button: Runs selected queries. (The button disabled if no queries are selected.)

Cancel button: Returns you to the Query Management page without running any queries.

3   Do one of the following to select which queries to run:

- To run all queries, click the **Select All** button ().

- To run a selected query, click its check box (☑).

- To clear all the check boxes, click the **Clear All** button (Clear All).

4   Click **Run**.

The Run Queries message box appears.

Run Queries

Queries will be run based on your selections. Progress of your Query request can be tracked by viewing your Inbox, and report will be generated when the process is complete.

Please click [Continue] to process your Query Request.

Continue   Cancel
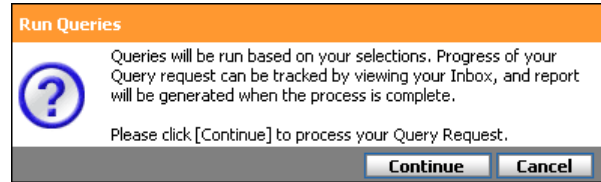
5   Click **Continue**.

DataLabs begins running the queries, and returns you to the Query Management page.

6   Click the **Inbox tab**. Go to the Jobs section.

If you have chosen pre-processing (otherwise, skip to step 8), an Inbox message shows the progress of the query pre-processing. When query pre-processing is complete, the Inbox notifies you. (You may need to refresh the page to see the new message.)

7   Click the Queries: #[N] – pre-processing complete message.

The Query Pre-processing Summary appears. It lists the number of queries that will fire, how many will resolve, and how many will generate exceptions (see "Queries" on page 233).

Query Run Summary: Process ID #1				
Query processing complete.				
Total Patients Run: 3	**Date/Time:** 11/09/2005 11:37:59 AM PST			
Total Queries : 3		Print	Close	
Query	**Version**	**Fired**	**Resolved**	**Exception**
🔍 Age_1	2.0	0	0	0
🔍 Age_1	2.0	0	0	0
🔍 Age_1	2.0	0	0	0
Totals:		**0**	**0**	**0**
			Print	Close

Note: Remember, no actual query processing has occurred yet. You must run the queries to resolve DCFs.

8   To run queries, click **Process Queries**.

DataLabs begins running the queries, showing the progress in the Inbox.

When query processing is complete, the Inbox lists a completion message.

Running the Query Wizard

You can use the Run Wizard command on the Actions palette to run queries for selected sites and patients. When you select a site or patient, the wizard runs all associated queries.

Caution: When queries are run automatically, they follow run rules and sequences. When you run them manually, these rules and sequences aren't followed, and you could generate more DCFs—and therefore more work—for your staff and site personnel. This is especially true for level 0-2 queries.

To run one or more selected queries:

1   From the Query management page, click the **Run Wizard** command on the Actions palette.

The Run Wizard page appears.
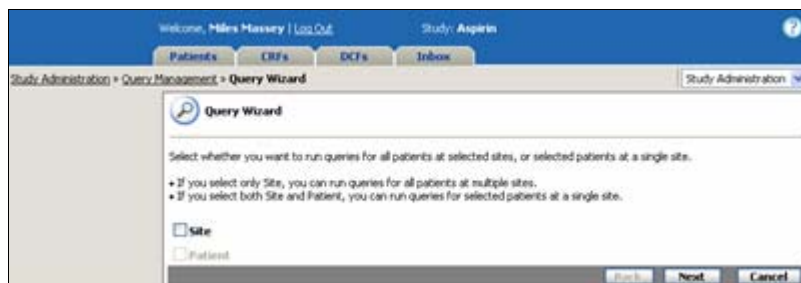
2   Select whether you want to run queries for all patients at selected sites, or selected patients at a single site.

- If you select only **Site**, you can run queries for *all patients at multiple sites* (see below).

- If you select both **Site** and **Patient**, you can run queries for *selected patients at a single site* (see page 122).

To run queries for all patients at multiple sites:
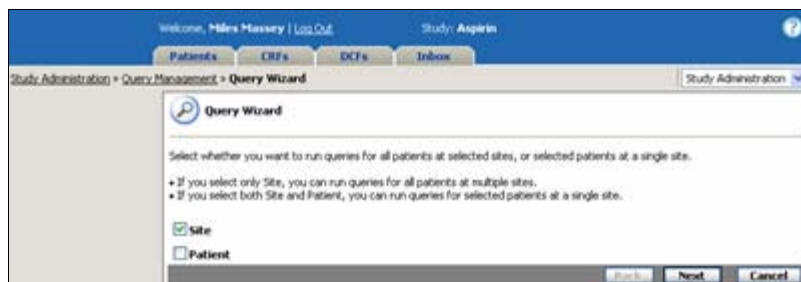
1   Select **Site**.

2   Click **Next**.

The site selection page appears. It lists only the sites that you have access to.
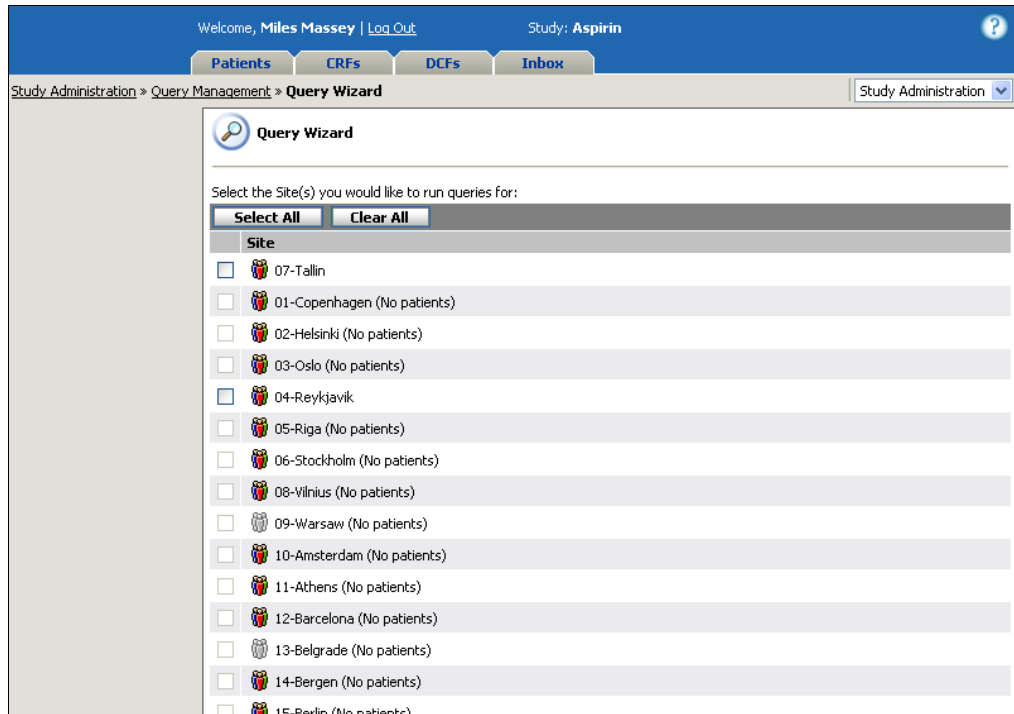
Note: This will run all queries for every patient belonging to the selected sites.

---

3   Select the sites you want to run queries for.

4   Click **Next**.

The Selection Criteria subtab shows the sites that will have queries run.

From this page, you can choose to **Pre-process queries**. This performs pre-processing to test the queries before actually processing data. Pre-processing does not change any data, but gives you a summary of the entire potential run process.

Tip: You will normally want to skip pre-processing since it doubles the amount of time required to run queries.

5   Click **Finish**.

DataLabs begins running the queries, showing the progress in the Inbox. For more information about query inbox messages, see Query Inbox Messages on page 138. When the query process is complete, the Inbox lists a completion message.

To run queries for selected patients at a single site:

1   Select **Site**.

The Patient check box is enabled.
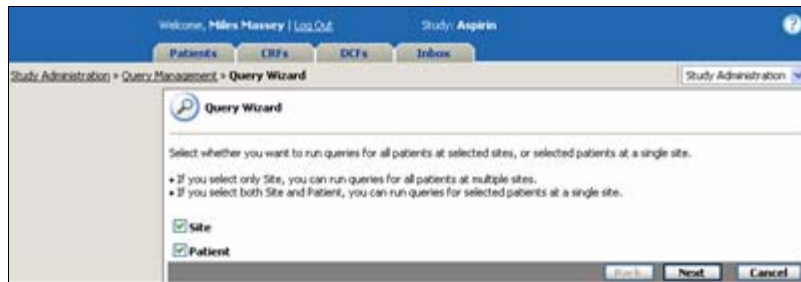
2   Select **Patient**.

3   Click **Next**.

The site selection page appears. It lists only the sites that you have access to.
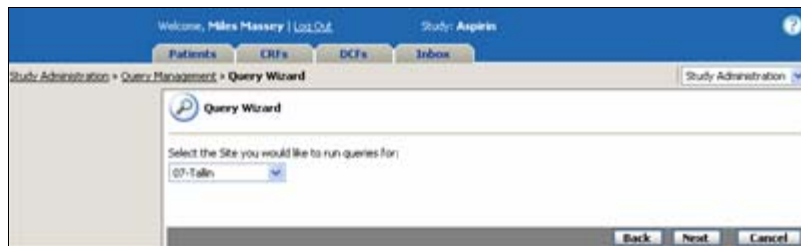
4   Select the site from the list, and click **Next**.

The patient selection page appears. It lists all patients for the selected site.

Note: If a patient is locked, the check box is disabled. If you have not allowed queries to run for frozen patients, these will be disabled as well. Select the patients you want to run queries for, and click **Next**.

The Selection Criteria subtab shows the sites and patients that will have queries run.

5 Click **Finish**.

DataLabs begins running the queries, showing the progress in the Inbox. When the query process is complete, the Inbox lists a completion message. For more information about inbox query messages, see Query Inbox Messages on page 138.

Query Inbox Messages

When you run queries from Query Management, the Jobs section of the Inbox displays a series of messages so that you can access the information behind it (*#[N]* is the number of sequential query runs since the study was loaded):

Pre-Processing Messages

Queries: #[N] – waiting. Query processing is waiting to start.

Queries: #[N] - pre-processing ([P]%). Queries are pre-processing is waiting to start.

Queries: #[N] - pre-processing complete. All selected queries are finished being pre-processed; clicking the link will open the summary of the pre-preprocessing, from which you can run query processing.

To view the summary and continue running query processing:

1   Click the subject line.

The Queries Pre-processing Summary appears.

2   Click **Process** to run query processing.

Processing Messages

Queries: #[N] - running ([P]%). Queries processing is running.

Queries: #[N] – complete. View Summary. All selected queries are finished being run; clicking the link will open the summary of the query processing.

To view the run summary:

1   From the Inbox, click the Queries: #[N] – complete. View summary. message.

The Query Run Summary appears. It lists the number of queries fired, how many were resolved, and how many generated exceptions. For more information on queries, see Queries on page 233.

Note: The counts represent every instance of the query on a form, including multiple rows on a table.

---

2   Click **Print** to send the summary to a printer.

3   Click **Close** to close the Query Run Summary.

The Query Run Summary list the following information.

Total Patients Run: Lists the total number of patients for which queries were run.

Date/Time: Lists the date and time of the query request.

Total Queries: Lists the total number of queries run.

Fired: Lists the number of queries that created a DCF due to the manual query run.

Resolved: Lists the number of DCFs that are resolved as a result of the manual query run.

Exception: Lists the number of queries that generated an exception.

Query Notification Message

If you have selected Query Notification in the user preferences and the Query Processing is complete you will receive an inbox message called Notify Query sent to your mail inbox. For more information about how to set your user preferences, see Changing Your User Preferences on page 47.

The **Notify Query** message will include the following:

ID: Query's unique identifier

Study: Study Name

Protocol (Version): Protocol name and version number

Site: Site name

Patient: Patient ID

Patient Status: Current status of the patient

Query Notification Date: Date the query notification was generated

Event – Form: The event name and form which the query notification was generated

Description: Description of the query

Action Request: Description of the action request
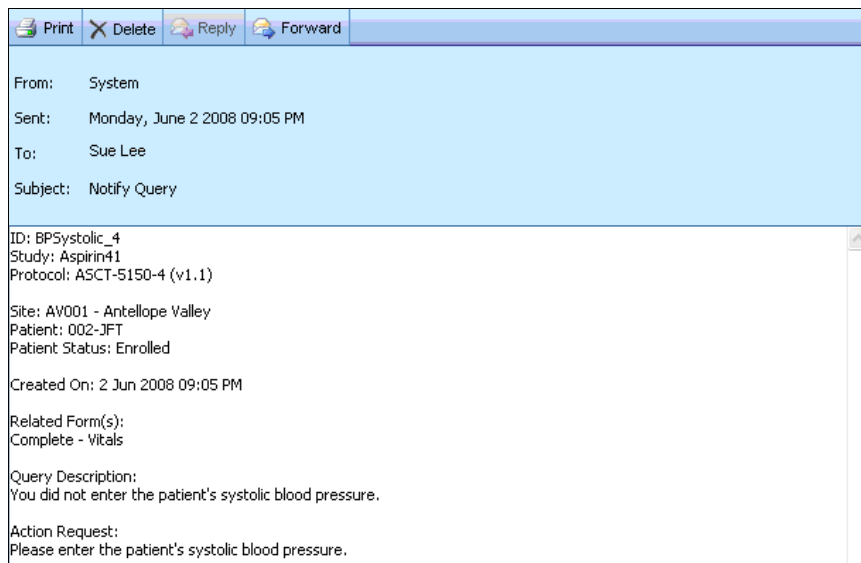
You will have the option to **Print, Delete**, or **Forward** this message.

Flag Management

Flag Management is handled through the **Flag Wizard** in the **Study Administration** section.

Flagging is a DataLabs feature allowing you to manage and set data verification statuses on CRFs. Flagging functions include:

Manage Flag Operations: Study Administrators are given the capability to set how flag status will be collected for data verification.

Setting Flags in CRFs: Determined during Flag Management Operations, data verification functions in CRFs allow you to set statuses for an entire CRF or to set statuses for each item within a CRF.

Changing Flags: Anytime during the study the responses to CRF questions may change. In these cases, DataLabs will automatically provide a visual display of any CRF or question that has been changed requiring re-verification.

Rollup and Reporting: Displays aggregated statuses for each patient and for all patients at each site and will provide summary metrics of the flags statuses for each site.

Flag Permissions Administration

You must have sufficient user rights to manage flags in DataLabs.

To edit flagging permissions:

1   From the drop-down list select **Study Administration**.

Data Manager Portal ⌄
Data Manager Portal

User Preferences
Study Administration
Export
Reporting
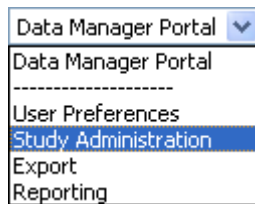
2   Select Group Management.

Select **Group Management**

Study Administration   Study Administration ⌄

Site Management
Add and maintain sites, or give users access to sites.

Study Management
Load or reset a study, set study parameters, or lock/unlock a study.

Group Management
Add user groups and set their permissions.

Signature Management
Define the text of the PI signature attestation.

User Management
Give users site access, set their default portals, or reset their passwords.

Query Management
View, run or search for queries.

Flag Management
Manage flag permissions and requirements.

Derivation Management
View, run or search for derivations.

Integration Management
Define general and critical criteria.

Casebook Management
Manage casebook reports.

3   Select the **Group Name** that you wish to change permissions in.

Choose the Group you want to change

4   In the Actions pallet, select **Edit Permissions**.

5   This will bring you to the **edit permissions** page. Click the + next to **Flag Permissions** or next to Expand All, to expand.

Click + to Expand

OR

Click + to Expand

6   From the **Edit Permissions** page you can change the flag permissions accordingly for a group.

User **Flag Permissions**

Flag Management Permissions

7   Select whether you want to **Allow** or **Deny** the group's flag permissions for D-Review, M-Review, and SD-Verify.

Group rights to perform flagging operations on CRFs will be set to one of the following:

Allow: Gives the group the ability to set a flag in a CRF form.

Deny: Denies the group the ability to set a flag in a CRF form.

8   Select whether you want a group to have access to the **Flag Management** features which will be granted/denied based on the following permissions granted:

Hide: Relinquishes the rights from the group to access the Flag Management feature for a particular group.

View: Grants access to the group to view the flag configuration in the Administration screen, but not to make changes to the configuration.

Edit: Allows the rights to change and view flag configuration for the study.

9 Click **Save** to record any changes.

Flag Management Wizard

The **Flag Wizard** takes you through the process of changing the settings for each flag. If you have flag edit permissions you will be allowed to take the following actions:

- Activate or De-activate Flags.

- Assign and change collection level between Item Level and CRF Level.

- Set flag to required or not required.

  If multiple studies are published, flag requirements can be set individually for each active protocol version.

To access the Flag Management Wizard:

1 From the drop-down list select **Study Administration**.
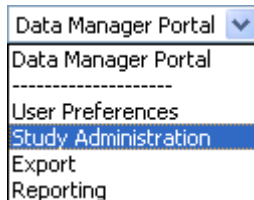
2 Select **Flag Management**.

Choose **Flag Management**
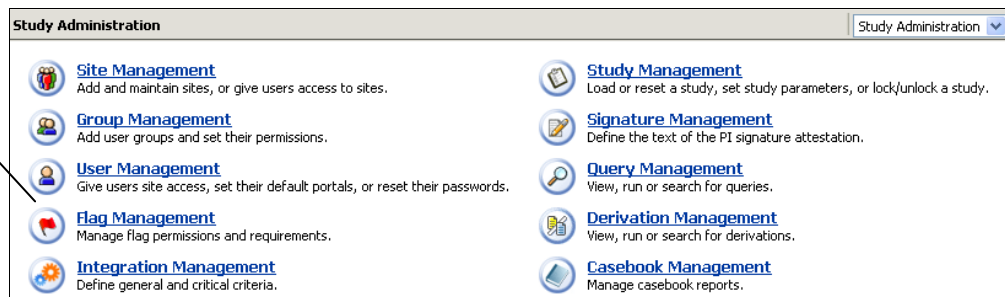
3 In the Actions palette click **Flag Wizard**.
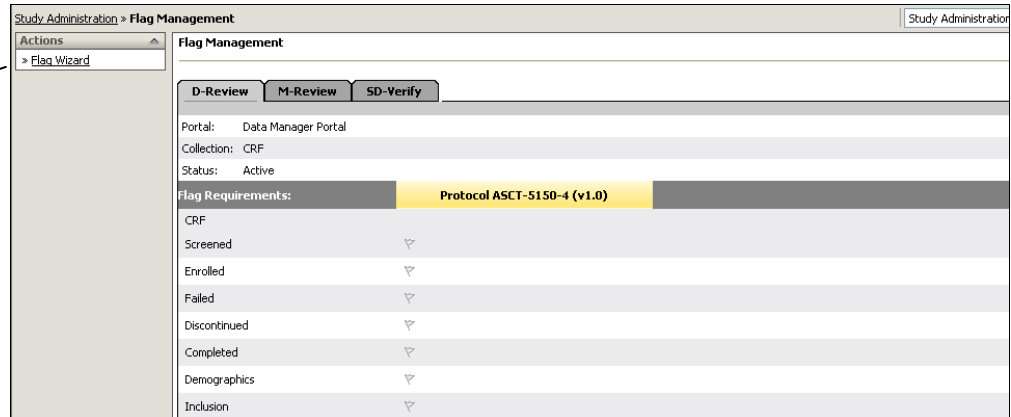
Running the Flag Wizard

When running the **Flag Wizard** no patients in the study may be "Locked." If Locked patients exist upon entering the wizard, you will be notified with the following error message.
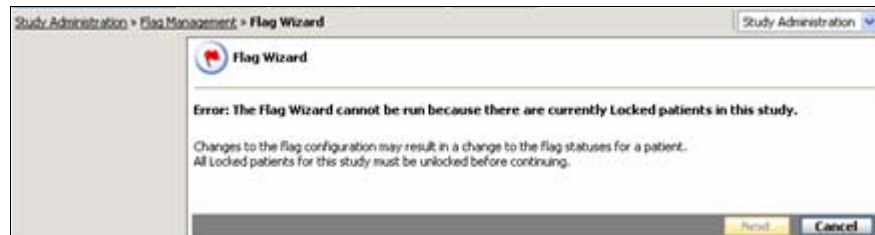
Flag Activation

Through the **Flag Wizard**, the flag will be set to **Active** or **Inactive**. Flag Activation is set at the flag level so you need to first select which flag you are choosing (D-Review, M-Review, SD-Verify).

To set flags to Active:

1 Select which flag(s) are to be changed from their current data collection method.
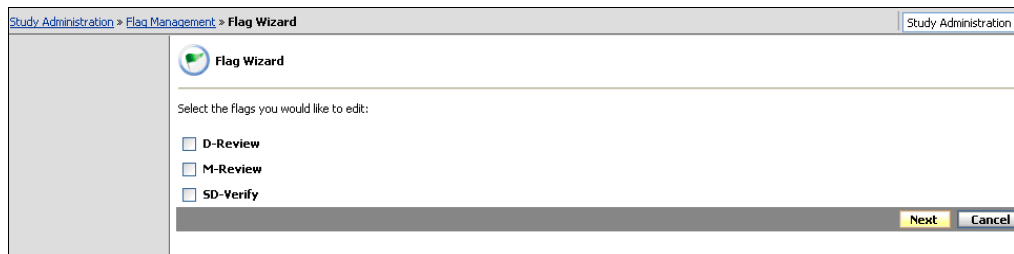
2 Click **Next**.

3 The **Flag Wizard** for that particular flag will appear. In the following example it is for the D-Review flag.

Choose Flag Status
Active / Inactive

4 Select Flag Status:

Active: Allows viewing and performing normal flagging operations.

Inactive: Prevents you from viewing or performing flagging operations for that particular flag. Flag columns on the CRF, the Patient View, the All Patient View and the CRF Form will not be visible to you. In Flag Management, DataLabs will not display in view mode screens, nor will the flag tab display.

Flag activation is independent for each Flag. For example, the flag state can be active for SD-Verify but inactive for D-Review & M-Review.

Changing Flag Status from Active to Inactive

If an **active** flag is changed to **inactive**, the following will occur:

- Any previous flag operations will be removed from the CRF and the columns displaying the Flag will be eliminated from view.

- Workflow and History will be maintained and flagging operation records will remain visible in the workflow tab and the item history (for Item Level Flagging operations only).

- Columns in the Patient View and All Patient view for the Flag will not be visible for the associated Flag.

- Statistics in the CRF will not be visible for any inactive Flags.

- Under Flag Management, the flag tab in the view mode will no longer be visible.

Changing Flag Status from Inactive to Active

If a flag that is **inactive** is changed to **active** during a study, the following will occur:

- All flags will be unset on the CRFs and reflected in the patient view rollups as work not complete for required flags. (Standard Rollup rules apply).

- The CRF rollup counts will be zero. (0)

- Under Flag Management, the flag tab in the view mode will become visible.

1 Select **Collection Level**.

Through the **Flag Wizard**, you have the option to define if flag collection is at the **CRF Level** or **Item Level** for each active flag.

Choose Collection Method

CRF Level: The collection level is done per CRF.

Item Level: The collection level is done per item on a CRF.

The flag collection type is independent for each flag. For example D-Review can be CRF Level and M-Review can be Item Level.

2   Select **Next** after choosing **Status** and **Collection** level.

3   The Edit Flag Requirements page will appear for **CRF Level** or **Item Level** collection depending on which was selected for that flag.

Flag collection will be either of the following:

Required: Flags on the CRF must be set. Required flags are distinguishable by their red icon display, both set and unset.

Set Required Icon

Unset Required Icon

Not Required: Flagging operation is optional for a particular question or CRF form.

Set Not Required Icon

Unset Not Required Icon

If flagging is collected at the **CRF Level**, the ability to set each CRF as Required or Not Required for each flag label is available.

Entire CRFs Can Be selected if collection is at CRF Level

If flagging is collected at the **Item Level**, then the option to set the flag as Required or Not Required on a CRF is available for each item separately or all items collectively.

Individual Items can be selected if collection is at Item Level

If flagging is collected at the **Item Level**, setting questions to Required within a CRF will only occur if:

■ Question is editable on the CRF form.

■ Question is not an encoded field.

■ Question is not a derived field.

If flagging is collected at the **Item Level**, conditional questions can be set to Required.

A question being **Hidden** has no effect on its ability to be set as required. It is the type of question (editable or not) which determines this.

4 Select **Next** after choosing which CRFs or Items are to be required.

5 After all desired flag changes have been made, click **Finish** to commit changes. Another check will be performed to ensure no patients are currently Locked.

Click **Finish** to
commit changes
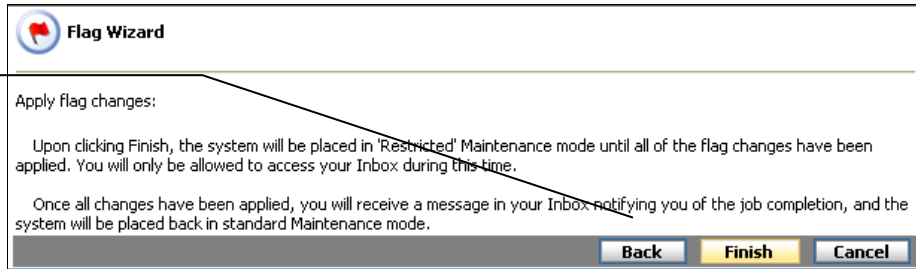
6 If Locked patients exist, the previous error message will be received and left on the last page of the wizard.

7 Click **Finish**. The system will be placed in "Restricted" Maintenance mode until all of the flag changes have been applied. You will only be allowed to access your Inbox during this time. Once all changes have been applied, you will receive a message in your Inbox notifying you of the job completion, and the system will be placed back in standard Maintenance mode.

Default Flag Configuration

The default setting for each flag is the following:

■ **Flag 1**

Label – SD-Verify

Status – Active (editable)

Portal Assignment – Field Monitor

Collection Level – CRF (editable)

■ **Flag 2**

Label – M-Review

Status – Active (editable)

Portal Assignment – Medical Monitor

Collection Level – CRF (editable)

■ **Flag 3**

Label – D-Review

Status – Active (editable)

Portal Assignment – Data Manager

Collection Level – CRF (editable)

Altering Flag Collection

From **Flag Management** DataLabs will allow the flagging collection method to change from Item Level collection to CRF Level collection or from CRF Level collection to Item Level collection. How DataLabs converts to the different collection levels depends on whether or not the CRF or Item was required, set or not set, skipped* or changed. The rules in the following sections describe how the flags will convert.

Altering flag configuration will only be available while the application is in maintenance mode, regardless if there is patient data.

CRF to Item Level Flag Collection – Required/Not Required

CRFs that were previously marked required convert to Item Level as follows:

- Every item which is modifiable (which includes conditional items) within the CRF will be marked required.

CRFs that were not required convert to Item Level as follows:

- No Items which are modifiable or conditional within the CRF will be required.

CRF to Item Level - Flag Statuses

When converting to Item Level, CRFs that have already been flagged will behave as follows:

- All "unset" in Item Level goes to "unset" in CRF Level.

- Some "unset" in Item Level goes to "unset" in CRF Level.

- Some "unset," some "on" and some "skip" in Item Level goes to "unset" in CRF Level.*

- Some "unset" and some "skip" in Item Level goes to "unset" in CRF Level.*

- Some "on" and some "skip" in Item Level goes to "on" in CRF Level.*

- All "skip" in Item Level goes to "on" in CRF Level.*

- All "on" in Item Level goes to "on" in CRF Level.

Patient Level Flag Collection Status Change – Rollups

If a patient has flags collected on any form, then DataLabs will re-calculate their flag status to reflect the change in flag collection at the patient level and at the all patient level.

Skipped Constraints

The ability to set a 4-state flag to "Skipped" will no longer be available as of v4.2. This is represented by the * under Item level flag statuses on page 155. However, the framework around the 4-state flags is not changing. This is to allow for legacy studies which already have flags set to Skipped to be upgraded to the new software, meaning that if a form in a v4.1 study is set to Skipped, when the software is upgraded to v4.2 or higher, that form will still display the Skipped status. Any form or item which maintains the Skipped status into v4.2 will be able to be set to "On" or "Off," but the ability to set it or any other item back to Skipped will not be available.

Any flag which carries a Skipped status forward from a legacy version will still display its appropriate icon, but will be counted as "On" for the purposes of rollups and calculations.

Casebook Management

Casebook Management provides an option for printing the Blank CRF Report. This report is a hard copy of the electronic DataLabs patient casebook. This paper version provides a visual representation of each form within a study. You can print a Blank CRF Report for each current and previously published study version.

Note: This report is not available for study versions that were published prior to DataLabs v4.6.

This report can be used:

■ To fulfill the FDA's requirement for the existence of a paper version of the electronic patient casebook.

■ To operate as a reference tool during on-site training of the DataLabs system to end-users.

Note: The ability to access Casebook Management is controlled by your security permissions.

To generate a Blank CRF Report:

1 From the drop-down list select **Study Administration**.

The Study Administration page appears.

2 Select **Casebook Management**.

Choose **Casebook Management**

The Casebook Management page appears.

3 Select the study version you want to generate the report for.

4 Click **Generate Report**.

The Casebook Management message box appears.
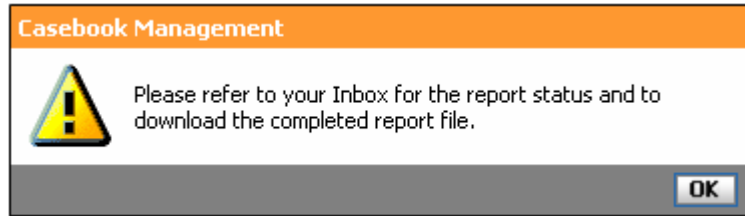
5   Click **OK**.

DataLabs begins generating the report, and returns you to the Casebook Management page.

6   Click the **Inbox** tab. Go to the Jobs section.

An Inbox message shows the progress of the job. When the Blank CRF Report generation is complete, it appears in your Inbox as a link to the file.

A sample of each page of the Blank CRF Report is shown below:

Time & Events Schedule

The time and events schedule shows the relationship between events and CRFs. If a form is associated with an event, the form is identified as one of the following:

Expected: The form is required.

Expected, Restricted: The form is required and only users with appropriate security permissions can access it.

Optional: The form is optional.

Optional, Restricted: The form is optional and only users with appropriate security permissions can access it.

Time & Events Schedule

Legend: ✔ Expected ✔ Expected, Restricted ● Optional ● Optional, Restricted

Name	Assessment	Common	Screening	Dosing	Review	Pain	Dosing 2	Review 2	Complete	Unscheduled
Scr	Screened	✔								
Enroll	Enrolled	●								
Fail	Failed	●								
Disc	Discontinued	●								
Comp	Completed	●								
Demo	Demographics		✔							
PRM	Patient Recruitment Method		✔							
MedHist	Medical History		✔							●
CRA	Cardio Risk		✔							
Incl	Inclusion		✔							
Excl	Exclusion		✔							
Vitals	Vital Signs			✔			✔	✔	✔	●
Dos	Dosing			✔	✔		✔	✔		●
Vitals2	Vital Signs 2				✔					●
GSF	Genetic Sample				✔					●
Pain	Pain					✔				●
AE	Adverse Event					✔				●
Lab	Laboratory							✔	✔	●
ConMed	Concomitant Medications								✔	●
SuppLabs	Supplemental Labs								✔	●
Status	Status								✔	●

Electronic Case Report Forms

For each electronic CRF within the study, the following information appears: the form label and name, the questions that appear on the CRF and their properties, and the questions that appear on the CRF and their associated properties.

Each CRF within the CRF section of the report will have the general look and feel of a checked out CRF.

Chapter 5:
Patient Workflow

Overview

This chapter covers the following material:

- Patients tab page layout

- Patient actions

- Overview of patient workflow and events

- Adding a patient

- Failing a patient

- Enrolling a patient

- Discontinuing a patient

- Completing a patient

- Overriding a patient's status

- Updating patient status forms

- Adding an event

- Adding an unscheduled event

- Editing an unscheduled event

Patients Tab Page Layout

Patients: Multi-Site View Layout

The multi-site view is the main view for the Patients tab. It presents patient information at the highest level.

On this page you can see how the patients are progressing through the study by looking at the status columns. The status columns display the number of patients currently in each status.

Click on the Site column header to sort the table by site name.

Click a site name to go to the multi-patient view (see Patients: Multi-Patient View on page 159).

Sites ▲	🔆 Screened	🔆 Failed	🔆 Enrolled	🔆 Discontinued	🔆 Completed	🖊 Signed	⏺ Frozen	🔒 Locked
01-Copenhagen	1	2	3	1	3	2	0	0
02-Helsinki	7	2	3	0	1	0	0	0
03-Oslo	3	2	6	1	2	2	1	0
04-Reykjavik	5	1	2	0	0	0	0	0
05-Riga	0	2	4	1	0	0	0	0
06-Stockholm	4	2	2	1	0	0	1	0
07-Tallin	0	1	1	1	3	1	1	1
08-Vilnius	7	1	2	0	0	0	0	0
09-Warsaw	1	0	0	0	0	0	0	0
10-Amsterdam	9	4	10	2	0	0	1	1
11-Athens	8	1	2	0	0	0	0	0
12-Barcelona	0	0	0	0	0	0	0	0
13-Belgrade	0	0	0	0	0	0	0	0
14-Bergen	0	0	0	0	0	0	0	0
15-Berlin	0	0	0	0	0	0	0	0
All Sites Totals:	**45**	**18**	**35**	**7**	**9**	**5**	**4**	**2**

(Page 1 of 2) ◄ ◀ 01-Copenhagen «to» 15-Berlin ▼ ▶ ►

The multi-site view contains the following options and information:

All Sites: Lists all sites you have access to. Selecting a site takes you to the multi-patient view for that site. For more information about the multi-patient view, see Patients: Multi-Patient View Layout on page 159.

Sites: Lists the sites you have access to and the sites' status (either Active or Inactive).

Clicking on a site takes you to the multi-patient view of that site. For more information about the multi-patient view, see Patients: Multi-Patient View Layout on page 159.

Status columns: Displays the number of patients currently in each status. These columns are not cumulative, that is, the Screened column doesn't include patients who have been Enrolled.

Icon	Status	Description
🔲	Screened (yellow)	Displays the number of patients with the current patient status of Screened.
🔲	Failed (red)	Displays the number of patients with the current patient status of Failed.
🔲	Enrolled (blue)	Displays the number of patients with the current patient status of Enrolled.
🔲	Discontinued (orange)	Displays the number of patients with the current patient status of Discontinued.
🔲	Completed (green)	Displays the number of patients with the current patient status of Completed.
🖊	Signed	Displays the number of patients for which all CRFs have been Signed.
🔵	Frozen	Displays the number of patients for which all CRFs have been Frozen.

Note: The Frozen count includes patients that are Frozen and patients that are both Frozen and Locked. |
| 🔒 | Locked | Displays the number of patients for which all CRFs have been Locked.

Note: A CRF must be frozen before it can be locked—in other words, a CRF that is locked must also be frozen. |

All Sites Totals: Displays the totals for the entire list, not the current page, even if the table spans more than one page. Totals should be for all sites you have access to even if there is more than one page of sites.

To view all patients at a single site:

■   Click the site name.

The multi-patient page appears with the list of patients for that site. For more information about the multi-patient view, see Patients: Multi-Patient View Layout on page 159.

To view all patients at a single site with a certain status:

■   Click the number of patients where the site name and status intersect.

Example: To view all the patients that have a screened status at Helsinki, click the cell on the Helsinki row, in the Screened column.

The multi-patient page appears with the list of patients for that site.

Patients: Multi-Patient View Layout

The multi-patient view shows a list of patients and their status within the study.

There are three ways to access the multi-patient view:

- View all patients at a site.

- View patients at a site with a certain status.

- Search for patients.

Click on the Patient ID column to sort the table by patient ID.

The status icons and flags give you a visual clue to the progress of each patient.

The multi-patient view contains the following options and information:

Palettes:

> **Search palette** – Provides simple and complex searches for patients. For more information about searching for patients, see Searching for a Patient on page 166.

> **Actions palette** – Performs patient-related actions. For more information about patient related actions, see Patient Actions on page 164.

> **Summary palette** – Displays the number of the patients for each status for the selected site. For more information about the summary palette, see Site Summary on page 165.

Patient ID: Displays the patient's status and ID. The patient ID is a combination of the patient's Screen ID and their initials (for patients who are being screened), or the patient's Enroll ID and their initials (for patients who have made it through the screening process). The patient's status icon indicates the patient's current status within the study and shows the patient's progress toward completing the study.

Clicking on the patient ID takes you to the patient view.

For a description of the patient status icons, see Patient Status Icons on page 158.

Status: Displays the patient's current status and indicates the patient's progress in completing the study.

Last Event: Shows the most recent event for which one or more CRFs have been submitted. An event typically corresponds to a patient visit.

DCFs: Displays the cumulative status of *all* DCFs for that patient. For more information about DCFs, see Chapter 8: DCF Management on page 264.

SD-Verify: Displays the cumulative status of the SD-Verify (Source Document Verify) flag. For more information about flags, see Chapter 7: Using Flags on page 240.

M-Review: Displays the cumulative status of the M-Review (Medical Review) flag. For more information about flags, see Chapter 7: Using Flags on page 240.

D-Review: Displays the cumulative status of the D-Review (Data Review) flag. For more information about flags, see Chapter 7: Using Flags on page 240.

Signed: Displays the cumulative signature status of all CRFs for the patient. For more information about signatures, see Chapter 9: The Signature Process on page 306.

Frozen: Displays the cumulative freeze status of all CRFs for the patient. For more information about freezing and locking data, see Chapter 10: Freezing and Locking Data on page 321.

Locked: Displays the cumulative lock status of all CRFs for the patient. For more information about freezing and locking data, see Chapter 10: Freezing and Locking Data on page 321.

To view a patient from the multi-patient view:

◼   Click the Patient ID.

The patient view appears.

Patient View Layout

The patient view is a summary of all events and forms associated with a patient.

There are three types of events:

Events: A patient protocol is broken out into a series of events. Each event—depending on how the study is set up—has a set of CRFs that are to be submitted.

Common: CRFs that do not correspond with one particular visit, but still contain important and necessary information regarding the patient. Common forms include patient status forms as well (screened, enrolled, etc.).

Unscheduled: Events that are not part of the original study design, but are necessary to collect patient data. For more information about adding unscheduled events, see Unscheduled Events on page 180.

Click here (⊞) to *expand all* events.

Click here (⊞) to *expand this* event.

Click here (⊟) to *collapse this* event.

Expanded events display each individual CRF associated with it.

The patient view contains the following options and information:

Palettes:

> **Search palette** – Provides simple and complex searches for patients. For more information about searching for patients, see Searching for a Patient on page 166.

Actions palette – You can perform available actions against this selected patient. For more information about the actions available for a patient, see Patient Actions on page 164.

Page Header:

Patient ID – Displays the patient's status and ID. The patient ID is a combination of the patient's Screen ID and their initials (for patients who are being screened), or the patient's Enroll ID and their initials (for patients who have made it through the screening process). The patient's status icon indicates the patient's current status within the study and shows the patient's progress toward completing the study.

Clicking on the patient ID takes you to the patient view.

For a description of the patient status icons, see Patient Status Icons on page 158.

Protocol – Displays the study version that the patient uses.

Primary Investigator – Displays the name of the PI (primary investigator) for this site.

Event: Displays each event in the order defined by the study designer. Click ⊞/⊟ to expand/collapse events. There are three types of events:

Scheduled Events – Patients in a study are expected to adhere to a data collection schedule throughout the duration of the study as defined by the study protocol. A scheduled event represents a pre-planned patient visit.

Common Event – The Common Event is associated with forms that can be collected at any time during the study or forms that are not associated with a particular event. An example of a form associated with the Common Event is a form used to collect patient information about concomitant medications.

Unscheduled Events – In a study, unforeseen circumstances may cause a patient to make a visit outside of the schedule of pre-planned patient visits. An unscheduled event represents an event that is not part of the pre-planned schedule. An example of an unscheduled event is a visit where a patient reports an adverse reaction.

CRFs: Displays the CRF status. For more information about CRF icon statuses, see CRF Icons on page 197.

DCFs: Displays the DCFs statuses. For more information about DCF icon statuses, see DCF Icons on page 273.

SD-Verify: Displays the SD-Verify (Source Document Verify) flag status.

M-Review: Displays the M-Review (Medical Review) flag status.

D-Review: Displays the D-Review (Data Review) flag status.

Signed: Displays the signature status.

Frozen: Displays the freeze status. For more information about the frozen status, see Freezing Patients on page 327.

Locked: Displays the lock status. For more information about the locked status, see Locking and Unlocking Patients on page 329.

Workflow Tab: Lists the patient workflow actions taken for this patient. For more information about workflow, see Workflow subtab on page 165.

To open a CRF:

1   From the patient view, click the expand icon (⊞) to list the CRFs.

2   Click the CRF.

DataLabs opens the CRF. For more information on how to open CRFs see Chapter 6: Entering Patient Data (CRFs) on page 184.

Patient Actions

On most patient-tracking pages, there are three actions palettes that can be used to manage the patients at the site you are currently working with:

Actions: Gives you a menu of actions you can take related to the patient.

Summary: Gives you a quick overview of all the patients in the site.

Search: Enables you to search for existing patients.

All three are covered below.

Actions Palette

The Actions palette allows you to perform workflow-related actions on a patient. Depending on the status of the patient—including any associated DCFs, signatures, flags, or frozen locked data—the commands available on the Actions palette will change. Below is a comprehensive list of the commands that could appear:

- Add Comment
- Create DCF
- Add Patient
- Enroll Patient
- Fail Patient
- Discontinue Patient
- Complete Patient
- Add Unscheduled Event
- Add Event(s)
- Freeze CRFs
- Thaw CRFs
- Lock Patient
- Unlock Patient
- Sign Casebook
- Request Signature
- M-Review CRFs
- D-Review CRFs
- SD-Verify CRFs
- Patient Status Override
- Freeze Patients

■ Thaw Patients

Site Summary

On the Patients tab there is a Summary palette which gives you an overview of the status of patients at the site you are currently working with.

Patient-Tracking Status

Icon	Status	Description
🧍	Screened (yellow)	Patients who are in the process of being screened: they have been added to the study because they have the basic requirements for being study candidates.
🧍	Failed (red)	Patients who have not met the detailed inclusion criteria (or who have met the exclusion criteria); this typically happens before they have begun to actively participate in the study.
🧍	Enrolled (blue)	Patients who have met the criteria and have entered the study; received an enrolled ID.
🧍	Discontinued (orange)	Patients who are unable to complete the study, either voluntarily, by protocol violation, or for any number of reasons.
🧍	Completed (green)	Patients who have completed the study by completing all their visits.
✏️	Signed	Patients who have had all CRFs Signed or Signed w/Changes; the PIs have signed off on all the data for these patients.
🔵	Frozen	The patients have had all CRFs frozen by the data manager and no data can be added or updated; this can happen for any number of reasons: for interim analysis, before the signature process, after the signature process, to name a few.
🔒	Locked	Patient-locking is an intermediate step to locking a study; the patients have completed all their visits, all DCFs have been resolved, and the Primary Investigator has signed off.

Workflow subtab

The Patient view has only one subtab, the Workflow subtab. It lists each action taken on the patient, showing the most recent action first.

Workflow		
Action	**Date/Time**	**User**
Unlocked	11/09/2005 05:27:07 PM PST	Miles Massey (mmassey)
Locked	11/09/2005 05:26:52 PM PST	Miles Massey (mmassey)
Frozen	11/09/2005 05:26:39 PM PST	Miles Massey (mmassey)
Enrolled	11/09/2005 05:26:11 PM PST	Miles Massey (mmassey)
Screened	11/09/2005 05:05:15 PM PST	Miles Massey (mmassey)

Action: Lists the name of the action taken on the patient.

Date/Time: Lists the date and time the action took place.

User: Lists the user who performed the action.

Searching for a Patient

On most views of the Patients tab, you can use the Search palette to search for a patient using a single search option, or a combination of several search options.

Patient ID	Search based on patient ID.
	You can enter a partial ID to broaden your search.
Patient Status	Search based on current patient status (screened, failed, enrolled, discontinued, completed).
Signature Status	Search based on signature status of the associated CRFs (ready, rejected, signed, not signed, changed).
Data Status	Search based on patient's data status (not frozen/locked, frozen/not locked, frozen, locked).

Tip: Use multiple search options to narrow your results.

Example: Select the Completed patient status and the Frozen data status. The results show only those patients that are completed and have been frozen.

Note: Searches are limited to the sites that you have permission to view.

To search for a patient:

1   Click the Expand button ⌄ at the top of the Search palette to see all the search options.

2   Enter or select your search criteria.

3   Click **Go**.

The multi-patient page appears with the list of patients meeting your search criteria.

Patient Workflow Sequence

The patient tracking workflow usually follows a basic sequence of events:

1   Adding a patient.

2   Updating an existing patient.

3   Enrolling a screened patient (or recording a screen failure for a patient).

4   CRFs and DCFs.

5   Flags & reviews.

6   Freezing and locking patients and CRFs.

7   PI Signatures.

8   Completing a patient (or discontinuing a patient).
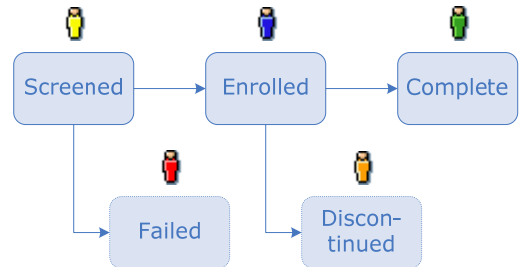
Note: These Functionalities are specific to **Data Manager** portal users. **2** Updating an existing patient. **4** CRFs and DCFs. **5** Flags & reviews. **6** Freezing and locking patients and CRFs. **7** PI Signatures.

Adding a Patient

The first step in patient-tracking is adding a new patient. When you are in the multi-patient view on the Patients Tab, you can use the Add Patient command to add a patient to the selected site.

Note: A new patient's status is initially "screened," pending being enrolled in the study or failed during the screening process.

To add a patient:

1   From the Patients: Multi-Patient View, click the **Add Patient** command on the Actions palette.

If you have more than one study version published—and the option to add new patients is set to allow for both study versions—the Add Patient dialog box appears with the default version selected. For more information about managing versions, see Managing Study Version on page 107.

2   Select a version and click **Continue**.

The Add Patient page appears.

3   Enter the **Screen ID** and **Patient Initials**.

4   Select or type the **Screened Date**.

5   Do one of the following:

- Click **Save** to save the patient and return to the previous view.

- Click **Save & Add Another** to save the patient and return to the Add Patient page.

- Click **Save & Enter Data** to save the patient and go to the patient view.

A confirmation drop-down appears, and you are returned to the patient view. The patient(s) you have added now have the status of screened (yellow). If you type a screen ID that has already been used within the site, you are prompted to re-enter it.

The Add Patient page contains the following options and information:

Screen ID: Defines the unique identifier for the patient.

Each of these fields is required.

Patient Initials: Defines the patient's initials (or other identifying characters).

Note: The Screen ID must be unique within a site. Once a patient is screened, the Screen ID is used to identify the patient within DataLabs—until the patient is enrolled.

Screened Date: Select or enter the date the patient was screened.

Note: For more information on study versions, see Study Version Management on page 90, and for more on migrating patients from the earlier version to the most recent, see Migrating Patients on page 108.

Failing a Patient

Once a patient has been added to DataLabs, but has not passed the screening process, you now have the option to fail the patient. (This is also called a "screen fail.")

To fail a patient:

1 From the patient view, click the **Fail Patient** command on the Actions palette.

The Fail Patient page appears.
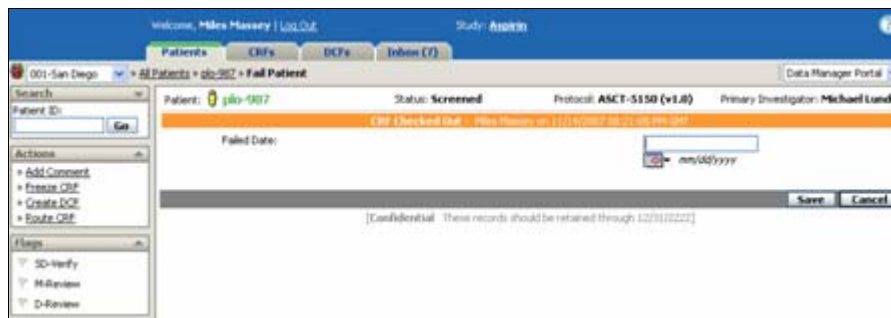
2 Select or type the **Failed Date**.

3 Click **Save** to fail the patient.

A confirmation drop-down appears, and you are returned to the patient view. The patient's status is now failed (red).

The Fail Patient page contains the following option:

Failed Date: Select or enter the date the patient was failed.

Enrolling a Patient

Once a patient has been added to the system and has successfully been screened, you have the option to enroll the patient.

To enroll a patient:

1 From the patient view, click the **Enroll Patient** command on the Actions palette.

The Enroll Patients page appears.

2   Enter the **Enroll ID**.

3   Select or type the **Enrolled Date**.

4   Click **Save** to enroll the patient.

A confirmation drop-down appears, and you are returned to the patient view. The patient's status is now enrolled 👤 (blue).

The Enroll Patient page contains the following options and information:

Enroll ID: Defines the unique Enroll ID for the patient. (If you enter an existing Enroll ID number, DataLabs gives you a warning.)

> Both of these fields are required.

Note: The Enroll ID must be unique within the study. Once a patient is enrolled, the Enroll ID is used to identify the patient within DataLabs, replacing the Screen ID. Once enrolled, the Patient ID is the combination of the patient's Enroll ID and initials.

Enrolled Date: Select or enter the date the patient was enrolled.

Recording Events, CRFs, & DCFs, Flags, Signatures

Note: This functionality is specific to **Data Manager** portal users.

After a patient has been enrolled, you begin collecting and recording clinical trial data. This process of study events (usually visits), the collecting CRFs (Case Report Forms), the generation of DCFs (Data Clarification Forms), reviewing data and flagging CRFs, obtaining signatures, and freezing and locking are covered in their own chapters in this *Guide*:

Topic	Chapter	Page
Patient data (CRFs)	Chapter 6: Entering Patient Data (CRFs)	184
Reviewing and flagging data	Chapter 7: Using Flags	240
Data Clarification Forms (DCFs)	Routing CRFs	221
Signatures	Chapter 9: The Signature Process	306
Freezing and locking	Chapter 10: Freezing and Locking Data	321

Discontinuing a Patient

Once a patient has been enrolled, you have the option to discontinue the patient. The Discontinue Patient command terminates a patient who is already enrolled in the study—but who cannot complete the study.

To discontinue a patient:

1   From the patient view, click the **Discontinue Patient** command on the Actions palette.

The Discontinue Patient page appears.
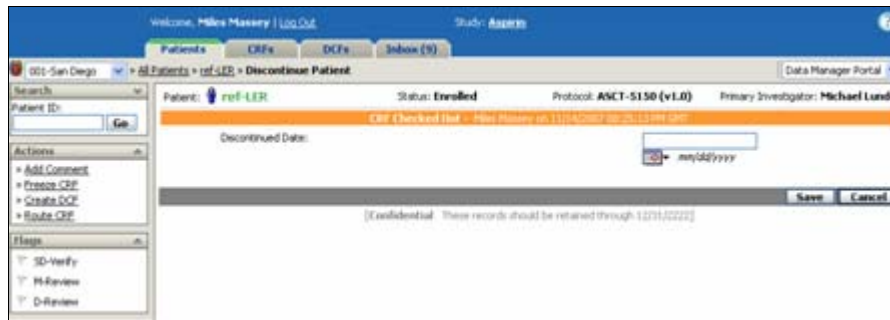
2   Select or type the **Discontinued Date**.

3   Click **Save** to discontinue the patient.

A confirmation drop-down appears, and you are returned to the patient view. The patient's status is now discontinued (orange).

The Discontinue Patient page contains the following option:

Discontinued Date: Select or enter the date the enrolled patient was discontinued.

Completing a Patient

Once a patient has completed the study, you have the option to complete the patient.

To complete a patient:

1   From the patient view, click the **Complete Patient** command on the Actions palette.

The Complete Patient page appears.

2   Select or type the **Completed Date**.

3   Click **Save** to complete the patient.

A confirmation drop-down appears, and you are returned to the patient view. The patient's status is now completed 🧍 (green).

The Complete Patient page contains the following option:

Completed Date: Select or enter the date the enrolled patient was completed.

Overriding a Patient's Status

Once a patient has been added, you have the option to override the patient's status. There will be times when you will need to change the status of a patient who has erroneously been enrolled, failed, discontinued, or completed.

Example: For example, a patient may have been enrolled in a study, but important data related to enrollment was missing, so the patient needs to be reverted back to Screened.

Note: The ability to override a patient's status is controlled by your security permissions.

To override a patient's status:

1   From the patient view, click the **Patient Status Override** command on the Actions palette.

The Patient Status Override page appears. This page shows the patient's current status, their status history, and lists the status you can change to or revert back to.

2   From the Change To list box, select the status you want to assign to the patient.

3   Click **Save** to change the patient's status.

A confirmation drop-down appears, and you are returned to the patient view.

Note: You can override a patient's status only one step at a time. That is, you can change a patient from completed to enrolled, but not from completed to screened. You would first need to change their status from completed to enrolled, and then from enrolled to screened.

When a patient is reverted, DataLabs "resets" their events and CRFs, and they are recorded in the study database. If a patient is re-enrolled, these CRFs are re-published as *new forms* with no evidence of the previously entered data. Any DCFs associated with the forms that were reset are deleted from the study.

Updating Patient Status Forms

Patient Status forms are the forms you used to change patient status (for example, Add Patient). Each of these is saved under the Common event on the patient view (along with any common forms designed for this study).

To update a patient status form:
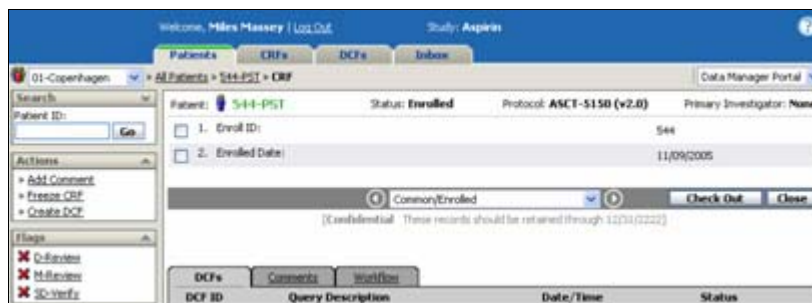
1   From the patient view, click the **Common** events open event icon ⊞.

The page displays all the common events that are applicable to the patient's current status.
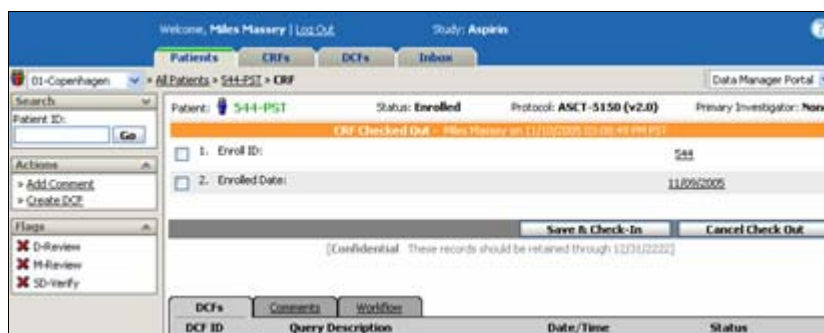
2   Click the patient status form you want to update.

The patient status form appears; if auto-checkout is turned off, the form is in view mode.

3   Click **Check Out** if auto-checkout is turned off.

4   Click a value to change it.

5   Make any necessary changes to the field.

6   Select the **Reason for change** (required).

Note: Entering **Additional Notes** is optional.

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7   Click **OK** to save the field.

8   To save the form and click **Save & Check-In**.

Any changes made to the patient are recorded in the Change History.

Note: Changing the Patient ID or Patient Initials changes it throughout DataLabs.

Events

Studies are divided into a series of events, and each event has a series of forms associated with it. It is in these forms that Patient data is collected. There are three types of events:

Visits: Patient event data collected in chronological order.

Common: General data that provides background information on the patient.

Unscheduled: Events that are not part of the original study design, but are necessary to collect patient data. For more information about adding unscheduled events see Unscheduled Events on page 180.

Event Publishing

During the design phase, the design team determines which events are published in the patient view during the patient workflow. When an event is published, it appears in the patient view, along with the CRFs that belong to it.

Example: There are a total of 10 events (not including the Common event). During the study design phase, two events (Visit01 and Visit02) were selected to be published when a patient is screened. The remaining eight events are published once a patient has been enrolled.

Adding an Event

You can use the Add Event(s) action to publish a pre-defined set of event(s) and their associated form(s) to a selected patient's casebook.

You can add event(s) only if event(s) are available to be published and if the patient is not locked.

Note: The ability to add event(s) is controlled by your security permissions.

To add pre-defined event(s) for a patient:

1 From the patient view, click **Add Event(s)** on the Actions palette.

> **Note**: The number of events that can be added to a patient's casebook is defined during the study design. If no more events are available to add to the patient's casebook, the following message appears, "There are no more events available for publishing."

The Add Event(s) page appears.

The Add Event(s) page shows the event(s) and form(s) that are to be published. You cannot make any changes to the event(s) and form(s) displayed on this page.

2 Click **Publish**.

You are prompted to confirm that you want to publish the event(s) and associated form(s).

Note: Once an event and its form(s) have been published to a patient's casebook, there is no way to unpublish the event and its form(s). If you do not want to collect patient data for the form(s), you should mark the form(s) as "not collected."

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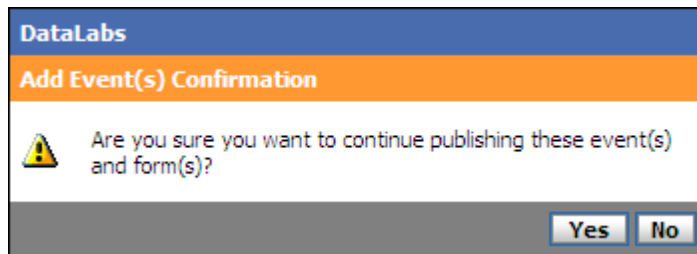
3 Click **Yes** to publish the event(s).
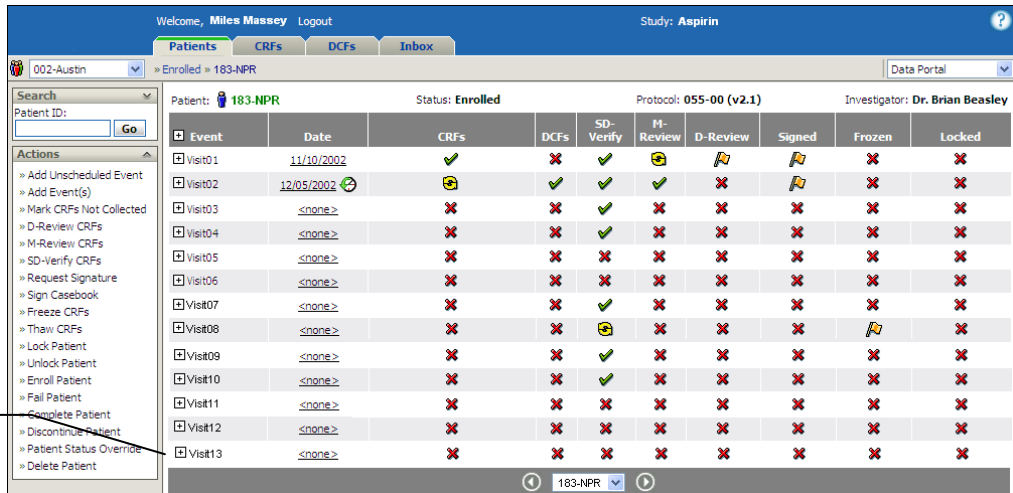
A confirmation drop-down appears and you are returned to the Patient view. The new event(s) have been added to the patient's casebook.

Note: The new event(s) may or may not appear in chronological order within the patient's casebook. The order in which the event(s) appear in the patient's casebook is determined by the study design.

The new events are added.

Adding the Event Date

When you're on the patient view, you can click an event date placeholder (<none>) to add or update it.

Note: If the event date has been disabled as part of the study design, you cannot enter an event date.

To add an event date:

1 Click **<none>**.

The Actual Event Date dialog box appears.

2 Do one of the following:

- Type the date using *mm/dd/yyyy* format (skip to step 5).

- Click the **Calendar** button .

The Calendar pop-up appears.

3 To change the month, year, or date, do one of the following:

- Click **<<** (previous) or **>>** (next) to change months.

- Click **Today** to go to today's date.
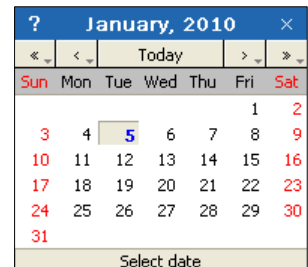
4 Click the date.

5 Click **Save**.

The Calendar pop-up closes, and the selected date appears on the patient view.

Changing the Event Date

When you're on the patient view, you can click an event date to update it.

To change an event date:

1 Click the **event date**.

The Actual Event Date: Edit dialog box appears.

2 Enter a new date value.

3 Select a **Reason for change**.

4 Add any **Additional notes** (optional).

5 Click **Save**.

The Calendar pop-up closes, the updated date appears in the patient view, and a Change History icon appears next to the date.

Note: The Change History icon will also display in the date field in the following circumstance.

- A date has been entered for an event.

- The event date has been disabled in the study design for the event in the current study version.

In this situation, the event date will not be shown and you cannot enter a date. However, you can view the previous event date information by clicking the Change History icon.

Unscheduled Events

Adding an Unscheduled Event

Although the study protocol determines the number of visits during the design phase of the study, there will be times where you will need to add an unscheduled event for a patient.

Example: For example, a patient visits between appointments because they have lost or misplaced the drugs given to them for the study. Or, a patient comes in to report an adverse reaction.

Note: The ability to add unscheduled events is controlled by your security permissions.

To add an unscheduled event for a patient:

1   From the patient view, click the **Add Unscheduled Event** command on the Actions palette.

   The Add Unscheduled Event: Step 1 page appears.
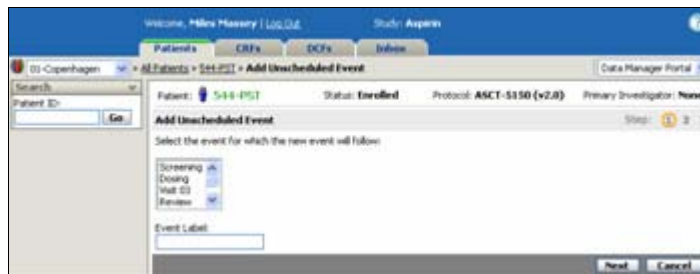
2   Select which existing event the new one will follow, type an **Event Label**, and click **Next**.

   The Add Unscheduled Event: Step 2 page appears.
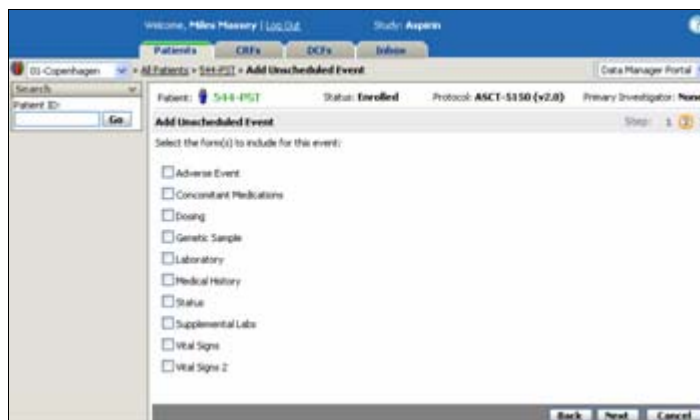
3   Select the forms to be used for this event, and click **Next**.

Note: These are existing forms that can be used in unscheduled events as determined in Designer.

The Add Unscheduled Event: Step 3 page appears. It shows you the name/number of the new event and its associated forms.
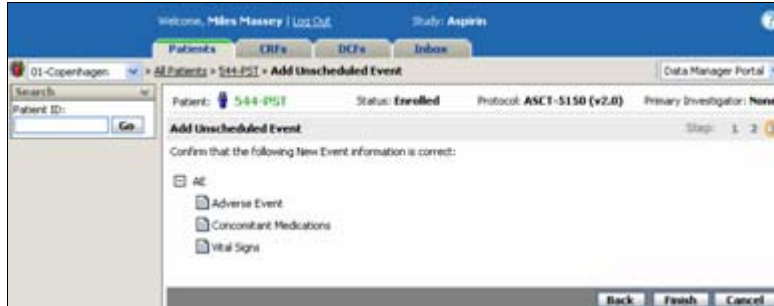
4 Click **Finish**.

A confirmation drop-down appears, and you are returned to the patient view. The event has been added to the patient based on the event you placed it after.

The new event is added.

Editing an Unscheduled Event

As the result of data entry errors, it may be necessary to modify the information of an unscheduled event or to remove an unscheduled event. When modifying an unscheduled event, you can delete the event, change the event label, add or remove forms from the event, or reposition the event within a patient's casebook.

Note: The ability to edit unscheduled events is controlled by your security permissions.

To edit an unscheduled event for a patient:

1 From the patient view, click the unscheduled event you want to edit.

The Unscheduled Event page appears.

2   Enter a new event label, if desired.

> **Note**: The event label may only contain alphanumeric characters, spaces, underscores, dashes, dots, and parentheses. Multiple spaces in the event label are displayed as a single space in the Patient view.

> **Note**: The event label must be unique within the patient's casebook.

3   Do one of the following to add or remove forms from the event:

- To add forms to the unscheduled event, in Available Forms, highlight the forms you want to add to the event and click **Add**.

- To remove forms from the unscheduled event, in Current Forms, highlight the forms you want to remove from the event and click **Remove**.

If you choose to remove all forms from the unscheduled event, the event will be removed from the patient's casebook.

> **Note**: A form cannot be removed from the event if the form contains comments, DCFs, form- or item-level flags, signatures, or any other patient data. A form also may not be removed if the form is currently checked out or is in PDE.

4   Do one of the following to reposition the event within the patient's casebook:

- To move the event to a higher position within the casebook, click **Move Up** to move the event to the desired location.

- To move the event to a lower position within the casebook, click **Move Down** to move the event to the desired location.

5 Click **Save** to save your changes.

6 If all forms have been removed from the unscheduled event, you are prompted to confirm the deletion. Click **Continue**.

A confirmation drop-down appears. You are returned to the patient view. The changes you made to the unscheduled event appear within the patient's casebook.

Note: If you remove all forms from an unscheduled event, the unscheduled event is also removed and will not appear within the patient's casebook.

Note: If the event label is not unique within the patient's casebook or contains invalid characters, an error message appears. Correct the error and re-save your changes.

To remove an unscheduled event:

Note: An event cannot be removed if one or more forms associated with the event contain comments, DCFs, form- or item-level flags, signatures, or any other patient data. An event also may not be removed if one or more of the forms associated with the event is currently checked or is in PDE.

1 From the patient view, click the unscheduled event you want to remove.

The Unscheduled Event page appears.

2 Click **Remove Event**.

3 You are prompted to confirm the deletion. Click **Yes**.

A confirmation drop-down appears. You are returned to the patient view. The event is removed from the patient's casebook.

Chapter 6: Entering Patient Data (CRFs)

Overview

This chapter covers the following material:

- Basic elements and layout of a CRF

- Understanding CRF status icons

- Searching for a CRF

- Checking forms in and out

- Entering data into an "un-started" CRF for the first time

- Saving a CRF

- Viewing a CRF

- Navigating between CRFs

- Editing an existing or submitted CRF

- Item Level Submit

- Clearing an item on a Submitted Form

- Kinds of fields and data you'll be entering

- Hidden fields

- Dependent questions

- Routing a CRF

- Understanding the Change History

- Printing Change History

- Using comments

- Understanding queries

- Marking a question "Not Answered"

- Marking a question "Not Collected"

CRFs Tab Page Layout

CRFs: Multi-Site View Layout

The multi-site view contains the following options and information:

Sites: Lists the sites and corresponding site status icon. The sites that you see in the list are those sites that you are allowed to access. For more information about user access to sites, see Giving a User Access to Sites on page 71 or Giving Users Access to a Site on page 106.

This could be all the sites, or just a subset. Clicking on a site takes you to the multi-patient view of that site. Clicking on this column header sorts the list by site.

Expected: Displays the total number of all CRFs for each site, *except* those that either are optional or have been marked "not collected."

Submitted: Displays the number of CRFs for each site that have been submitted.

D-Review: Displays the number of CRFs for each site that have been marked D-Review.

DR Changed: Displays the number of CRFs that have been marked D-Review for each site where visible CRF data has changed since they were marked D-Review.

Note: If your default portal is the Data Manager Portal, then these three columns will show you the D-Review and DR Changed values. But if your default portal is the Field Monitor portal or Medical Monitor portal, these columns will show SD-Verify and M-Review values, respectively.

Signed: Displays the number of CRFs for each site that have been signed.

Frozen: Displays the number of frozen CRFs for each site.

Locked: Displays the number of locked CRFs for each site.

Note: Clicking on any of the cells in the Submitted through Locked column takes you to the multi-CRF view. For more information about the multi-CRF view, see CRFs: Multi-CRF View Layout on page 190.

Totals: Displays the totals for the *entire list*, not the current page, even if the table spans more than one page.

To view all patients at a single site:

■ Click the site name.

The multi-patient view appears with the list of patients for that site.

To view all CRFs at a single site with a certain status:

■ Click the number of CRFs where the site name and CRF status intersect.

Example: For example, to view all CRFs that are expected for Helsinki, click the cell on the 02-Helsinki row, in the Expected column.

The multi-CRF view appears with the list of CRFs.

CRFs: Multi-Patient View Layout

The multi-patient view contains the following options and information:

Palettes:

> **Search palette** – Provides simple and complex searches for CRFs.
>
> **Actions palette** – Performs actions against select patients. For more information about the actions palette, see Patient Actions on page 164.
>
> **Summary palette** – Displays the number of the CRFs for each status within this site.

Patient-status Icon/Patient ID: Displays the patient's status and ID. The status icon also tells which patients are frozen ( ) and locked ( ).

Clicking on this column header sorts the list by patient ID. Clicking on the patient ID takes you to the patient view. For more information about the patient view, see

Patient View on page 161.

Expected: Displays the total number of CRFs for that patient, *except* those that either are optional or have been marked "not collected."

Submitted: Displays the number of CRFs that have been submitted for that patient.

D-Review: Displays the number of CRFs that have been marked D-Review for that patient.

DR Changed: Displays the number of CRFs that have been marked D-Review for that patient where visible CRF data has changed since they were marked D-Review.

Note: If your default portal is the Data Manager Portal, then these three columns will show you the D-Review and DR Changed values. But if your default portal is the Field Monitor portal or Medical Monitor portal, these columns will show SD-Verify and M-Review values, respectively.

Signed: Displays the number of CRFs that have been signed for that patient.

Frozen: Displays the number of CRFs that have been frozen for that patient.

Locked: Displays the number of CRFs that have been locked for that patient.

To view all CRFs for a single patient:

■   Click the Patient ID.

The multi-CRF view appears with the list of the patient's CRFs.

To view all CRFs with a certain status for a single patient:

■   Click the number of CRFs where the patient ID and CRF status intersect.

Example: For example, to view all CRFs that are expected for patient 1964-EEL, click the cell on that row, in the Expected column.

The multi-CRF view appears with the list of the patient's CRFs with the selected status.

CRFs: Multi-CRF View Layout

The status icons and flags give you a visual clue to the progress of each CRF: the basic goal is a row of green check marks (✔).

Palettes: The Search, Actions and Summary palettes are the same as on the multi-patient view. For more information on the multi-patient view, see CRFs: Multi-Patient View Layout on page 188.

Patient-status Icon/Patient ID: Displays the patient's status and ID. For more information about the patient-status icon, see Site Summary on page 165.

Event: Displays the event associated to the CRF.

CRF: Displays the CRF name and status icon. For more information about the CRF name and icon, see CRF Icons on page 197.

DCFs: Shows the cumulative status of all DCFs associated to the CRF.

D-Review: Indicates if the CRF has been marked D-Review.

Note: If your default portal is the Data Manager Portal, then these three columns will show you the D-Review values. But if your default portal is the Field Monitor portal or Medical Monitor portal, these columns will show SD-Verify and M-Review values, respectively.

Signed: Indicates if the CRF has been signed.

Frozen: Indicates if the CRF has been frozen.

Locked: Indicates if the CRF has been locked.

To open a CRF:

■   From the multi-CRF view, click the CRF.

   The CRF opens.

CRF Layout

It is important to be familiar with the CRF (Case Report Form) screen. A sample layout is illustrated below:
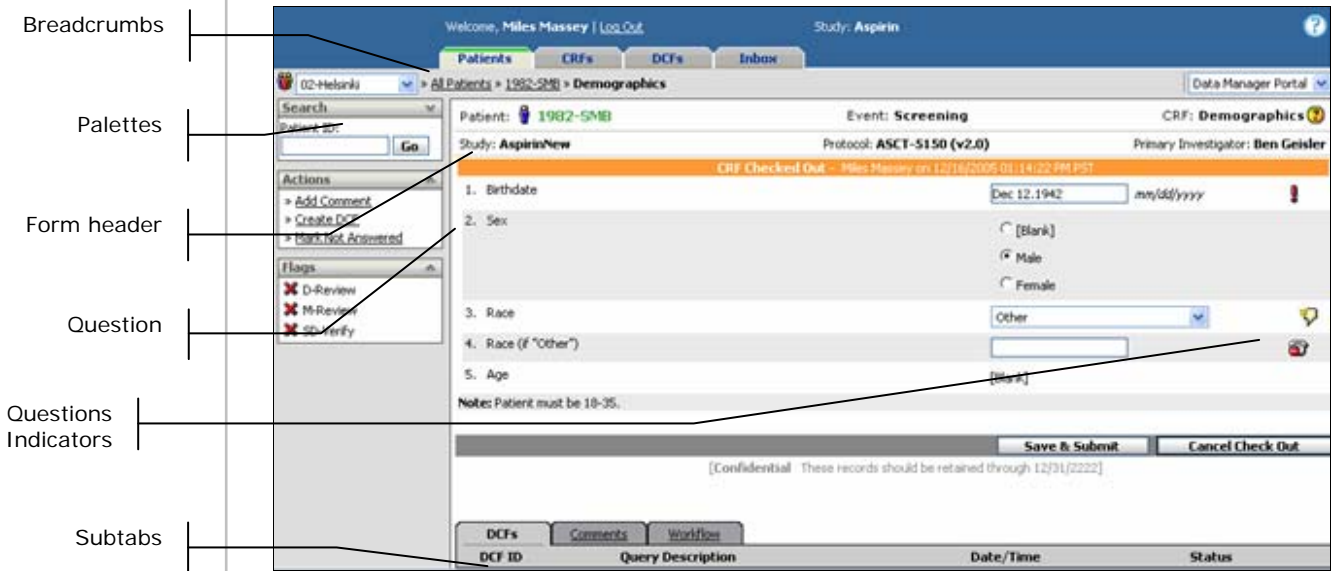
Breadcrumbs

Breadcrumbs show your current "path" in DataLabs. You can click any of the links on this bar to navigate DataLabs.
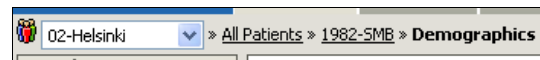
Palettes

Depending on what is displayed in the Body of the page, DataLabs makes various palettes available.

Search palette: Gives you the ability to search for patients using a variety of search criteria. For more information about searching for patients, see Searching for a Patient on page 166.

Actions palette: The actions available to you are determined by what is displayed in the page body and by your security permissions. Some examples:

   Add Comment – Adds a comment to the CRF. For more information about adding comments, see Comments on page 229.

> **Create DCF** – Creates a DCF for the CRF. For more information about creating a DCF for a CRF, see Routing CRFs on page 221.

> **Freeze CRF** – Restricts the ability to make changes to the CRF (only visible when the CRF is not yet frozen or locked).

> **Thaw CRF** – Restores the ability to make changes to the CRF, if it has been frozen (only visible if the CRF is frozen but not locked).

Flags palette: Shows the status of each flag. You can only edit the flags in *view mode*. For more information about how to edit flags, see Chapter 7: Using Flags on page 240.

> **SD-Verify** – Displays the status of the SD-Verify flag for this CRF.

> **M-Review** – Displays the status of the M-Review flag for this CRF.

> **D-Review** – Displays the status of the D-Review flag for this CRF.

Note: Flags can only be set while in view mode. While in edit mode the flag status is shown but cannot be changed. For more information about setting flags while in view mode, see Viewing a CRF on page 205.

CRF Header

The CRF header displays the basic CRF information.

Patient: Displays the current patient status, and the patient ID (a combination of their Screen/Enroll ID and initials).

Event: Displays the event the CRF is associated to.

CRF & Help : Displays the CRF's title, and opens custom help for this CRF created by the study designer.

Tip: To learn how to add custom CRF Help to DataLabs, please refer to the *Installation Guide*.

Study: Displays the study name.

Protocol: Displays the study's protocol and version.

Primary Investigator: Displays the name of the Primary Investigator (PI) for the site.

Alert Bar: Only displays when a CRF is:

CRF Checked out – If the CRF is checked out, the alert bar reads "CRF Checked Out – *username* on *date*." This message displays if anyone—you or another user—has the CRF checked out.

Note: If a CRF is currently checked out by someone else, you cannot check it out to edit it. Instead, it will open in view mode.

Frozen – If the CRF is frozen, the alert bar reads "CRF Frozen." Since you cannot make changes to form data on a frozen CRF, the CRF opens in view mode.

Note: You can, though, create DCFs for, add comments to, request signatures for and sign frozen CRFs.

Locked – If the CRF is locked, the alert bar reads "CRF Locked." Since you cannot make changes to a locked CRF, the CRF opens in view mode. The only action you can take on a frozen CRF is to unlock it—if you have permission.

Questions

The CRF body contains the content of the form:

Data Fields: Individual, discrete pieces of information—such as a height, weight or systolic blood pressure—that answer the CRF questions. For more information about data fields, see Data Fields on page 215.

Data Tables: Groups of similar information, such as medications, diagnoses or adverse events, where similar information is gathered on each item, such as the rate, route and frequency that a drug is being taken. For more information about data tables, see Data Tables on page 215.

Right-Click Action Menu

When you enter patient or CRF data the right-click action menu gives you up to five of the following options depending what type of collection method is chosen (Form Level or Item Level Collection):
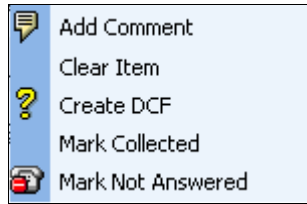
Add Comment: Allows you the ability to leave a comment in Form or Item Level collection.

Clear Item: Allows you the ability to clear data from a field when in Item Level collection.

Create DCF: Allows you the ability to create a DCF in Form or Item Level collection.

Mark Collected: To submit a form in Item Level collection all questions must be answered or marked as collected.

Mark Not Answered: Sometimes it is necessary to skip a data field and come back to it later. When a form is checked out you are able to mark items as not answered and come back to them later in both Form and Item Level collection. For more information about marking a question not answered see Marking a Question "Not Answered" on page 235.

Retention & Signature
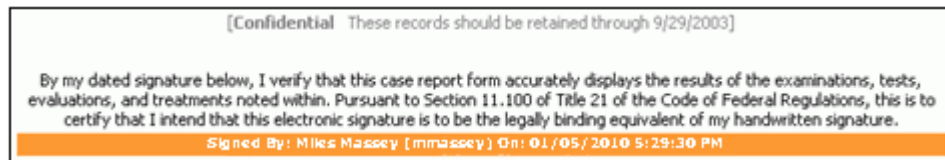
Retention Information: Displays a standardized message that the form is confidential and should be retained through a certain date.

Electronic Signature: If the CRF has been signed, the electronic signature is displayed on the CRF: the attestation, the signer's name, and a time-date stamp.

Question Icons

The icons alert you that a question has extra information attached to it:

Invalid: Marks a question that has an answer that is in an invalid format or is out-of-range. This icon displays when you exit the field, alerting you so that you can correct the data before submitting the CRF (and thus avoid triggering a query and causing a system-generated DCF to be created). For each field, the study designer has the option to set:

Whether it is **required**. If a required field is left unanswered, the field is marked with a ▮ icon.

A data format: numeric, text, date, etc. If the answer provided is not one of these types—alpha characters in a numeric field, for example—the field is marked with a ▮ icon.

The **range** that the data needs to fall within: date range, numeric range, etc. If the answer provided is outside of the range—a date not in the date range, for example—the field is marked with a ▮ icon.

The **minimum/maximum length**—the total number of characters or numbers—entered in the field. For numeric fields, the decimal point is not counted in the length, so the length for "123.456" is 6.

The **minimum/maximum precision**—the number of digits to the right of the decimal— for numeric fields. For example, a max precision of 3 would allow "123.456" but not "12.3456."

Move your pointer over the icon to view a mouse-over description of the error. For more information about minimum and maximum query precision, see Queries on page 233.

Change History: Signifies a question that has edits made to it after its initial entry. Click the icon to open the change history list and view the previous values.

Comment: Signifies a question that has one or more comments attached. Click the icon to view the comment. For more information on comments, see Comments on page 229.

DCF: Signifies a question that has a DCF attached. Click the icon to go to the DCF subtab at the bottom of the page.

Mark Not Answered: Signifies a question that has been intentionally skipped. Click the icon to unmark the question. For more information about marking a question not answered, see Marking a Question "Not Answered" on page 235.

Paging

Note: Paging controls are only available for an open CRF when you are in *view mode*. If you have a CRF checked out, the paging controls will disappear, since any changes you make to a CRF would be lost if you navigate to another form. This is especially important to note if you have auto-checkout turned on.

However, if the CRF is frozen (and therefore available to be checked out), the paging controls will appear.

CRFs Page

The CRFs view has three subtabs: DCFs, Comments, and Workflow. For more information about CRF subtabs, see Chapter 6: Entering Patient Data (CRFs) on page 184.

DCFs Subtab

The DCFs subtab lists all DCFs generated for the CRF, including manually created and automatically generated DCFs, as well as active and closed DCFs. Clicking on the DCF opens the DCF. For more information about DCFs, see Routing CRFs on page 221.

DCF ID: Lists the unique ID assigned by system.

Query Description: Lists the contents of the Query Description field.

Date/Time: Lists when the DCF changed status.

Status: Lists the current status of the DCF.

Comments Subtab

The Comments subtab lists all comments associated with the CRF, either pertaining to specific questions, or the entire form. Clicking on the comment opens the comment in view mode. For more information about the comments subtab, see Comments on page 229.

#: Lists the question number the comment is associated to. If the comment is for the CRF itself, the column reads "Form."

Value: Lists the value of the question at the time the comment was made.

Comment: Lists the text of the comment.

Date/Time: Lists when the comment was saved (blank if the comment is for the form itself.

Workflow Subtab

The Workflow subtab lists each action taken for the CRF, showing the most recent action first.

Action: Lists the name of the action taken on the CRF.

Date/Time: Lists the date and time the action took place.

User: Lists the user who performed the action.

CRF Icons

DataLabs uses icons to give you a visual cue as to the status of patient CRFs.

Cumulative
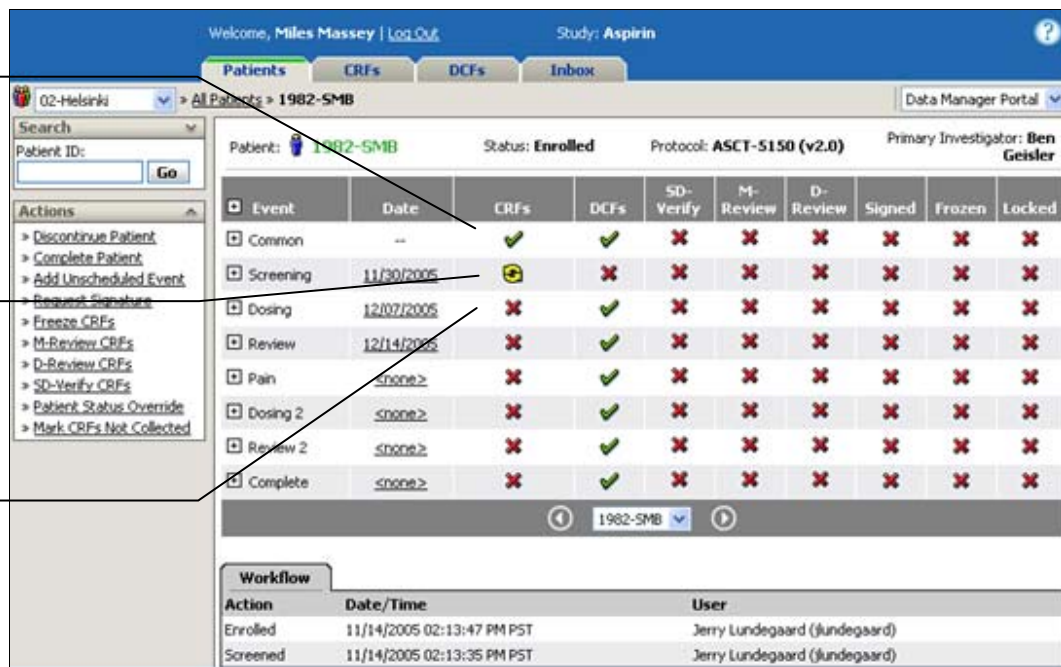
Where there are multiple CRFs, DataLabs uses three icons to show the cumulative status of all the CRFs under the event it represents.

None: No CRFs have started data entry or have been submitted.

Some: At least one CRF has begun data entry or has been submitted.

All: All CRFs have been submitted.

All the CRFs for the Common event have been completed and submitted.

At least one of the CRFs in the Screening event has begun data entry.

None of the CRFs for the Dosing event have even begun data entry.

Individual

When you expand an event, each individual CRF is represented by a status icon:

Not Started: A form that has been published but never saved carries a status of "Not Started." Form data items will display in entry mode. The CRF is "empty": the CRF has not been opened, and data entry not started.

Optional: A Form that has been setup by the study designer to be optional will carry a status of "Optional." Optional forms that have never been saved are not counted as expected. Once data has been saved on an optional form, it is included in the expected CRF count.

Submitted: A CRF where data entry has been completed will carry a status of "Submitted." If the study has been configured for CRF Level submit, the form will attain the "Submitted" status upon the first save. If the study has been configured for Item Level submit, the form will attain the submitted status after all individual items on that form have been submitted.

Not Collected: A form that has been marked not collected will carry a unique status. Any form can be marked not collected except patient status forms. Forms marked "Not collected" are not included in the expected count.

Partially Complete: A CRF where data entry has begun but has not completed will carry a status of "Incomplete." This status applies only if the study has been configured for Item Level Submit.

CRF Reset: The CRF has been reset to its original values. For more information, see Resetting a CRF on page 209.

Patient Status: A patient status form. The figure color changes to correspond with the patient status.

The figure below illustrates how cumulative status icons reflect what lies beneath them.
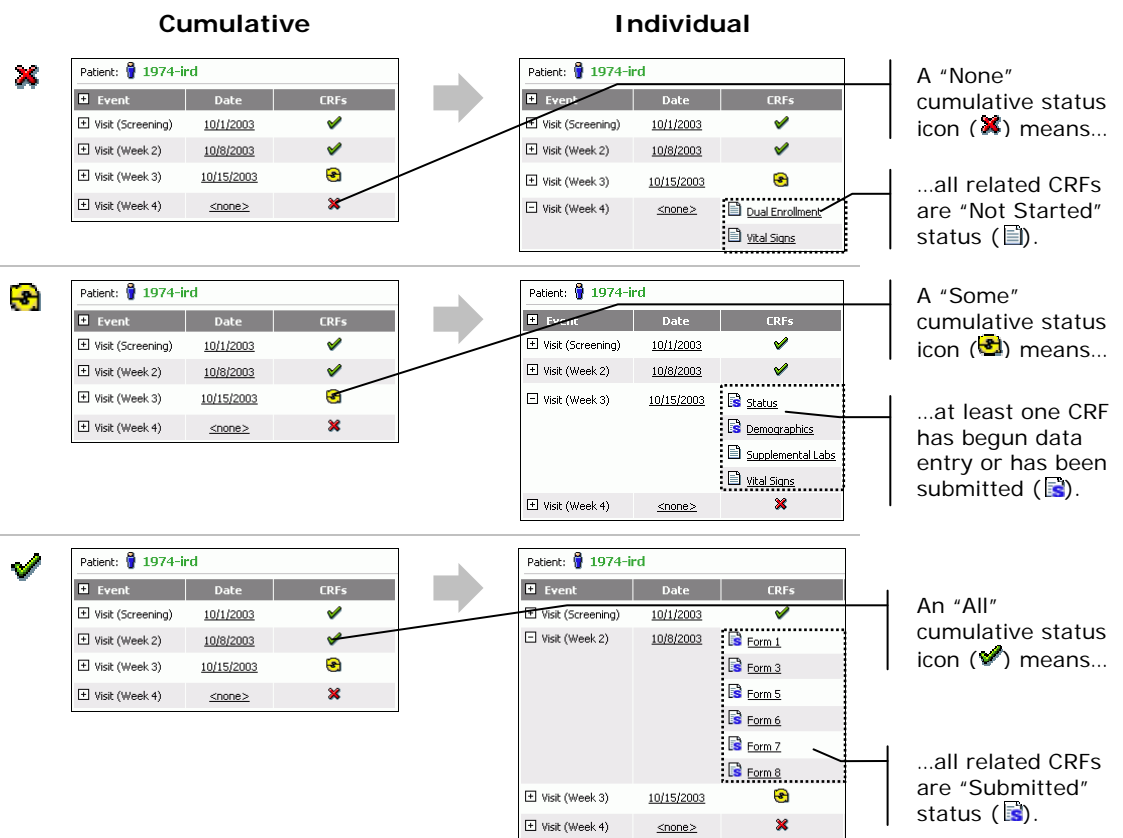
Using CRF Icons to Track Progress

The status icons and flags give you a visual cue to the progress of CRFs and events. Basically, a green check (✔) means there is progress or completion, a red X (✖) means there is no progress or there are issues to address, and a yellow recycle symbol (♻) means that there is at least one CRF complete.

The basic goal is a row of green check marks (✔).

For more information on DCFs, signatures, freezing, and locking—and their status icons—see the respective chapter on each.

Searching for a CRF

On most views of the CRFs tab, you can use the Search palette to search for a CRF using a single search option, or a combination of several search options.

Patient ID	Search based on patient ID. You can enter a partial ID to broaden your search.
Patient Status	Search based on current patient status (screened, failed, enrolled, discontinued, completed).
Signature Status	Search based on signature status of the associated CRFs (ready, rejected, signed, not signed, changed).
Data Status	Search based on patient's data status (not frozen/locked, frozen/not locked, frozen, locked).
Event	Search for CRFs belonging to a specific event.
CRF	Search for CRFs using a specific form.
SD-Verify Flag	Search for CRFs marked with the SD-Verify flag.
M-Review Flag	Search for CRFs marked with the M-Review flag.
D-Review Flag	Search for CRFs marked with the D-Review flag.

Tip: Use multiple search options to narrow your results.

Example: Select the Completed patient status and the Frozen data status. The results show only those patients that are completed and have been frozen.

Note: Searches are limited to the sites that you have permission to view.

To search for CRFs:

1   Click the Expand button ⌄ at the top of the Search palette to see all the search options.

2   Enter or select your search criteria.

3   Click **Go**.

The multi-CRF page appears with the list of CRFs meeting your search criteria.

Checking Forms In and Out

To ensure that only one user at a time is working on a CRF, DataLabs has a check in/out feature. Checking a CRF out "locks" it and prevents more than one user from opening and editing the CRF. When a CRF is checked out, other users are only able to open it in view mode.

All users by default open CRFs in view mode and must check out the form to edit it.

To check out a CRF:

1 Click the CRF name.

The CRF page appears in view mode.

2 Click **Check Out**.

The CRF page appears in edit mode.

3   Enter data into the form.

4   Click **Save**.

The form is submitted and you are returned to the page from which you accessed the CRF.

Auto Checkout

While by default users open a CRF in view mode and then check it out to edit it, you can set your user preferences to automatically check out a CRF when you open it.

Note: To learn how to turn on Auto Checkout, see Changing Your User Preferences on page 47.

To open a CRF (with Auto Checkout on):

1   Click the CRF name.

The CRF page appears in edit mode.

2   Enter data into and edit the form.

3   Click **Save**.

Entering Data into a CRF for the First Time

The first step in entering patient data is to open a CRF. The first time you open a CRF, you can only do so through the patient view.

Note: Editing a CRF works somewhat differently than entering data for the first time. For more information on editing a CRF, see Editing a Submitted CRF on page 207.

To enter data into a patient CRF:

1 Select a Patient from the patient view.

2 From the Event column, click the + symbol to display the CRFs for that event in the CRFs column.

3 Click the CRF name.

The Edit CRF page appears.

Note: If you have Auto Checkout turned off in your user preferences, the form will open in view mode—you need to click the Check Out button at the bottom of the form to edit the CRF.

4 Enter the data in the fields.

5 Click **Save**.

The different kinds of fields and data are described in the following sections.

Saving a CRF

DataLabs allows you the ability to save form data.

CRF Level Collection

If the data collection is defined as CRF Level, the entire form will be saved and the change history trail will begin for all questions.

Item Level Collection

If the data collection is defined as Item Level, saving a form will only save and begin the change history trail for the following:

- Items which have had data entered.

- Items which the user has marked as collected.

- System fields (derivation, encoding).

Items which are not indicated previously will remain as new entry fields. You will have the option to mark all unanswered questions "collected."

CRFs with User-editable and External fields

The following table summarizes the status assigned when a CRF is saved and the CRF contains both user-editable and external fields.

Types of fields on the CRF	Types of fields populated	Resulting CRF status
User-editable fields only	All fields	Partially submitted
User-editable fields only	Some, but not all fields	Fully submitted
External fields only	All fields	Fully submitted
External fields only	Some, but not all fields	Fully submitted
Both external fields and user-editable fields	All fields	Fully submitted
Both external fields and user-editable fields	User-editable fields only	Fully submitted
Both external fields and user-editable fields	External fields only	Partially submitted

Viewing a CRF

Clicking on a CRF within DataLabs opens the CRF in view mode by default.

Note: If you have Auto Checkout turned *on* in user preferences, any CRF you click becomes checked out and opened in edit mode.

Tip: Only select Auto Checkout if you are actively performing data entry. Data Manager Portal users typically have Auto Checkout turned *off*.

To view a CRF:

■   Click the CRF name.

The View CRF page appears.

All data is displayed in view only mode. Values that have never been entered are displayed as "[Blank]."

Note: All fields are read-only and cannot be changed.

Navigation Control: Used to navigate between CRFs. For more information about navigation controls, see Navigating Between CRFs on page 205.

Check Out: Used to open the CRF in edit mode. For more information about opening a CRF in edit mode, see Editing a Submitted CRF on page 207.

Navigating Between CRFs

You will find the navigation controls useful to page through a list of CRFs. The CRFs listed are based upon the results of the page you came from (in other words, one level of detail higher).

Example: If you clicked on a CRF from a patient view, you will page through a list of all of that patient's CRFs.
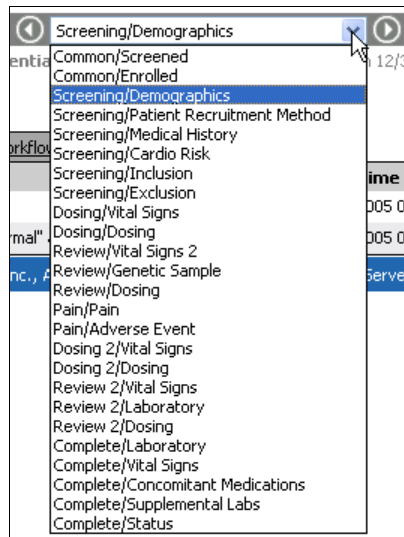
 Previous CRF button: Moves to the previous CRF.

 Selection Box: Displays a list of CRFs (Event/Form).

 Next CRF button: Moves to the next CRF.

Editing a Submitted CRF

After you have submitted a CRF, you can still go back and edit it. Any changes you make will be noted in the change history for each question.

Note: If you have Auto Checkout turned *on*, any CRF you click will open in edit mode.

To edit an existing patient CRF:

1   Click the CRF name.

The CRF page appears in view mode.
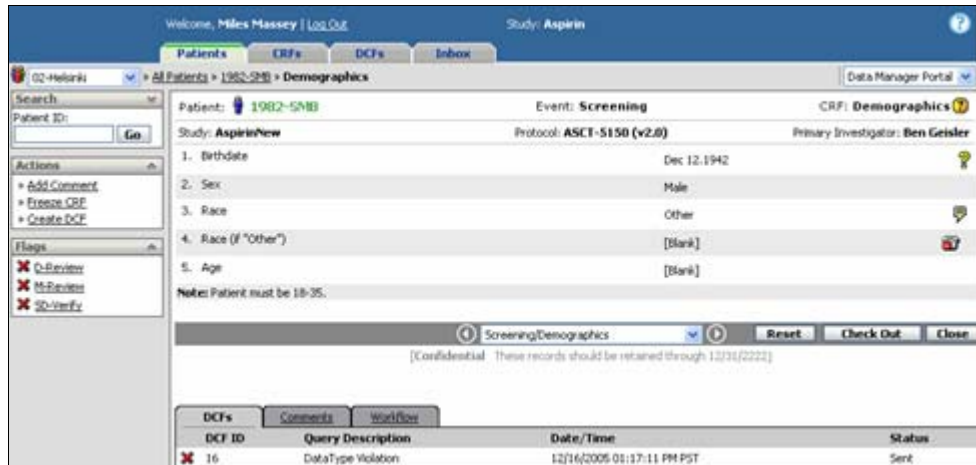
2   Click **Check Out**.

The CRF page appears in edit mode.
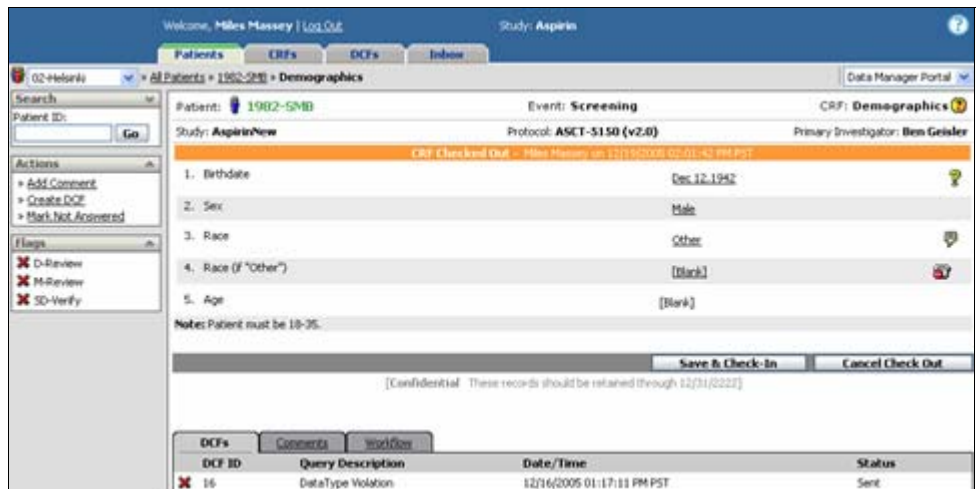
3   Click the question.

The question expands so that you can update the answer and record reasons for the change.

4   Enter or select the new value.

5   Select the **Reason for change** (required).

Note: Entering **Additional Notes** is optional.

---

6   Click **OK**.

DataLabs saves the changed data and marks the question with a Change History icon ( ).

7   Do the same for any other questions.

8   Click **Save**.

Note: Remember to save and check-in the CRF. Otherwise, any changes you made will be lost.

Resetting a CRF

A user with the proper permissions can reset a CRF to its original values. A CRF cannot be reset if it is frozen or locked. Typically, you would reset a CRF if data for the wrong patient was entered into the CRF.

When you reset a CRF, the CRF's status changes to "Not Started" and the following data changes:

■   Data entered by users and encoding fields are cleared.

■   Table rows are deleted.

■   Derived fields are recalculated.

■   DCFs associated with basic edit check queries are closed. DCFs associated with cross-form edit checks are re-evaluated.

■   Form-level and item-level flags are set to "Off."

■   Requests for signature are cancelled. If the CRF has already been signed, the signature flag is set to "Off" (the PI's signature is cancelled).
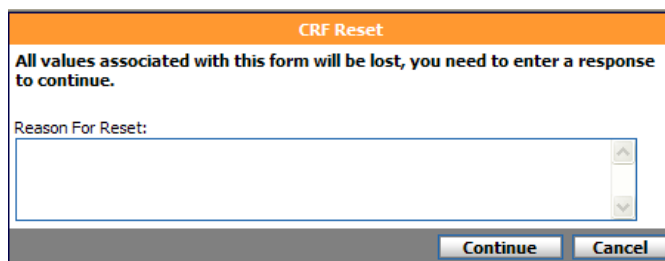
The following data does not change when a CRF is reset:

■   External fields are not cleared.

■   User comments are not cleared.

An entry is made in the Change History and Workflow for each item that has changed as a result of resetting the CRF.

To reset an existing patient CRF:

1   From the Patient View, click the CRF you want to reset.

The CRF page appears.

2   On the Action palette, click **Reset CRF**. The **CRF Reset** dialog box appears.

3 Type the reason you are resetting the CRF and then click **Continue**.

DataLabs resets the values on the form. The reason you entered for resetting the form is recorded on the Workflow tab for the form. Any item that has changed as a result of resetting the CRF is marked with a Change History icon ( ).

A message is sent to your Job Inbox to inform you of the CRF's reset status. When the reset is complete, the message provides a link to the CRF and displays the following text: *CRF Reset: <Form> in <Event> has been reset for <Patient ID>.*
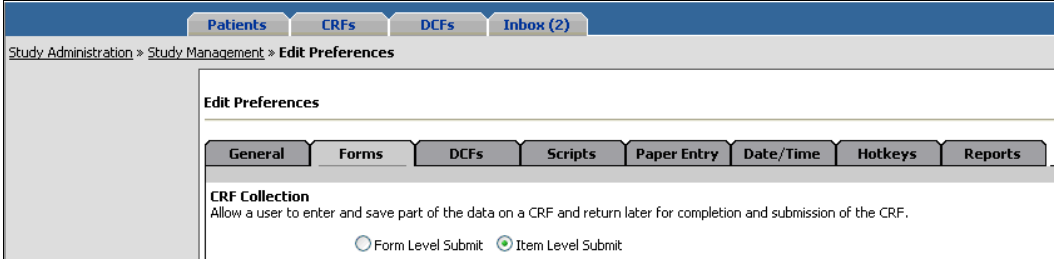
Item Level Submit

You will have the option to save selected questions on a CRF, while leaving the remaining questions as new entry fields. This option is available when a study is in Item Level Submit. For more information about Item Level Submit see Study Management: Forms Tab on page 78.

Item Level Submit is only available in Electronic Data Capture (EDC) mode. Any form submitted through Paper Data Entry (PDE) will have all values submitted.

Setting Study Preferences

Item Level Submit is a study-wide setting controlled by security through Study Management.

Changing the data collection method for the study from Form Level Submit to Item Level submit (or vice versa) after patient data has already been entered, has no effect on previously entered data or forms. Changing the collection method only affects forms saved from that point forward.

Entering Item Level Information

If the study has been defined as Item Level Submit, each question must be either answered or marked as collected in order to be considered "Submitted." Fields are considered Item Level submitted if you save the information on the form after:

- Value is entered into a field.

- An option is selected from a codelist.

- The field is identified as "Mark Collected" or "Mark Not Answered."

  For more information about Mark Collected or Mark Not Answered see The "Entry Complete" check box at the bottom of the CRF has been selected.

Entry Complete submits all fields in form when saved

Clearing an Item on a CRF

You can clear a previously saved item when data collection has been defined as Item Level Submit.

To clear an Item on a CRF:

1   **Check Out** the form where the item to clear is located.

2   The selected form opens and you can enter data.

3   Right-click the item to clear.

4   The right-click action menu appears.
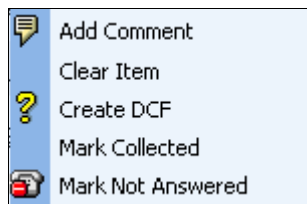
5   Select **Clear Item**.

6   The Clear Item window appears:
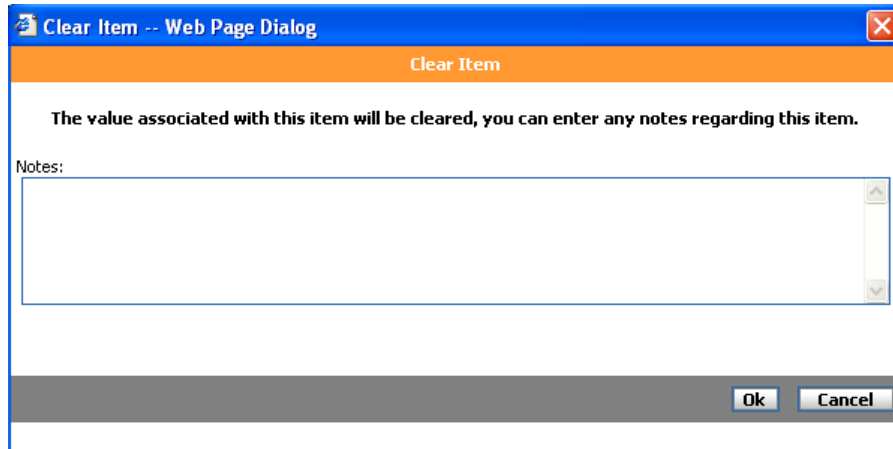
7 Enter any information about the item, such as the reason for clearing the item.

8 Click **OK**.

9 The Checked Out form view returns.

If an item is cleared the value is set back to its default and the field reverts to a new entry field. Any existing change history for that item remains, and a new history entry is made that indicates the change back to the default value. The CRF must be checked out to you in order to clear an item.

Note: If you attempt to clear an item that has not been submitted (highlighted blue), the following error message appears.
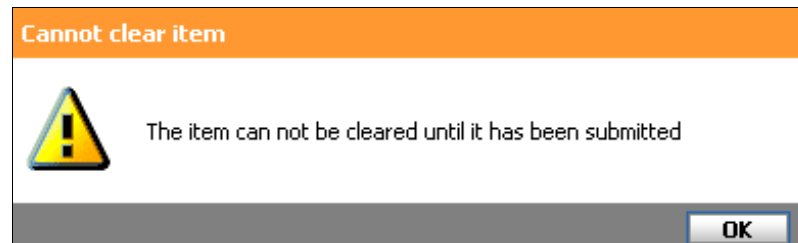
Note: If you attempt to clear an item that is a derived, external, or autobuild sequence field, the following error message appears.
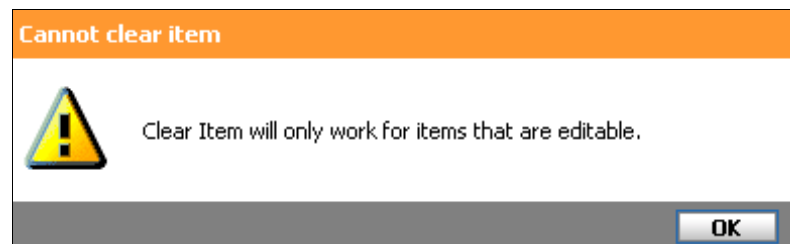
Display Modes

Form - Display Modes – Form Level Collection

There are three form display modes which are seen when Form Level Submit has been selected.

Entry Mode: Displays blank entry box/selection box/radio button.

Edit Mode: Displays value which can be clicked on to edit.

Read-Only Mode: Displays the value only; which you will not be able to edit.

- Derivations

- Data from an External Source

Field - Display Modes – Item Level Collection

There are two modes of field display with actions specific to each when Item Level Submit has been selected.

User Editable Fields: These allow the following right-click menu options and the ability to input data into the fields.

- Add Comment

- Clear Item

- Create DCF

- Mark Collected

- Mark Not Answered

Ready-only Fields: These allow the following right-click menu options and are un-editable.

- Add Comment

- Create a DCF

There are three types of Read-only fields on forms when in Item Level Submit.

Derived Fields: Fields with derivation data.

Hidden Encoded Fields: Fields with Encoded data.

External Fields: Fields from outside sources which do not have the ability to be edited.

Data Formats

The data on a CRF is in two basic formats: data fields and data tables.

Data Fields

Data Fields are individual, discrete pieces of information, such as a height, weight or systolic blood pressure. Fields can either appear in a single question or populate a data table (see below). There are many different types of data elements:

Date: Used to enter a fully formed calendar date (mm = month, dd = day, yyyy = year), such as 08/02/1972.

Numeric: Contain numeric values in a format determined by the study design. When entering data into a numeric field, the desired numeric format is shown to the side of the data entry field. For example, the format field might show "[12345.123]," prompting you to enter a numeric value with a precision of up to three decimal places (e.g., 99999.999). The format for the field can be found in the CRF Help () if the study designer has provided it.

Drop-down combo box: Offers a pre-determined list of options, either in the form of a drop-down combo box or option buttons, of which you can only choose one:

Text: Used to enter alphanumeric information.

Data Tables

Data tables are groups of related information, such as medications, diagnoses or adverse events, where similar information is gathered on each item. Entering data into a data table is the same as other data elements; you're just entering it into a table rather than a single field.

To add data to a table:

1 Click **Add New Row**.

A new row appears with data fields to fill in.

2. Enter all concomitant medications:			
	Indication	Medication	Continuing?
2.1.	[Blank]	[Blank]	[Blank]
2.1.1. Indication:			
2.1.2. Medication:			
2.1.3. Possible Interaction:			
2.1.4. Start Date:		mm/dd/yyyy	

2 Enter the data in the fields.

3 Click Add to add the record to the data table.

DataLabs adds the row to the table.

7. Sample Table:				
	Drug Name:	Condition:	Start Date:	Stop Date:
7.1.	Ibuprofen	Muscles aches	9/28/2003	10/3/2003
				Add New Row

4 Repeat the previous steps to add additional records to the table.

To edit a row:

1 Click an item in a row.

The row appears with data fields.
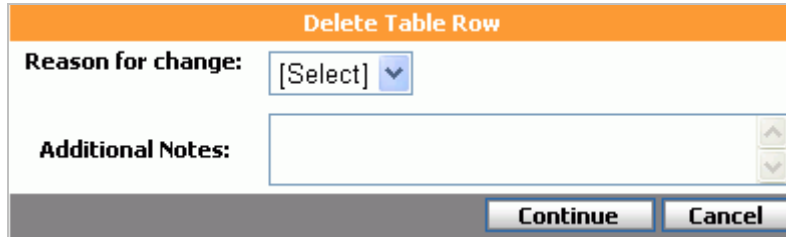
7. Sample Table:				
	Drug Name:	Condition:	Start Date:	Stop Date:
7.1.	Ibuprofen	Muscles aches	9/28/2003	10/3/2003
7.1.1. Drug Name:		Ibuprofen		
7.1.2. Condition:		Muscles aches		
7.1.3. Start Date:		9/28/2003		
7.1.4. Stop Date:		10/3/2003		
			Delete	OK
				Add New Row

2 Make any necessary edits to the data.

3 Click **OK** to save the changes.

To delete a row:

1 Click the row item.

The row appears with data fields.

2   Click **Delete** to delete the row.

The Delete Table Row window appears.

3   Select the Reason for change (required).

4   Type any Additional notes (optional).

5   Click **Continue**.

DataLabs deletes the row.

Although the data has been "deleted" from the study, in order to preserve the integrity of the audit trail, the values are still visible in the table but struck out.

To show a deleted row:

■   Click **Show Deleted Rows**.

The deleted row appears in the table.

To restore a deleted row:

Note: If a row was deleted due to a CRF reset, the row cannot be restored.

1   If deleted rows are not shown, click **Show Deleted Rows**.

2   Click a deleted item row.

The deleted row appears with data fields.

3 Click **Restore**.

The Restore Table Row window appears.

4 Select the **Reason for change** (required).

5 Type any **Additional notes** (optional).

6 Click **Continue**.

DataLabs restores the row.

Hidden Fields

DataLabs allows the ability to show and hide items that have been designated as hidden fields by the study designer. The ability to show/hide hidden fields is controlled by security rights. The default setting for all CRFs is "Hide" Hidden Fields.

Below is an example that shows how a Hidden Row expands.

Each item will have a sequential row number. In the case of hidden fields, when hidden fields are displayed they will carry a "#" suffix. For example, if a hidden field is displayed after row 1, the hidden field row will be numbered 1.1.

Hidden Field
Displayed 1.1

Dependent/Conditional Questions

Dependent questions are a series of related questions that need to be answered only if the answer(s) to preceding question(s) require further clarification.

Example: The smoking history of the patient is an example of dependent question.

Dependent questions are not editable until they are needed.

Inactive conditional fields will be displayed grayed out.

Grayed Out
conditional Field

Inactivated Fields have the following characteristics:

- If data has already been entered into a conditional field that is inactivated, DataLabs will return the field to the default value defined by the study designer and an entry will be made in the change history.

- Inactivated fields can be flagged, but cannot have any other actions taken against them.

- If a study is defined as Item Level collection, conditional fields which are inactive will not be submitted upon Save, but will not count in determining if the form is complete.

- If one or more DCFs exist for a conditional field when it is inactivated, DataLabs will automatically close the DCFs whether auto or manually generated. "Closed due to conditional field change" will be entered as the answer.

To answer a series of dependent questions (example):

1 Select "**yes, in the past**" from the **Cigarette Smoker?** drop-down box.

Questions 4 through 6 become active.

F. Smoking/Alcohol/Caffeine Use		
3. Cigarette Smoker?	yes, in the past	
4. Year began smoking cigarettes:		mm/dd/yyyy
5. Average number of cigarettes smoked per day:		
6. Year quit smoking cigarettes: (if current smoker, leave blank)		mm/dd/yyyy

2 Type the date for **Year began smoking cigarettes**.

3 Type the **Average Number of cigarettes smoked per day**.

4 Type the date for **Year quit smoking cigarettes**.

Conditional Field Limitations

- Conditional fields are only dependant upon parent fields within the same form.

- Conditional fields outside of a table cannot be dependant upon a parent field in a table.

- Conditional fields within a table cannot be dependant upon a parent field outside of that table.

- Conditional fields will not be activated if the parent field is equal to "blank" or is "null."

Routing CRFs

Routing is a way to send data within DataLabs. DataLabs provides the ability to route a CRF to another active user within the site. The content of a routed CRF message is similar to a general inbox message, with the following differences:

- The message contains a hyperlink to the appropriate CRF.

- The message contains header information which includes:

   Patient, Event, CRF, Study, Protocol, Investigator.

Note: The recipient of the CRF must have rights to view the CRF, otherwise the link will be disabled and a rule tip will indicate the restriction to the user.

To Route a CRF:

1   Open the CRF you would like to send. Routing is a form level action so it is done directly from the desired form. In the below example the "Screen Patient" CRF is chosen.

Click **Route CRF**

2   From the Actions palette click **Route CRF**. The "Route CRF" screen appears.

Send Message

Print Message

Priority of message can be set to normal or high.

3   Next, you will have the option of choosing the recipients to send to.

4   Select the **To** button.

5   The **Select User** page appears.

> **Note**: Only users associated with the sites that the sender is associated to and who have opted–in to receiving messages will appear. See Setup Section in User Preferences.

6   Select the User Names from the list to whom you would like to send the message and click **OK**.

This brings you back to the **Untitled Message** page.

7   Type a Subject and Message.

8   Click **Priority** to send via High Priority () or leave unhighlighted for normal message status.

9   Click **Send**.

Routing a CRF: Actions

The Following actions can be taken from the **Route CRF** page:

Send – Send Message.

When a CRF is successfully routed the following message will display: "Route CRF Successful."

Print – Print the message.

Priority – You have the option to mark the message as **High Priority**. When high priority is selected, the **Priority** button () is highlighted.

By choosing **High Priority** the message in the recipient's inbox will have a high priority icon (⊠) in the place of the standard message icon (✉).

Viewing a Routed Message

Routed messages appear in the recipients' Inbox.

1   From the **Inbox Tab** select **Mail** in the Folders palette.

Click on Desired Message
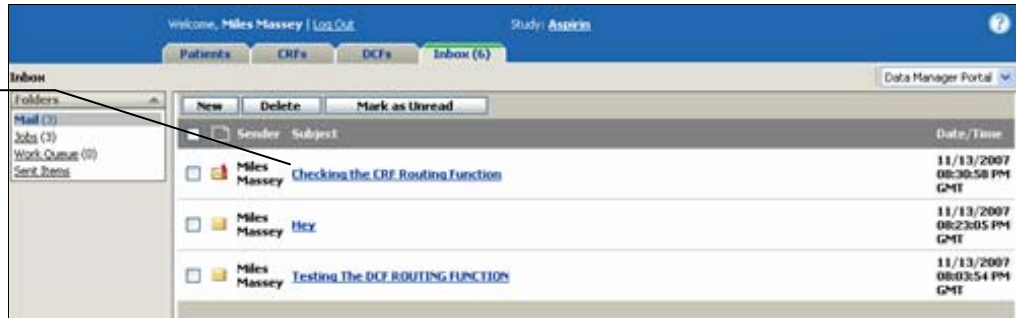
2   From the **Inbox** select desired message. This will bring you to a **Routed CRF Message** similar to the following:

Choose to forward to someone in DataLabs
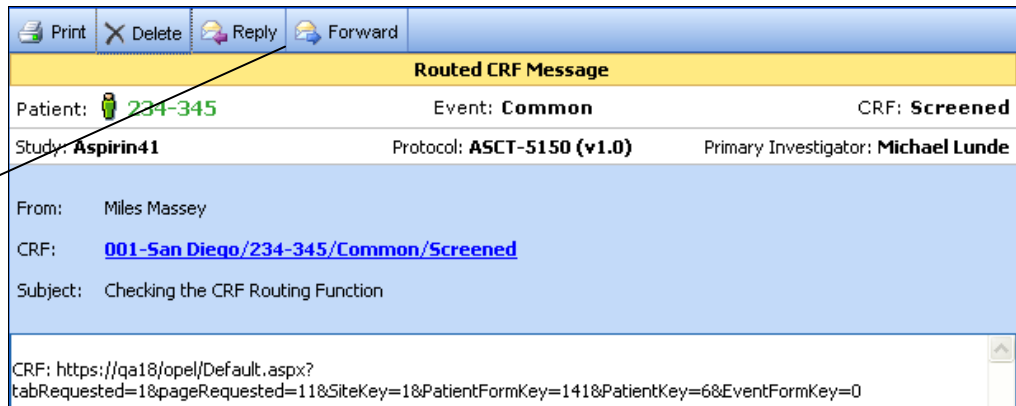
In the **Routed CRF Message Header** you will find the following pertinent information regarding the CRF:

Patient: Displays patient ID and patient icon indicating the status of the patient.

Event: Name of the event the CRF belongs to.

CRF: Name of the corresponding CRF.

Study: Name of the current study.

Protocol: Name of protocol and version number.

Investigator: Name of the primary investigator for the site.

In the **Routed CRF Message Body** you will find the following:

Routed
Message Body

> From: Miles Massey
>
> CRF: **001-San Diego/234-345/Common/Screened**
>
> Subject: Checking the CRF Routing Function
>
> CRF: https://qa18/opel/Default.aspx?
> tabRequested=1&pageRequested=11&SiteKey=1&PatientFormKey=141&PatientKey=6&EventFormKey=0
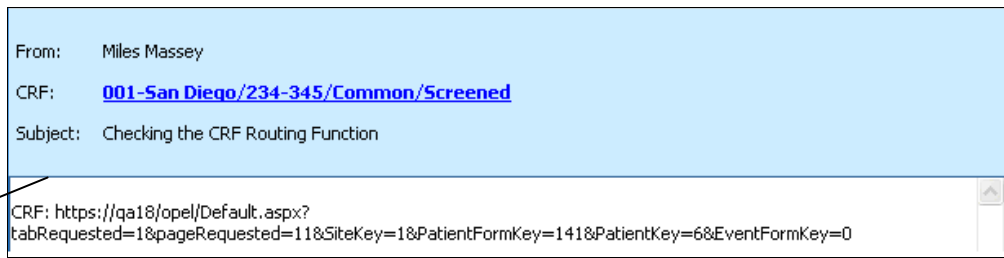
From: Sender – the user who routed the CRF.

CRF: Links to the routed CRF. If you don't have permissions to view this CRF, mousing over the link will display a tooltip notifying you that you do not have access to the CRF.

Subject: Displays the subject as entered by the sender.

Message: This is the message the sender chose to include.

Change History

Change History Activation

All study related forms (forms listed under an event) maintain a field-level change history when the data item has been saved the first time. The history will record all of the modifications that are made to that item.

Change History Icon

If a field value is changed the **change history** icon (🌀) is displayed to the right of the field.

Change History Icon

Field/Value Display

Before a data item has been saved, the field will be presented in a data entry format (open form field). Once the item has been saved, the field will be presented in a display format (linked text).

Open Form Field:

Open Form Field displayed prior to **Saving**.

Linked Text:

Linked Text
display occurs
after CRF is
Saved.

Changing Field Value

To change a data item that *has not been saved*:

1   Enter/select the new value.

2   Save the CRF.

To change a data item that *has been saved*:

1   **Check-Out** the CRF.

2   Click the value and the row is expanded which includes:

- Blank field to enter/select new value.

- Codelist for the reason for change.

- Text area for entering additional notes.

3   The user can click **OK** to accept new value or **Cancel** to return to previous view.

Once the CRF has been saved, a change history icon () will display next to the field.

Regular questions and table questions both use the same functionality for changing a value. DataLabs keeps a change history record of all data that is saved. So once a CRF is saved and checked in, any subsequent changes to the data in the form is tracked by the change history. If a question has been updated after its initial entry, it is marked with a **Change History** icon (🔄).

To view the change history for a field on a CRF:

■   From a CRF page, click the **Change History** icon 🔄.

The Change History pop-up window appears.
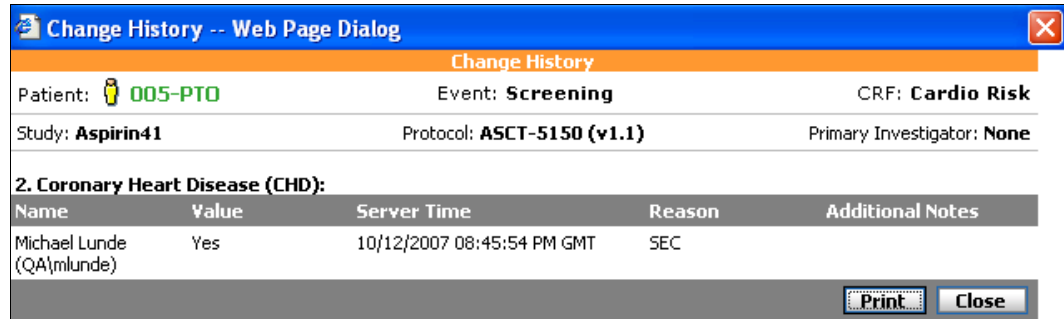
Question: Shows the full text of the question.

Name: Shows the display name of the user who made the data change.

Value: Displays the question's value after being changed.

Server Time: Displays the time (on the server, not the client) at which the change took place.

Reason: Displays the required reason given why the change was made.

Additional Notes: Displays any additional optional comments on why the change was made.

There is a user level preference to view either the complete change history or the basic change history for an item.

Complete Change History

Will display all history items including (but not limited to) Paper Data Entry, Initial Entry, Table Row Delete, Table Row Restore, Form Versioning and CRF Reset. With the selection to view the entire history an additional column, named Source, will be displayed in the change history window to help in identifying when the change was made.

Basic Change History

Will display the normal change history for an item and changes that result from resetting an item. Does NOT include Paper Data Entry, or Table Row Delete/Restore.

Additionally, the entire change history of an item can be viewed using concurrent reporting.

Printing a Change History

If you need to print a change history, you can click the Print button.

To print the change history:

■   From the Change History pop-up window, click **Print**.

This sends a printable version of the change history to your default printer.

Caution: Because of helper applications and "spyware" that sometimes get installed on a browser, some users may encounter an error when trying to print a change history. For more information about this error, see Printing Runtime Error on page 361.

Comments

You can add a comment to either the CRF or the question for clarification.

Adding Comments

To add a comment to a CRF:

1   From an open CRF, click the **Add Comment** command on the Actions palette.

The Add Comment dialog appears.

2   Type your comment in the text field.

3   Click **Save**.

The form comment is saved and appears under the Comments subtab.

To add a comment to a question:

1   From an open CRF, right-click the question you want to add a comment to.

2   Select **Add Comment** item.

3   The Add Comment window appears

4   Type your comment in the text field.

4   Click **Save**.

The field comment is saved and a comment icon (📝) appears next to the question. The comment is also listed under the Comments subtab.

Viewing Comments

To view a field comment:

■   From a CRF page, click the **Comment** icon 📝.

The Comments subtab opens.

To view a comment:

1   From Comments subtab, click the comment.

The View Comments window appears.

2   Click **Close** to close the box.

Provisional Comments

If you add comments to a new CRF that you've opened but have not saved, those comments are marked with a provisional comment icon ( ). When you edit provisional comments, the changes are not recorded in the Change History. When you save and submit a CRF with provisional comments, those comments are converted to regular comments and are marked with that icon ( ), and the comment is saved to the database.

Note: The only exception to these rules is *new rows* in tables. Comments added to a new row in a table question are provisional—even if the CRF has previously been saved and submitted—until the form has been checked in.

The comment is marked provisional because the CRF has been checked out for the first time, but has not been saved and submitted.

Note: Provisional comments do not appear on the Comments subtab.

Queries

There are two methods that DataLabs uses to clarify data that is entered into the study:

Manually-generated DCFs: These are Data Clarification Forms generated by any number of reviewers and data managers, who review the data as it is entered into DataLabs. These DCFs are identified by the user who creates them. For more information about manually-generated DCFs, see Chapter 8: DCF Management on page 294.

Query-generated DCFs: DCFs automatically generated by DataLabs when a user saves CRF data. These queries are created and scripted in the design phase.

Note: For more information on DCFs and the data review process, see Chapter 8: DCF Management on page 294.

Types of Queries

Queries are created at two levels:

Question level: Checks the value of a field when you navigate from it to make sure it is valid. This indicator fires when you exit the field, alerting you that you may need to correct the data before submitting the CRF (and thus avoid triggering a query). For each field, the study designer can set one of the following:

> **Required** – If a required field is left unanswered, the field is marked invalid.
>
> **Data format** – If the answer provided is not of the proper data format—numeric, text, date, etc—the field is marked as an invalid format.
>
> **Range** – If the answer provided is outside of the defined range—date range, numeric range, etc.—the field is marked as range invalid.
>
> **Minimum/maximum length** – If the answer provided exceeds (or is less than) the total number of characters or numbers required, the field is marked as an invalid format. For numeric fields, the decimal point is not counted in the length, so the length for "123.456" is 6.
>
> **Minimum/maximum precision** – If the answer provided exceeds (or is less than) the required precision—the total number of digits to the right of the decimal—the field is marked as an invalid format. For example, a max precision of 3 would allow "123.456" but not "12.3456."

If any of these fires true, the question is marked with an Invalid status icon ( ), and when you try to save the CRF, you receive a warning that a DCF will be generated if you continue with saving the CRF. You have the option to cancel the save, and go back and correct the data you entered.

Form level: Compares values between fields on a CRF when you save and submit the form.

Answering Queries

If a query fires, you have the option to go back to the question and correct the value you entered. If this resolves the query, the Invalid status icon is removed from the question and the DCF is given the resolved status.
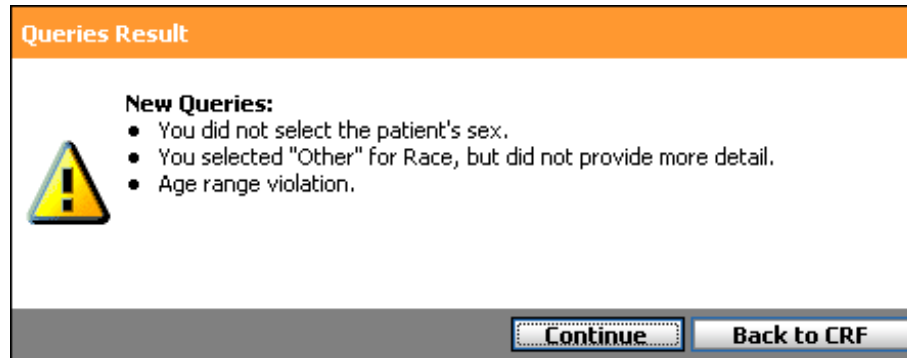
Caution: If you fully submit a form that contains partial data and, as a result, a query is generated, returning to the form and clearing the Entry Complete box does not automatically "unsubmit" the blank items. You must mark each blank item as "not collected," clear the Entry Complete box and resubmit the form.

Auto-Closing Resolved Queries

Note: This Functionality is specific to **Data Manager** portal users.

One of the settings in Study Management enables DataLabs to automatically close any resolved queries. If this setting is turned on, and you correct the answer to a question so that it resolves a query, DataLabs automatically moves it from the Resolved status to Closed. Otherwise, all DCFs with a Resolved status must still be reviewed by data management personnel before they can be closed.

Note: For more information on automatically closing all DataLabs resolved DCFs, see Study Management on page 74.

Marking a Question "Not Answered"

Sometimes questions on a CRF are purposefully skipped during data entry. Data management personnel may want to distinguish between questions intentionally not answered, and those skipped unintentionally. Mark Not Answered enables the site to mark those CRF questions that were intentionally skipped.

If a question is marked not answered:

- DataLabs turns off level 0-2 queries for that question (but still runs level 3-5 queries). See "Query Management" on page 125 for an overview of query levels.

- When the study data is exported, the field is given a pre-defined value to show that it's not answered. This value is set in Study Management. See "Updating the Study Preferences" on page 77 for an overview of query levels.

Note: During the design phase, Designer gives you the option to assign a question-level query to a question marked not answered.

Note: If a question within a table row is marked as not answered and you want to delete the row, save and check in the CRF. Then, check-out the CRF again and delete the table row.

To mark a question "not answered":

1 From an open CRF, right-click the question you want to mark "not answered."

2 Click the **Mark Not Answered** item.

Note: The Mark Not Answered command is only available when you are in edit mode.

The "not answered" icon () appears next to the question.

The question is marked "not answered."

To unmark a question, do one of the following:

- Right-click the not answered icon, and click **Unmark** on the pop-up menu.

- Answer the question, and click **Save & Check-In**.

Marking a Form "Not Collected"

Sometimes a CRF is purposely skipped during data entry. Data management personnel will want to distinguish between forms intentionally not collected, and those skipped unintentionally. Marking CRFs "Not Collected" enables the site to mark those CRFs that were intentionally skipped.

Note: CRFs that are locked or checked out cannot be marked as "not collected."

Any CRF marked "not collected" is automatically unmarked if it is edited and submitted.

Only new, un-submitted forms can be marked "not collected." Once a CRF has been submitted, it cannot be marked.

To mark one or more CRFs "not collected" for a single patient:

1   Open the patient in the patient view.

2   Click the **Mark CRFs Not Collected** command on the Actions palette.

The Mark CRFs Not Collected page appears.

3   Do one of the following:

- To mark all CRFs for the patient "not collected," click the **Select All** button.

- To mark all CRFs for a specific event, click the **All** button for that event.

- To mark each individual CRF, click the check box.

4   Click **Save**.

A confirmation box appears: "Mark CRFs Not Collected Successful."

The Mark CRFs Not Collected page contains the following items:

Patient: Displays the current patient status, and the patient ID (a combination of their Screen/Enroll ID and initials).

Investigator: Displays the name of the assigned PI for the patient.

Status: Displays the patient's current status.

Protocol: Displays the study's protocol.

Select All button: Selects all the CRFs listed on the page to be marked "not collected."

Clear All button: Clears all previously selected CRFs.

All button: Selects all CRFs for the event. Pressing it again deselects all CRFs for that event.

Event Name: Displays the name of the event.

CRF: Displays the CRF name and status icon.

Note: Check boxes are disabled if the CRF is checked out or locked.

Save button: Saves the settings and returns you to the patient view.

Cancel button: Returns you to the patient view without marking any CRFs.

Multiple Patients

Note: This Functionality is specific to **Data Manager** portal users.

Another way to mark CRFs as uncollected is to search for specific forms from the CRFs tab.

To mark one or more CRFs "not collected" for multiple patients:

1   Click the CRFs tab.

2   Enter your search criteria in the Search palette and click **Go**.

The multi-patient view appears listing the results of the search.
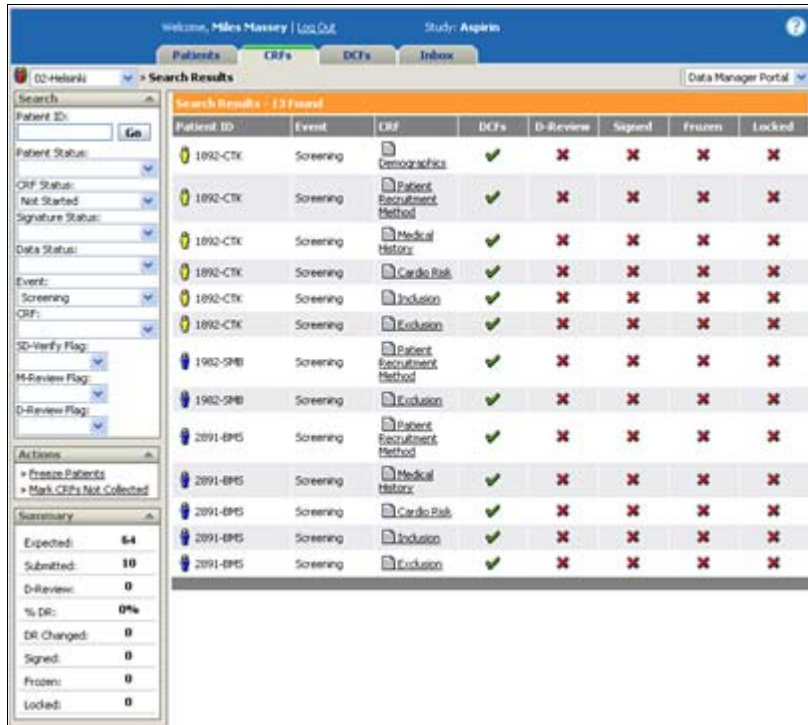
3   Click the **Mark CRFs Not Collected** command on the Actions palette.
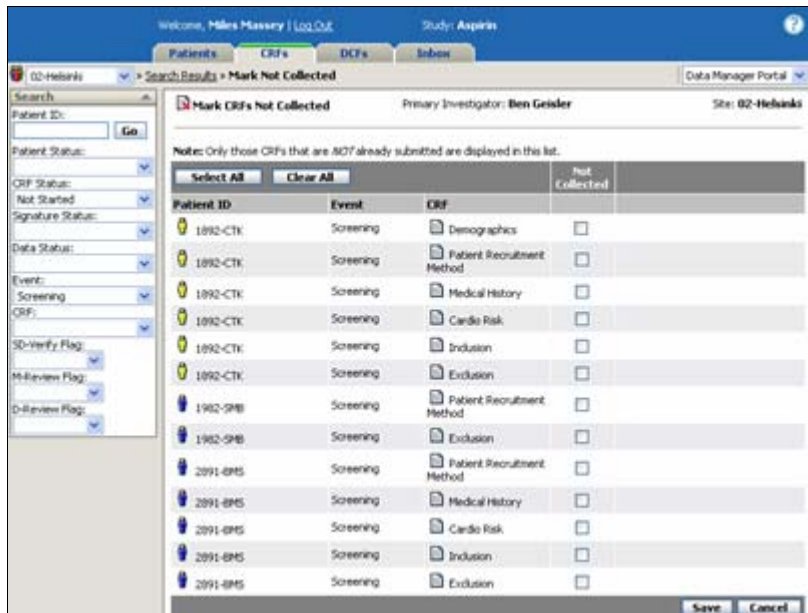
The Mark CRFs Not Collected page appears.

4   Do one of the following:

To mark all CRFs "not collected," click the **Select All** button (Select All).

To mark each individual CRF, click the check box (☑) in the Omit column.

5   Click **Save**.

A confirmation box appears: "Mark CRFs Not Collected Successful."

Chapter 7: Using Flags

Overview

This chapter covers the following material:

■   Flag statuses: cumulative and individual

■   Editing flags

    CRF-level

    Patient-level

■   CRF-level flag collection

■   CRF flag rollup statistics

■   Item-level collection

    Setting flag status

    Table questions – rollup

    Flagging column display

■   Flag history

Introduction

In DataLabs, you can use flags to indicate the CRFs or items that should be reviewed by a field monitor, medical monitor, or data manager. For example, a field monitor may need to review a CRF's data to ensure compliance with study protocol.

Monitors can use the All Patients View and Patients View to identify the CRF and items that require review. After a monitor has verified the data, the monitor can set the CRF's or item's flag status to "on" to indicate that the data has been reviewed.

DataLabs provides three pre-defined flags that can be used to indicate that a CRF or CRF item requires review:

SD-Verify: CRF or item requires verification of the source document by a field monitor.

M-Review: CRF or item requires review by a medical monitor review.

D-Review: CRF or item requires a document review.

Before a study begins, the study administrator defines the type of review, if any, that is required for each CRF or item and determines each user's ability to view and set flag statuses and D-Review) is defined by the study administrator before the study begins.

For information on defining the CRFs and items that require review, see "Flag Management" on page 141. For information on granting permission to users to view and set flag statuses, see "Group Management" on page 55.

Methods for Setting and Collecting Flags

DataLabs provides two methods for setting and collecting flags:

CRF-level flag collection: If CRF-level flag collection is used for a flag, such as the M-Review flag, reviewers can change the flag status for an individual CRF, for all CRFs associated with a patient, or for all CRFs for a patient that are associated with a specific event.

Item-level flag collection: If item-level flag collection is used for a flag, such as the D-Review flag, reviewers can change the flag status for an individual CRF, for all CRFs associated with a patient, or for all CRFs for a patient that are associated with a specific event.

The flag collection method for each type of flag (SD-Verify, M-Review, and D-Review) is defined by the study administrator before the study begins. For information on defining the CRFs and items that require review, see "Flag Management" on page 141.

Identifying CRFs and Items for Review

Reviewers can use the following views to identify the CRFs and items that need to be reviewed:

All Patients View: Shows the status of each type of flag (SD-Verify, M-Review, and D-Review) for all patients for a site.

Patient View: Shows the status of each type of flag for a patient's events and for an individual patient's CRFs.
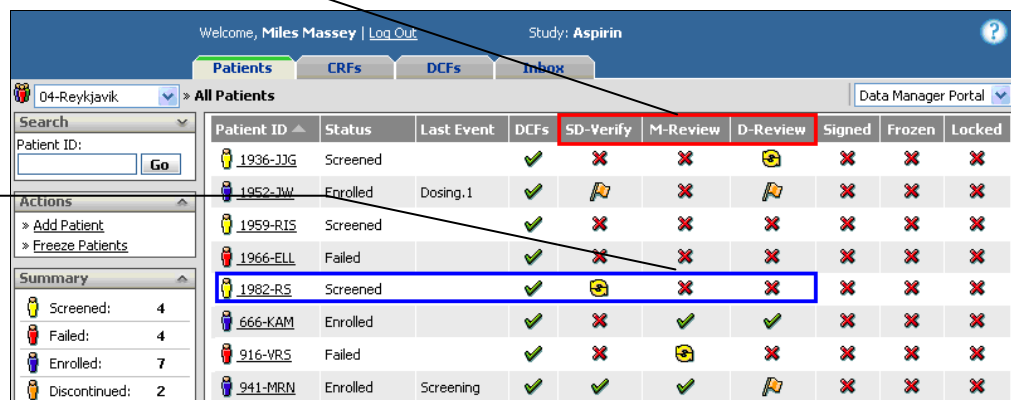
CRF View: Shows the status of each type of flag for the individual items on a CRF. (Applies only to flags collected at the item-level.)

Viewing Flag Statuses (CRF-level collection)

For CRF-level flag collection, monitors can set the flag status for CRFs (but not for individual items on the CRF). Monitors can use the All Patients view to identify the patients having CRFs that need to be reviewed.

A column is shown for each type of flag.

The cumulative status for each type of flag is shown for each patient.

The All Patients View shows the cumulative status of each type of flag (SD-Verify, M-Review, and D-Review) for each patient. Each flag can have one of the following statuses:

All of the required flags have been set to "on" for the patient's CRFs.

None of the required flags have been set to "on" for the patient's CRFs.

Some, but not all of the required flags have been set to "on" for the patient's CRFs.

Visible data was changed on at least one of the patient's CRFs after the CRF's flag was set to "on."

If a flag associated with a patient has the status of ✖, 🔄, or 🚩 the patient has one or more CRFs that need to be reviewed.

To identify the specific events and CRFs that need to be reviewed, click the patient ID. The Patient View appears.

The cumulative status for each type of flag is shown for each event.

Expand the event to see the flag status for each CRF associated with the event.
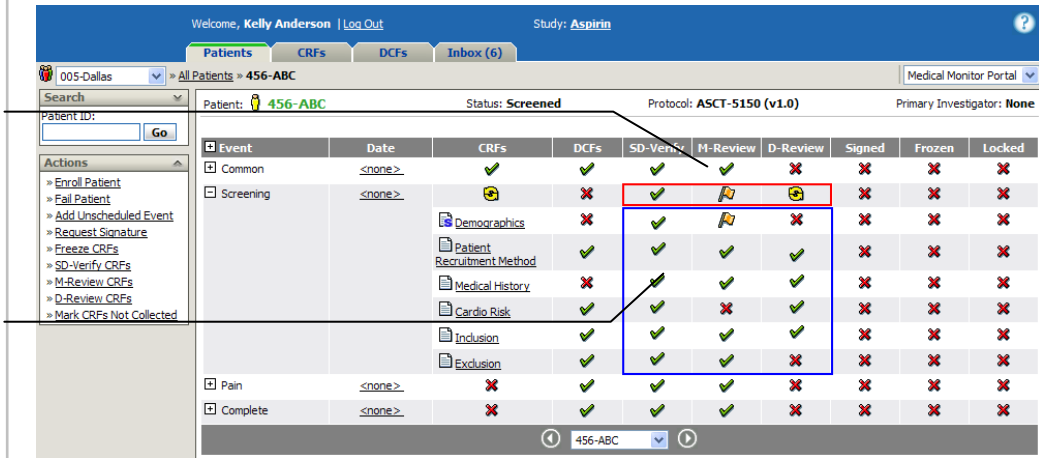
The Patient View shows the cumulative status of each type of flag for each event. An event can have one of the following statuses:

All of the required flags have been set to "on" for the CRFs associated with the event.

None of the required flags have been set to "on" for the CRFs associated with the event.

Some, but not all of the required flags have been set to "on" for the CRFs associated with the event.

Visible data was changed on at least one of the CRFs associated with the event after the CRF's flag was set to "on."

If a flag associated with an event has the status of ✖, 🔄, or 🚩 the patient has one or more CRFs that need to be reviewed. By expanding an event, you can view the status of each type of flag for the CRFs associated with the event. A CRF can have one of the following statuses:

The CRF's flag has been set to "on."

The CRF's flag has not been set to "on."

Visible data on the CRF was changed after the CRF's flag was set to "on."

If a flag has the status of ✖ or 🚩 the CRF needs to be reviewed. For information on changing the flag status for a CRF, see "Setting Flag Statuses for a CRF or Item" on page 249.

Viewing Flag Statuses (Item-level collection)

For item-level flag collection, monitors can set the flag status for individual items on a CRF. Monitors can use the All Patients view to identify the patients having CRF items that need to be reviewed.

A column is shown for each type of flag.

The cumulative status for each type of flag is shown for each patient.

The All Patients View shows the cumulative status of each type of flag (SD-Verify, M-Review, and D-Review) for each patient. A flag can have one of the following statuses:

- All of the flags have been set to "on" for all required items on the patient's CRFs.

- None of the required flags have been set to "on" for the patient's CRFs.

- Some, but not all of the flags have been set to "on" for the required items on the patient's CRFs.

- Visible data was changed on at least one of the patient's CRFs after an item's flag was set to "on."

If a flag associated with a patient has the status of ,   , or   the patient has one or more CRF items that need to be reviewed.

To identify the specific events and CRFs that need to be reviewed, click the patient ID. The Patient View appears.

The cumulative status for each type of flag is shown for each event.

Expand the event to see the flag status for each CRF associated with the event.

The Patient View shows the cumulative flag status for each event. An event can have one of the following statuses:

None of the flags have been set to "on" for the required items on CRFs associated with the event.

Some, but not all of the flags have been set to "on" for the required items on CRFs associated with the event.

All of the flags have been set to "on" for the required items on CRFs associated with the event.

Visible data was changed on at least one of the CRFs associated with the event after the CRF's flag was set to "on."

If a flag associated with an event has the status of , , or the patient has one or more CRF items that need to be reviewed. By expanding an event, you can view the status of each type of flag for the CRFs associated with the event. A CRF can have one of the following statuses:

None of the flags have been set to "on" for the required items on the CRF.

Some, but not all of the flags have been set to "on" for the required items on the CRF.

All of the flags have been set to "on" for the required items on the CRF.

Visible data on the CRF was changed after the flag for any item was set to "on."

Visible data for a required item was changed after the item's flag was set to "on."

If a flag associated with a CRF has the status of , , , or the CRF has one or more items that need to be reviewed. Click the CRF name to open the CRF.

The cumulative status for each type of flag is shown for each event.

An item can have one of the following statuses:

    The item's flag has not been set to "on." (Required items only)

    The item's flag has been set to "on." (Required items only)

    The item's data was changed after the item's flag was set to "on."

    The item's data was changed after the item's flag was set to "on." (Required items only)

Table Questions — Rollup

The option to change or set the status associated to each question or row-question within a table for those with sufficient user rights is available.

They will have the ability to set "On" or "Off" for a specific question. This includes both standard and special (status) forms.

Tables with row questions may be editable or conditional; therefore, flagging operations occur within table questions.

The row header question reflects the current state of the flag operations for the sub questions that apply by displaying the appropriate rollup flag.

Row Header
Question

If one or more of the questions within the row header question is required, then the row header question is required. For a required row header question, the following rules apply:

- If all sub questions are set to "required" within the table and have an "on" status then the row header question flag status is "work complete."

- If all questions set to "required" beneath the row header question have an unset status, then the row header question status flag is unset "work incomplete."

- If some of the questions set to "required" within the table have an "on" status, then the row header question status is "some."

- If a row question has been changed, the question will display a changed flag and the row header question will display a changed flag.

- Skipped is considered to be "on."

If none of the questions beneath the row header question are required, the row header question is not required. For a table question that is not required, the following rules apply:

- If one or more row questions are set to on, the header question is set to "on" ("work complete").

- If a row question has been changed, the question will display a changed flag and the row header question will display a changed flag.

- Skipped, not required is considered to be "on," not required.

For more information about the skipped constraints, see Skipped Constraints on page 150.

Setting Flag Statuses for a CRF or Item

The flag associated with a CRF or item is automatically set to "off" until a reviewer manually sets the flag to "on." When a flag is set to "off," it typically indicates that the information associated with the flag needs to be reviewed. For example, if the M-Review flag associated with a Cardiac Risk form is set to "off," the form may need to be reviewed by the medical reviewer.

After a reviewer has verified the information associated with a flag, the reviewer can set the flag to "on." The cumulative flag status for the form is updated on the Patient page and the cumulative flag status for the patient is updated on the All Patients page.

If *CRF-level flag collection* is used for the flag, you can set flags for individual CRFs or for multiple CRFs associated with a patient.

If *item-level flag collection* is used for the flag, you can set a flags for individual items on a CRF, for individual CRFs, or for multiple CRFs associated with a patient.

The following restrictions apply when setting flags on a question:

■   The Flag is active.

■   Question is editable on the CRF.

■   Question is not an encoded field.

■   Question is not a derived field.

■   CRF is checked in (not-editable).

■   CRF has been submitted.

Note: The system administrator determines each user's ability to view and set flag statuses. For information on granting permission to users to view and set flag statuses, see "Group Management" on page 55.

Changing Flag Status on Multiple Forms (CRF-level flag collection)

To set the flag status for an individual CRF:

1   Open the CRF you want to flag in *view mode*.

Click **D-Review** to set the CRF's D-Review flag status to "on" or "off."
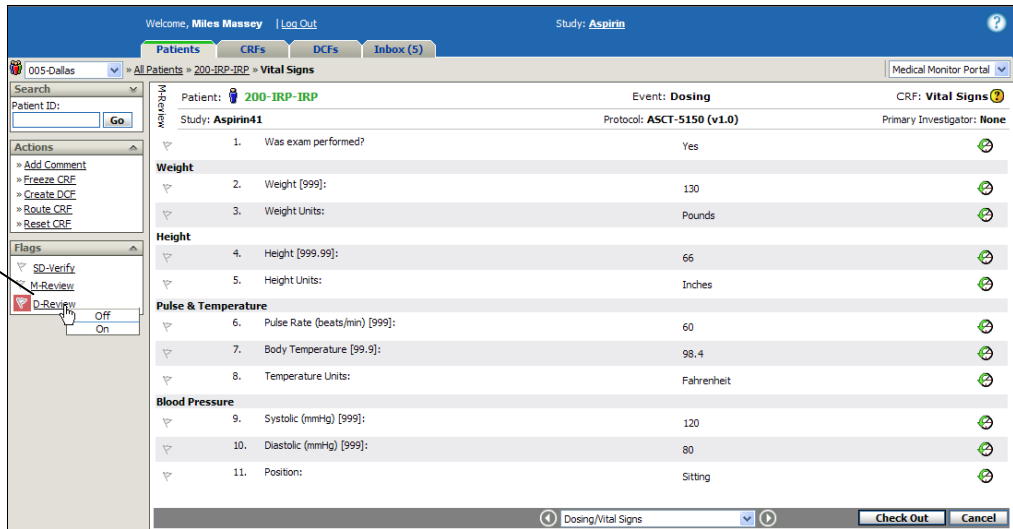
2 On the Flags palette, click the flag you want to set. A pop-up menu appears.

3 Do one of the following:

Click **On** to indicate that the form has been reviewed or verified.

Click **Off** to indicate that the form has not been reviewed or verified.

A confirmation message appears and the flag's status is updated on the Flags palette.
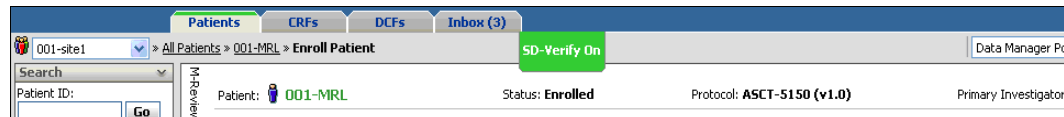
To change the flag status for multiple CRFs:

1 On the Patients tab, open the patient's casebook.

Click **D-Review CRFs** to set the D-Review flag status to "on" or "off" for multiple CRFs.
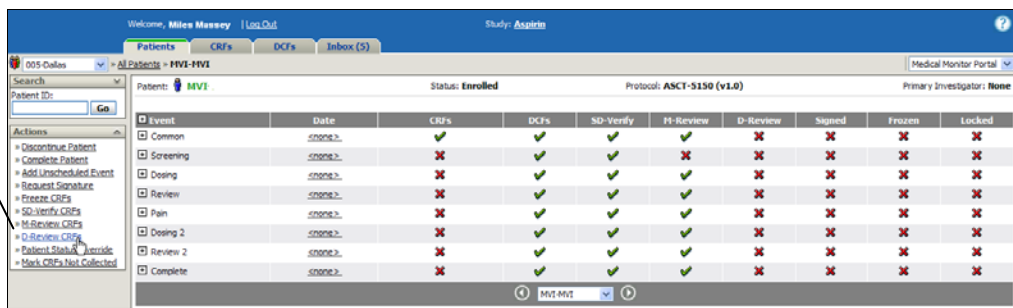
2 On the Actions palette, click the flag you want to set.

The <flag> CRFs page appears which shows each event within the study and each CRF associated with an event.

"All On" sets the required flags to "on" all CRFs

"All" sets the required flags to "on" for all CRFs associated with an Event

An individual Button sets the required flags to "on" for a CRF
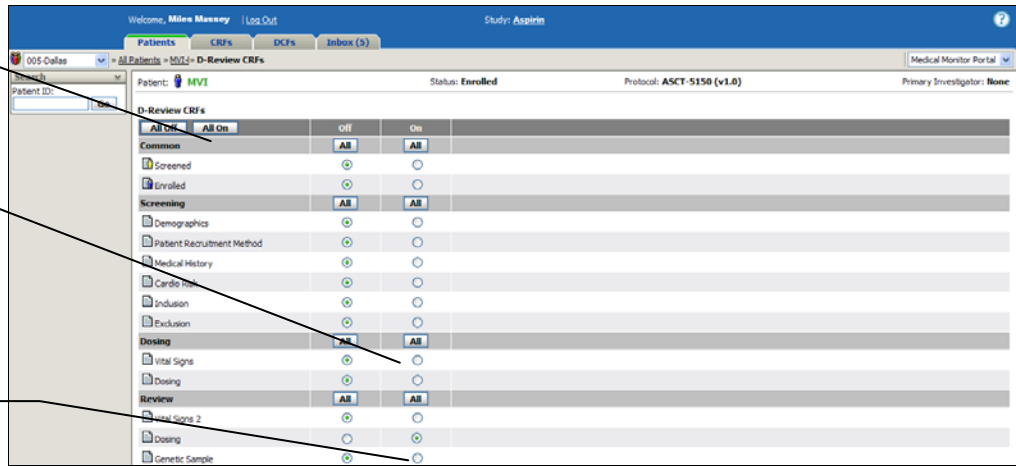
3   Do one of the following:

Click [All On] to indicate that all CRFs associated with the patient have been reviewed or verified.

Click [All] to indicate that all CRFs associated with the event have been reviewed or verified.

Click ⦿ to indicate that an individual CRF has been reviewed or verified.

4   After making your selection, click **Save**.

A confirmation message appears.
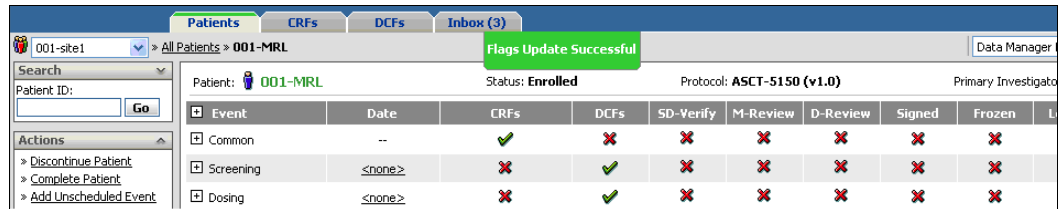
Setting Flag Statuses (Item-level flag collection)

To set the flag status for individual items:

1   In view mode, open the CRF that contains the item(s) you want to flag.

Right-click an
item's flag to
set the item's
flag status to
"on" or "off."
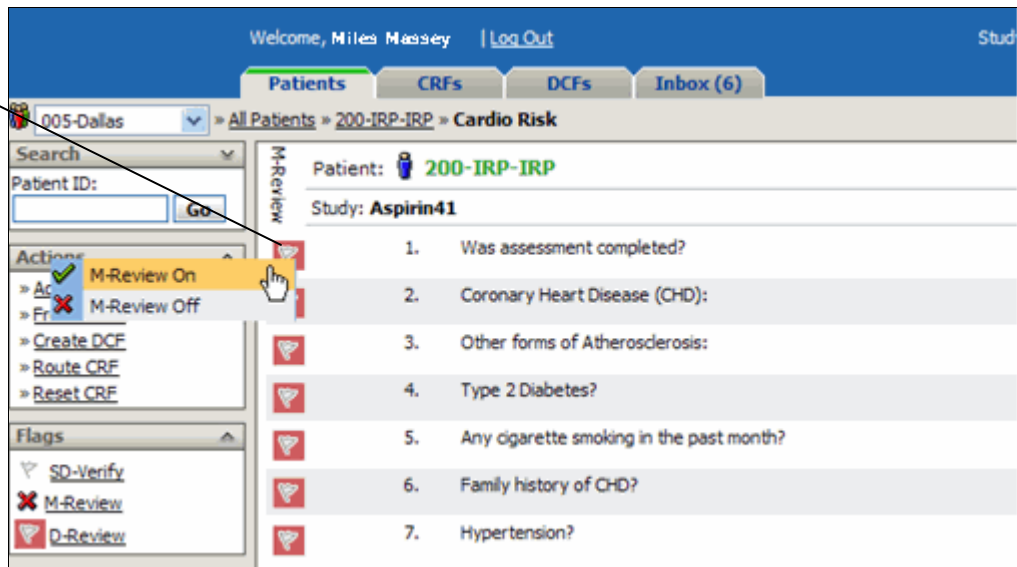
2   Right-click the flag you want to set. A pop-up menu appears.

3   Do one of the following:

Click **<flag name> - On** to indicate that the item has been reviewed or verified.

Click **<flag name> - Off** to indicate that the item form has not been reviewed or verified.

The individual flag's status is updated and the cumulative flag status for the CRF is updated on the Flags palette.

To set the flag status for an individual CRF:

1   Open the CRF you want to flag in *view mode*.

Click **D-
Review** to
set the D-
Review flag
status to "on"
or "off" for all
items on the
CRF.
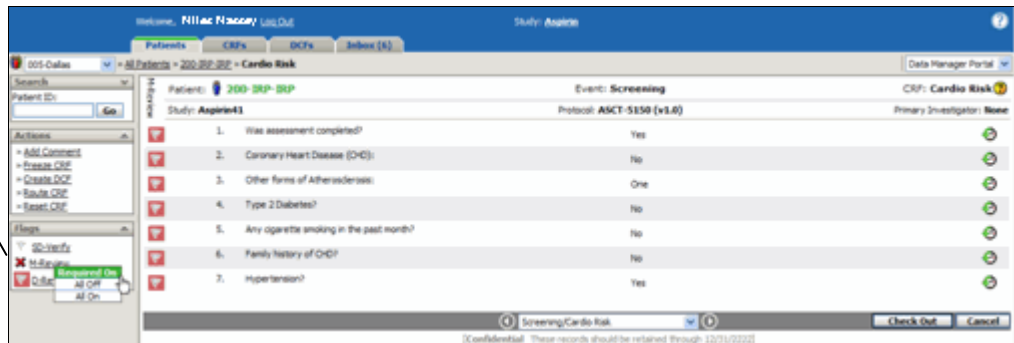
2   On the Flags palette, click the flag you want to set. A pop-up menu appears.

3   Do one of the following:

Click Required **On** to set only the required flags to "on" and to indicate that the required items have been reviewed or verified.

Click **On** to set all flags (both required and not required) on the CRF to "on"

Click **Off** to set all flags (both required and not required) on the CRF to "off" to indicate that the items have not been reviewed or verified.

A confirmation message appears and the flag's status is updated on the Flags palette.
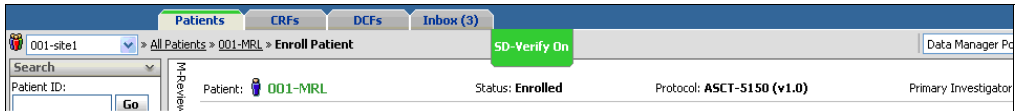
To change the flag status for items on multiple CRFs:

1   On the Patients tab, open the patient's casebook.
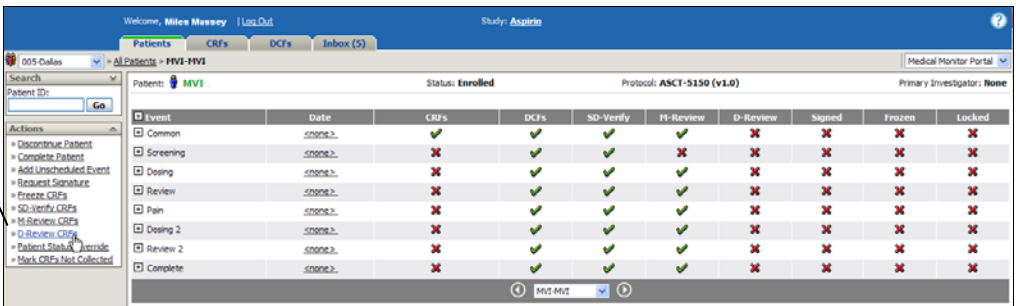
Click **D-Review CRFs** to set the D-Review flag status to "on" or "off" for multiple CRFs.

2   On the Actions palette, click the flag you want to set.

The <flag> CRFs page appears which shows each event within the study and each CRF associated with an event.

"All On" sets flags to "on" for all items on the patient's CRFs

An individual button sets flags to "on" for all items on a CRF

"All" Required On sets required flags to "on" for all items on CRFs associated with an event

"All" All On sets flags to "on" for all items on CRFs associated with an event

"All" All Off sets flags to "off" for all items on CRFs associated with an event
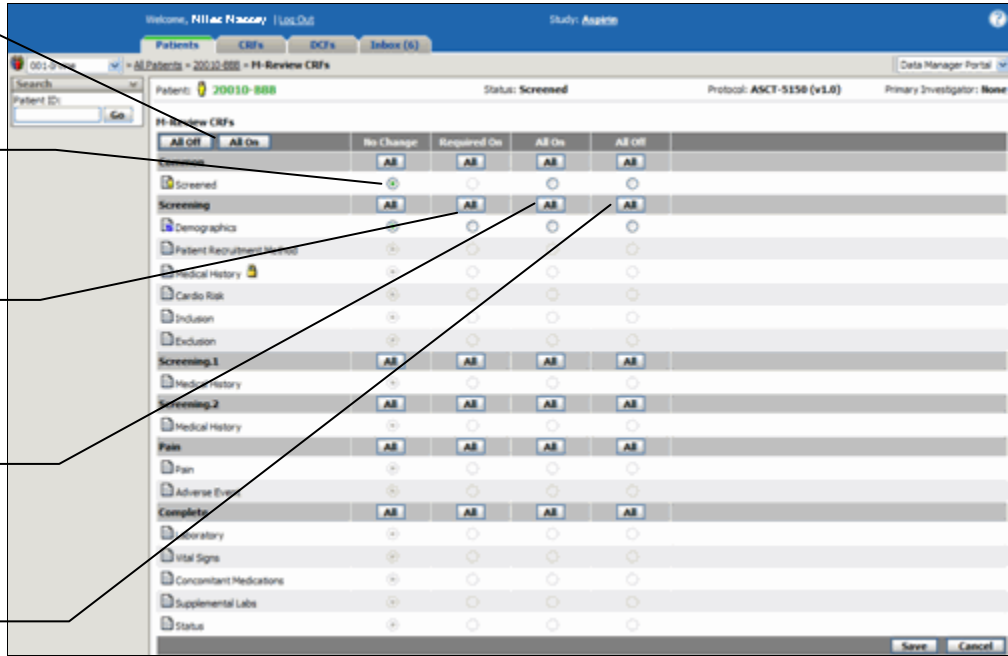
3   Do one of the following:

Click [All On] to set all flags to "on" for all of the patient's CRFs to indicate all CRFs for the patient have been reviewed or verified.

Click **Required On** [All] to set all required flags to "on" for all items on CRFs associated with an event. This indicates that all CRFs associated with the event have been reviewed or verified.

Click **All On** [All] to set all flags to "on" for all items on CRFs associated with an event. This indicates that all CRFs associated with the event have been reviewed or verified.

Click **All Off** [All] to set all flags to "off" for all items on CRFs associated with an event. This indicates that all CRFs associated with the event have not been reviewed or verified.

Click ⊙ to set all required flags to "on" for a CRF to indicate that the required flags on the CRF have been reviewed or verified.

4   After making your selection, click **Save**.

A confirmation message appears.
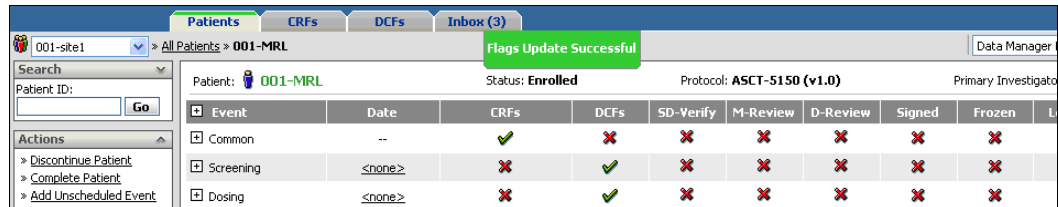
Viewing CRFs That Have Been Reviewed or Changed

The types of flags you can view and edit depends on the permission assigned to you and the type of portal you use to view patient information.

For more information on permissions, see Group Management on page 55.

> **Field Monitor Portal:** The CRFs tab of the Field Monitor portal shows statistics for the SD-Verify flag.

> **Medical Monitor Portal:** The CRFs tab of the Medical Monitor portal shows statistics for the M-Review flag.

> **Data Manager Portal:** The CRFs tab of the Data Manager portal shows statistics for the D-Review flag.

For each portal, reviewers can use the CRFs tab to see the number of CRFs that have been reviewed for each site and each patient. The total reflects CRFs for which all required flags have been set to "on."

Reviewers can also use the CRFs tab to see the number of CRFs that have been changed since the CRF was reviewed.

Multi-Site > Multi-Patient

The numbers shown in the <Flag>-Verify column is a link. Click the link to go to the CRFs: Multi-Patient view to see a list of all of the CRFs that have been reviewed for each patient.

The numbers shown in the <Flag> Changed columns are links. Click the link to go to the CRF: Multi-Patient view to see a list of all patient CRFs that have been changed since the CRF was reviewed.

Field Monitor Portal

Field monitors can use the CRFs tab of the Field Monitor Portal to see the number of CRFs that need to have source documents reviewed for each site and each patient.

CRFs: Multi-Site View

The multi-site view shows the total number of CRFs where the CRF two columns of SD-Verify information.

Sites ▲	Expected	Submitted	SD-Verify	SDV Changed	Signed	Frozen	Locked
001-site1	272	30	1	1	0	0	0
002-Site 2	0	0	0	0	0	0	0
All Sites Totals:	272	30	1	1	0	0	0

SD-Verify: Displays the total number CRFs marked with the SD-Verify flag for each site.

SDV Changed: Displays the number of CRFs that have been marked SD-Verify (Source Document Verify) for each site where visible CRF data has changed since they were marked SD-Verify.

CRFs: Multi-Patient View

The multi-patient view display two columns of SD-Verify information.

Patient ID ▲	Expected	Submitted	SD-Verify	SDV Changed	Signed	Frozen	Locked
001-MTL	25	2	1	1	0	0	0
002-PTL	25	3	0	0	0	0	0
003-PTM	25	3	0	0	0	0	0
004-PTN	10	1	1	0	0	0	0
005-PTO	14	1	0	0	0	0	0
006-PTK	14	2	0	0	0	0	0
007-PTR	15	2	0	0	0	0	0
008-PTF	15	2	0	0	0	0	0
009-PTX	25	2	0	0	0	0	0
010-PUY	26	3	0	0	0	0	0
011-PTH	26	3	0	0	0	0	0
012-PHS	26	3	0	0	0	0	0
014-PTZ	26	3	0	0	0	0	0

Site Summary:
Expected: 272
Submitted: 30
SD-Verify: 1
SDV Changed: 1
Signed: 0
Frozen: 0
Locked: 0

SD-Verify: Displays the total number CRFs marked with the SD-Verify flag for each patient.

SDV Changed: Displays the number of CRFs that have been marked SD-Verify (Source Document Verify) for each patient where visible CRF data has changed since they were marked SD-Verify.

Multi-CRF View

The multi-CRF view displays one column of SD-Verify information.

SD-Verify: Displays whether the CRF has been marked with the SD-Verify flag.

Medical Monitor Portal

The CRFs tab of the Medical Monitor portal shows statistics for the Medical Review (M-Review) flag.

CRFs: Multi-Site View

The multi-site view displays two columns of M-Review information.

M-Review: Displays the total number CRFs marked with the M-Review flag for each site.

MR Changed: Displays the number of CRFs that have been marked M-Review (Medical Review) for each site where visible CRF data has changed since they were marked M-Review.

CRFs: Multi-Patient View

The multi-patient view displays two columns of M-Review information.

M-Review: Displays the total number of CRFs marked with the M-Review flag for each patient.

MR Changed: Displays the number of CRFs that have been marked M-Review (Medical Review) for that patient where visible CRF data has changed since they were marked M-Review.

Multi-CRF View

The multi-CRF view displays one column of M-Review information.

M-Review: Displays whether the CRF has been marked with the M-Review flag.

Data Manager Portal

The CRFs tab of the Data Manager portal shows statistics for the Data Review (D-Review) flag.

CRFs: Multi-Site View

The multi-site view displays two columns of D-Review information.

D-Review: Displays the total number CRFs marked with the D-Review flag for each site.

DR Changed: Displays the number of CRFs that have been marked D-Review (Data Review) for each site where visible CRF data has changed since they were marked D-Review.

CRFs: Multi-Patient View

The multi-patient view displays two columns of D-Review information.

D-Review: Displays the total number of CRFs marked with the D-Review flag for each patient.

DR Changed: Displays the number of CRFs that have been marked D-Review (Data Review) for that patient where visible CRF data has changed since they were marked D-Review.

Multi-CRF View

The multi-CRF view displays one column of D-Review information.

D-Review: Displays whether the CRF has been marked with the D-Review flag.

Flag History

Flag History for CRF-Level Flag Collection

If flag statuses are set at the CRF level, you can use the CRF's Workflow tab to view changes to flag statuses.

Action	Date/Time	User
DCFs	Comments	**Workflow**
Action	**Date/Time**	**User**
D-Review [On]	10/08/2007 09:36:53 PM GMT	Miles Massey (QA\mmassey)
M-Review [On]	10/08/2007 09:27:38 PM GMT	Miles Massey (QA\mmassey)
Submitted	10/02/2007 04:14:52 PM GMT	Miles Massey (QA\mmassey)
Published	10/02/2007 04:14:52 PM GMT	Miles Massey (QA\mmassey)

Flag History for Item-Level Flag Collection

If flag statuses are set at the item level, changes to the flag status for a specific item are recorded to the item's change history.

Change History

Patient: 200-IRP   Event: **Screening**   CRF: **Demographics**

Study: **Aspirin41**   Protocol: **ASCT-5150 (v1.0)**   Primary Investigator: **None**

2. Sex

Name	Value	Server Time	Reason	Additional Notes
Miles Massey (QA\mmassey)	Male	03/05/2009 10:01:42 PM GMT	Flag Action	D-Review [On]
Miles Massey (QA\mmassey)	Male	03/05/2009 05:46:55 PM GMT	Flag Action	M-Review [On]
Miles Massey (QA\mmassey)	Male	03/05/2009 05:43:33 PM GMT	Initial Entry	Submitted

Print   Close

As flag statuses are set for each item, the CRF's Workflow tab records the cumulative status of the CRF.

Action	Date/Time	User
DCFs	Comments	**Workflow**
Action	**Date/Time**	**User**
D-Review [On]	03/05/2009 10:01:42 PM GMT	Kelly Anderson (QA\kanderson)
M-Review [On]	03/05/2009 06:48:12 PM GMT	System (System\System)
M-Review [Some]	03/05/2009 06:46:10 PM GMT	System (System\System)
M-Review [On]	03/05/2009 05:46:55 PM GMT	Kelly Anderson (QA\kanderson)
Submitted	03/05/2009 05:43:33 PM GMT	Kelly Anderson (QA\kanderson)
D-Review [Changed]	03/05/2009 05:43:33 PM GMT	System (System\System)
M-Review [On]	03/05/2009 05:28:54 PM GMT	Kelly Anderson (QA\kanderson)
D-Review [On]	03/05/2009 05:27:11 PM GMT	Kelly Anderson (QA\kanderson)
Published	02/24/2009 11:59:42 PM GMT	Kelly Anderson (QA\kanderson)

For example:

■ A CRF has three items that require flagging. If one item is set to "on" and two are left unset, the Workflow tab will show that an action occurred because the cumulative flag status changed from "all flags unset" to "some flags set."

■ The same CRF is opened and the flag is set to "on" for an additional question. Two flags are now set to "on" and one is set to "off." However, no action is recorded to the Workflow tab because the cumulative flag status remains as "some flags set."

■ The same CRF is opened and the flag is set to "on" for the remaining question. All flags for the CRF are now set to "on." The Workflow tab will show that an action occurred because the cumulative flag status changed from "some flags set" to "all flags set."

Chapter 8: DCF Management

Overview

This chapter covers the following material:

- DCF page layout

- DCF icons

- Searching for a DCF

- DCF workflow

- Creating a manual DCF

- Viewing and editing a draft or new DCF

- Sending a draft DCF

- Deleting a draft DCF

- Answering a manual DCF

- Resolving a query-generated DCF

- Closing an answered or resolved DCF

- Routing a DCF

- Printing a DCF

- Custom DCF fields

DCFs Tab Page Layout

Data Clarification Forms (DCFs) are used to manage the resolution of queries and other general questions posed by a study user. If there is any question about something that was entered (or not entered) into a CRF, a DCF is generated.

DCFs can be generated in one of two ways: some DCFs are generated *automatically* by queries created by the study designer; other DCFs are *manually* created by the study personnel.

DCFs: Multi-Site View Layout

Click on a site name to view all patients with DCFs at that site ...

... or click on a table cell to view all DCFs of that status at the site. For more details see DCFs: Multi-DCF View on page 270.

Sites ▲	Draft	New	Sent	Viewed	Answered	Resolved	Closed	Aging AVG
01-Copenhagen	2	8	10	1	1	1	2	6.7
02-Helsinki	2	6	8	3	1	0	3	3.1
03-Oslo	1	15	17	5	3	3	6	0
04-Reykjavik	0	1	3	0	0	0	0	0
05-Riga	0	0	0	0	0	0	0	0
06-Stockholm	0	7	9	2	0	1	1	0
07-Tallin	0	15	17	1	1	1	0	21.3
08-Vilnius	0	7	9	1	0	0	0	0
09-Warsaw	0	1	3	0	0	0	0	0
10-Amsterdam	3	12	14	1	3	0	1	0
11-Athens	0	16	18	2	0	0	0	0
12-Barcelona	0	0	0	0	0	0	0	0
13-Belgrade	0	0	0	0	0	0	0	0
14-Bergen	0	0	0	0	0	0	0	0
15-Berlin	0	0	0	0	0	0	0	0
All Sites Totals:	**8**	**88**	**108**	**1**	**9**	**6**	**13**	**0.9**

The multi-site view contains the following options and information:

All Sites: Allows you to select a site from the list rather than clicking on the site name in the body. This is useful if you want to switch quickly between sites.

Clicking on any of the cells takes you to the multi-DCF view. For more information about the multi-DCF view, see DCFs: Multi-DCF View Layout on page 269.

Sites: Lists the sites and corresponding site status icon. The sites that you see in the list are those sites that you are allowed to access. For more information about site users, see Giving a User Access to Sites on page 71 or Giving Users Access to a Site on page 106.

This could be all the sites, or just a subset. Clicking on a site takes you to the multi-patient view of that site. For more details on multi-patient view, see DCFs: Multi-Patient View Layout on page 268.

Clicking on this column header sorts the list by site.

Draft: Lists the number of DCFs that have a draft status (the DCF had been created but not sent). While data manager portal users can view draft DCFs, site portal users cannot.

Sent: Lists the number of DCFs that have a sent status (the DCF has been sent, but hasn't been viewed).

Viewed: Lists the number of DCFs that have a viewed status (the DCF has been received and opened).

Answered: Lists the number of DCFs that have an answered status (the DCF has been answered).

Resolved: Lists the number of DCFs that have a resolved status. DCFs that have been automatically generated by a query can be resolved by editing the CRF so that the condition that fired the query is no longer true. DataLabs automatically resolves the associated DCF when the DCF no longer fires.

Example: For example, if a query generated a DCF because data was not entered in a required field, if you edit the CRF and enter valid data in the required field, the DCF will be automatically resolved.

Closed: Lists the number of DCFs that have been closed.

Aging AVG: Lists the average number of days for DCFs to go from sent to either answered or resolved. The aging period begins when a DCF is sent and ends when it is answered or resolved. Only *currently* pending DCFs are counted in the Aging Average (DCFs that have been answered or resolved are not figured in the average).

The total aging average is average DCFs aging time for all sites you've been assigned (though not all sites in the study).

Totals: Displays the totals for the entire list, not the current page, even if the list spans more than one page. Totals should be for all sites even if there is more than one page of sites.

Note: Clicking on any of the cells takes you to the multi-DCF view. For more information about the multi-DCF view, see DCFs: Multi-DCF View Layout on page 269.

To view all patients with DCFs at a single site:

- Click the site name.

The multi-patient view appears with the list of DCFs for that site.

To view all DCFs at a single site of a certain status:

■ Click the number of patients where the site name and status intersect.

Example: For example, to view all DCFs that have a Draft status at Helsinki, click the cell on the Helsinki row, in the Draft column.

The multi-DCF view appears with the list of DCFs for that site and status.

DCFs: Multi-Patient View Layout

The multi-patient view contains the following options and information:

Search palette: Provides simple and complex searches for patients. For more information about DCF searches, see Searching for a DCF on page 275.

Summary palette: Displays the number of the DCFs for each status for that site.

Columns: Clicking on the patient ID, or the values in the columns, takes you to the multi-DCF view. For more information on the multi-DCF view, see DCFs: Multi-DCF View Layout on page 269.

Patient-status Icon/Patient ID: Lists the patient's status and ID.

Draft through Closed columns: Lists the number of DCFs for each of the shown statuses.

To view all DCFs for a single patient:

■ Click the patient ID.

The multi-DCFs view appears with the list of DCFs associated with that patient.

To view all DCFs for a single patient with a certain status:

■   Click the number of DCFs where the patient ID and DCF status intersect.

Example: For example, to view all DCFs that have a draft status for patient 1964-EEL, click the number in the patient's row and in the Draft column.

The multi-DCFs view appears with the list of DCFs meeting your criteria.

DCFs: Multi-DCF View Layout

Palettes: The Search and Summary palettes are the same as on the multi-patient view. For more information on the multi-patient view, see DCFs: Multi-Patient View Layout on page 268.

Search Results: Lists the number of DCFs found if search is used.

Patient-status Icon/Patient ID: Displays the patient's status and ID.

DCF ID: Lists the unique ID assigned by system. Clicking on the DCF takes you to the DCFs view.

Status: Lists the current status of each DCF.

Query Description: Lists the description of the DCF.

Aging: If the DCF is still active, the column lists the number of days since sent. If the DCF's status is draft, answered, resolved or closed, "-" is displayed.

Ready to Print: Displays whether the DCF has been marked "Ready to Print."

To open a DCF:

■   From the multi-DCF view, click the DCF ID.

   The DCF opens in the DCF View.

DCF Layout

Breadcrumbs

Breadcrumbs show your current path in DataLabs and help you to navigate DCFs. The breadcrumbs show you *site drop-down combo box » DCF filter » patient ID » DCF number.*

Palettes

Palettes give you context-sensitive utilities, commands and references based on the page or view you are currently in.

Search palette: Gives you the ability to search for DCFs using a variety of search criteria. For more information about searching for DCFs, see Searching for a DCF on page 275.

Actions palette: Enables you to print, respond to or change the workflow status, or delete the DCF. This palette appears only in the DCF view.

Summary palette: Lists the number of DCFs of each status for the site.

Search   **Flags**   **Action**   **Summary**

DCF Header

The header displays the basic DCF information.

Patient: Displays the current patient status, and the patient ID (a combination of their Screen/Enroll ID and initials).

Investigator: Displays the name of the PI (primary investigator) for this site.

Created By: Displays the name of the user who created the DCF.

DCF ID: Displays a unique system-generated ID number.

DCF Status: Displays the current status of the DCF.

Query Reference: Shows how the DCF was created, either by a query or manually.

> **Auto** – If the DCF was automatically generated by a query, this shows the *designer ID/clinical ID/external ID*.

> **Manual** – If the DCF was created manually, this shows "Manual."

Related Form(s)

The Related Form(s) lists the CRFs associated with the DCF. Clicking on one of the CRF opens the CRF in the default view (view or edit, depending on your default settings). For more information about CRFs, see Chapter 6: Entering Patient Data (CRFs) on page 184.

Related Form(s)	Event	Reference
Vital Signs	**Screening**	**4: Height [999.99]:**

Related Form(s): Lists the CRFs. Clicking the CRF name will open the form.

Event: Displays the name of the event the CRF falls under.

Reference: Displays the question referenced; move your pointer over the reference to display the complete question (up to 25 characters).

Body

The body contains the content of the DCF:

Query Description: Displays (or defines, for Draft DCFs) the question that must be resolved.

Action Requested: Displays (or defines, for Draft DCFs) a description of the action desired.

Response: Defines the response to the DCF.

Custom fields: Displays the custom fields (if any).

Save: Saves any changes you make to the DCF. For all non-draft DCFs, only custom fields can be changes.

Cancel: Returns you to the previous page without saving any changes to the DCF.

Retention information: Displays a standardized message that the form is confidential and should be retained through a certain date.

Workflow Subtab

The Workflow subtab lists each action taken for the DCF, showing the most recent action first.

Action: Lists the name of the action taken by a user for the DCF.

Date/Time: Lists the date and time the action took place.

User: Lists the user who performed the action.

DCF Icons

DataLabs uses icons to give you a visual cue as to the status of DCFs. Where there are multiple DCFs, DataLabs uses two icons to show the status of all DCFs.

✖ **Open:** There is at least one open DCF. An "open" DCF has the status of Sent/Received/Viewed or Answered, but has not been Resolved or Closed.

✔ **None:** There are no open DCFs—either none have been created, or all have been answered or resolved.

Note: The Resolved DCFs setting in Study Preferences enables DataLabs to automatically close any system-resolved DCFs. If this is turned on, any DCF that has been resolved through a change in the CRF data is changed from the Resolved to Closed status. If auto-close is turned off, DCFs with a Resolved status must still be reviewed by data management personnel before they can be manually closed. For more information on automatically closing all system resolved DCFs, see Study Management on page 74.

There are *no* open DCFs (✔) for this event—either none have been created, or all have been resolved.

There is *at least one* open DCF (✖) for this CRF.

These cumulative icons are used in the same way for individual DCFs as well:

✖ **Open:** There is an open DCF.

✔ **None:** There is no open DCF—one hasn't been created or it has been resolved.

The figure below illustrates how cumulative status icons reflect what lies beneath them.

Searching for a DCF

On every view of the DCFs tab, you can use the Search palette to search for a DCF using a single search option, or a combination of several search options.

Patient ID	Search based on patient ID.
	You can enter a partial ID to broaden your search.
DCF ID	Search for a DCF based on its unique DCF ID.
	You can enter a partial ID to broaden your search.
Created By	Search for DCFs created by a specific user:
	All system – Search for query-generated DCFs.
	All manual – Search for manually-created DCFs.
	Username – Search for DCFs created by a specific user (from a list of users who have access to this site).
DCF Status	Search for DCFs with a specific status (draft, sent, viewed, answered, resolved, closed).
CRF	Search for DCFs attached to a specific CRF.
Aging/Days Old	Search for DCFs based on the number of days between being sent and being answered or resolved.
Ready To Print	Search based on whether the "ready to print" flag has been set.
Custom Field/Custom Field Value	Search based on the value of the selected custom field.
Batch ID	Search for DCFs printed in the specified batch ID.

Tip: Use multiple search options to narrow your results.

Note: Searches are limited to the sites that you have permission to view.

To search for DCFs:

1 Click the Expand button ▼ at the top of the Search palette to see all the search options.

2 Enter or select your search criteria.

3 Click **Go**.

The multi-DCF page appears with the list of DCFs meeting your search criteria.

DCF Basics

Custom Fields

In Study Management, two custom DCF fields can be defined to accommodate custom workflows. They can also be used as criteria when searching for DCFs. For more information about defining custom fields, see Updating the Study Preferences on page 77.

To view and print the custom field change detail:

1   Click the **Custom Field** icon.

The custom field change detail message box appears.

2   Do one of the following:

Click **Print** to print the detail.

Click **Close** to close the message box.

DCFs for Restricted Forms

Note: This Functionality is specific to **Data Manager** portal users.

If a DCF is generated for restricted form, the DCF will be listed in the Multi-DCF view on the Data Manager portal. Only users with permission to edit the restricted form will be able to click the DCF ID and open the DCF.

These DCFs belong to a restricted form and cannot be opened.

DCF Workflow

The following diagram outlines the basic workflow that a DCF—manually generated and query-generated—follows:
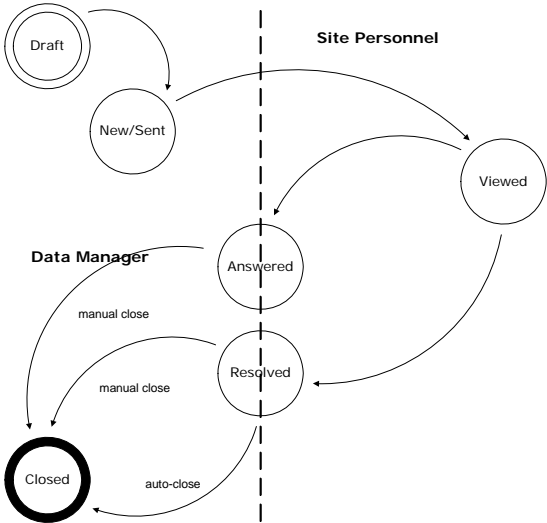
Note: This Functionality is specific to **Data Manager** portal users. For manually-generated DCFs Draft and New; they are Data Manager specific. For automatically-generated DCFs New and Sent; they are Data Manager specific.

Steps the DCF goes through from creation to completion:

Manually-generated DCFs	**Automatically-generated DCFs (Queries)**

Draft: The DCF had been created but not yet sent. Data management can view draft DCFs, site personnel cannot.

New: The paper workflow DCF is ready to be sent to the site.

Sent: The DCF has been sent by the data manager.

Viewed: The DCF has been opened and viewed by a site portal user.

Answered: The DCF has been answered manually by a site portal user.

Closed: The DCF has been closed by a data manager portal user.

New: The paper workflow DCF is ready to be sent to the site.

Sent: The DCF has been created automatically from a query and sent by DataLabs.

Viewed: The DCF has been opened and viewed by a site portal user.

Resolved or Answered:

Answered – The DCF has been answered manually by a site portal user.

Resolved – The DCFs has been resolved by DataLabs because a user has edited the CRFs so that the data is in the proper range.

Closed: The DCF has been closed either by DataLabs (auto-close is turned on) or by a data manager portal user.

Each step the DCF has been through is shown in the Workflow subtab.

Workflow		
Action	**Date/Time**	**User**
Ready To Print Flag Set To [OFF]	10/19/2005 04:10:33 PM PST	System User (system)
Closed	10/19/2005 12:54:52 PM PST	Miles Massey (mmassey)
Answered	10/19/2005 12:54:47 PM PST	Miles Massey (mmassey)
Ready To Print Flag Set To [ON]	10/19/2005 10:30:31 AM PST	Miles Massey (mmassey)
Viewed	10/19/2005 10:15:46 AM PST	Miles Massey (mmassey)
Sent	10/19/2005 09:56:04 AM PST	System User (system)

Note: Once a query-generated DCF has been given the status Answered, the query will not continue to run for that question unless the data is changed from an invalid value to a valid value. (For example, if the resting pulse entered is outside the normal range and a query fires for it, but it turns out that the patient is an elite athlete, by changing the DCF status to Answered, the query will not re-run unless the pulse is changed to a value that is inside the normal range. Once the pulse is changed to a value that is within the expected range, the query status is reset, and will fire if invalid data is entered for that patient.)

Electronic and Paper Workflows

Note: This Functionality is specific to **Data Manager** portal users.

A DCF goes through a slightly different draft-sent workflow for sites using electronic data capture versus those using paper data entry. The differences are noted below:

Status	EDC	PDE
Draft	The DCF is in draft form and is not yet ready to be sent to the site.	The DCF is in draft form and is not yet ready to be sent to the site.
New	-	The DCF is ready to be sent, but has not yet been printed and forwarded to the site.
Sent	The DCF has been finalized and has been sent electronically to the site for review.	The DCF has been printed and sent to the site for review.

Creating a Manual DCF

Note: This Functionality is specific to **Data Manager** portal users.

When you find something on a CRF that needs to be clarified or corrected—and isn't something that would generate an automated query—you may need to create a DCF. This DCF is then sent to the site to be answered or corrected.

You can either create a DCF:

- At the form level—for the entire CRF.

- At the question level—for a single item/question on the CRF.

To create a DCF for a <u>form</u>:

1   From the open CRF you want to create a DCF for, click the **Create DCF** command on the Actions palette.

The Create DCF page appears.

2   Type a **Query Description** that explains what needs to be resolved.

3   Type the **Action Request** that must be taken by the site to resolve this DCF.

4   Do one of the following to select the **Status**:

If you *are not* ready to send the DCF right away, select **Draft**.

If you *are* ready to send the DCF now, select **Sent**.

For sites using a *paper workflow*, if you are ready to print and send the DCF to the site, select **New**.

5   Complete any custom fields.

6   Click **Save**.

You are returned to the CRF and the "Create DCF Successful" message appears.

To create a DCF for a <u>question/item</u>:

1   From an open CRF, right-click the question you want to create a DCF for.

| 4. Race (if "Other") | Mixed | |

2   Select **Create DCF** Item.

The DCF Draft page appears.

3   Type a **Query Description** that explains what needs to be resolved.

4   Type the **Action Request** that must be taken by the site to resolve this DCF.

Tip: Be sure to include very clear information in Query Description and Action Required fields. You may even want to copy (CTRL+C) and paste (CTRL+P) the text of the question into the text you write for your Query Description. That way if there are multiple DCFs

generated for the same CRF, the user can be clear which question this DCF refers to when viewing it in the Inbox or from the DCF subtab.

5   Do one of the following to select the **Status**:

If you *are not* ready to send the DCF right away, select **Draft**.

If you *are* ready to send the DCF now, select **Sent**.

6   Complete any custom fields.

7   Click **Save**.

Draft and New DCFs

Note: This Functionality is specific to **Data Manager** portal users.

Unlike sent DCFs, draft DCFs—whether they are CRF- or question-level—do not appear on either the Patients tab or CRFs tab views; not in the DCFs column, nor marked with the DCF icon (![icon]). To view, change or delete a draft DCF, you must access it through the DCFs tab.

New DCFs are those using a paper workflow that is ready to be printed and sent to the site to be answered.

Viewing and Editing DCFs

You can change or delete a DCF if it is still in draft (or new) mode, either if you are in the midst of creating it (and change your mind), or if it has been saved as a draft or new DCF.

Note: If a DCF is associated with a restricted form, you must have the proper permissions to be able to view DCFs associated with restricted CRFs.

To view a DCF:

1 Click the **DCFs tab**.

2 Do one of the following:

Click the Site name, then click the value in the Draft (or New) column for the patient, and then click the DCF ID for the DCF.

Click the value in the Draft (or New) column for the site, and then click the DCF ID for the DCF.

DataLabs opens the DCF.

To edit and save a DCF:

1   From the open DCF, change the text of the **Query Description** or **Action Request**, and update the custom fields (if any).

2   Click **Save**.

The DCF will now appear on views accessible from the Patients tab or CRFs tab (see The Patients Tab Navigation on page 27 or The CRFs Tab Navigation on page 33).

Submitting a Draft DCF

When a draft DCF in a paper workflow is ready to be printed and sent to the site, and marked as "New," you will use the Submit command on the Actions palette.

To send a draft DCF:

1   Open a *draft* DCF that is going through a paper workflow.

2   From the Actions palette, click **Submit**.

DataLabs changes the DCFs status to "New" when you are returned to the DCF view.

Sending a DCF

When a draft or new DCF is ready to be sent, you will use the Send command on the Actions palette.

To send a DCF:

1   Open the DCF.

2   From the Actions palette, click **Send**.

DataLabs sends the DCF and changes the DCFs status to "Viewed" when you are returned to the DCF view. It now appears on the Patients tab and CRFs tab views; as well as in the DCFs column, and is marked with the DCF icon ( ). The sent DCF cannot be edited, only answered.

Deleting Draft DCFs

Only *draft* DCFs can be deleted.

To delete a draft DCF:

1 Open a draft DCF.

2 From the Actions palette, click **Delete**.

The DCF is deleted; it cannot be restored.

Manually-Generated DCFs

Manually-generated DCFs are created by reviewers and study personnel, those who review the data as it is entered into DataLabs. These DCFs follow a slightly different workflow than those generated automatically by a query.

Answering a DCF

When you open a manually-generated DCF, you are expected to provide a response; the response is then reviewed.

Note: If a restricted CRF is associated with the DCF, you must have the proper permissions to access the restricted form. If you do not have the proper permissions, the form name appears on the DCF as text, instead of a link to the CRF.

To answer a manually-generated DCF:

1 Open a DCF that has a "Sent" or "New" status.

2 From the Actions palette, click **Answer**.

3 From the pop-up menu, do one of the following:

To provide a response without editing the CRF, click **Answer** (see step 6 below).

To edit the CRFs to answer the DCF, click the **CRF Name** (see the following steps).

The CRF opens in edit view (if you have auto-checkout turned on).

4 Make the necessary changes to the CRF.

5 Click **Save & Check In**.

The "CRF has been saved and checked in successfully" message appears and you are returned to the DCF.

6   From the Actions palette, click **Answer**, and then click **Answer** on the pop-up menu.

The Answer DCF dialog box appears.

7   Type a **Response** and click **Save**.

Your answer is saved and the DCF status is changed to Answered.

Closing a DCF

Once the site has responded to a DCF (or a query) by answering it, it is up to the discretion of the data manager to accept the answer given.

To close a DCF:

1   Open a DCF.

Note: You can close any DCF that has a New, Sent, Resolved, or Answered status.

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2   From the Actions palette, click **Close**.

The "CRF has been saved and checked in successfully" message appears and you are returned to the DCF. Its status is now "Closed."

3 Click the **Close button**.

You are returned to the multi-DCF view. A closed DCF is shown as a None icon ( ) in the various views (see DCF Icons on page 273).

Routing DCFs

Routing is a way to send data within DataLabs. DataLabs provides the ability to route a DCF to another active user within the site. The content of a routed DCF message is similar to a general inbox message, with the following differences:

- The message contains a hyperlink to the appropriate DCF.

- The message contains header information which includes:

  Patient, Patient Status, DCF Status, DCF ID, Query Reference, Primary Investigator, Created By.

Note: The recipient of the DCF must have rights to view the DCF, otherwise the link will be disabled and a rule tip will indicate the restriction to the user.

To route a DCF:

1 Open the desired DCF which you would like to route. Routing is a DCF-level action so it is done directly from the desired DCF. In the below example the DCF ID 1 was chosen.

2 From the Actions palette click **Route DCF**. The Route DCF screen appears.

3 Next, you will have the options of choosing the recipients **To** send to. Select the **To:** button.

4 The **Select User** page appears.

Note: Only users associated with the sites that the sender is associated to and who have opted–in to receiving messages will appear. See Setup Section in User Preferences.

---

5 Select the User Names from the list whom you would like to send the message to and click **OK**.

This brings you back to the **Untitled Message** page.

6 Type a Subject and Message.

7 Click **Priority** to send via High Priority () or leave unhighlighted for normal message status.

8 Click **Send**.

9 This will send the message to the appropriate users and bring you back to the Inbox page.

Routing a DCF: Actions

The following actions can be taken from the Route DCF page:

Send – Send Message

When a DCF is successfully routed the following message will display:

Print – Print the message.

Priority – You have the option to mark a routed message as **High Priority**. When high priority is selected you will know by the Priority button () being highlighted.

By choosing **High Priority** the message in the recipient's inbox will have a high priority icon () in the place of the standard message icon ().

Viewing a Routed Message

Routed messages appear in the recipients' Inbox.

1   From the **Inbox Tab** select **Mail** in the Folders palette.

Click on Desired Message
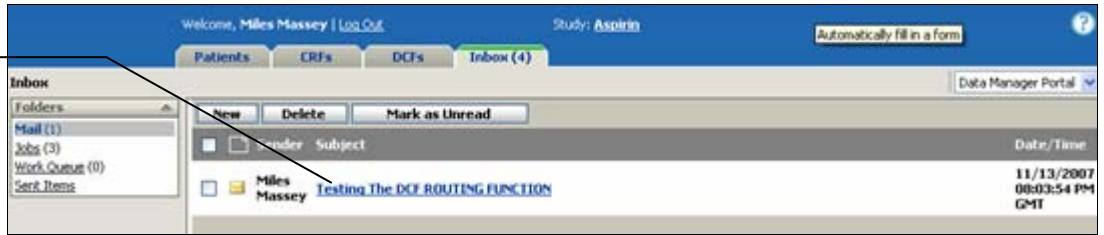
2   From the **Inbox** select desired message. This will bring you to a Routed DCF Message page similar to the following:

Reply to Sender of DCF

Forward to another user in the system
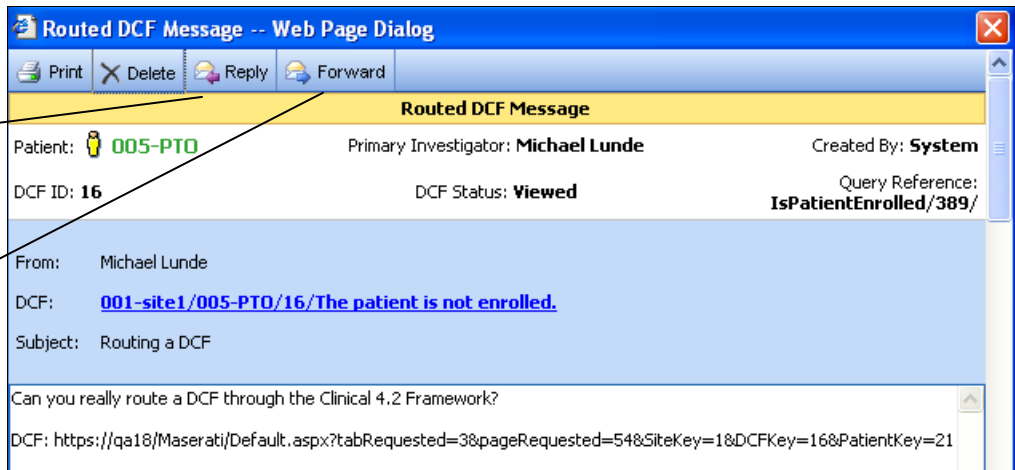
In the **Routed Message Header** you will find the following pertinent information regarding the DCF:

Patient: Displays patient ID and patient icon indicating the status of the patient.

Primary Investigator: Name of the Primary Investigator for the site.

Created By: Displays the creator of the DCF. If the DCF is created as a result of a Query, this will display "system."

DCF ID: Displays appropriate DCF ID.

DCF Status: Displays where in the DCF process the DCF is (example: Viewed).

Query Reference: Displays the query the DCF is associated to. If the DCF was created manually this will display "manual."

In the **Routed Message Body** you will find the following:
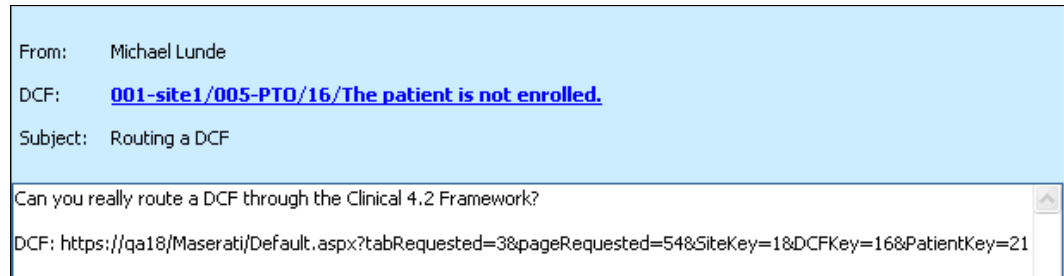
From: Sender – The user who routed the DCF.

DCF: Links to the routed DCF. If you do not have permissions to view this DCF when you mouse over the link a tool tip will display an indication that you do not have access to the DCF.

Subject: Displays the subject as specified by the sender.

Message: This is the message the sender chose to include.

Query-Generated DCFs

A query is a logical test that is run against data in DataLabs that returns a value of true or false. When a query returns a "True" value, it is commonly referred to as "fired."

Queries can be setup to automatically generate DCFs when they fire. Query-generated DCFs are automatically created by DataLabs when a user saves CRF data that causes a query to fire. Queries are created and scripted in the design phase to automatically check the content of data entered into the forms.

Queries

There are two types of queries generated by DataLabs. Both types of follow the same rules for triggering, running, and re-firing. The difference is in what occurs after the return value is received.

DCF-type: If a DCF-type query returns true it will generate a DCF for the appropriate forms.

Notify-type: If a Notify-type query returns true it will send an entry to the inbox table.

The message will contain the following information:

ID – Query's unique identifier.

Study – Study name.

Protocol (Version) – Protocol name and version number.

Site – Site Name.

Patient – Patient ID.

Patient Status – Current status of the patient.

Possible Statuses:

- Screened

- Failed

- Enrolled

- Discontinued

- Completed

Query Notification Date – Date the query notification was generated.

Event-Form – The event name and form for which the query notification was generated.

Description – Description or the query.

Action Requested – Description of the action request.

If you select Query Notification in User Preferences you will get a message in the inbox for all notification queries that fire for a site you have rights to.

Check to select **Query Notification**

All queries are DCF-type by default. Likewise any new queries will be DCF-type by default. If a query is set to a **Notify-type** and that query is modified as a result of a Study Update, the type will not be affected, that is it will remain as Notify.

Changing Query Type

When a query is changed from **DCF-type** to **Notify-type**, the user will be notified that "By changing this query to type "Notify" any existing DCF for this query will be closed. Are you sure you want to continue?"

You will be given the option to: **Continue** or **Cancel**. By Continuing, any outstanding DCF for that query will be Closed with a response of "Query Type changed from DCF to Notification."

Query Generation

Queries are generated at two levels:

Question level: The query checks the value of a field when you navigate from it to make sure it is valid. This indicator fires when you exit the field, alerting you that you may need to correct the data before submitting the CRF (and thus avoid triggering a query). For each field, the study designer can check the field data for the following:

> **Required** – The field cannot be left unanswered (blank).

> **Data format** – The data entered must be the proper data format (integer, float, text, date, etc.).

> **Range** – The data entered is outside of the defined range (numeric range, date range, etc.).

> **Minimum/maximum length** – The data entered exceeds the total number of characters or numbers allowed. For numeric fields, the decimal point is not counted in the length, so the length for "123.456" is 6.

> **Minimum/maximum precision** – The data entered exceeds the maximum precision— the total number of digits to the right of the decimal. For example, a max precision of 3 would allow "123.456" but not "12.3456."

> If any of these fires a query, the question is marked with a DCF icon ( ).

Form level: Compares values between fields on a CRF when you save and submit the form.

Query Processing

All queries associated to a particular CRF are run when a form is submitted. Once a CRF has been submitted, only queries associated to modified fields are run when the form is saved.

Note: You may design queries to generate a DCF when you submit a form and the value fires "true" to being outside of its pre-defined check range. This will occur even if the previous DCF was manually closed and/or the previous value was valid or invalid.

For all non-form data, all associated queries are run when the data is saved.

Initial-Single CRF

When an individual form is saved for the first time, all queries for that CRF are run. All DCF-type queries that fire true are displayed to the user, with the following exceptions:

- Those that have not been designated as "Warn User."

- If the user is in the Site Portal, those that will generate or resolve Draft DCFs.

The user has the option to continue or cancel. If the user continues, DCFs are generated. If the user cancels, they are returned to the form.

Upon **Save** of the form, all necessary DCFs and Notifications are processed.

Save-Single Form

When an individual form is modified and saved again, only those queries that are associated to a field that has changed are run.

All DCF-type queries that change from true to false (resolved) or false to true (fired) are displayed to the user, with the following exceptions:

- Those that have not been designated as "Warn User."

- If the user is in the Site Portal, those that will either generate or resolve Draft DCFs.

When in production mode, the question number and query description are displayed for each.

Notify-type queries will not be shown in the activity message.

Warn User

DCF-type queries which are marked as "Warn-User" will indicate error icon (exclamation point) upon changing data if the query will fire, and through a query activity message upon saving the form if the query will either fire or be resolved through the process of the save. Queries which would fire but are not marked as "Warn User" are not displayed in the query activity message.

Warn User is locked to OFF for Notify-type queries.

Resolving a DCF

Whenever possible, you should try to resolve a query-generated DCF by correcting the data rather than answering the DCF. This way you save study personnel the extra step of verifying correct data.

To resolve a query-generated DCF:

1 Open a DCF that has a "Sent" status.
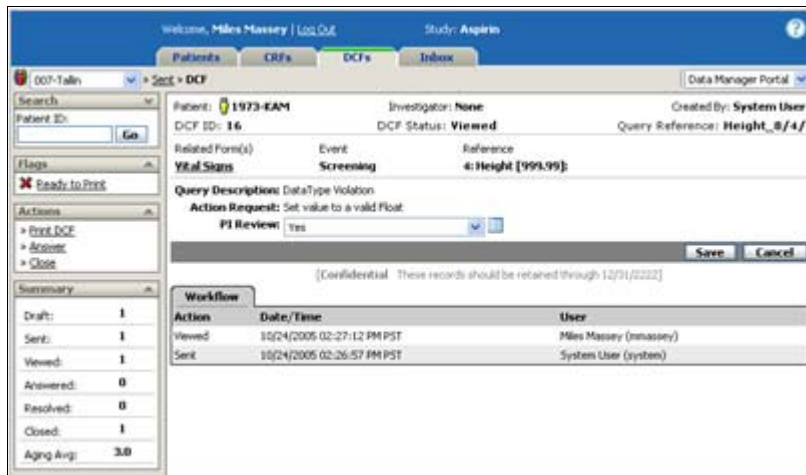
2 From the Actions palette, click **Answer**, and then click the **CRF Name** on the pop-up menu.

The CRF opens in edit view (if you have auto-checkout turned on). The question that fired the query is marked with a DCF icon ( ).

3 Make the necessary changes to the question.

4 Click **OK**.

5 Click **Save & Check In**.

The Queries Result message box appears, noting that the query was resolved.

6   Click **Continue**.

The "CRF has been saved and checked in successfully" message appears and you are returned to the DCF. The DCF now has a "Resolved" status.
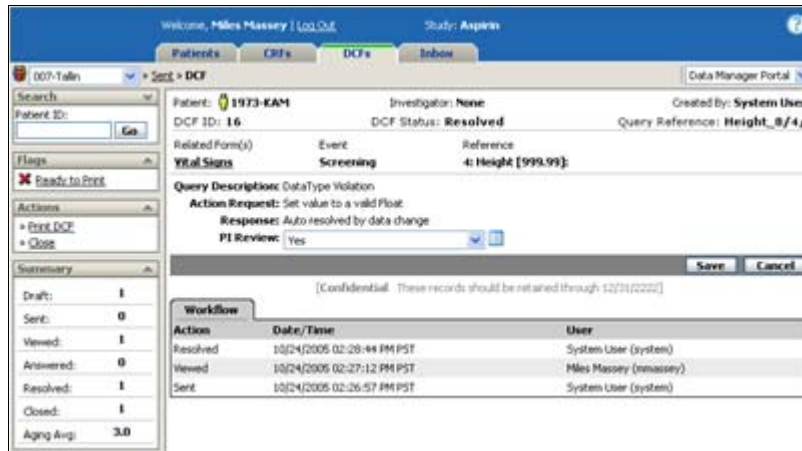
Closing a Resolved DCF

Note: This Functionality is specific to **Data Manager** portal users.

Once the site has responded to a DCF by resolving it, it is up to the discretion of the data manager to accept the answer given.

Note: If you have auto-close enabled (see Study Management on page 74), you do not need to manually close the DCF.

To close a DCF:

1   Open a DCF.

Note: You can close any DCF that has a New, Sent, Resolved or Answered status.

2   From the Actions palette, click **Close**.

The "CRF has been saved and checked in successfully" message appears and you are returned to the DCF. Its status is now "Closed."
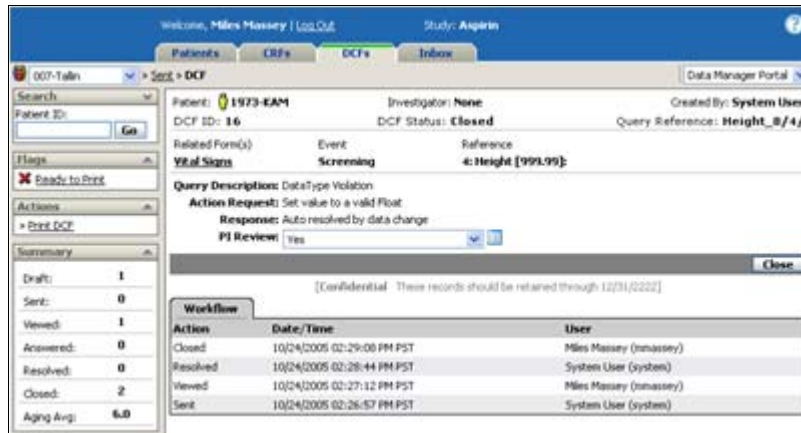
3 Click **Close**.

You are returned to the multi-DCF view. A closed DCF is shown as a None icon (✓) in the various views (see DCF Icons on page 273).

Auto-Closing Resolved DCFs

Note: This Functionality is specific to **Data Manager** portal users.

One of the settings in Study Management enables DataLabs to automatically close any resolved queries. If this setting is turned on, and you correct the answer to a question so that it resolves a query, DataLabs moves it from the Resolved status to Closed. (If auto-close is turned off, DCFs with a Resolved status must still be reviewed by data management personnel before they can be closed.)

Note: For more information on automatically closing all system-resolved DCFs, see Study Management on page 74.

Printing DCFs

DataLabs allows you to create PDF versions of DCFs that can be saved and printed. The PDF contains all the DCF details, as well as a barcode that can be scanned.

Data Clarification Form

Study: **AspirinNew**		DCF ID: **12**
Protocol: **ASCT-5150**		Batch ID: **6**

Patient: **1973-KAM**	Patient Status: **Enrolled**	DCF Status: **Draft**	
Site: **007 - Tallin**	Created By: **Miles Massey**	Created on: **10/21/2005 9:15:38 PM**	

Related Forms	Event	Reference
Demographics	**Screening**	**4.Race (if "Other")**

Query Description: "Mixed" is not specific.
Action Request: Please provide more detail.
Response:

Signature: _____   Date: _____

DataLabsXC Clinical©
Printed on: **10/25/2005 10:34:31 AM**   Page   1 Of 1

Printing Individual DCFs

Using the Print DCF command on the Actions palette, you can create a PDF version of the DCF you currently have open.

To save and open the print file:

1 Open the DCF in the DCF view.

2 From the Action palette, click **Print DCF**.

   The File Download dialog box appears.

3 Do one of the following:

Click the **Save** button to save a PDF version of the DCF to your computer.

Click the **Open** button to open a PDF version of the DCF in Adobe Acrobat.
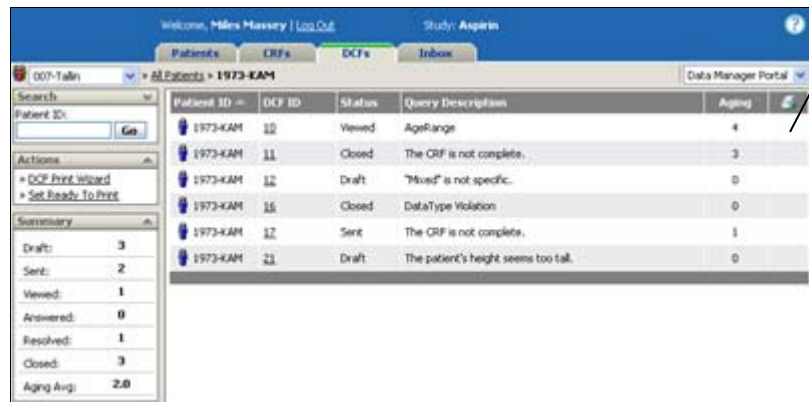
Batch Printing DCFs

Note: This Functionality is specific to **Data Manager** portal users.

For studies that use a paper DCF workflow, DataLabs allows you to mark DCFs that are ready to be printed, and then to print them in batches.

Flagging DCFs "Ready to Print"

The "ready to print" flag is simply that: the DCF is marked with a print flag. You can flag a DCF "ready to print" at either the patient level/view, or at the DCF level/view.
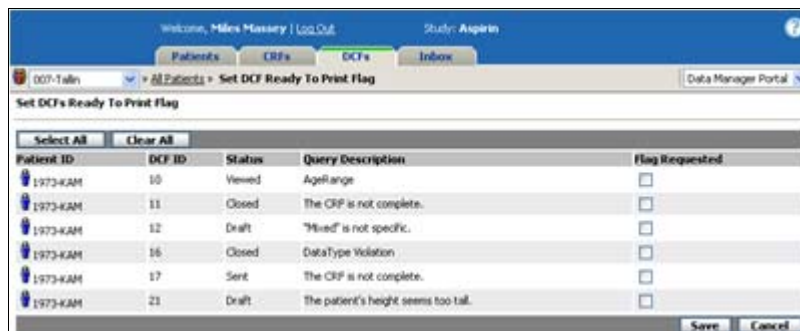
"Ready to print" column

To set DCFs "ready to print" from the patient view:

1 From the Action palette, click **Set Ready to Print**.

The Set DCFs Ready to Print Flag page appears.

2 Select the DCFs you want to mark in the **Flag Requested** column.

You can also **Select All** or **Clear All** of the flags.

3   Click **Save**.

The "Ready to Print Completed"
message appears when you are
returned to the patient view. The
DCFs are now flagged with a "ready
to print" icon.

Patient ID ▲	DCF ID	Status	Query Description	Aging	🖨
👤 1973-KAM	10	Viewed	AgeRange	4	
👤 1973-KAM	11	Closed	The CRF is not complete.	3	
👤 1973-KAM	12	Draft	"Mixed" is not specific.	0	🖨
👤 1973-KAM	16	Closed	DataType Violation	0	
👤 1973-KAM	17	Sent	The CRF is not complete.	1	
👤 1973-KAM	21	Draft	The patient's height seems too tall.	0	🖨

Printing Flagged DCFs

Using the **Set Ready to Print command on the** Action palette, you can create a PDF of the
DCFs that have been flagged "ready to print."

To print:

1   On the DCFs tab, navigate to the patient view.

2   From the Action palette, click **Set Ready to Print**.

The DCF Print Wizard page 1 appears.
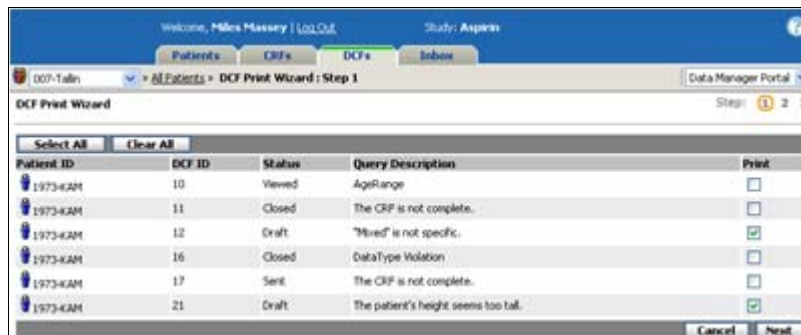
3   Change any **Print** selections and click **Next**.

The DCF Print Wizard page 2 appears.
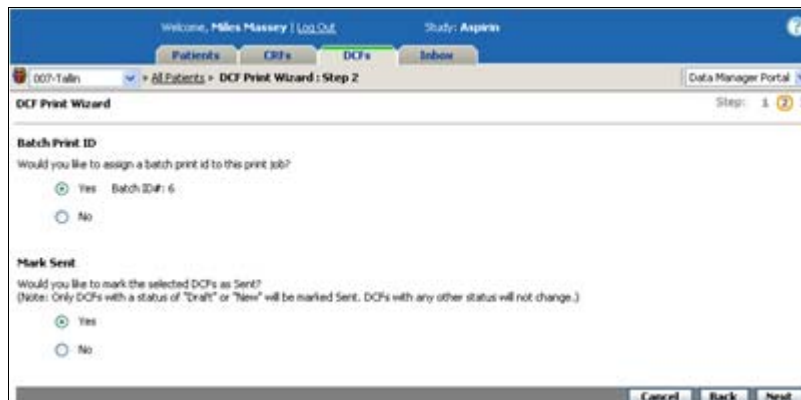
4 Select whether you want a **Batch Print ID** assigned to the print job.

The Batch Print ID is sequentially numbered, allowing you to keep track of the total DCF print jobs done for the study.

5 Select whether you want, of the DCFs selected to print, the Draft or New DCFs **Marked as Sent**.

6 Click **Next**.

The DCF Print Wizard page 3 appears.

7 Click **Finish**.

The "DCF Print has been queued successfully" message appears when you are returned to the patient view. The DCFs are now queued to be printed.

8 Click the **Inbox tab**.

The Inbox displays a "DCF Print Request Ready" message. The length of time it takes for the export to complete depends on the number of DCFs you are exporting.

Saving and Opening a DCF Batch Print

When the print request is complete, it appears in your Inbox as a link to the file.

To save and open the print file:

1 Click the "DCF Print Request COMPLETE" link.

The File Download dialog box appears. The exported PDF file has been compressed into a ZIP file.

2 Click the **Save** button.

The Save As dialog box appears.

3 Choose the folder you want to save the ZIP file to, and click **Save**.

The PDF contains all the DCF details, as well as a barcode.

Chapter 9: The Signature Process

Overview

This chapter covers the following material:

- The signature process

- Signature statuses

- Requesting signatures

- Responding to signature requests

  Signing

  Rejecting

  Skipping

- Searching for CRFs ready for signature

Signature Process

When a patient (or a subset of CRFs) is ready for signature, the study personnel can initiate the signature process.

Note: While signing and freezing CRFs occur at roughly the same point in the workflow, whether a CRF is frozen before it is signed, or signed before it is frozen, varies from study to study. For more on freezing CRFs, see Chapter 10: Freezing and Locking Data on page 321.

The signature process has two basic steps:

1   The data manager reviews the CRFs—and any related DCFs and flags—and requests a signature by the assigned PI.

2   The Primary Investigator reviews the CRFs, and decides to sign, skip, or reject the signature requests on one or more CRFs for a patient.

> **Note**: DataLabs does not require a CRF to be frozen or signed in a particular order. You can freeze a CRF at any time, just as you can request a signature at any time. DataLabs is flexible so that you can apply the freeze/sign rules of your organization.

Signature Display

When a CRF is signed, the electronic signature is displayed in the CRF.

The electronic signature is made up of the following elements (and is recorded in the audit trail):

Attestation: The content of the signature—what it attests to, and how it meets legal requirements.

Signature: Displays both the display name and username of the PI.

Date and time: Displays when the CRF was electronically signed.

Note: If the signature attestation is changed during the course of a study, only CRFs signed after the change will bear the newer attestation. See Chapter 9: The Signature Process on page 306 for more information.

Signature Statuses

DataLabs uses icons to give you a visual representation of the status of CRFs during the signature process.

Cumulative

Where there are multiple CRFs for a patient, DataLabs uses four icons to show the cumulative signature status of all the CRFs.
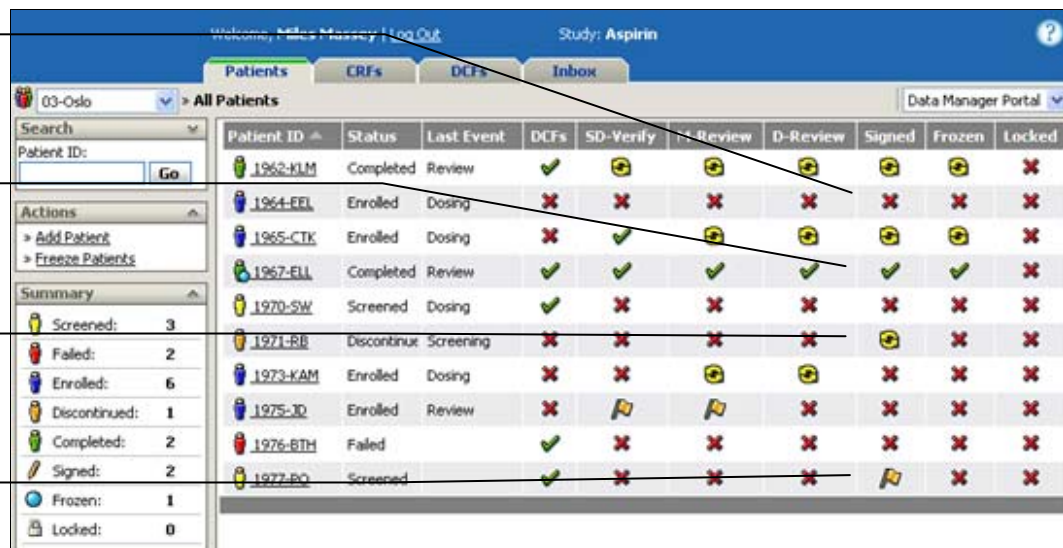
None: No CRFs have been signed.

Some: Some CRFs have been signed.

All: All CRFs have been signed.

Changed: Visible data on at least one CRF has been changed since being signed.

None of the CRFs for this patient have been signed.

All of the CRFs for this patient have been signed.

Some of the CRFs for this patient have been signed.

Visible data on at least one signed CRF has been **changed**.

Individual

When you expand a visit, the individual flag for each CRF signature is represented by a status icon:

Not Signed: The CRF has *not* been signed.

Signed: The CRF has been signed.

Changed: The CRF has been signed, but visible data has been changed since being signed.

Not signed/Signature Requested: The CRF has *not* been signed, and a signature has been requested.

Signed/Signature Requested: The CRF has been signed, but another signature is requested.

Changed/Signature Requested: The CRF has been signed, visible data has been changed since being signed, and another signature is requested.

Not signed/Signature Request Rejected: The CRF has *not* been signed, and a signature request has been rejected.

Signed/Signature Request Rejected: The CRF has been signed, and a subsequent signature request has been rejected.

Changed/Signature Request Rejected: The CRF has been signed, visible data has been changed since being signed, and a subsequent signature request has been rejected.

Invalid: The CRF signature is invalid.

The figure below illustrates how cumulative flags reflect what lies beneath them.

Cumulative   **Individual**

A "None" cumulative flag (✖) means...

...none of the CRFs are signed.

A "Some" cumulative flag (♲) means...

...at least one CRF has been signed (✔), but some have not (✖).

An "All" cumulative flag (✔) means...

...all related CRFs have been signed (✔).

A "Changed" cumulative flag (⚑) means...

...visible data on at least one signed item has been changed (⚑).

Using Signature Icons to Track Progress

The status icons give you a visual representation of the progress of the signature process. Basically, a green check (✔) means there is progress or completion, a red X (✖) means there is no progress or there are issues to address, a yellow recycle symbol (♲) means that there is at least one CRF signed, and an orange flag (⚑) means at least one signed CRF has been changed since signing.

A row of green
check marks
(✔) is a basic
goal.

For more information on CRFs, DCFs, flags, freezing and locking—and their status icons—see
the respective chapter on each.

Requesting a Signature

Note: This Functionality is specific to **Data Manager** portal users.

When a CRF has met the necessary criteria to be completed, it is time to submit it to the Primary Investigator for signature.

Note: CRFs that are locked or checked out cannot be signed.

To request signatures for a patient:

1   Open the patient in the patient view.

2   Click the **Request Signature** command on the Actions palette.

The Request Signature page appears.
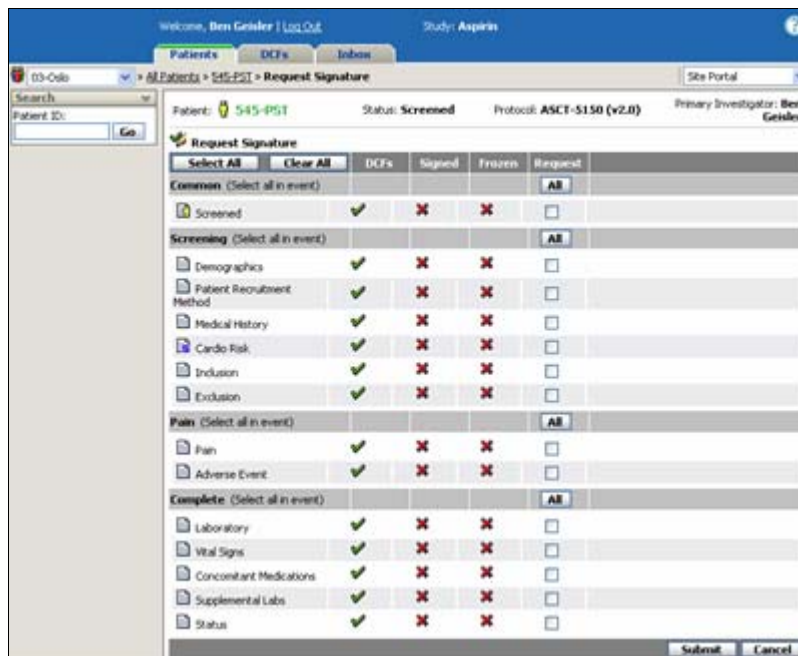
3   Do one of the following:

To request signatures for all CRFs for the patient, click the **Select All** button (Select All).

To request signatures for all CRFs for a specific event, click the **All button** (All) for that event.

To request a signature for each individual CRF, click the check box (☑).

4   Click **Submit**.

The Request Signature page contains the following items:

Patient: Displays the current patient status, and the patient ID (a combination of their Screen/Enroll ID and initials).

Investigator: Displays the name of the assigned PI for the patient—the person who receives the requests for signature.

Status: Displays the patient's current status.

Select All button: Selects all the CRFs listed on the page to be submitted for signature.

Clear All button: Clears all previously selected CRFs.

All button: Selects all CRFs for the event. Pressing it again deselects all CRFs for that event.

Event Name: Displays the name of the event.

CRF: Displays the CRF name and status icon (see Chapter 6: Entering Patient Data (CRFs) on page 184).

DCFs column: Displays the DCF status for each CRF (see Routing CRFs on page 221).

Signed column: Displays the signature status of each CRF.

Frozen column: Displays the freeze status of each CRF (see Chapter 10: Freezing and Locking Data on page 321).

Request column: Marks CRFs "Ready for Signature." If the box is already checked, deselecting it will cancel the signature request.

Note: Check boxes are disabled if the CRF is checked out.

Submit button: Submits the signature request(s) and returns you to the patient view.

Cancel button: Returns you to the patient view without submitting CRFs for signature.

Responding to Signature Requests

Prior to final approval and sign off on a patient's CRFs, the Primary Investigator should review the data before providing final signature. During the final review of CRFs, the PI will have the opportunity to review data and provide the final signature, or reject the signature request.

There are three ways to determine which CRFs are ready for signature:

■ Review each patient CRF individually, opening each event to look for signature requested status icons (, ,).

■ Look in your Inbox to see if any patient CRFs are ready for signature (see Signature Request Inbox Messages on page 315).

■ From an open patient, click **Sign Casebook** on the Actions menu to list all CRFs assigned to you that have been submitted for signature.

Note: The Sign Casebook command appears only if there are CRFs ready to be signed.

You can take the following actions in response to a request for signature:

Sign: You are attesting to its accuracy by signing this CRF.

Skip: You are not yet taking action in signing or not signing this CRF.

Reject: You choose not to sign, providing a detailed explanation is required.

Signature Request Inbox Messages

If you have checked "Notify me of signature requests" in User Preferences, any requests for signature are listed in the Work Queue section of the Inbox (see Changing Your User Preferences on page 47).

Example: For example, often sites have study coordinators who will monitor the signature requests and notify the Primary Investigator when there are new ones.

To check your Inbox:

1   Click the **Inbox tab**. Go to the Work Queue section.

The Work Queue appears.
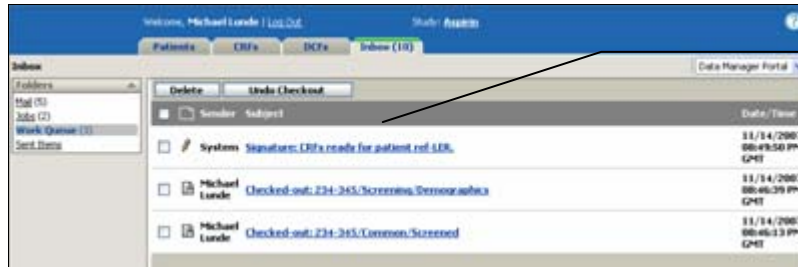
This Inbox item is a CRF ready to be signed.

2   Click the item marked with the pencil icon (✐) and with the subject "CRFs ready for signature."

The View Patient page appears.

3   Click the **Sign Casebook** command on the Actions menu.

The Sign Casebook page appears for that CRFs (see the following section on how to sign a CRF).

Signing CRFs

You can use the **Sign Casebook** command on the Actions palette to list all CRFs assigned to you that have been submitted for signature.

Note: CRFs that are locked or checked out cannot be signed.

To sign CRFs:

1   Open the patient who has CRFs ready for signature in the patient view.

The signature status for the CRFs ready for signature are marked with one of the icons described in Signature Statuses on page 309.

2   Click the **Sign Casebook** command on the Actions palette.

The Patient view page appears, listing all the patient CRFs ready for signature.

3 Do one of the following for each event:

To *skip* signing all CRFs for a specific event, click the **All button** (**All**) in the **Skip** column. (This column is checked by default.)

Note: CRFs marked skip appear in this list the next time it is opened.

To *sign* all CRFs for a specific event, click the **All button** (**All**) in the **Accept** column.

To *Reject* all requests for signature for a specific event, click the **All button** (**All**) in the **Reject** column.

Note: If you choose to reject CRFs for signature, see Rejecting a Signature Request on page 318.

To skip, accept or reject a request a signature for each individual CRF, click the appropriate option button (⊙) for each CRF.

4 To sign the CRFs, type your **Username** and **Password**.

5 Click **Submit**.

The Sign Casebook page contains the following items:

Patient ID: Displays the current patient status, and the patient ID (a combination of their Screen/Enroll ID and initials).

Investigator: Displays the name of the assigned PI for the patient.

Status: Displays the patient's current status.

Note: Only those CRFs that have the signature status of "Ready" are displayed in this list.

Event Name: Displays the name of the event.

CRF: Displays the CRF name and current status icon (see Chapter 6: Entering Patient Data (CRFs) on page 184). If the CRF is checked out, the lock icon is displayed and option buttons are disabled. Clicking the CRF will open it in view mode.

DCFs column: Displays the DCF status for each CRF (see Routing CRFs on page 221).

Signed column: Displays the current signature status of each CRF.

Option buttons: Selects what kind of response to take for each request for a signature:

Skip – Takes no action for the signature request.

Accept – Accepts the signature request. When at least one is marked "Accept" the PI signature section becomes active.

Reject – Rejects the signature request. A link for "Add Reason" appears; after a comment is added, "Edit Reason" is displayed in the column.

All buttons: Selects the actions for all CRFs for the event.

Example: For example, if you click the All button in the Skip column for Visit01, DataLabs marks all CRFs for Visit01 as "Skipped" for signature.

PI Signature Attestation: Displays the attestation that will be assigned to the CRFs that are signed. The attestation—while displayed—is assigned to a CRF only if at least one signature has been marked "Accept."

Username: Defines your username—required by DataLabs to re-authenticate the PI before the electronic signature can be assigned to the CRF, even if you are already logged into DataLabs.

Password: Defines your password—also required, even if you are already logged into DataLabs.

Submit button: Submits the signature(s) and, if the PI is authenticated, returns you to the patient view.

Cancel button: Returns you to the patient view without submitting any signatures.

Rejecting a Signature Request

If it is necessary to reject a request for a signature, you will be required to provide a comment.

To reject a request for a signature:

1 From the Sign Casebook page, select which CRFs you are rejecting a signature request:

To *Reject* all requests for signature for a specific event, click the **All button** (**All**) in the **Reject** column.

To reject a request for a signature for each individual CRF, click the appropriate option button (◉) for each CRF.

An "Add Reason" link appears for the rejected CRF(s).

2   Click the **Add Reason** link.

The Rejection Reason pop-up window appears.

3   Type your reason for rejecting the signature request in the Reason box.

4   Click **OK**.

The "Add Reason" changes to read "Edit Reason."

The Rejection Reason pop-up window contains the following items.

Patient ID: Displays the current patient status, and the patient ID (a combination of their Screen/Enroll ID and initials).

Investigator: Displays the name of the assigned PI for the patient.

Event: Displays the event the CRF is associated to.

CRF: Displays the name of the corresponding CRF.

Site: Displays the site the patient belongs to.

Reason: Defines the text of the reason for rejection.

OK button: Saves the comment and saves the CRF signature rejection.

Cancel button: Closes the window without rejecting the CRF signature.

Chapter 10: Freezing and Locking Data

Overview

Note: This Functionality is specific to **Data Manager** portal users.

This chapter covers the following material:

CRF level

- Freezing and Thawing CRFs

Patient level

- Freezing and thawing patients

- Locking and unlocking patients

Study level

- Locking and unlocking a study

Freezing, Thawing, Locking, Unlocking

As a study progresses, it will become necessary to finalize the data by protecting it from any changes. There are two "levels" of data protection—freezing and locking—that you can use.

Freezing: Temporarily protects data from being edited. Freezing does not have the "official" status of locking, and can be applied to a CRF or patient for any number of reasons.

Thawing: "Unfreezes" a frozen CRF or patient so that the data can be edited.

Locking: Protects data from being edited. Locking data is part of clinical trial workflow, and is an "official" status.

Unlocking: "Un-protects" locked data—since official clinical trial protocol defines how data is locked, unlocking data may require proper documentation and justification.

You can also freeze and lock different classes of data:

> **CRF:** Freezes/locks individual CRFs.

> **Patient:** Freezes/locks individual patients (and therefore their CRFs).

> **Study:** Locks all study data, including patients and CRFs.

The following pages detail the steps you can take to freeze and lock data.

Overview of Actions Allowed

When a patient or CRF is frozen or locked, you are limited in what kind of actions you can perform against the underlying data.

Action	Permitted	Forbidden
Freeze CRF	Flags can be changed.	No visible data can be changed.
	Derived fields will still update.	No DCFs can be created.
		No Comments can be added.
Freeze Patient	Same as frozen CRFs (previous).	Same as frozen CRFs (previous).
Lock Patient	CRFs can be viewed.	No visible data can be changed.
		No DCFs can be created.
		No Comments can be added.
		No flags can be changed.

Freezing and Thawing CRFs

Freezing restricts the ability to change CRF data—although CRFs can still have DCFs assigned, be signed and flagged.

Note: While you can freeze data both at the CRF and patient level, you are only able to lock data at the patient level. See Freezing and Locking Patients on page 327.

Freezing CRFs

You can freeze one or more CRFs from the patient view using the Freeze CRFs command on the Actions palette.

Note: While signing and freezing CRFs occur at roughly the same point in the workflow, whether a CRF is frozen before it is signed, or signed before it is frozen, varies from study to study. For more on freezing CRFs, see Chapter 9: The Signature Process on page 306.

To freeze one or more CRFs for a patient:

1 Open the patient in the patient view.

2 Click the **Freeze CRFs** command on the Actions palette.

The Freeze CRFs page appears, listing the patient's CRFs.
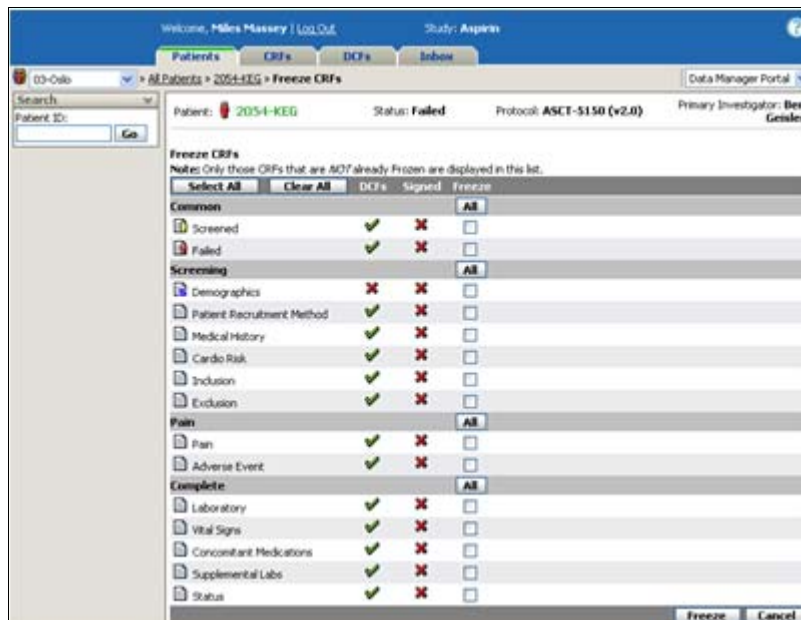
Note: Only those CRFs that are not already frozen are displayed in this list.

3   Do one of the following:

To freeze all the patient's CRFs, click the **Select All** button (Select All).

To freeze all the CRFs for an event, click the check box (☑) for that event for that event.

To freeze an individual CRF, click its check box (☑).

To clear all the check boxes, click the **Clear All** button (Clear All).

4   Click **Freeze**. (Clicking the **Cancel** button returns you to your original page *without* freezing CRFs.)

DataLabs freezes the selected CRFs and returns you to the page you accessed Freeze CRFs page from. The status icons in the Frozen column reflect the new statuses, this time the CRFs you froze have a green check mark ✔ in the Frozen column.

Thawing CRFs

If you need to edit data on a frozen CRF, you can thaw one or more frozen CRFs from the patient view using the Thaw CRFs command on the Actions palette.

To thaw one or more CRFs for a patient:

1   Open the patient in the patient view.

2   Click the **Thaw CRFs** command on the Actions palette.

The Thaw CRFs page appears, listing the patient's frozen CRFs.

Note: Only those CRFs that are already frozen are displayed in this list.

---

3 Do one of the following:

To thaw all the patient's CRFs, click the **Select All** button (**Select All**).

To thaw all the CRFs for an event, click the check box (☑) for that event.

To thaw an individual CRF, click its check box (☑).

4 Click **Thaw**. (Clicking the **Cancel** button returns you to your original page *without* thawing CRFs.)

DataLabs thaws the selected CRFs and returns you to the page you accessed the Thaw CRFs page from. The status icons in the Freeze column reflect the new statuses.

Freezing and Locking Patients

The benefit of using the multi-patient view is that you can save time by performing an action against multiple patients rather than one at a time. From this page, you can perform an action (freeze, thaw, lock, unlock) against one or more patients in the table.

Note: When you freeze or thaw at the patient level, what you are really doing is freezing or thawing all CRFs associated with the patient(s). You aren't actually freezing the patient. So if you were to freeze all of a patient's CRFs individually, the patient would end up, by default, being shown as frozen.

Note: Editing a patient's frozen CRF after they have been frozen thaws that CRF, and therefore thaws the patient (but the other CRFs remain frozen). Similarly, since a patient workflow Common form (Enroll, Fail, etc.) can be checked out when a patient is frozen, once the form has been checked back in the patient is no longer frozen.

Freezing Patients

You can freeze one or more patients from the multi-patient view using the Freeze Patients command on the Actions palette.

To freeze a patient:

1   From the CRFs: Multi-Patient view, click the **Freeze Patients** command on the Actions palette.

    Note: The commands available on the Actions palette depend on the current state of the patients listed on the page. (For example, if none of the patients are frozen, the Freeze Patients command appears, but the Thaw Patients command does not.)

    The Freeze Patients page appears listing all the patients you were looking at on the multi-patient view page (but who are not already frozen). From here, you can select which patients you want to freeze.
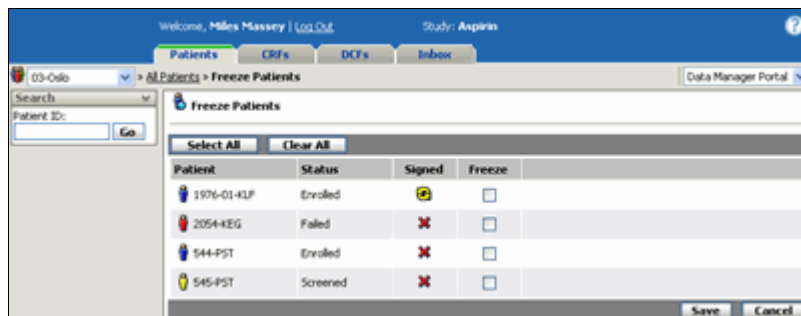
2   Do one of the following:

Click **Select All** to mark all the check boxes.

Click **Clear All** to unmark all the check boxes.

Click the **check boxes** to individually select and deselect the patients you want to freeze.

3   Click **Freeze**. (Clicking the **Cancel** button returns you to your original page *without* freezing any patients.)

You return to the page you accessed the Freeze Patients page from, but this time the patients you froze have a green check mark ✔ in the Frozen column, and the patient status icons now have a blue sphere (🔵).

Patient ID ▲	Status	Last Event	DCFs	SD-Verify	M-Review	D-Review	Signed	Frozen	Locked
1962-KLM	Enrolled	Dosing	✖	🔄	🔄	🔄	🔄	🔄	✖
1976-01-KLF	Enrolled	Screening	✖	🚩	🚩	✖	🔄	✔	✖
2054-KEG	Failed	Screening	✖	✖	✖	✖	✖	✔	✖
544-PST	Enrolled		✔	✖	✖	✖	✖	✖	✖
545-PST	Screened	Screening	✔	✖	✖	✖	✖	✖	✖

These two patients are Frozen…

…and are flagged in the Frozen column.

Thawing Patients

You can thaw one or more frozen patients from the multi-patient view using the Thaw Patients command on the Actions palette.

To thaw a patient:

1   From the CRFs: Multi-Patient view, click the **Thaw Patients** command on the Actions palette.

Note: The commands available on the Actions palette depend on the current state of the patients listed on the page. (For example, if some but not all of the patients are frozen, the Freeze Patients, Thaw Patients, and Lock Patients commands appear.)

The Thaw Patients page appears listing all the frozen patients you were looking at on the multi-patient view page. From here, you can select which patients you want to thaw.
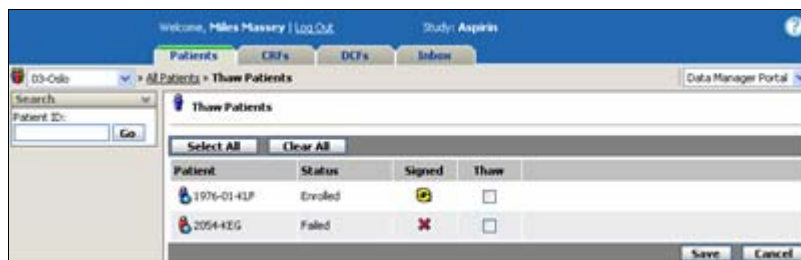
2   Do one of the following:

Click **Select All** to mark all the check boxes.

Click **Clear All** to unmark all the check boxes.

Click the **check boxes** to select and deselect the patients you want to thaw.

3   Click **Thaw**.

You return to the page you accessed Thaw Patients page from, but this time the patient's status icon has returned to normal. (Clicking the **Cancel** button returns you to your original page *without* thawing any patients.)

Locking and Unlocking Patients

You can lock one or more patients from the multi-patient view using the Lock Patients command on the Actions palette.

Note: You can only lock patients who have already been frozen.

Note: All event-related forms must be checked in before you can lock a patient—except the patient workflow Common forms (Enroll, Fail, etc.). If you have one of these forms checked out, you can still lock the patient given all their other forms are checked in. Once you try to check in the form, an error will appear saying that you cannot check in the form because the patient is now locked. You must unlock the patient to check in the form.

To lock a patient:

1   From the Patients: Multi-Patient view, click the **Lock Patients** command on the Actions palette.

The Lock Patients page appears listing all the frozen patients you were looking at on the multi-patient view page (since you can only lock patients that have already been frozen).
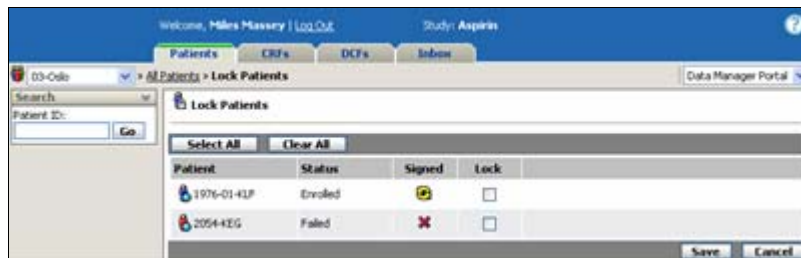
2   Do one of the following:

Click **Select All** to mark all the check boxes.

Click **Clear All** to unmark all the check boxes.

Click the **check boxes** to select and deselect the patients you want to lock.

3 Click **Lock**. (Clicking the **Cancel** button returns you to your original page *without* locking any patients.)

You return to the page you accessed Lock Patients page from, but this time the patients you locked now have a padlock on their status icon ( ).

These two patients are Locked...

...and are flagged in the Locked column.

Patient ID ▲	Status	Last Event	DCFs	SD-Verify	M-Review	D-Review	Signed	Frozen	Locked
1962-KLM	Enrolled	Dosing	✖	🔄	🔄	🔄	🔄	🔄	✖
1976-01-KLF	Enrolled	Screening	✖	🚩	🚩	✖	🔄	✔	✔
2054-KEG	Failed	Screening	✖	✖	✖	✖	✖	✔	✔
544-PST	Enrolled		✔	✖	✖	✖	✖	✖	✖
545-PST	Screened	Screening	✔	✖	✖	✖	✖	✖	✖

To unlock a patient:

1 From the Patients: Multi-Patient View, click the **Unlock Patients** command on the Actions palette.

The Unlock Patients page appears listing all the locked patients you were looking at on the multi-patient view page. From here, you can select which patients you want to unlock.
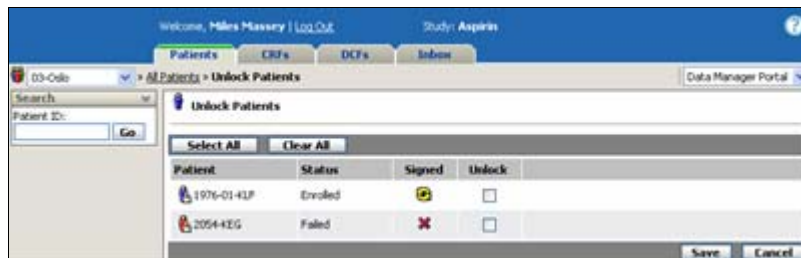
2 Do one of the following:

Click **Select All** to mark all the check boxes.

Click **Clear All** to unmark all the check boxes.

Click the **check boxes** to select and deselect the patients you want to unlock.

3 Click **Unlock**. (Clicking the **Cancel** button returns you to your original page *without* unlocking any patients.)

You return to the page you accessed Unlock Patients page from, but this time the patient's status icon has returned to its previous frozen state.

Locking a Study

At the end of a study, when all CRFs are completed, DCFs resolved and signatures collected, and the data is complete, it is time to lock the study.

Note: See Study Management on page 74 for more information on study management.

To lock a study:

1 Click the **Study Administration** item on the Administration menu (which is near the top-right corner of the page).

The Study Administration page appears.
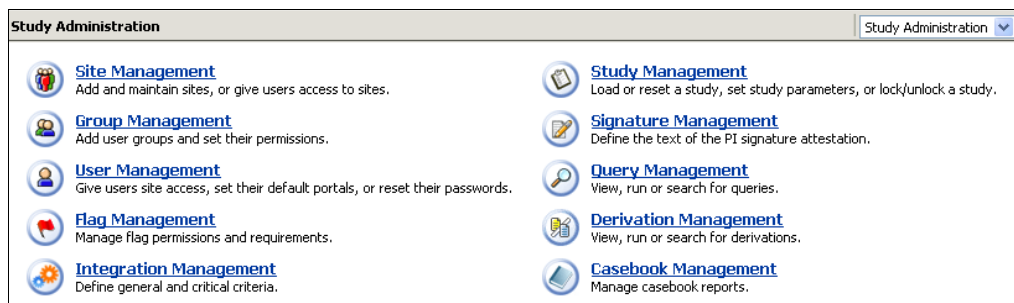
2 From the Study Administration page, click 📖 **Study Management**.
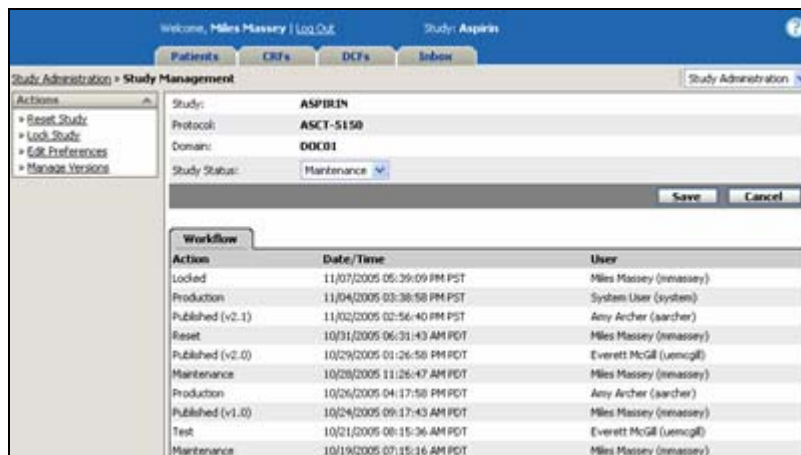
The Study Management page appears.

3 From the Study Management page, click the **Lock Study** command on the Actions palette.

A warning box appears, asking, "Locking this study will restrict the ability to make changes to data. Are you sure you want to do this?"

4   Click **Continue**.

Another message box appears, telling you, "Lock Study Successful," and a lock icon displayed to the right of the study name.
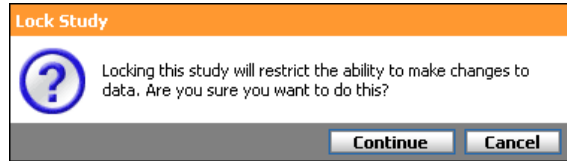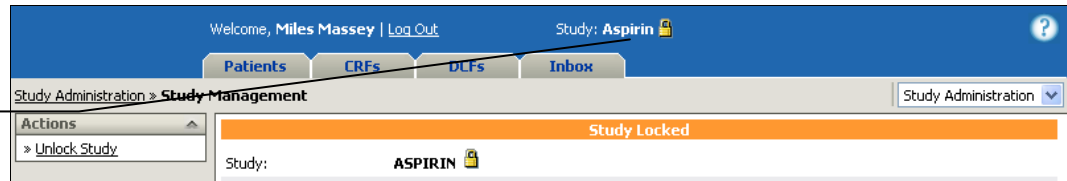
The study is locked.

Unlocking a Study

For the rare occasion you need to unlock a study after having locked it, you can use the Unlock study command on the Actions palette.

To unlock a study:

1   From the Study Management page, click the **Unlock Study** command on the Actions palette.

A warning box appears, asking, "Unlocking this study will allow the ability to make changes to data. Are you sure you want to do this?"
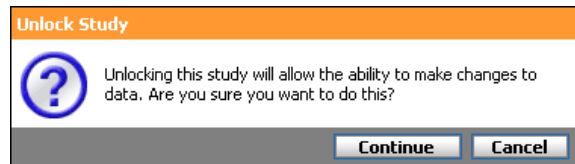
2   Click **Continue**.

Another message box appears, telling you, "Unlock Study Successful," and the lock icon is removed from the right of study name.

Chapter 11: Inbox and Messages

Overview

This chapter covers the following material:

- About the Inbox

- Accessing the Inbox

- Working with Inbox Messages

- Routing a CRF or DCF

- Inbox Preferences

About the Inbox

The DataLabs Inbox functions as a system-wide internal email client. The Inbox displays all system and user-generated messages and notifications for a user.

Note: Your DataLabs email can automatically be forwarded to an external email address if an outgoing email server has been configured for the study and if a valid email address has been entered in your User Preferences.

The Inbox is organized into four folders: Mail, Jobs, Work Queue, and Sent Items. Each folder receives specific Inbox messages as follows:

Mail

The Mail folder shows messages for routed CRFs and DCFs, messages from other DataLabs users, and alerts.

From the Mail folder, you can read messages, delete messages, create new messages and mark messages as unread.

Subject	▲ Date/Time
Routed CRF	**Thu 22 Oct 2003 09:50:28 PST**
Routed DCF	**Thu 22 Oct 2003 09:15:41 PST**
We are ready for your site visit	Wed 21 Oct 2003 10:25:06 PST
Data Verification for Site 501 is complete	Mon 19 Oct 2003 16:47:47 PST

Jobs

The Jobs folder shows messages about the status of jobs: flag management, derivations, exporting, queries, users, studies (staging, publishing, migrating), and DCFs. The messages appear only for features you have permission to view.

From the Jobs folder, you can read messages, delete message, and mark messages as unread; however, while a job is in progress, the message the shows the job's progress cannot be deleted or marked as unread.
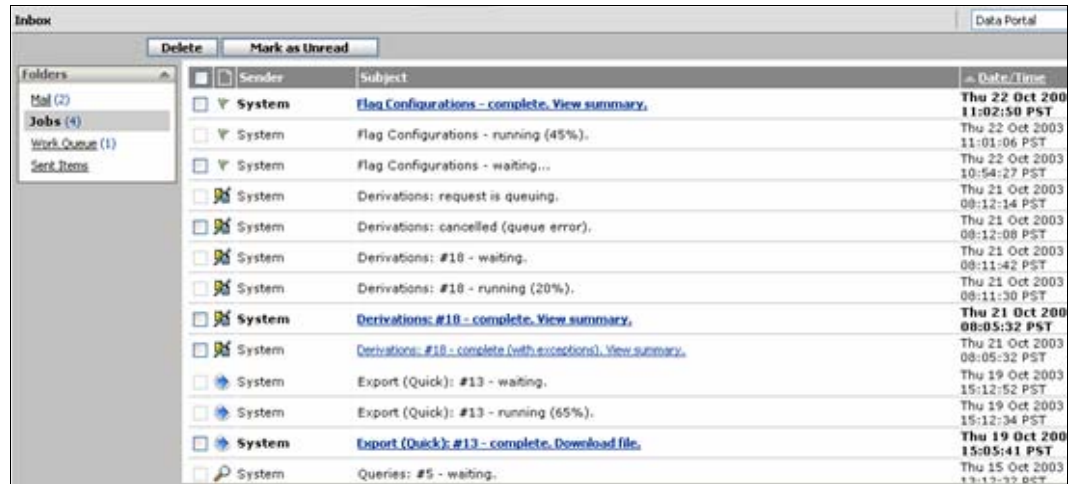
Work Queue

The Work Queue folder shows messages for the CRFs checked out to you and patients whose casebooks are ready for signature.

From the Work Queue folder you can delete messages or cancel CRF checkout; however CRF checkout messages cannot be deleted.

Sent Items

The Sent Items folder shows the message you have sent. From the Sent Items folder you can delete messages.
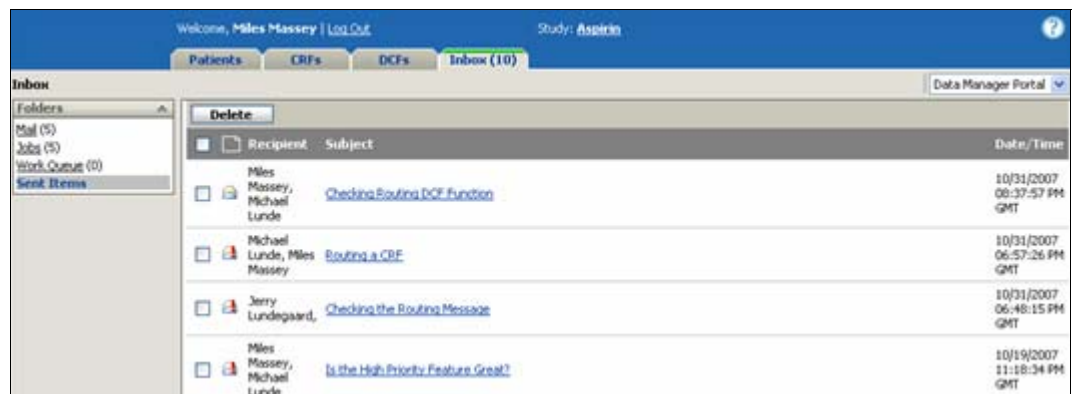
When a message is new or marked as unread, the subject appears in bold text. After the message has been viewed, the subject appears in normal (non-bold) text.

The following information is shown for each message:

Sender: Sender of the message—for the messages listed, "System." (For Sent messages, the recipient is shown instead of the Sender.)

Subject: Lists a description of the message and links to the appropriate page in DataLabs.

Date/Time: Displays the date and time the message was received.

Email Status icon: Shows what the message pertains to:

 Checked-out CRF

 Signature request

 Derivation management messages

 Query management messages

 Exported data messages

 Flag Configuration

 High Priority Message

Accessing the Inbox

To access the Inbox:

■   Click the **Inbox** tab. The Inbox appears.

Note: The number in parentheses on the Inbox tab displays the number of *new* messages in your inbox.

Click **New** to compose a new message.

Returns read mail to its original format (**bold** text and a closed envelope icon ✉)
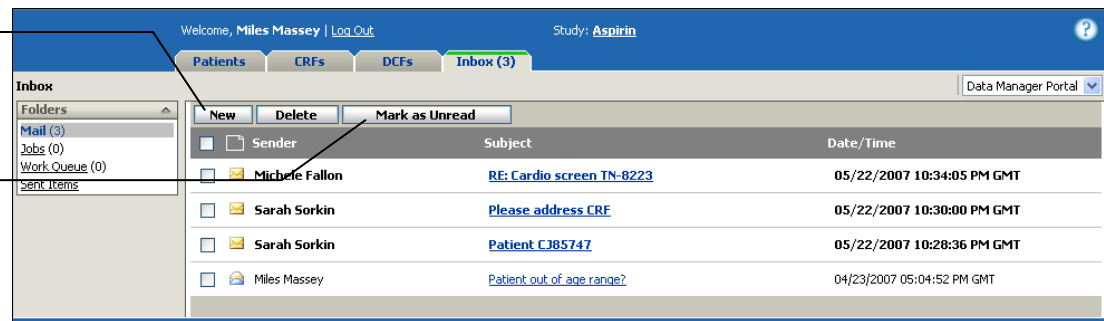
Receiving Mail

When a message is new, the subject text will display in bold. After the message has been viewed, the text will display normal. Marking a message as **Unread** will revert the subject line display to bold.

Note: Your DataLabs email can automatically be forwarded to an external email address if an outgoing email server has been configured for the study and if a valid email address has been entered in your User Preferences.

Check boxes: Used to select messages to be deleted or marked as unread. CRF checkout messages and in-progress messages cannot be deleted.

Viewing Messages

When viewing a message, the following actions will be available:

Print: Open the message in a printable format and prompts the print dialog window.

Delete: Permanently delete the message.

Reply: Reply to the sender of the message.

Forward: Forward the message to a new recipient.

Status Icon: Indicates whether the message pertains to:

    📄 Checked-out CRF

    ✏️ Signature request

    📋 Derivation management messages

    🔍 Query management messages

    ➡️ Exported data messages

    🌐 Flag Configuration

    📧 High Priority Message

Sender: Sender of the message—for the messages listed, "System."

Subject: Lists a description of the message and links to the appropriate page in DataLabs.

Date/Time: Displays the date and time the message was received.

To view a message:

1   Click the **Inbox tab**. The Inbox appears.

2   Open the folder that contains the message you want to view. The folder opens.

3   Click the link for the message you want to view. The message opens.
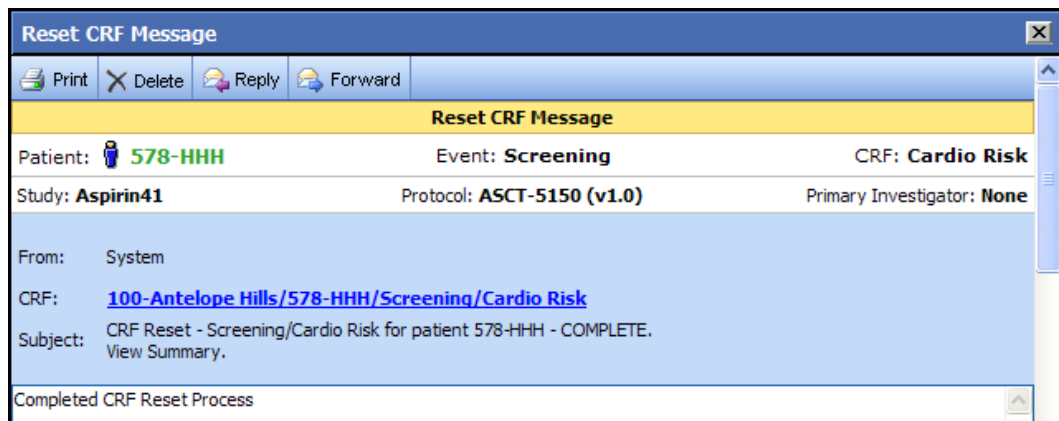
To print a message:

1   Open the message you want to print.

2   Click **Print**. The Print dialog box appears.

3   Select the printer you want to use to print the message.

4   On the Print dialog box, click **Print**.

To delete a message:

1   Click the check box for each message you wish to delete.

2   Click **Delete**.

To reply to a message:

1   Open the message you want to reply to.

2   Click **Reply**. The Sender's name immediately appears in the To box in the message header.
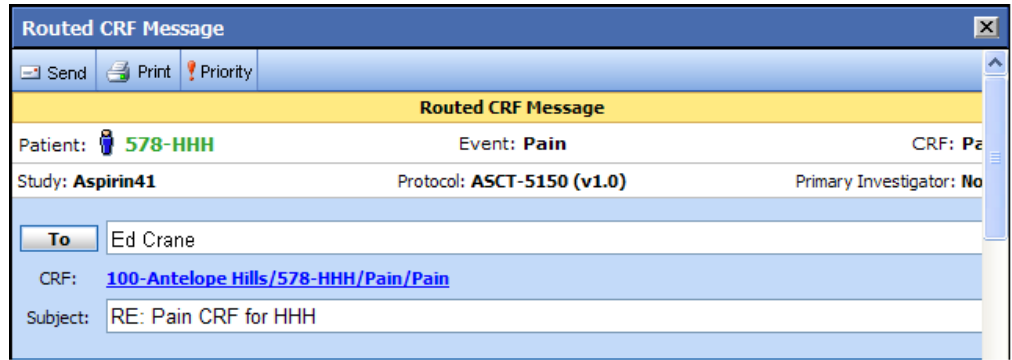
3   Click **Send**.

To forward a message:

1   Open the message you want to forward.

2   Click **Forward**. The To box appears in the message header.

3   Click the To button. The Select Users dialog box appears.
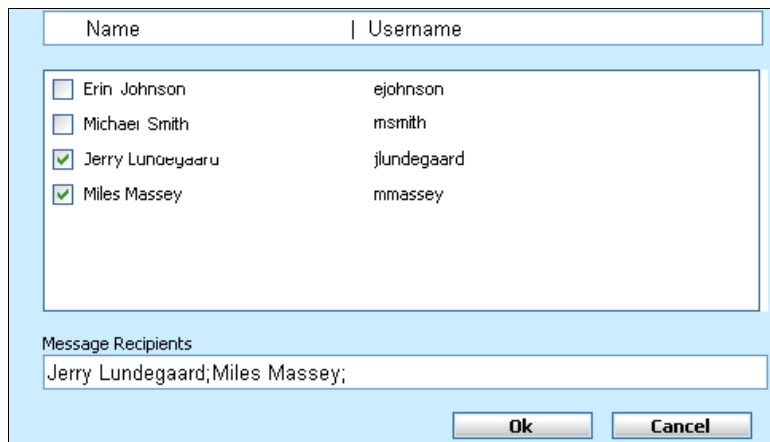
4   Select the users you want to send the message to. When you select a user, the user's name appears in the Message Recipients box.

5   Click **OK**. The Select Users dialog box closes.

6   Click **Send**.

Sending Mail

Sending mail in DataLabs is similar to using a standard email client, however messages can only be sent to other registered DataLabs Inbox users. A message can be sent to a user in any site that you are a registered user on. While the Inbox is not intended to be used to send mail to outside email clients, you can configure DataLabs to forward messages to an outside email client.

To create a new message:

1   From the **Inbox** page, click **New**. The Untitled Message page appears.

2   Click the To button. The Select Users page appears.

Note: Only users associated with sites you are associated with and who have "opted–in" to receiving messages appear on the Select Users page.

3   Select the users you want to send the message to. When you select a user, the user's name appears in the Message Recipients box.

4   Click **OK**. The Untitled Message page reappears.

5   Enter a subject and message.

6   Click **Send**. The message is sent to the users you selected.

Inbox Messages

You will notice that some of the messages that appear in the Inbox have active check boxes and can be deleted, while others do not. Here is a summary of the types of messages that appear and whether they can be deleted:

Subject	Links to	Delete?	Note
See Checked out CRFs on page 343.			
Checked-out: *patient ID/event/form name*	The checked out CRF.	No	Checking in (or Cancel Check Out) the CRF will remove this message from the Inbox.
See Signature Request Inbox Messages on page 315.			
Signature: CRFs ready for *patient ID*	The patient.	Yes	When you select "Notify me of signature requests" in User Preferences (see Changing Your User Preferences on page 47), you will receive messages for any patients in all sites you are a member of. Because some of the received requests may not pertain to you, you are allowed to delete these Ready for Signature notifications.
See Query Inbox Messages on page 138.			
Queries waiting	No link.	No	Query processing is waiting to start. The server checks every 20 seconds for query processing requests.
Query pre-processing	No link.	No	No actual data is being processed—DataLabs is testing the selected queries to give you a summary of the entire potential run process.
Query pre-processing complete	A summary of queries.	No	You must click this link to go to the summary page to start the actual query processing.
Query running	No link.	No	It shows the processing status and is replaced by the Query complete notification.
Query complete	A page showing a summary of all the queries run.	Yes	If you complete the Run Queries process multiple times, there will be a link to the summary for each one.
See Derivation Inbox Messages on page 123.			
Derivations queuing	No link.	No	Derivation processing is waiting to start.
Derivations cancelled (queue error)	No link.	Yes	Derivation processing was started, but encountered an error.
Derivations waiting	No link.	No	Derivation processing is waiting to start. The server checks every 20 seconds for derivation processing requests.
Derivations running	No link.	No	It shows the processing status and is replaced by the Derivation complete notification.
Derivations complete	A page showing a summary of all the derivations run.	Yes	If you complete the Run Derivations process multiple times, there will be a link to the summary for each one.
Derivations complete (with	A page showing a summary of all the	Yes	This is essentially the same as the Derivations complete summary, except that it lists the

Subject	Links to	Delete?	Note
exceptions)	derivations run.		exceptions generated by the derivations as well.
See Exported Data Inbox Messages on page 353.			
➡ Export waiting	No link.	No	Export is waiting to start. The server checks every 20 seconds for export requests.
➡ Export running	No link.	No	It shows the processing status and is replaced by the Export complete notification when file export is complete.
➡ Export Complete	The exported file so you can save it to your computer.	Yes	If you complete the Data Export process multiple times, there will be a link to the resulting file for each one.
See Flag Activation on page 144.			
◉ Flag Configuration waiting	No link.	No	Flag Configuration is waiting to start. The server checks every 20 seconds for Flag Configuration requests.
◉ Flag Configuration running	No link.	No	It shows the processing status and is replaced by the Flag Configuration complete notification when Flag Configuration is complete.
◉ Flag Configuration Complete	A page showing a summary of all the flag configurations run.	Yes	If you complete the Flag Configuration process multiple times, there will be a link to the resulting file for each one.
Synchronizing Users Complete	No link.	Yes	See Synchronizing Users on page 64.
Study File has been staged (*StudyName* v*N*)	The study version properties for the staged file.	Yes	See Staging a Fileon page 95.
Study File has been staged (*StudyName* v*N*). See compare report for details.	The study version properties for the staged file.	Yes	Compare Report action is available on the Actions palette.
Publishing of Study file (*StudyName* v*N*) - complete.	The Study Version Management page.	Yes	Note Publishing.
Migration of Site for Study file (*StudyName* v*N*) – complete. *N* of *N* patients migrated successfully.	The exported file so you can save it to your computer.	Yes	Compare Report action is available on the Actions palette.

Checked out CRFs

Since you can have more than one CRF open at a time—that is, you have checked out a CRF, but have not checked it back in—the Inbox shows all the CRFs you currently have checked out, as well as CRFs that are checked out by other users that have access to your site.

The "Checked-out" message (🖼) lists the patient ID/event/form name of the CRF that is checked out, and links to that CRF. It also lists the site the CRF belongs to and the date and time the CRF was checked out. For checked out CRFs messages, check boxes are disabled.

To view the CRF associated with a message:

1   Click the **Inbox** tab. The Inbox appears.

2   Click the Work Queue folder. The folder opens.

3   Click the subject line of the message for the CRF you want to open. The CRF appears.

To check in a CRF (or cancel check out):

1   Click the subject line of a message to open the CRF.

     The CRF appears.

2   Do one of the following:

- Click **Save**.

- Click **Cancel**.

—OR—

1   Click the check box for each CRF you want to check in.

2   Click **Undo Checkout**. The CRF is immediately checked back in and is removed from your Work Queue folder.

Routing CRFs or DCFs

Routing is a way to send data within DataLabs. DataLabs provides the ability to route a CRF or DCF to another active user within the site. The content of a routing message will be similar to the general message, with the following differences:

- The message contains a hyperlink to the appropriate item

- Header information which includes:

- CRF: Patient, Event, CRF, Study, Protocol, Investigator

- DCF: Patient, Patient Status, DCF Status, DCF ID, Reference, Created by

- If there is a DCF or CRF that is routed to a user who does not have rights to view the routed item, the link will be disabled and a rule tip will indicate the restriction to the user.

For more information on additional steps please see Chapter 7: Entering Patient Data (CRFs) on page 221 and Chapter 8: DCF Management on page 290 for additional steps on the subject.

Inbox Preferences

To access Inbox preferences:

In the Administration drop-down menu, select **User Preferences**.

The Inbox preferences include the following options:

Email Address: Enter an external email address to which DataLabs can forward Inbox messages to.

Email Forwarding: Specify an email address to which DataLabs can forward Inbox messages to.

Inclusion/Exclusion from messaging directory: Choose if you want to be added to the message recipient list. If you choose to Exclude, you will not receive mail messages from other users, but you will still receive system generated messages.

Signature notification: If you need to monitor signature requests for a, checking this box has DataLabs send a notice to your Inbox whenever you are sent a request for signature. For more information on the signature process see Chapter 9: The Signature Process on page 306.

Query notification: Allows the user to receive a mail message in their DataLabs Inbox whenever a Notification Query fires true for a site they have access to. Default is set as unchecked. For more information see Query Inbox Messages on page 138.

Inbox preferences are accessed on the User Preferences screen.

Chapter 12: Exporting Data

Overview

DataLabs enables you to export system data in two ways:

■   Quick Export, which exports *only patient data*, so that it can be viewed and analyzed by externals tools.

■   Archive Export, which exports DataLabs site & patient data so that it can be published at the end of a study as PDF files that are compliant with the FDA's regulatory standards and can be used for investigator review.

Both methods export the data as CDISC ODM 1.2.1-compatible XML.

To access the export screen:

■   From the Administration menu, click **Export**.

The Export screen appears.
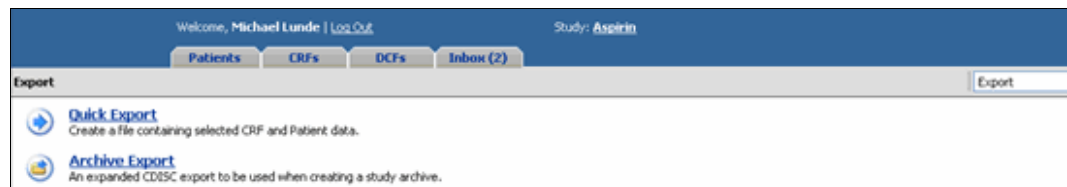
Note: Select how much data you wish to export wisely. The more data you choose to export, the more time it will take, the more demand will be placed on the server, and the larger the resulting file will be.

Note: An exported file is saved in the study database on the server until it is deleted from the Inbox. Therefore, exports should be saved to a local computer (and then manually deleted from the Inbox).

Tip: You can limit which users have the ability to export by setting their group permissions. For more information about editing permissions see Editing the Permissions for a Group on page 60.

Export Prerequisites

You can only perform an export if there is at least one study published and you have access to one or more sites.

If you try and do an export and a study has not been published, then the following will apply:

■ Message alert will be displayed, "In order to perform an export, a study must be published," when the mouse hovers over the Quick Export or Archive Export option.
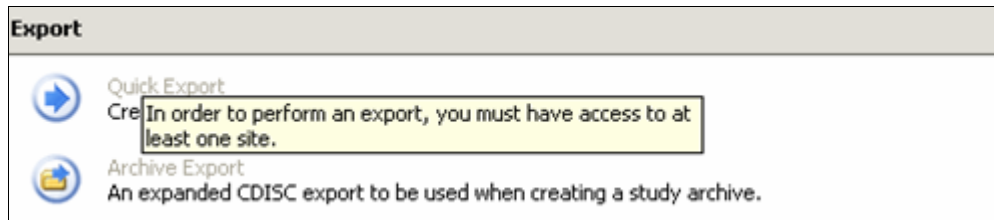
■ Export menu shall remain enabled but you will not be able to access the Quick or Archive Export functions.

If a study has been published but you do not have access to at least one site, then the following will apply:

■ Message alert will be displayed, "In order to perform an export, you must have access to at least one site," when the mouse hovers over the Quick Export or Archive Export options.
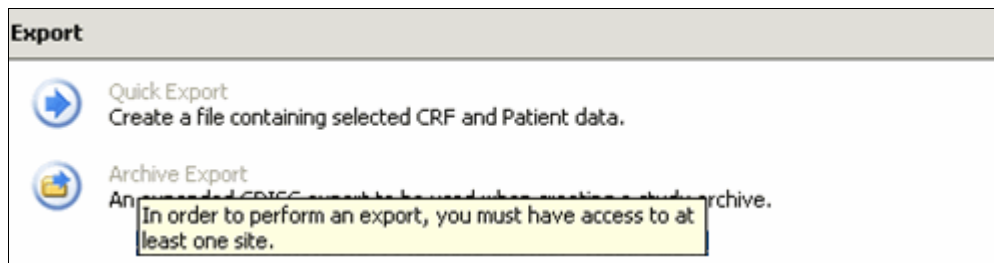
■ Export menu shall remain enabled but you will not be able to access the Quick or Archive Export functions.

Quick Export

Quick Export exports DataLabs data as a CDISC ODM 1.2.1-compatible XML file so that it can be viewed and analyzed by external tools. The exported data is essentially a "snapshot" of DataLabs study data (see What Is Exported on page 353). You can export data for all sites and patients or limit it to just a subset—you are limited to those sites that are assigned to you. DataLabs exports a single XML file that is packaged into a ZIP file.

To export data:

1 From the Export menu, click **Quick Export**.

Note: The Quick Export link is disabled until a study is published, a site is added and a user is associated to a site.

The Quick Export page appears.

The Quick Export page gives you the following export options.

Site: Select which site to export from the list of sites you have access to. You can also select *all* sites you have access to, but not a combination of multiple sites.

Patient: After selecting a site, you can select a specific patient from that site or all patients from that site to export. You must select a site before this field becomes available.

Event: Allows you to select which events to export. If you've selected a site or patient, you are limited to events available to that site or patient.

Example: For example, you may want to analyze all the Screening event data for patients at the 5151-Santa Monica site.

Forms: Selects which CRFs to export. If you've selected a site, patient or event, you are limited to forms available to that site, patient or event.

Example: For example, you may want to analyze all Vital Sign form data for patient 1973-KAM.

Format: Selects the file format, currently only CDISC ODM 1.2.1 (*.xml).

2   Select your export options.

3   Click **Export**.

The Quick Export dialog box appears, telling you a link to the exported file will appear in your Inbox.
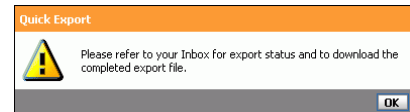
4   Click **OK**.

5   Click the **Inbox** tab.

6   Click **Jobs** from the action palette.

The Inbox displays a "waiting" message. The length of time it takes for the export to complete depends on the number of CRFs you are exporting.

7   When the export is complete, it appears in your Inbox as a link to the file.

To save a Quick Export file:

1   Click the Export (Quick): #[N] – complete (100%). Download file link.

The File Download dialog box appears. The exported XML file has been compressed into a ZIP file.

2   Click the **Save** button.

The Save As dialog box appears.

3 Choose the folder you want to save the ZIP file to, and click **Save**.

To delete the Quick Export file from the server:

1 From the Inbox, click the check box for the exported file.

2 Click **Delete**.

Exported Data Inbox Messages

When you have exported data using the data export, there are three inbox messages used to show the progress of the export:

Export (Quick): #[N] - waiting

Export (Quick): #[N] - running ([P]%)

Export (Quick): #[N] - complete. Download file.

(Where #[N] is the number of sequential export runs since the study was loaded.)

The export messages ( ) lists the export number. Once the export is complete, the inbox message serves as a link to the ZIP file that was exported so that you can download it. The check box enables you to select the exported file and delete it from the server.

What Is Exported

The Quick Export will create an XML document containing any site, patient, event and form data which you selected in the export criteria unless specifically filtered out.

- All site data that you have access to.

  Note: If a site has been queued for migration, the data for that site will not be exported.

- All patient data associated to those sites.

- All published event data for the selected patient(s).

- All published form data for those events regardless of their submittal status.

- If a form has been reset, only the data that is currently submitted for the form appears in the XML document.

- If you do not have permission to view restricted access forms, the data associated with restricted access forms will not be exported.

- All filtering options are independent except the "patient" field, which will be populated based on the selected site and the associated patient(s) in that site. The patient drop down will be disabled until a site is selected.

  Note: It is possible that exports can occur with no patient data.

Filtering Examples

1 Each of the four filters default if All is selected.

All of the information listed will appear in the XML document.

2 You select a specific event and form from the filters; and site and patient are left at All.

The only patient data that is exported will be instances of the form within the specified event. The exported file will include all sites and patient level information, but only the specified form data will be exported.

3 You select a specific event and the remaining three filters are defaulted to All.

All site and patient level data is included; and only the form data related to the selected event, will appear in the XML document.

4 You select a specific form and the remaining filters are defaulted to All.

Then all site, patient, and event level data will appear in the XML document even if they do not contain the selected form. The only form level data which will be exported will be for the selected form.

Note: Any forms in Paper Data Entry will be excluded from export until the form is submitted.

The following summarizes what is and is not included in the exported file:

Included:

Study ID and Protocol ID

Site ID and Patient ID

Form Data

Excluded:

Event Dates

Changes History

Comments, DCFs

Patient Workflow Status

Signatures & Flags

Freeze/Lock Statuses

For a detailed list of which CDISC elements are included (and which are not), see Export File Elements on page 364.

Archive Export

Archive Export exports DataLabs data so that it can be published at the end of a study as PDF files that are compliant with the FDA's regulatory standards and can be used for investigator review, inspection and archival purposes.

Archive Export creates a "transactional" export of the DataLabs study data, selecting specific sites, which include patient data, exporting a structured set of XML files (extended CDISC ODM 1.2.1-compatible) and collecting them into a single ZIP file.

You can then load this ZIP file into a standalone Study Archive Utility to convert the XML files into a set of PDFs.

To export data:

1   Select **Export** from the dropdown in the upper right.

2   The Export Screen appears.
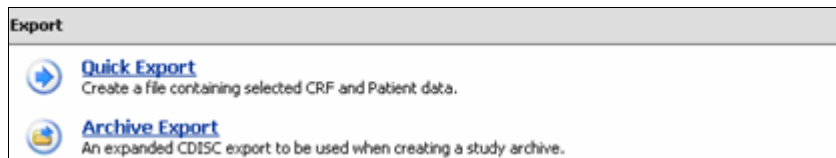
3   Click **Archive Export**.

4   The Archive Export screen appears.
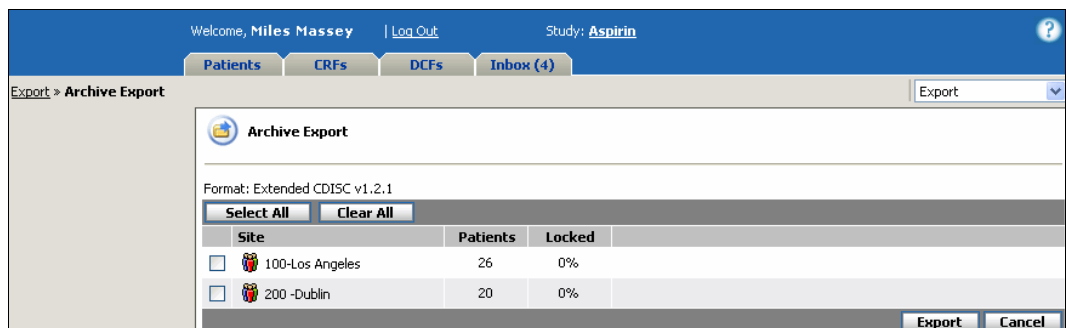
The Archive Export screen gives you the following export option.

Sites: Select which site to export from the list of sites you have access to.

5   Select the sites you wish to export.

6   Click **Export**.

The Archive Export dialog box appears telling you a link to the exported file will appear in your Inbox.

7 Click **OK**.

8 Click the Inbox tab and select **Jobs**.
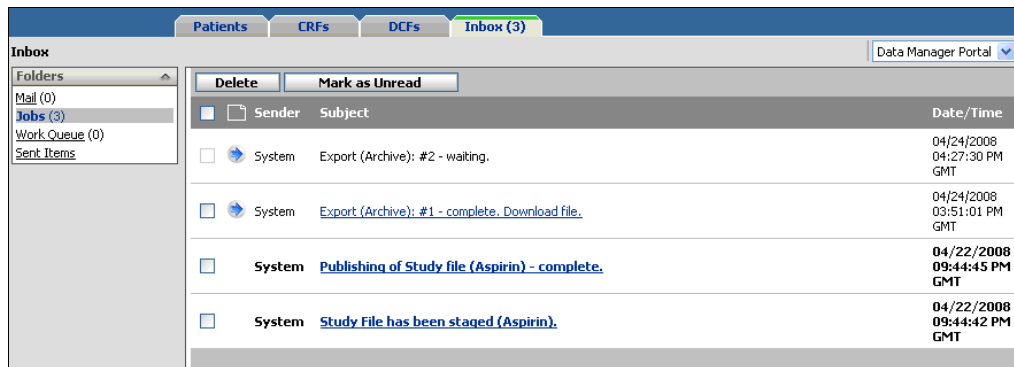
The Inbox displays a "running" message. The length of time it takes for the export to complete depends on the number of sites and CRFs you are exporting.

The following are the stages shown in the inbox which indicate the progress of the export request.

Waiting – The export request is in the queue, but the process has not begun yet.

Running – The export process is occurring.

The status of an export during this stage shows you:

- Percentage complete between 0-99%; which is the number of patients exported divided by the total number of patients to be exported.

- Site ID for site currently being processed

- Patient ID for patient currently being processed

- Number of patients exported out of the total number of patients to be exported for the site.

- Exception – An error occurred and the export request could not be performed.

- Complete – the export process reached 100% and finished successfully.

When the export is complete, it appears in your Inbox as a link to the file.

What is in the XML Document?

The Archive Export document contains both site and patient data for the selected sites, which will contain:

CRF data

- Data submitted to a CRF

- Data which was submitted on an item level (not including cleared items or are initial default values)

- Derived field data

- Encoded field data

- Read-only field data

- Patient Workflow data

DCF data

- The change history of all submitted data (excluding PDE forms)

- All published event data

- All published forms, even if a form does not have a submitted status

Note: If a form has been reset, the XML document contains a complete history of all data that was saved or submitted for the form, both before and after the reset occurred.

Note: If a site has been queued for migration, the data for that site will not be exported.

Note: If you do not have permission to view restricted access forms, the data associated with restricted access forms will not be exported.

To save an Archive Export file:

1 Click the <u>Export (Archive): #[N] – complete. Download file.</u> link. The File Download dialog box appears. The exported XML files have been compressed into a ZIP file.

2 Click **Save**. The Save As dialog box appears.

3 Choose the folder you want to save the ZIP file to, and click **Save**.

From here, you can use the Study Archive Utility to publish the data as PDF files that are compliant with the FDA's standards. See the Study Archive Utility Manual that comes with the product for more details on the data that is exported and how it is organized.

Note: When you open the zipped XML file in the Study Archive Utility, only valid Archive Export ZIP files are listed. For a ZIP file to be valid, it must:

- Free of tampering (validated by a CheckSum)

- Contain a valid electronic signature

To be safe, you should not edit the XML or otherwise tamper with it.

To delete the Archive Export file from the server:

1 From the Inbox, click the check box for the exported file.

2 Click **Delete**.

Appendices

Frequently Asked Questions

Study Administration

Why can't I change my user account status from "Active" to "Inactive" in User Management?

You cannot inactivate the user account you are logged in as. (If you were able to, you would lock yourself out of DataLabs and have no way to log back in.)

CRFs

How come when I go to a form it is read only? Why do I have to check it out first?

DataLabs has a methodology of Check In and Check Out. If you are a Site, you probably want to just go to forms and be able to add/edit them. For that type of account, you would have the Auto Checkout feature turned on so that you don't have to check out the form, it is automatically done for you. If you are a reviewer and you just want to flip through forms, you would have Auto Checkout turned off. You can turn this feature on and off by going to the User Preferences, located in the upper right hand side of the screen under the drop down box. Changing the Auto Checkout from no to yes and clicking Save will make it so forms are checked out to you automatically.

How come I can only edit one visit? Where are the other forms?

The DataLabs system allows you to define which visits and forms appear based on the patient's status. For example, for a screened patient, the study only has the Visit 1 forms. Once enrolled, Visit 2 shows up. Forms that are not attached to a specific visit like Con Meds would be located under Common.

How can I get help in DataLabs?

If you click the question mark in the yellow circle at the top right of the screen, it will take you to a menu of topics for help. These help links will launch a flash-based movie that demonstrates the section of the software that you are asking about. There are also manuals in PDF format.

Why does a new form have a Change History already defined for it?

If a patient's status was changed, DataLabs "un-publishes" any events and CRFs associated with the previous status (but saves the information in the Change History). When the patient is re-enrolled, those events and CRFs are re-published and their Change History is published with them. (See Overriding a Patient's Status on page 173.)

Troubleshooting

This section contains solutions and explanations of various situations and issues that you may encounter while using DataLabs.

Printing Runtime Error

Symptom

From the Change History dialog box, you click Print and the following warning appears.
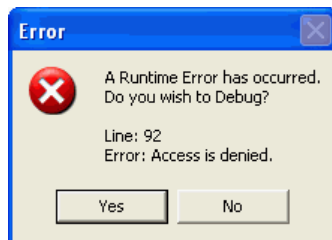

```
A Runtime Error has occurred.
Do you wish to debug?

Line:92
Error: Access is denied.
```

Problem

Often this problem is caused by a "bad" browser plug-in or "spyware."

To test whether this is the case:

1   From the **Tools** menu on your browser, click **Internet Options**.

2   Click the **Advanced** tab.

3   Uncheck **Enable third party browser extensions (requires restart)** and click **OK**.

4   Restart your computer.

5   Log in to DataLabs and try to print the Change History.

   If you are able to print, then you have a "bad" browser plug-in or "spyware" that is interfering with printing.

6   Go back to **Tools** > **Internet Options** > **Advanced**, check **Enable third party browser extensions (requires restart)** and click **OK**.

You will need to remove or disable the culprit plug-in, browser helper object (BHO), "spyware" or "adware."

Solution

The print error can be caused by any number of plug-ins and third party extension. This section will highlight some of the ways you can address the most common culprits.

Caution: We list the following tools as examples of what you can use to rid your browser of spyware and "unfriendly" helper applications. If you install and use any of these applications, **you do so at your own risk**. Review the software, the applications that they delete, and check with your system administrator before implementing any of them on your computer.

To identify the offending plug-in:

1 Download BHO Demon (http://www.spywareinfo.com/downloads/bhod/).

2 Disable each plug-in in turn, and see whether you can pinpoint the culprit that way.

3 To disable a plug-in, follow the BHO Demon directions.

To remove malicious or bothersome plug-ins, browser helper objects (BHOs), or "spyware" or "adware" applications, use one of the following tools:

■   SpyBot Search & Destroy (http://www.safer-networking.org/index.php?lang=en) — utility that removes spyware from your computer.

■   Lavasoft Ad-aware (http://www.lavasoftusa.com/) — removes adware, privacy-invading cookies, and the like.

■   McAfee AntiSpyware (http://us.mcafee.com/root/package.asp?pkgid=182&cid=9904) — eliminates malicious applications.

■   SpywareInfo (http://www.spywareinfo.com/bhos/) —a list of known "browser helper objects."

To remove Divago Surfairy:

■   See http://support.microsoft.com/?kbid=811165.

File Download Dialog Box

If you happen to uncheck the **Always ask before opening this type of file** check box on the File Download dialog box, Internet Explorer will automatically open the file you are downloading in IE. This means that if you try to download the XML for a study version, the entire XML will open in IE. To avoid this, make sure **Always ask before opening this type of file** remains checked.
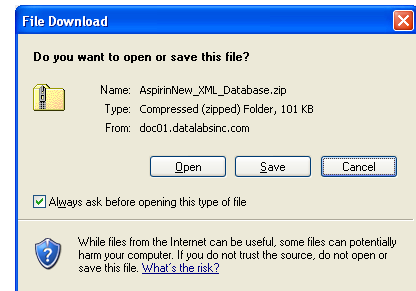
Note: If the check box has been deselected on your machine, and IE attempts to open rather than save the file, please check with your IT department to enable this dialog box.

Export File Elements

The following table summarizes CDSIC 1.2.1 elements are included in the export file:

Included		**Excluded**	
3.1	ODM	5.1	Admin Data:
3.2	Study	5.2	User
3.3	GlobalVariables	5.23	Location
3.4	StudyName	5.25	SignatureDef
3.5	StudyDescription	7	Clinical Data:
3.6	ProtocolName	7.3	EventData – 7.18 Audit Record
3.10	TranslatedText	7.4	FormData – 7.18 Audit Record, 7.13 Signature, and 7.8 Annotation
4.1	MetaDataVersion	7.7	ItemData – 7.18 Audit Record and 7.8 Annotation
4.3	Protocol		
4.4	StudyEventRef		
4.7	FormDef		
4.8	ItemGroupRef		
4.11	ItemDef		
4.18	CodeListRef		
4.21	CodeList		
4.22	CodeListItem		
4.23	Decode		
7.1	ClinicalData		
7.2	SubjectData		
7.4	FormData		
7.6	ItemGroupData		
7.7	ItemData		
7.22	SiteRef		

See http://www.cdisc.org/models/odm/v1.2.1/index.html, for more information on the CDISC 1.2.1 ODM.

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