Oracle® Clinical Remote Data Capture Onsite

User's Guide

Release 5.2

E86392-01

August 2017

ORACLE®

Oracle Clinical Remote Data Capture Onsite User's Guide, Release 5.2

E86392-01

Contents

4 Managing Discrepancies

5 Reviewing Investigator Comments

6 Reviewing Special Listings

7 Performing Custom Reviews

8 Verifying CRFs

9 Approving CRFs

10   Using Search

11   Viewing Summary Reports

12   Generating CRF Reports

13 Using Source Data Verification

A Description of the CRF Icons

B Patient Auto-Selection in Partial Source Data Verification

Index

Preface

This guide describes how to use the Oracle Clinical Remote Data Capture Onsite (RDC Onsite) application. It describes the tasks that clinical research associates, site monitors, investigators, site coordinators, and data managers perform daily.

This preface contains the following topics:

- Audience
- Documentation Accessibility
- Finding Information and Patches on My Oracle Support
- Finding Oracle Clinical Documentation
- Conventions

Audience

This guide is for Oracle Clinical RDC Onsite users. It assumes a basic understanding of Microsoft Windows terminology and usage, as well as a general understanding of the site's role in the clinical trials processes. Knowledge of Oracle Clinical functionality or experience with RDC Onsite is helpful, but not required to successfully use this guide.

System administrators should use this guide in conjunction with the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*. Study and CRF designers should use this guide in conjunction with *Oracle Clinical Creating a Study*.

Documentation Accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at
http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through My Oracle Support. For information, visit
http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info or visit
http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

Finding Information and Patches on My Oracle Support

Your source for the latest information about Oracle Clinical Remote Data Capture Onsite is Oracle Support's self-service Web site My Oracle Support (formerly MetaLink).

Before you install and use Oracle Clinical Remote Data Capture Onsite, always visit the My Oracle Support Web site for the latest information, including alerts, White Papers, installation verification (smoke) tests, bulletins, and patches.

Creating a My Oracle Support Account

You must register at My Oracle Support to obtain a user name and password account before you can enter the Web site.

To register for My Oracle Support:

1. Open a Web browser to https://support.oracle.com.

2. Click the **Register** link to create a My Oracle Support account. The registration page opens.

3. Follow the instructions on the registration page.

Signing In to My Oracle Support

To sign in to My Oracle Support:

1. Open a Web browser to https://support.oracle.com.

2. Click **Sign In.**

3. Enter your user name and password.

4. Click **Go** to open the My Oracle Support home page.

Finding Information on My Oracle Support

There are many ways to find information on My Oracle Support.

Searching by Article ID

The fastest way to search for information, including alerts, White Papers, installation verification (smoke) tests, and bulletins is by the article ID number, if you know it.

To search by article ID:

1. Sign in to My Oracle Support at https://support.oracle.com.

2. Locate the Search box in the upper right corner of the My Oracle Support page.

3. Click the sources icon to the left of the search box, and then select **Article ID** from the list.

4. Enter the article ID number in the text box.

5. Click the magnifying glass icon to the right of the search box (or press the Enter key) to execute your search.

   The Knowledge page displays the results of your search. If the article is found, click the link to view the abstract, text, attachments, and related products.

Searching by Product and Topic

You can use the following My Oracle Support tools to browse and search the knowledge base:

- Product Focus — On the Knowledge page under Select Product, type part of the product name and the system immediately filters the product list by the letters you have typed. (You do not need to type "Oracle.") Select the product you want from the filtered list and then use other search or browse tools to find the information you need.

- Advanced Search — You can specify one or more search criteria, such as source, exact phrase, and related product, to find information. This option is available from the **Advanced** link on almost all pages.

Finding Patches on My Oracle Support

Be sure to check My Oracle Support for the latest patches, if any, for your product. You can search for patches by patch ID or number, or by product or family.

To locate and download a patch:

1. Sign in to My Oracle Support at `https://support.oracle.com`.

2. Click the **Patches & Updates** tab. The Patches & Updates page opens and displays the Patch Search region. You have the following options:

   - In the **Patch ID or Number** field, enter the number of the patch you want. (This number is the same as the primary bug number fixed by the patch.) This option is useful if you already know the patch number.

   - To find a patch by product name, release, and platform, click the **Product or Family** link to enter one or more search criteria.

3. Click **Search** to execute your query. The Patch Search Results page opens.

4. Click the patch ID number. The system displays details about the patch. In addition, you can view the Read Me file before downloading the patch.

5. Click **Download.** Follow the instructions on the screen to download, save, and install the patch files.

Finding Oracle Clinical Documentation

The latest product documentation for Oracle Clinical and Oracle Clinical Remote Data Capture Onsite is available on the Oracle Help Center at `https://docs.oracle.com/health-sciences/oc-rdc-52/index.html`.

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
`monospace`	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

1

Getting Started with Remote Data Capture Onsite

Oracle Clinical Remote Data Capture Onsite (RDC Onsite) is a Web application that works with studies that are defined and designed using Oracle Clinical. You can use RDC Onsite to collect, review, and report clinical data collected during a patient visit in a clinical study.

This chapter includes the following topics:

- About Electronic Data Capture
- Terminology to Know and Understand
- About RDC Onsite User Roles
- Starting the RDC Onsite Application
- Starting at the Home Page
- Changing Your RDC Onsite Login Password
- Setting Your Preferences for Lists and Dates
- Getting Help and Assistance
- Logging Out

About Electronic Data Capture

With electronic data capture, you enter research information from source documents into the computer, and save it to a database located at the host company. Electronic data capture facilitates real-time processes, which means that as site users enter and update data, the project team and sponsor can access the same data immediately after it has been saved to the database.

Some advantages of using electronic data capture are as follows:

- Real-time access to captured data
- Simultaneous execution of tasks by multiple user groups
- Accurate tracking of patient enrollment
- High-quality data ensured by electronic edit checks
- Remote review and monitoring

Terminology to Know and Understand

RDC Onsite uses many terms that are common in the clinical studies and clinical trials industry. However, some of the terms have a different meaning from the standard. It is important to understand the differences. This section clarifies the use of certain terms in the RDC Onsite application and documentation.

Case Report Form (CRF)

A **case report form** (CRF) is a paper or electronic record associated with a patient in a clinical study. Its purpose is to facilitate accurate collection of clinical data.

Strictly speaking, a CRF has no data. It is a blank form. Once you enter and save data into the form, it is an *entered* CRF or a document. However, in both the clinical trials industry and in this user guide, CRF can refer to either an empty CRF or an entered CRF. For clarity in a potentially ambiguous context, this user guide uses terms such as *entered CRF*, *document*, and *empty CRF*.

Many companies refer to *eCRFs* when using an electronic data capture system. In this user guide, all CRFs are electronic CRFs, unless the term *paper CRF* is used explicitly.

Page

A **page** refers to an RDC Onsite application page. RDC Onsite, like all applications or sites on the World Wide Web, is made up of pages.

Many companies refer to a CRF as a page. In some cases, this user guide refers to multi-page CRFs and pages within a CRF.

Casebook

A **casebook** refers to the definition of visits expected, and the CRFs expected at each visit. A patient casebook is one instance of the casebook, either with or without data entered. Some companies refer to an entire casebook as a CRF.

A casebook is a collection of phases, patients, visits, and CRFs within a study.

Discrepancy

A **discrepancy** is any data that falls outside of an expected range of values or is otherwise flagged during the edit check process as an error. Some examples of a discrepancy are an invalid date or an age greater than the maximum age for the study.

RDC Onsite checks the data and raises discrepancies (an electronic query) at various times in the data entry process. For example, suppose the age range for the patients in your clinical trial is 20 to 40 years old. If you enter 50 for the age of a patient, RDC Onsite immediately displays a message that the value is out of range. Because RDC Onsite verifies certain data against a set of values, you can immediately correct errors or discrepancies during the data entry process.

About RDC Onsite User Roles

Your **user role**, together with privileges granted to you, determine your activities with RDC Onsite. Your user role defines what you can and cannot do in the RDC Onsite application. For example, your user role may let you enter data, modify data, and resolve discrepancies, but not let you verify or approve the data.

By default, RDC Onsite includes the following pre-defined user roles:

- Site user
- Investigator

- Clinical Research Associate (CRA)

- Data manager

In addition, your sponsor can create and define various other user roles for your instance of RDC Onsite. The following sections describe the default user roles.

Site User

A site user enters patient data into electronic Case Report Forms (CRFs). Site users can start to enter data after the database development is complete, and the study is underway. Entering data and addressing system-generated discrepancies take place simultaneously. Persons with this user role include study coordinators, site coordinators, nurses, research assistants, and data entry personnel.

Investigator

The investigator is the physician responsible for the study at a particular site. The investigator approves CRFs and sometimes also enters data.

After data for a patient is entered and reviewed, and all discrepancies are resolved, the investigator electronically signs the forms, confirming the veracity of the entered data.

Clinical Research Associate (CRA)

As soon as possible after data is saved at the site, the Clinical Research Associate (CRA) reviews study data and addresses issues, performing source data verification either remotely or during a site visit. The CRA, commonly called a clinical monitor or monitor, is an employee of the sponsor or the Clinical Research Organization (CRO).

After data for a patient is entered and reviewed, and all discrepancies are resolved, the CRA has the privileges to electronically verify the forms, confirming that all information has been reviewed.

Data Manager

The data manager is a member of the study team and works at the sponsor site. The data manager uses RDC Onsite to monitor enrollment, track study progress, and review the data for overall quality, patterns, and trending. In addition, the data manager may enter, review, and resolve discrepancies.

Starting the RDC Onsite Application

Because RDC Onsite is a Web application, you do not need to install any additional software onto your computer. You use your Web browser to access the RDC Onsite application over the network.

Requirements for Running the RDC Onsite Application

The requirements to run the RDC Onsite application are as follows:

- A computer with a high-speed internet connection.

- An internet browser. For the full list of supported browsers, see *Oracle Health Sciences Applications Supported Technology Stack* (Doc ID 180430.1).

- The Web address for the RDC Onsite application.

- A unique user name and password for your login.

Your sponsor provides you with the Web address of the RDC Onsite application, your login user name, and your login password. RDC Onsite does not require additional software.

Using Internet Explorer

Checking the Internet Explorer Settings

Prior to running RDC Onsite for the first time, you must:

- Verify that your version of Internet Explorer meets the minimum requirement
- Check that the Internet Explorer connection, security, and privacy settings are configured properly

Although RDC Onsite is compatible with the default Internet Explorer settings, the settings for your computer may have been modified. If you ever have difficulty starting up the RDC Onsite application, always check the Internet Explorer settings.

To check the Internet Explorer settings:

1. Open Internet Explorer.

2. Open the **Help** menu and select **About Internet Explorer** to view the version number. RDC Onsite requires Version 6.0 or later of Internet Explorer.

3. Open the **Tools** menu and select **Internet Options.**

4. Click the **Advanced** tab.

5. Scroll down to the **HTTP 1.1 settings.** Make the following changes:

    a. Select the **Use HTTP 1.1** check box.

    b. Select the **Use HTTP 1.1 through proxy connections** check box.
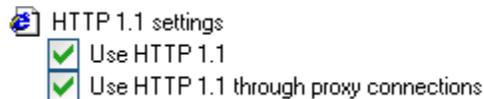
6. Scroll down to the **Security** setting. Make sure the **Do not save encrypted page to disk** setting is not selected:
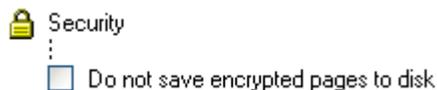
7. Click the **Security** tab. Make the following changes:

    a. Select the Web content zone for which you want to make security settings. You can select **Internet, Local intranet,** or **Trusted sites.**

    b. Click the **Custom Level** button to open the Security Settings window.

    c. Scroll down to **Run ActiveX controls and plug-ins,** and then click **Enable.**
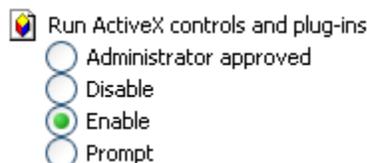
    d. Scroll down to **Scripting**. Under **Active scripting**, click **Enable.**
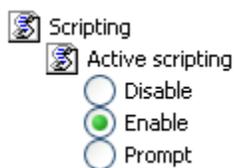
    e. Click **OK** to save your changes and close the window.

8. Click the **Privacy** tab. Make the following changes:

    a. Drag the Settings (cookie-blocking) slider to **Medium High** or lower.

    b. Select the **Block pop-ups** check box.

    c. Click **Settings.**

    d. Click the **Filter Level** field and then select either **Low** or **Medium** from the list.

    e. Click **Close.**

9. Click **OK** to save all your changes and close the Internet Options window.

Modifying Internet Explorer's Compatibility View Settings

RDC Onsite does *not* support the compatibility view available on Internet Explorer versions 8 and above. If the setting is enabled in the browser, when you try to access RDC Onsite, you see the following message: "The current compatibility setting is not supported." There are three places to turn off Compatibility View:

■ In the Internet Explorer **Tools** menu, toggle between turning Compatibility View on and off by clicking Compatibility View.

■ The above setting is overridden by those found in the **Tools** menu under the **Compatibility View Settings**. Uncheck both **Display intranet sites in Compatibility view** and **Display all websites in Compatibility View**.

■ The Compatibility View icon:

Configuring the Cache Settings for the Internet Explorer

You can improve the performance of the RDC Onsite application by properly configuring the amount of disk space that the Internet Explorer uses to cache temporary Internet files. This caching space increases the speed at which RDC Onsite displays pages and CRFs.

The recommended size for the cache depends on the design of the CRFs in your study, your usage patterns, and the number of other Web sites and applications that you frequently access. Check with your sponsor for recommendations on the amount of disk space to specify for the cache.

To set the cache settings for the Internet Explorer:

1. Open Internet Explorer.

2. Open the **Tools** menu and select **Internet Options.**

3. Click the **General** tab. In the Temporary Internet Files section, click the **Settings** button to open the Settings dialog box.

    a. Select **Automatically** for the **Check for newer versions of stored pages** setting.

    b. Set the **amount of disk space** to use for the Temporary Internet Files folder.

    c. Click **OK** to save your changes and close the dialog box.

4. Click the **Advanced** tab.

    a. Scroll to the **Security** section.

    b. Make sure the **Empty Temporary Internet Files folder when browser is closed** check box is not selected:

5. Click **OK** to save all your changes and close the Internet Options window.

Using iPad

Functionality on an iPad is somewhat different from functionality using Internet Explorer, for example:

- When navigating through tables with multiple records, the default number of items displayed is 25, and you can scroll down to view the list up to 25 records. If the number of items to display exceeds this limit, RDC Onsite adds **Next** and **Previous** links so you can browse the entire list.

- Functionality that requires using the Ctrl key, right-mouse clicks, or double-clicks is not available on iPad.

Logging In to RDC Onsite

Before you can log in to RDC Onsite, you must obtain a user name, a password, and a Web address from your sponsor.

As shown in Figure 1–1, the default Login page for RDC Onsite includes the login fields, a **Login** button, and a **Help** link. Your sponsor can customize the login process, so your Login page may look different from the illustration in Figure 1–1.

Figure 1–1 Default Login Page for RDC Onsite
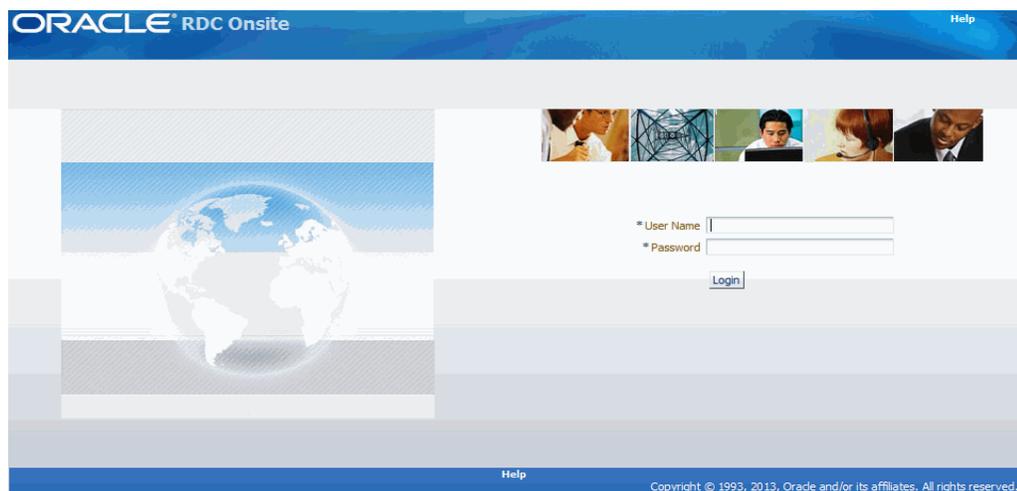
To log in to RDC Onsite:

1. Open Internet Explorer.

2. Click the **Address** field and then type the Web address for RDC Onsite. You must obtain the Web address from your sponsor.

3. Click **Go.**

4. Wait for the RDC Onsite Login page to display.

5. Click the **User Name** field and type your assigned user name.

   - Your user name is not case-sensitive.

   - Your sponsor associates your user name with particular privileges and access rights to RDC Onsite.

6. Click the **Password** field and type your password.

   - Your password is not case-sensitive.

   - To ensure security, RDC Onsite displays asterisks as you type your password.

   - You can modify your password after you log in. See "Changing Your RDC Onsite Login Password" on page 1-12 for more information.

7. Click **Login.** RDC Onsite validates your user name and password, and then displays the Home page.

Shortcut to the Login Page

To start future sessions quickly, add the RDC Onsite Login Web address to your Favorites list in the Internet Explorer. While adding to favorites, please include URL only until Login?. The URL should specifically not contain TMSAMBERID=... This can cause the following error: "Please open browser in new session mode".

Custom Options for the Login Page

Your sponsor can customize the Login page as follows:

- Include a link that lets you request a new password, which is especially helpful if you have forgotten your password. See "Resetting a Forgotten Password" on page 1-7 for more information.

- Include a link that opens another Web page and provides information on how to contact your sponsor or your Help Desk. See "Contacting Your Help Desk" on page 1-18 for more information.

- Place a custom logo at the top of the page.

In addition, your sponsor can add a button or link to an existing Web page that automatically starts the RDC Onsite application in a separate browser window.

Resetting a Forgotten Password

If you forget your password, you cannot log in to RDC Onsite. To request a new password, you can:

- Contact your Help Desk

- Use the **Reset Password** link, if available, on the Login page

> **Note:** Do not confuse resetting a forgotten password with changing a password. If you know your password but want to change it, use the Change Password link instead of the Reset Password link. The Change Password link is available after you successfully log in to RDC Onsite.

To request a new password from the Login page:

1. Start RDC Onsite and wait for the Login page to display.

2. Click the **Reset Password** link.

3. Enter your user name at the prompt.

4. Click **Reset.** RDC Onsite returns to the Login page and displays a message confirming your request for a new password.

   You will receive your new password through e-mail.

   If the **Reset Password** link is not available or if you need additional assistance with your password, contact your Help Desk.

Once you receive your new password and successfully log in to RDC Onsite, you should immediately change the system-assigned password to one that you can easily remember. See "Changing Your RDC Onsite Login Password" on page 1-12 for more information.

Starting at the Home Page

When you log in to RDC Onsite, the application opens the Home page—the starting point for all your activities.

Figure 1–2 uses the Home page to illustrate the major parts of a page in the RDC Onsite application: the page header, the page footer, and the page work space.

- The **page header** is at the top of every page. The header provides information about your current session and global links for tasks such as logging out, changing passwords, and getting help. The options in the page header are always available to you. They do not change as you navigate from page to page.

- The **work space** is where you perform your daily activities. The work space includes tabs for navigating to other pages and tools that let you view, enter, and update patient data. The content of the work space varies depending on the page.

- The **page footer** is at the bottom of every page. The footer includes an About RDC link, the links for page navigation (same as the page tabs), and the same global links found in the page header. The options in the page footer are always available to you. They do not change as you navigate from page to page.

Figure 1–2 Major Parts of a Page in RDC Onsite
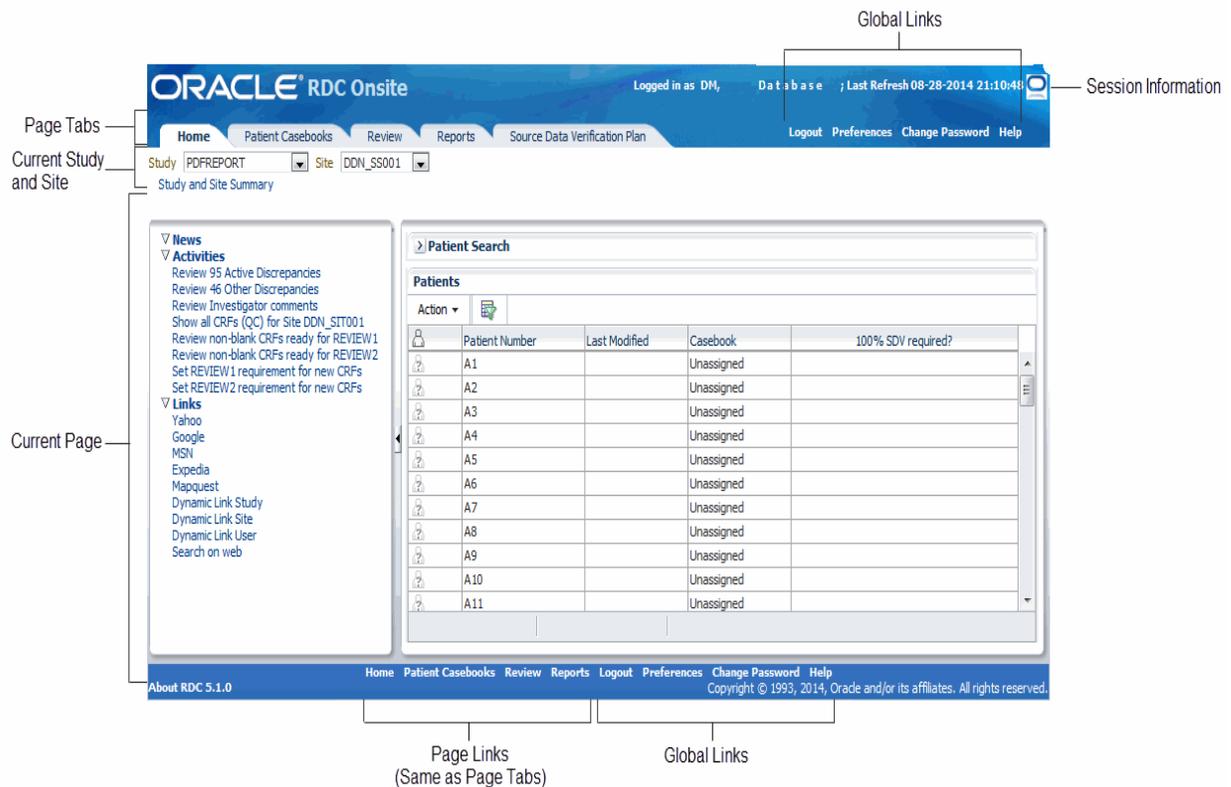
About the Main Pages

You use the page tabs to open and display the following the main pages of the RDC Onsite application:

- Home page

- Patient Casebooks page

- Review pages (includes the Review CRFs page, Review Discrepancies page, Review Investigator Comments page, and Review Special Listings page)

- Reports page

- Source Data Verification Plan page
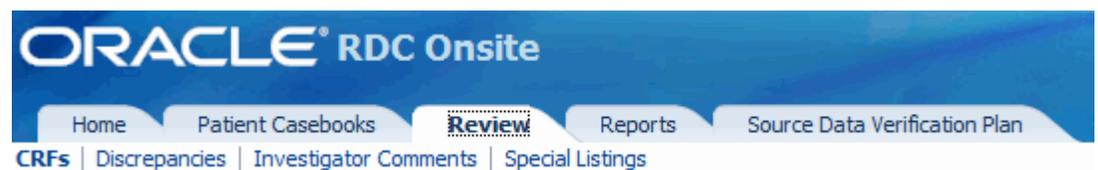
Home Page

When you log in, RDC Onsite always opens to the Home page, which is the starting point for many of your tasks or activities. The Home page lists the patients for the current study and site. You can select one or more patients and then select an action to perform, such as open the Patient Casebooks. You can also search for certain patients, view a Patient Summary Report, or access news alerts from your sponsor.

If there is an active SDV plan and you have the necessary privileges, a column with **100% SDV required?** is displayed containing a check mark for the patients selected for verification against the source data.

Patient Casebooks Pages

The Multi- and Single-Patient Casebooks pages let you view patient data and CRFs laid out in a spreadsheet, or grid pattern, reflecting casebook organization. The Patient Casebooks pages are unique in RDC Onsite for several reasons:

- They are the only pages where you can start data entry for a CRF.

- They are the only pages that provide a casebook-oriented view of a patient's expected and entered CRFs, displayed in a spreadsheet format; other pages display information in a list format.

Review Pages

The Review pages access information about CRFs, discrepancies, investigator comments, and special listings.

- The Review CRFs page lets you review CRFs for verification and approval.

- The Review Discrepancies page lets you correct and manage discrepancies to ensure that the data is complete, accurate, and compliant with the study protocol.

- The Review Investigator Comments page lets you review, add, and update investigator comments to a response in the CRF.

- The Review Special Listings page displays additional information, such as adverse events (AEs) and concomitant medications (ConMeds), for a patient.

  The Review Special Listings page is available in RDC Onsite only if the Oracle Thesaurus Management System (TMS) is installed and integrated with the Oracle Clinical database.

Reports Page

The Reports page lets you generate, view, and print patient data reports and blank casebook reports. You can also monitor reports currently in progress and search for a specific report.

Source Data Verification Plan Page

Depending on your privileges, the Source Data Verification Plan page allows you to view, modify or create an SDV plan that is specific to your site.

The default settings for the SDV plans are set in Oracle Clinical, but you can change them for the site and study with the UPDATE_SDVPLAN privilege.

The links on this page allow you to access the published, draft and obsoleted versions of the Patient Plan and Critical Forms Plan. In addition, if your Patient SDV Plan specifies an auto-select rate and/or an initial patient count, the fields in that plan show the current SDV eligibility and auto-selection statuses of each patient.
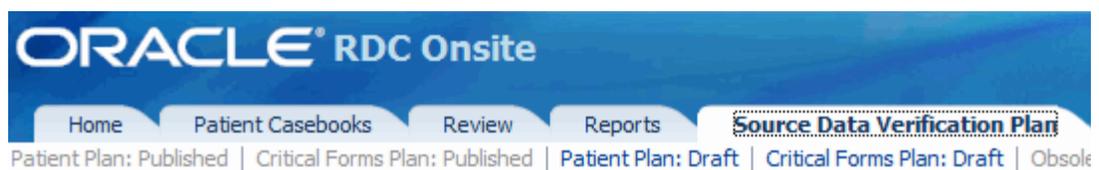
> **Note:** The Source Data Verification Plan page is visible only if you have BROWSE_SDVPLAN, VERIFY, or UPDATE_SDVPLAN privileges. For more information, see "Functional Privileges for RDC Onsite Users" in *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

About the Session Information

RDC Onsite displays valuable information about the current session in the header of every page. A *session* is the time period when you are logged in to RDC Onsite.

RDC Onsite uses the following format to display session information:

Logged in as *user name* (*role*, *database*); Last Refresh *dd-mmm-yyyy hh:mm:ss*

For example:

Logged in as Deb Fowler(DM, Database); Last Refresh 23-May-2013 12:25:22

Session information provides the following details:

- The user name and role of the person currently logged in to RDC Onsite. Your user name authorizes you to log in to the application. Your role defines the type of tasks you can complete and grants you specific privileges. For example, your role might be site user, CRA, investigator, or data manager. Based on your role, you may be able to enter data, process discrepancies, review comments, and print reports.

- The name of the database currently being used for this session. This database stores the information you enter and modify.

- The date and time of the last refresh.

About Last Refresh

RDC Onsite displays the date and time the view was last refreshed. A refresh updates the data on the current page.

By default, RDC Onsite uses the following standard format to display the date (day, month, and year) and time (hours, minutes, and seconds) of the last refresh:

dd-mon-yyyy hh:mm:ss

For example:

31-Dec-2009 11:17:21

If the Preferences link is available, you can change the *date format* of the last refresh. You can display the date in the Standard, US, European, or Swedish format. For more information, see "Setting Your Preferences for Lists and Dates" on page 1-14.

The *time* of a last refresh always corresponds to the time setting currently defined for your PC. Note that the **Display timestamps in local timezone** check box on the Preferences page has no effect on the display of the last refresh time.

When a Session Times Out

A session begins when you successfully log in to RDC Onsite. The session ends either when you log out or when RDC Onsite times out due to inactivity.

By default, RDC Onsite times out after 30 minutes of inactivity. However, your sponsor can change the timeout interval to another value. If you remain inactive in a session for the specified period of time, RDC Onsite automatically times out and logs you out of the application.

> **Caution:** Unsaved work is lost when a session times out. To avoid losing your work when RDC Onsite times out, check the timeout period for your study, and routinely save your work.

The automatic timeout provides added security to unauthorized use of the application. If a timeout occurs, RDC Onsite prompts you to log in again.

About the Global Links

RDC Onsite displays global links on the right side of the page header. Note that for convenient access, RDC Onsite also displays the global links in the page footer. By default, RDC Onsite has four global links.

You can use the global links to:

- Log out of the RDC Onsite application.
- Set your preferences for how RDC Onsite displays data. You can select the format of dates, and select your local time zone.
- Change your login password.
- Open and search the online help.

> **Note:** Your set of global links may be different from the default links. Your sponsor can customize RDC Onsite as follows:
>
> - Make the **Preferences** link unavailable.
> - Rename the **Change Password** link.
> - Add a link that displays contact information for your site, sponsor, or CRO. The default name of this link is **Contact Us**, however, your sponsor can rename the link.

Changing Your RDC Onsite Login Password

When you log in to RDC Onsite for the first time, you should change your system-assigned password immediately. Password security depends on you changing your password periodically and protecting your password from others.

In addition, your sponsor sets an expiration date for your password. Accordingly, RDC Onsite prompts you to change your password from time to time.

> **Note:** To change your password, you must know your current password. If you have forgotten your password, see "Resetting a Forgotten Password" on page 1-7 for details on requesting a new password.

To change your RDC Onsite login password:

1. Click the **Change Password** link in the page header. RDC Onsite opens the Change Password page.
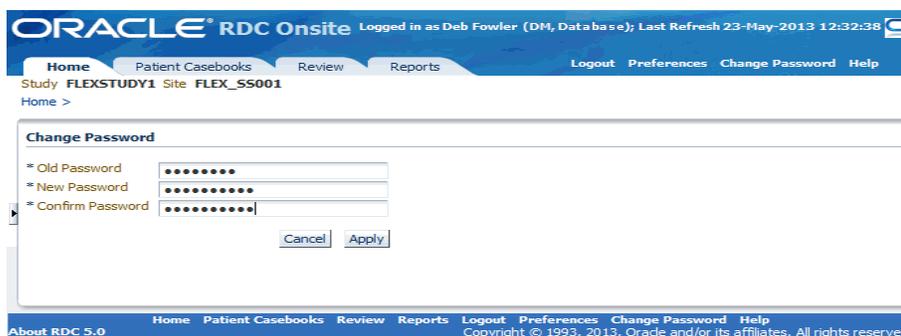
2. Click the **Old Password** field and enter your current password.

3. Click the **New Password** field and enter a new password.

4. Click the **Confirm Password** field and re-enter your new password. Enter passwords carefully. Your new and confirm passwords must match to change your password successfully. Passwords are not case-sensitive.

5. Click **Apply.**

When you change your password, RDC Onsite automatically logs you out.

Custom Options for the Change Password Link

By default, RDC Onsite displays a **Change Password** link in the page header and the page footer. However, your sponsor can:

- Rename the link

- Change the page that displays when you click the link and the process you use to change your password

> **Note:** The previous procedure describes the standard method for changing your password. Your process may be different if your sponsor customized the RDC Onsite application.

Expiration Date for Your RDC Onsite Login Password

Your sponsor sets an expiration date for your login password. Accordingly, RDC Onsite prompts you to change your password when your password has expired.

When your password expires, and you attempt to log in with the expired password, RDC Onsite automatically redirects you to the Reset Expired Password page. In this case, you cannot continue until you successfully change your password. You must then log in with your new password.

Setting Your Preferences for Lists and Dates

RDC Onsite displays different lists of information on the various pages in the application. For example, there are lists of patients, lists of discrepancies, lists of investigator comments, and lists of reports. In addition, RDC Onsite dates information entered into the database and displayed on the screen.

The **Preferences** link in the page header lets you set your preferences for the maximum number of items to display and for the format of dates.

> **Note:**   Your sponsor may have customized RDC Onsite so that the **Preferences** link is not available.

To set your preferences:

1. Click the **Preferences** link in the page header. RDC Onsite opens the Preferences page.

2. Select any of the following preferences:

    ■   **Number of items to display: News, Activities, and Link —** Specifies the maximum number of items to display in the News, the Activities, and the Links sections on the Home page. The default setting is 20 items per section.

        If the number of items to display exceeds the limit, use the scrollbar to browse the entire list.

    ■   **Input Date Format —** Defines the format in which you need to enter dates into a CRF. RDC Onsite uses the specified format to record dates in the database. If you do not enter dates in the correct input format, RDC Onsite displays an error message.

        Select your sponsor's recommended date format. The available input formats are:

        –   dd-mon-yyyy (Standard)

        –   mm-dd-yyyy (US), default setting

        –   dd-mm-yyyy (European)

        –   yyyy-mm-dd (Swedish)

    ■   **Display Date Format —** Defines the format that RDC Onsite uses to display dates. This setting affects only the *display* of dates. It does not affect the format RDC Onsite uses to *record* dates into the database. The available formats are:

        –   Same format that you selected in the **Input Date Format** field

– dd-mon-yyyy (Standard), default setting

■ **Display timestamps in local timezone —** Specifies that RDC Onsite displays time stamps in terms of your local time zone. This setting affects only the *display* of time stamps for events such as when the CRF was last modified, approved, verified, or locked. It does not affect the format RDC Onsite uses to *record* time stamps in the database. RDC Onsite always stores time stamps according to the time zone of the database server.

> **Note:** The **Display timestamps in local timezone** setting does not affect the display of the *last refresh time.* The time of a last refresh always corresponds to the time setting currently defined for your PC.
>
> The **Display Date Format** setting, however, does affect the format of the last refresh *date.*

3. Click **Apply.** RDC Onsite automatically applies and saves your changes. Once you apply your changes, you can click any page tab or link to continue with your work. Your changes remain in effect until you modify your preferences again.

Restoring the Default Values for Preferences

You can click the **Cancel** button on the Preferences page at any time to reset your preferences to the default values. See Table 1–1 for the default values.

Table 1–1   Default Values for Preferences

Preference	Default Value
Number of items to display: News, Activities, and Links	20
Input Date Format	mm-dd-yyyy (US)
Display Date Format	dd-mon-yyyy (Standard)
Display time stamps in local time zone	Check box selected

Getting Help and Assistance

RDC Onsite has many ways for you to get help and assistance while you are working in the application. You can:

■ Use the online HTML-based help system

■ Use the customized help provided by your sponsor for information on the CRFs and data entry fields specific to your study

■ Display tips about icons, buttons, and other controls

■ View release and configuration information for your version of RDC Onsite

■ Contact your Help Desk

Using the Online Help System

RDC Onsite provides complete documentation in an HTML-based help system. The online help includes all the information in the user guide. To locate information in the help system, you can browse from topic to topic, select topics from the table of contents or index, or search for specific words or phrases.

To open the online help system:

1. Click the **Help** link in the page header. The Help window displays the topic relevant to the current page. The icons on the toolbar let you:

   - Open the Navigation pane

   - Display the previous topic

   - Display the next topic

   - Print the current topic

   Note that the Help window does not display the Navigation pane initially.

2. Click the **Show Navigation** icon to open the Navigation pane at the left side of the window. The Navigation pane and the toolbar now include tabs and icons that let you:

   - View and select help topics from the table of contents

   - View and select help topics from the index, if available

   - Search for a specific word or phrase in the online help

   - Add the current topic to your list of favorites

   - Show the location of the current topic in the table of contents

To resize the Navigation pane, drag the vertical border.

> **Tip:** To avoid cluttering your desktop with extra browser windows, close online help windows as soon as you finish reading the topic.

Navigating from Help Topic to Topic

Table 1–2 summarizes the tools that you can use to navigate within the online help.

Table 1–2   Tools for Navigating through the Online Help

Toolbar Icon	Description
	Displays the next topic. To revisit previously viewed topics, right-click in the Help window and then select **Back** or **Forward** from the menu.
	Displays the previous topic. To revisit previously viewed topics, right-click in the Help window and then select **Back** or **Forward** from the menu.
	Opens the Navigation pane on the left side of the Help window. The Navigation pane and toolbar now include additional tabs and icons that let you view and select help topics from the table of contents or index, search for a specific word or phrase in the online help, add a topic to your list of favorites, and show the location of the current topic in the table of contents.
Contents	Displays the table of contents. To expand (or collapse) the list of topics, click a book icon. To display a topic in the Help window, click the link for that topic.
Index	Displays the index for the online help.
Search	Displays the Search field so you can find help topics that match one or more words.
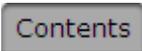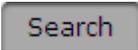
Table 1–2   (Cont.) Tools for Navigating through the Online Help

Toolbar Icon	Description
Favorites	Lets you add the current topic to your list of favorite help topics. These favorite topics are available once you open the online help.
	In addition, you can right-click in the Help window and then select **Add to Favorites** to add the current help page to your list of favorite Web pages. You can then open the page from the Favorites menu in Microsoft Internet Explorer.
	Synchronizes the topic displayed in the Help window with its location in the table of contents.
	Prints the current topic.
	Alternatively, you can right-click in the Help window and then select **Print** from the menu.

Searching for Topics in the Online Help

You can enter search criteria to find all the topics that contain the specified words. When specifying search words, note that:

- The help topic must contain *all* the words you entered to result in a match. For example, if you enter *Casebooks Page*, the search finds all topics that have the word *Casebooks* AND the word *Page* in the title or body content.

- The search is not case-sensitive. For example, if you enter *onsite*, the search finds any topic that has *onsite*, *Onsite*, *ONSITE*, or *OnSite*.

- The search does not match other forms of the words you entered. For example, the word *navigate* does not match *navigates*, *navigating*, or *navigator*. Conversely, the word *navigates* does not match *navigate*.

To find help topics based on search words:

1. Click the **Help** link in the page header.

2. Click the **Show Navigation** icon to open the Navigation pane.

3. Click **Search.**

4. Enter one or more search words in the box.

5. Click **Go.** The Navigation pane lists and ranks the topics, if any, that match your search criteria. Topics with a title that matches all your search words are at the top of the list.

6. Click a title to display that topic in the Help window.

Using Links to Navigate within the Online Help

In addition to the navigation tools in the Help window, you can click the following underlined links to move from topic to topic:

- Click cross-reference links to display referenced topics

- Click the links at the end of a topic to view related subtopics

Viewing CRF and Field Help Customized by Your Sponsor

The CRFs used in a clinical trial vary from study to study. The information requested on each form may be unique to your study. In addition, you may need help with the type of information required in a field in the CRF.

When setting up RDC Onsite, your sponsor has the option to provide help information specific to the CRF as well as to each field in the CRF.

For more information on viewing help for the CRF currently displayed in the Data Entry window, see Chapter 3, "Entering and Updating Patient Data."

Getting Tips about Tools

RDC Onsite has many tools—icons, buttons, and arrows—that you select when using the application.

To identify a tool, position the pointer over the tool, and then pause. A tool tip displays the name or function of the tool. In addition, the tool tip includes the corresponding keyboard shortcut, if one is available. For example:

To get more information about the tool, search the online help.

Viewing Release and Configuration Information about RDC Onsite

To view product specific information about RDC Onsite, click the **About RDC** link in the page footer. RDC Onsite displays information such as:

- The version number
- The application server configuration (release number and date applied)
- The database configuration (package, release number, and date applied)

Contacting Your Help Desk

When configuring the RDC Onsite application, your sponsor can include a custom link for contacting your Help Desk. When you click the link, RDC Onsite opens a custom Web page created by your sponsor. The page displays contact information, such as phone numbers and e-mail addresses, for your Help Desk.

The default name for the link is **Contact Us.** However, your sponsor can change the name of the link during the setup process. The link, if available, appears with the other global links in the page header and footer.

Logging Out

To log out of RDC Onsite, click the **Logout** link in the page header. RDC Onsite ends your session and closes the application. Depending on the manner of logging out, you see one of the following messages on the Logout page:

- You are successfully logged out. Click here to log in again.
- Your session timed out. Click here to log in again.
- Your Password has been changed successfully. Click here to log in with new credentials.

  The word *here* in the above messages is a hyperlink that routes you back to the Login page.

Note: For security reasons, and to prevent tampering, you should always use the **Logout** link to exit from the RDC Onsite application properly. Do not close the window and assume you have logged out.

2

Learning the Common Tools

Oracle Clinical Remote Data Capture Onsite (RDC Onsite) organizes information into several pages, which are oriented towards tasks. These tasks include searching for patients or CRFs, opening patient casebooks, reviewing patient data, and printing reports.

Each page has common tools and controls that you use to complete your tasks. This chapter includes the following topics:

- Selecting Your Current Study and Site
- Using the Patient Selection List on the Home Page
- Sorting the Entries in a List
- Navigating from Page to Page
- Searching for Patients or CRFs
- Working with Customized News, Activities, and Links
- Viewing a Summary Report for a Patient

These pages facilitate review of data and serve as a means to navigate to the Data Entry window to work with a specific Case Report Form (CRF).

The Data Entry window is a separate browser window that displays the CRF you select and open from either the Patient Casebooks page or the Review pages. You can enter data or update a CRF only from within a Data Entry window. For more information on using the Data Entry window, see Chapter 3, "Entering and Updating Patient Data."

Selecting Your Current Study and Site

Before you enter or update patient data in a CRF, you should always check that you are using the correct study and site.

At the top-right of the Home page and the Patient Casebooks page, RDC Onsite displays the name of the study and site that you are currently using. For example:

Study FLEXSTUDY1 ▾ Site FLEX_SS001 ▾

RDC Onsite lists the studies and sites available to you in alphabetical order. Note that:

- When you log in the first time, RDC Onsite accesses and displays the first study and site available to you.

■ When you log in again, RDC Onsite accesses and displays the study you last visited.

Available Studies and Sites

The studies and sites available to you depend on the studies you are participating in, your user role, and the privileges assigned to you by the study sponsor.

Most users work exclusively on a single site in a study. If that is the case for you, the study and site you work on are your only choices. You do not need to select the study and site.

However, if you work on more than one study or more than one site, *always* check that you are using the correct study and site *before* you add or modify any data.

The lists displayed in the Study and Site fields include only valid sites and studies. A valid site must have an investigator and at least one patient assigned. A valid study must have at least one valid site assigned. If the study or site you need is unavailable, contact your Help Desk.

Your Current Study and Site

To select a study and a site:

1. Open the Home page.

   Alternatively, you can go to the Patient Casebooks page, which also has the same fields for selecting your study and site.

2. Click the **Study** field and then select a study from the list. Note that RDC Onsite inserts a --Select Site-- message into the Site field and updates the list of sites based on the study you selected:

3. Click the **Site** field and then select a site from the list. RDC Onsite accesses the selected study and site.

   > **Caution:** Always make sure you select the site when changing studies in order to refresh the screen with current data.

Summary Report of the Current Study and Site

You can review information and metrics about a study and site using the **Study and Site Summary** link located on top on the following pages:

■ Home page

■ Patient Casebooks page

■ Reports page

For example:

See Chapter 11, "Viewing Summary Reports" for more details on the information in the Study and Site Summary Report.

Using the Patient Selection List on the Home Page

When you open the Home page, the Patient Selection List displays all the patients for the current site in the study. The Patient Selection List has two major components:

- The Patient Search pane

- The Patients list

By default, the Patient Search pane is collapsed. You can click the ⟩ button to expand the Patient Search pane. You can then specify criteria to search for and display a subset of patients.
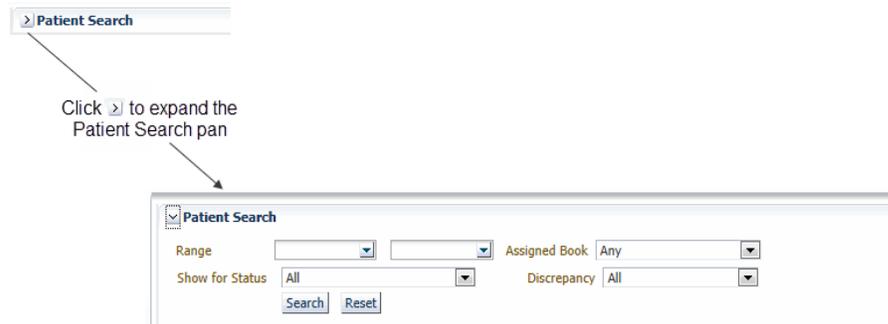
The **Patients** list provides:

- Several ways that you can select one or more patients. See Action.

- Colored icons that indicate the status of the data already entered. See Patient Icon.

- Information about each patient, such as patient number, date when patient data was last modified, and the assigned casebook.

- If configured for your installation, clicking the patient number opens the Single Patient Casebooks page for the patient. See Patient Number.

- Options for the task you want to complete from the **Action** menu once you select one or more patients. See Action.

Action

The **Action** menu lists the actions available to execute on the selected patients. For example, you can:

- Open the casebooks for the selected patients and enter new data

- Review CRFs already entered for the selected patients

- Review discrepancies or investigators comments for the selected patients

- Generate a Patient Data Report for the selected patients

The first two options in the **Action** menu are **Multi-Patient View** and **Single Patient View**. They both open the Patient Casebooks page for the patient or patients selected. **Single Patient View** provides a way to view a single patient's casebook CRFs across visits. See "Single Patient View" on page 3-6, or "Multiple Patient View" on page 3-9 for more information about these pages.

Patient Icon

The icon column displays a patient icon that resembles a human figure. The color of the icon is significant and provides valuable information about the patient data. Table 2–1 defines the meaning of the color of each icon.

Table 2–1   Patient Icons

Icon	Color	Description
	Gray with a question mark	No data has been entered for this patient number. You can use the patient number to enter data for a new patient.
	White	The patient data has no **open** discrepancies.
	Red	The patient data has one or more active discrepancies. An **active** discrepancy requires attention by you or a member of your user group.
	Yellow	The patient data has one or more other discrepancies. An **other** discrepancy requires attention from another user or user group.

Patient Number

The Patient Number column displays the system-assigned unique number for each patient.

If the single patient view of the Patient Casebooks page is available and patient links are active in your installation, the patient number is a link that opens the Single Patient Casebooks page for the patient.

Last Modified

The Last Modified column displays the date of the latest modification to the patient's data. A modification can be any of the following actions:

- Updating data
- Routing or resolving discrepancies
- Verifying, approving, locking, or unlocking a CRF

Casebook

The Casebook column displays the name of the casebook to which the patient is assigned, or displays **Unassigned** if the patient is not assigned to any casebook.

Selecting Patients and CRFs

On many pages in RDC Onsite, you select one or more rows for processing. Depending upon the page, this could be patients or CRFs.

On the Home page, for example, you first select the patients and then you select the action you want to perform. You may want to open casebooks to update CRFs, review discrepancies, review investigator comments, or generate reports.

Your options for selecting patients are as follows:

- To select one patient or CRF, click the respective row.

- To select several patients or CRFs displayed on contiguous rows, hold down the **Shift** key, and click the row for the first and the last row for the patients in the group you want to select.

- To select patients or CRFs that are displayed on non-contiguous rows, hold down the **Ctrl** key, and click the rows that you want to select.

- To select all patients or CRFs displayed on the current page, click one row and then press **Ctrl + A.** Alternatively, you can click on the table header for the patient icon.

> **Note:** You can use combinations of keys including **Ctrl** on all supported devices except for iPad.

Selecting Your Task

Once you select the patients or CRFs that you want to process, you select the task you want to perform.

The **Action** drop-down menu displays a list of actions you can take on the selected patients or CRFs. The options available in the list depend on the page and on your user role.

To select your next task:

1. Select one or more patients that you want to process.

2. Click the **Action** menu in the toolbar and then select the action you want to perform from the list.
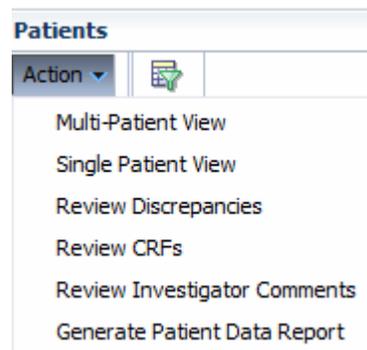
Sorting the Entries in a List

RDC Onsite displays information in rows and columns. You can sort the data by certain columns in ascending or descending order. For example, on the Home page, you can click any of the following column headers to sort the list based on the contents in that column:

- Patient Number

- Last Modified

- Casebook

When you initially open the Home page for a session, RDC Onsite automatically sorts the patient list in alphanumeric order by patient number. For example, A1, A2, A11, A12, A40, G6, J1, J2, J11. Note that the column headers do not indicate the initial sort:

	Patient Number	Last Modified	Casebook

To sort the list in another order, click a column header. An up arrow indicates the list is sorted in ascending order; a down arrow indicates the list is sorted in descending order. You can click the same column heading to toggle between an ascending and a descending sort.

Last Modified ▲▽ — Indicates the list is sorted in ascending order based on the contents of this column.

Last Modified △▼ — Indicates the list is sorted in descending order based on the contents of this column.

Examples of Sorting Columns

Because clinical studies tend to have many patients, sorting a list can help you find information quickly and efficiently. Sorting has many benefits.

Sorting to Find Available Patient Numbers

When you sort the Last Modified column in descending order, RDC Onsite displays the blank entries at the top of the list. A blank entry indicates that no modifications have been made, and therefore, the associated patient number has not yet been used. This sort provides an alternate way for you to locate available patients numbers when you need to enter data for a new patient.

	Patient Number	Last Modified △▼	Casebook
	H10099		BOOK C
	H10100		BOOK C
	H10019		Unassigned
	H10018		Unassigned
	H10095		BOOK C
	H10001	12-22-2010 04:58:...	BOOK A
	H10093	08-01-2007 23:35:...	BOOK C
	H10092	08-01-2007 23:33:...	BOOK C
	H10091	08-01-2007 23:32:...	BOOK C

Sorting to Find Patients with Recently Modified Data

As you enter and modify data for a set of patients, you may also find it useful to sort the patient list by the Last Modified column. The ascending sort places those patients with the oldest date of modification at the top of the list, followed by the most recently modified and the blank entries (no data yet entered so no modifications).

Sorting to Find Patients by Casebook

If your patients all belong to the same casebook, sort on the Casebook column to group patients within the list regardless of patient number or modification date. You can then easily see the status of each patient and determine which CRFs require your attention.

Unique Sort on the Patient Number

Upon initial entry to the Home page or any of the Review pages, RDC Onsite sorts the entries numerically by patient number (ID). However, when you select the Patient Number column header to re-sort the list, RDC Onsite sorts the entries alphabetically.

Navigating from Page to Page

There are many ways to navigate from page to page. The way you choose to navigate depends on your current task and your preference for how to work. In addition, each navigation method has advantages.

To navigate from page to page, you can:

- Click one of the page tabs

- Drill down to the appropriate page

- Click a breadcrumb

- Click an Activities link

Using the Page Tabs

You can use the page tabs to navigate from page to page in RDC Onsite. The tabs provide direct access to a page.

Note that for convenient access, the page footer has four links that correspond to each page tab. You can click either a page tab or a page link to navigate directly to that page.
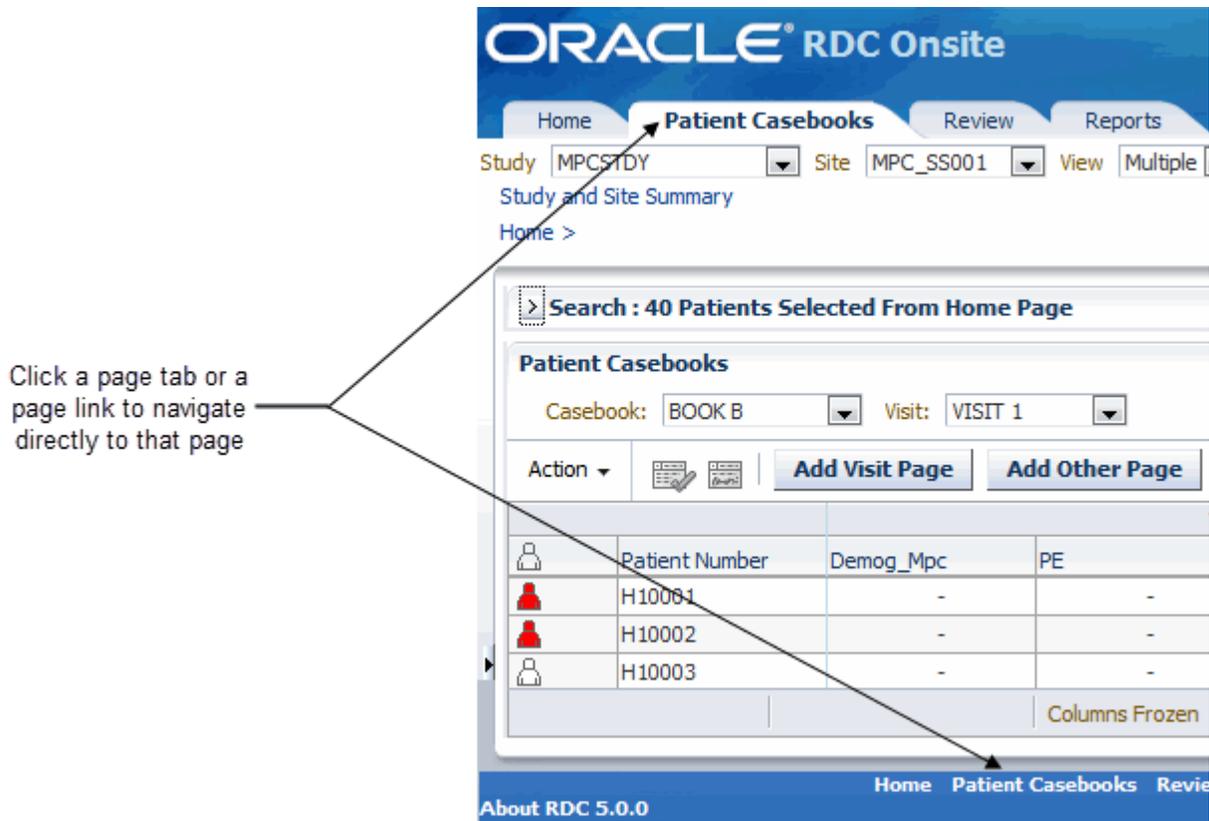
Whenever you navigate directly to a page by clicking a page tab or page link, RDC Onsite always resets the search criteria to the default values and displays the page in its default state. For example:

- Whenever you click the **Home** tab, RDC Onsite opens the Home page, *displays patient data* for the current study and site, resets the search criteria to the default values, and collapses the Search pane.

- When you click the **Patient Casebooks** tab, RDC Onsite opens the Casebooks page, *displays no patient data*, resets the search criteria to the default values, and expands the Search pane. You can change the criteria in the Search pane; you must click **Search** to retrieve and display the patient data.

Returning or navigating directly to a page is useful when you have finished a set of tasks in other parts of the application and are ready to begin another task. In addition, you may want to use tabs to navigate to the Patient Casebooks and Review pages if you either have a preference for using a particular page or make frequent use of searches.

Drilling Down and Using Breadcrumbs

Drilling down is the process of selecting one or more patients or CRFs, and then selecting an action. The action opens another page in the application and displays data only for the patients or CRFs you selected.

You can drill down to navigate:

- From the Home page to the Patient Casebooks page or to any of the Review pages

- From the Patient Casebooks page to any of the Review pages

- From the Review CRFs page to the Review Discrepancies page or the Review Investigator Comments page

Visual Clues of Drilling Down

When you drill down to a page, RDC Onsite displays several visual clues, or indicators, on the page:

- The tabs indicate the current page. In Figure 2–1, Review CRFs is the current page.

- Breadcrumbs, which appear directly below the page tabs, show the path you took to arrive at the current page. **Breadcrumbs** keep track of your location within RDC Onsite and provide a path (or trail) for you to follow back to your starting point.

  The greater than sign (>) separates each part of the path. You click a link to navigate back to another point in the path.

- The title in the Search pane indicates the number of patients or CRFs you selected for the drill-down action.

Figure 2–1   Breadcrumb and Selection Indicator Display
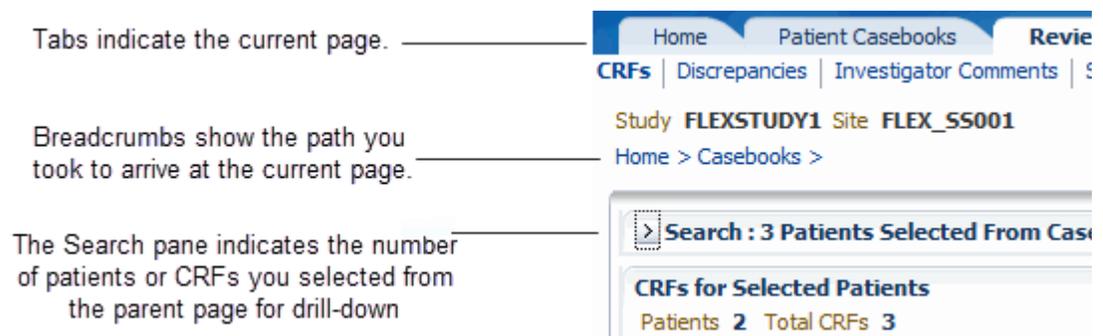
Drill-down Return: Breadcrumb versus Page Tab

To return from a drill-down, you can use the breadcrumbs or the page tabs. However, the functionality is not the same. For example, clicking the Casebooks breadcrumb is not the same as clicking the Patient Casebooks tab. Each method has advantages depending on what you want to do.

To return from a drill-down, you can use either of the following methods:

- **Breadcrumb —** Click a link in the breadcrumb to return to that particular page. In this case, RDC Onsite re-displays the selected page and rolls back to the previous set of search parameters, patients, and CRFs. Note that this is different from what happens when you use the page tabs to return from a drill-down.

- **Page Tabs —** Click the **Home, Patient Casebooks**, or **Review** tab to navigate directly to that page. In this case, RDC Onsite re-displays the selected page in its default state and resets all search criteria to the default values.

  For the Home page, RDC Onsite displays all patients for the site, regardless of the set of patients last displayed. For the Patient Casebooks or Review CRFs page, RDC Onsite does not display any data on the page. You must click **Search** in the Search pane to retrieve data.

Example: Drilling Down to Patient Casebooks and Discrepancies

The following example steps through the process of drilling down from the Home page to the Patient Casebooks page and then to the Discrepancies page.

To drill down:

1. Go to the Home page.

2. Expand the Patient Search pane.

3. Search for all open discrepancies.

   a. Click the **Discrepancy Status** field and then select **Open (Active&Other)** from the list.

   b. Click **Search.**

4. Select five patients from the Patients list.

5. Click the **Action** menu and then select **Multi-Patient View** from the list.

   Note that RDC Onsite:

   - Opens the Patient Casebooks page and displays only the five selected patients in the casebook spreadsheet.

   - Displays a collapsed Search pane. The title bar of the Search pane indicates that 5 patients were selected from the Home page.

   - Displays a **Home >** breadcrumb to indicate your path to this point.

6. Select two red or yellow colored patient icons from the casebook spreadsheet

7. Click the **Action** menu and then select **Review Discrepancies** from the list.

   Note that RDC Onsite:

   - Opens the Review Discrepancies page and lists only the discrepancies for the two selected patients.

   - Displays a collapsed Search pane. The title bar of the Search pane indicates that 2 patients were selected from the Patient Casebooks page.

   - Updates the breadcrumb trail and now displays **Home > Casebooks >** to indicate the path you took to get to this point.

To return from the drill down, you can:

- Click the **Casebooks >** breadcrumb to return to the Patient Casebooks page. In this case, RDC Onsite displays only the five patients you previously selected from the Home page. You can now perform another action with this set of patients.

- Click the **Home >** breadcrumb to return to the Home page. In this case, RDC Onsite displays only those patients that satisfy the results of your current search (only patients with open discrepancies).

- Click a page tab. In this case, RDC Onsite opens the page in its default state and resets the search parameters to the default values for the page. Clicking a page tab is useful when you want to start a new task or work with a new set of patients.

Searching for Patients or CRFs

Every page in RDC Onsite provides a Search pane that helps you locate and focus on the patients, CRFs, discrepancies, and reports that you need for your work.

Although the available search criteria varies on each page, the Search pane provides you with many search options. For example, you can:

- Search for patients by range or by whether any data has been entered
- Search for CRFs that have discrepancies, need verification, or need approval
- Search for CRFs by name or by visit

In addition, you can combine search criteria to narrow your results. For example, you can search for all CRFs that are for Visit 1 *and* have a name of VITALS *and* need to be approved. For more information, see Chapter 10, "Using Search."

Working with Customized News, Activities, and Links

As shown in Figure 2–2, the Home page includes the following three sections that can be customized by your sponsor:

- The News section
- The Activities section
- The Links section

These sections are located on the left side of the Home page.

Figure 2–2   News, Activities, and Links Sections on the Home Page
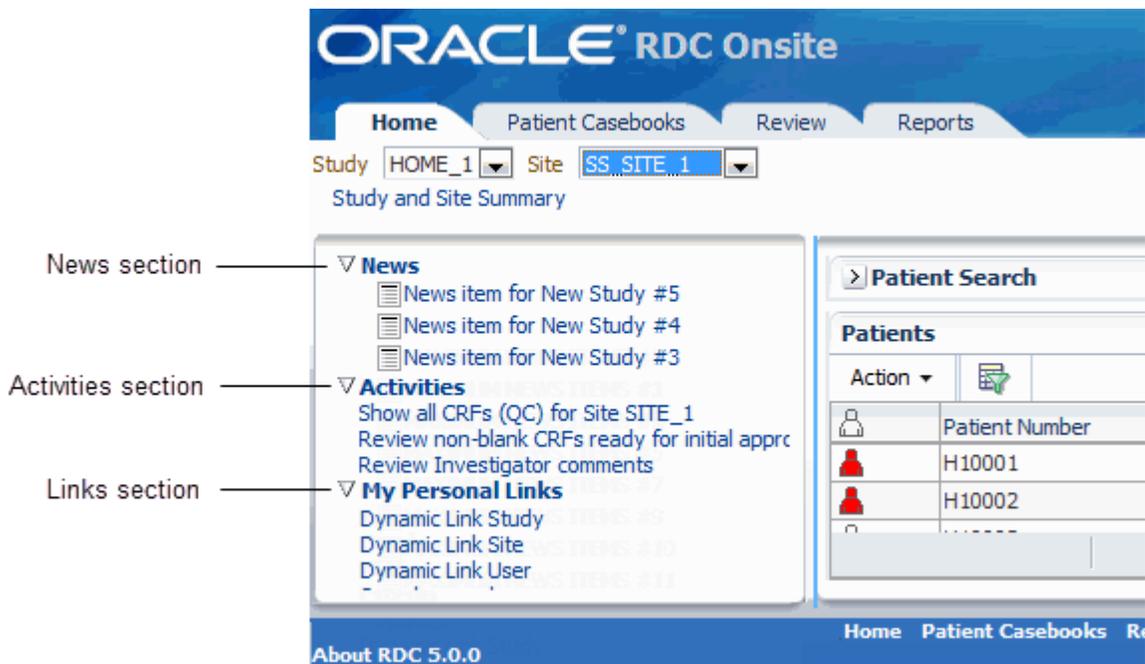
Using the News, Activities, and Links Sections Effectively

To customize your use of the News, Activities, and Links sections, you can:

- Click the **Preferences** link in the page header to define how many items to display in the News, Activities, and Links sections at a time. The default is 20 items per section.

- Click the section title to sort the list in ascending order. Click the title again to sort in descending order.

Reading the Daily News

Your sponsor publishes important information you need to know in the News section on the Home page. See .

Figure 2–3   Reading the Daily News on the Home Page
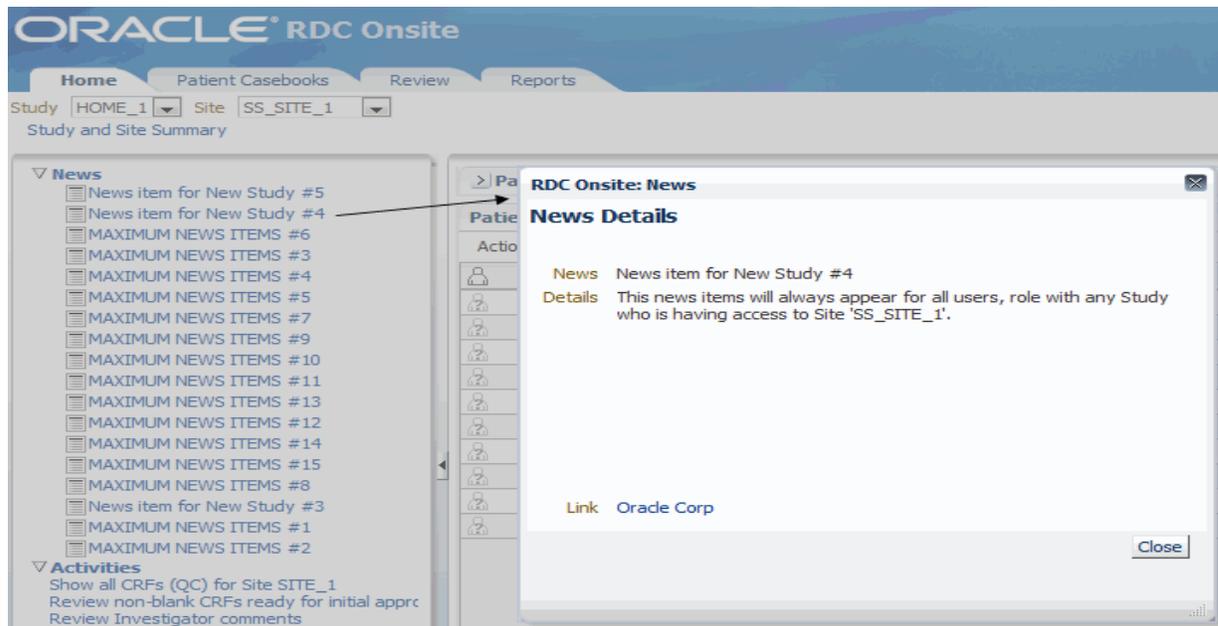
News items can be about any topic, including:

- Notices of group meetings, training classes, or other events

- Changes to the study protocol or procedures

- Progress reports

- Upgrades to the RDC Onsite application

News may be specific to your site and your role. Each time you log in, scan the News section for newly listed items, and ensure you are up-to-date with the latest information specific to your study and site.

When you click a News item, RDC Onsite displays the news headline and text in the News Details window.

In addition, your sponsor can include a link that lets you get more information. For example, suppose a News item announces an updated terminology list. When creating the News item, your sponsor can include a link to the terminology Web site. When you click the link, RDC Onsite displays the information in a new browser window.

> **Tip:**   To avoid cluttering your display, close each window as you
> finish reading the news.

Taking a Shortcut to Your Activities

Your sponsor can customize tasks to suit your role and then display these tasks as links in the Activities section of the Home page. These links are a shortcut to your most common tasks.

▽ **Activities**
Show all CRFs (QC) for Site FLEX_SS001
Review 1 Active Discrepancies
Review 1 Other Discrepancies
Review Investigator comments

Your list of activities may be different from another system user. Your sponsor can define activities for a user role, a set of users, or all roles.

In addition, RDC Onsite includes a default set of activities that your sponsor may or may not include. Your sponsor can add other activities as well. Contact your Help Desk for questions about the links in your Activities section.

Following Your Activities Trail

Clicking an **Activities** link on the Home page lets you navigate directly to the Review pages of the application with a built-in set of search criteria, rather than with a selected set of patients. RDC Onsite opens the appropriate page and displays the data defined by the customized search.

When you navigate using Activities, the target page opens with the Search pane collapsed, and the name of the activity displayed on the pane. Note that RDC Onsite displays the **Home >** breadcrumb at the upper left of the page.

If you click an Activities link, RDC Onsite displays the appropriate page with the data automatically filtered for you. For example, if you click the **Review Active Discrepancies** link, RDC Onsite automatically opens the Review Discrepancies page and displays only those discrepancies that require your action.

Using the Default Activities Links

RDC Onsite includes the following default links in the Activities section.

- To open the Review CRFs page and list the CRFs ready for verification, click **Review Non-blank CRFs ready for Initial Verification.** This link is displayed only if you have CRA privileges.

- To open the Review CRFs page and list the CRFs ready for approval, click **Review Non-blank CRFs ready for Initial Approval.** This link is displayed only if you have investigator privileges.

- To open the Review Discrepancies page and list all discrepancies that require action by you or your user group, click **Show Active Discrepancies.**

- To open the Review Discrepancies page and list all discrepancies that require action by other users or groups, click **Show Other Discrepancies.**

In case you have a custom review type privilege, you also see displayed:

- **Review non-blank CRFs ready for** *your_review_type*

- **Set** *your_review_type* **requirement for new CRFs**

Your sponsor may have created different activities, so you can have a different default view. For more information, see *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

Using Customized Shortcuts to Relevant Web Sites

Your sponsor lists relevant Web addresses in the Links section on the Home page. For example, your sponsor may include a link to the National Institute of Health, to the Oracle Thesaurus Management System for standard terminology, or to a medical dictionary.

When you click a link, RDC Onsite displays the associated Web site in a separate browser window.

▽ **My Personal Links**
Dynamic Link Study
Dynamic Link Site
Dynamic Link User

Viewing a Summary Report for a Patient

You can click a patient icon to view and print the latest overall metrics for that patient. The report includes the following information:

- General (birth date, gender, age, site, last update)

- Number of active, other, and closed discrepancies

- Number of CRFs with active, other, or no open discrepancies

- CRF Verification, Approval and Custom Review status, depending on your privileges

- Dates of visits

- Links to other information such as adverse events

See Chapter 11, "Viewing Summary Reports" for more information on the Patient Summary Report.

3

Entering and Updating Patient Data

The Home page of Oracle Clinical Remote Data Capture Onsite (RDC Onsite) lists all the patients in a selected study and site. You work with this data to create, update, review, and maintain patient data.

This chapter includes the following topics:

- Starting Data Entry for Patients in a Clinical Study
- Using the Patient Casebooks Page
- Using the Data Entry Window
- Entering Data in a CRF
- Updating Existing Data in a CRF
- Saving a CRF
- Removing Data from a CRF
- Generating a CRF Report or a CRF History Report
- Viewing the Audit History of a CRF Field
- Using the Navigator Pane for Discrepancies and Investigator Comments
- Adding Pages
- Validating Patient Data

Starting Data Entry for Patients in a Clinical Study

The general process for entering patient data involves the following tasks:

- Selecting Your Current Study and Site
- Finding Patients for Data Entry
- Opening the Patient Casebooks
- Selecting a Patient CRF for Data Entry

Selecting Your Current Study and Site

The studies and sites available to you depend on the studies you are participating in, your user role, and the privileges assigned to you by the study sponsor.

Before you enter or update patient data in a CRF, you should always check that you are using the correct study and site.

At the top-left of the Home page and the Patient Casebooks page, RDC Onsite displays the name of the study and site that you are currently using. For example:

Study [FLEXSTUDY1] Site [FLEX_SS001]

You can click the Study and Site fields to select from those available to you. Note that:

- When you log in the first time, RDC Onsite accesses and displays the first study and site available to you.

- When you log in again, RDC Onsite accesses and displays the study you last visited.

Most users work exclusively on a single site in a study. If that is the case for you, the study and site you work on are your only choices. You do not need to select the study and site. However, if you work on more than one study or more than one site, *always* check that you are using the correct study and site *before* you add or modify any data.

The lists displayed in the Study and Site fields include only valid sites and studies. A valid site must have an investigator and at least one patient assigned. A valid study must have at least one valid site assigned. If the study or site you need is unavailable, contact your Help Desk.

To select the study and site you want to access:

1. Open the Home page.

2. Click the **Study** field and then select a study from the list. Note that RDC Onsite inserts a --Select Site-- message into the Site field and updates the list of sites based on the study you selected:

Study [FLEXSTUDY1] Site [--Select Site--]

3. Click the **Site** field and then select a site from the list. RDC Onsite accesses the selected study and site, and then updates the list of patients for the selected study and site.

> **Note:** Make sure you select the site after changing studies in order to refresh the screen with current data.

You can similarly change your study and site from the Patient Casebooks page. After you select your study and site, you enter search criteria and click **Search** to display patient data in the casebook spreadsheet.

Finding Patients for Data Entry

When you need to enter data for a patient for the first time, you do not actually add a patient to the study. Instead, you select an unused patient number (ID) from the Home or the Patient Casebooks page. Some sponsors pre-assign patient numbers, so you may know exactly which one to use. In other cases, you are instructed to select the next available patient number.

Unused patient numbers have grayed-out patient icons with a question mark symbol.

Depending on your sponsor's instructions, you can locate a new patient number (ID) in various ways.

To find a patient without entered data, you can:

- Scroll through the patients list on the Home page to find the next available patient number

- Filter the patient list to show only patients without data entered

- Search for a particular patient number, or a range of patient numbers

Selecting the Next Available Patient Number

If your sponsor instructs you to use the next available patient number (ID) for a new patient, select one or more unused patient numbers from the list of patients on the Home page and then proceed to the Patient Casebooks page. Alternatively, you can filter the list to display only those patients without data entered.

Filtering the Patients List to Find Unused Patient Numbers

You can use the search options to filter the patients list and display only those patient that have no data entered. These patient numbers are available for you to use for data entry.

To filter the patients list to find unused patient numbers (IDs):

1. Open the Home page.

2. Click the ⟩ button to expand the Patient Search pane.

3. Click the **Show for status** field and then select **Patients with no data entered** from the list.

4. Click **Search** to display only unused patient numbers (IDs).

Finding Particular Patient Numbers

If at your site, patient numbers are pre-assigned to specific patients, you need to find specific patient numbers or ranges before starting data entry.

To find one patient or a range of patients:

1. Open the Home page.

2. Click the ⟩ button to expand the Patient Search pane.

3. Enter your search criteria in the **Range** field to find either a single patient or a range of patients.

   You can also click the down arrow to access the list of values for all the patients in the site, together with the respective Casebook. Here you can choose one patient, or click on the **More...** link at the bottom of the list that opens a separate window called Search and Select: Patient. Pick the patient or perform a search by entering the patient number in the text box at the top of the window and press the Enter key. Once the patient is selected, click **Ok**.

4. Click **Search** to retrieve and display the patients that satisfy your search criteria.

Opening the Patient Casebooks

On the Home page, you select the patient numbers (IDs) to start data entry, and then drill down to the Patient Casebooks page to enter data against those patients.

Alternatively, you can select the Patient Casebooks tab, and then search for the patient numbers (IDs) on that page instead. By default, you see the multiple patients view. You can view all the visits for a single patient by choosing Single from the View drop-down list. The single view displays the first patient in the multi-view, then you can navigate through the list to see each patient in turn.

To enter data for one or more patients:

1. Open the Home page.

2. Click the row or rows to select one or more patients.

3. Click the **Action** menu and then select **Multi-Patient View** from the list.

   The Patient Casebooks page opens and displays the selected patients in the Casebook Spreadsheet. Note that:

   - The Search pane is collapsed, and the title in the Search pane indicates the number of patients you selected from the Home page. For example:

   - The breadcrumb displays Home > to indicate your navigation path to the Patient Casebooks page.

   - By default, the Patient Casebooks page displays in the multiple patients view all the CRFs expected for Visit 1 for the selected patients. You can select another visit, search for a different set of patients, or enter data into a CRF.

See "Using the Patient Casebooks Page" on page 3-4 for more information on selecting visits, selecting patients, navigating around the page, and opening CRFs.

Selecting a Patient CRF for Data Entry

After you select one or more patients on the Home page and drill down to the Patient Casebooks page, you click an empty CRF icon (a gray square with a green arrow) to open the CRF in a Data Entry window. You can now enter patient data into the selected CRF.

For more information on opening CRFs, using the tools in the Data Entry window, and entering patient data, see the following sections:

- "Using the Data Entry Window" on page 3-13

- "Entering Data in a CRF" on page 3-19

Using the Patient Casebooks Page

This section contains the following topics:

- "Single Patient View" on page 3-6

  - "Casebook Spreadsheet" on page 3-8

  - Searching and filtering in Single Patient Casebook Spreadsheet

- "Multiple Patient View" on page 3-9

  - "Navigating in the Multiple Patient Casebook Spreadsheet" on page 3-9

  - "Selecting a Visit for the Multi-Patient Casebook page" on page 3-9

- – "Displaying the Study Interval with the Visit Name in the multiple patient view" on page 3-11

- ■ "Clicking a CRF Icon to Enter or Update Data" on page 3-11

- ■ "Nonflexible and Flexible Clinical Studies" on page 3-11

You can use the Patient Casebooks page in two alternate views: Single Patient and Multi-Patient. In the **Patient Casebooks** tab, on top of the page, you can select your view from the drop-down list next to the View button:
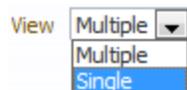
The Single Patient View displays all the visits for a Single patient, starting with the first patient in the multi-patient view list, the patient selected directly from the Home page or as the result of a search by patient number.

The Multiple Patient View shows a single visit for a selection of patients.

> **Note:** Your administrator may choose to deactivate the single view for your installation.

About the Patient Casebook Page The Patient Casebooks page — either in multiple or single patient view — is the only page in RDC Onsite from which you can start data entry. It also provides a casebook-oriented view of the expected and entered CRFs for the displayed patients. See Figure 3–1.

To open the Patient Casebooks page, you can:

- ■ Click the **Patient Casebooks** tab to access the page directly in the default multiple patient view.

- ■ Select one or more patients on the Home page, and then drill down to the Patient Casebooks page, in either multiple or single patient view.

You navigate to the Patient Casebooks page either by selecting the **Patient Casebooks** tab or by drilling down from the Home page.

Figure 3–1   Patient Casebooks Page

Single Patient View

> **Note:**   Your administrator may choose to deactivate the single patient view for your installation.

The Patient Casebooks in the single patient view displays the current Study and Site at the top of the page, and has the Search panel collapsed. The middle section is the Patient Summary panel. The Search panel is collapsed if you came from the Home page or the multiple patient casebooks view with a patient selection in effect. Otherwise, the Search panel is expanded to allow you to select a patient or patient range.

At the bottom of the page, the Patient Casebook grid shows all the visits and CRFs for the patient. The Patient Summary includes all the information independent of account configuration. Please take into consideration that the panel can include a count of 20 CRFs with discrepancies, but you may be able to see only 10 when you click on the link because of your user role.

About the Patient Summary

The Patient Summary displays up-to-date metrics for the current patient selected.

This includes the following information for the selected patient:

- **Patient Information —** At the top, displays the patient number, entered and deleted CRF's, and the dates of the first and latest entry.

- **Visits —** Displays the time and date of the patient's past and upcoming visits.

- **CRFs —** Lists the number of CRFs with open discrepancies, with active discrepancies, and with other discrepancies.

- **Discrepancies —** Lists the number of discrepancies by discrepancy status.

- **CRFs Approval Status —** Lists the number of CRFs with the following approval statuses: approved, requires approval, and requires re-approval.

- **CRFs Verification Status —** Lists the number of CRFs with the following verification statuses: verified, requires verification, and requires re-verification.

  Note: The Verification Status metrics are visible only to users with BROWSE_VERIFY privileges or higher.

- **Links —** Lists up to three custom links that open other Web pages and provide additional information on the patient. These links are available only if your

sponsor customized the Patient Summary Report to include the links. For example, your sponsor may include a link to the Adverse Events for the patient.

- **Custom Review** — If your sponsor has defined one or more custom review types, and your account has the appropriate privileges, lists the number of CRFs in each review status for all your assigned custom review types.

About the Counts in the Patient Summary

In each section of the page, except the Discrepancy Counts, you can click on the links describing the respective metrics in order to filter what you see displayed in the Patient Casebook grid at the bottom of the page.

About the Patient Casebook Spreadsheet

The Patient Casebook Grid displays multiple visits for the patient in focus in the single view page.

Using the Single Patient Casebook page, if the patient has not been assigned to a casebook (only possible for non-flexible studies), you can choose which casebook to use for data entry. You can also filter CRFs according to status of verification, approval, and number of discrepancies. All the options you have in the **Filter** drop-down list correspond to a link in the Patient Summary Panel.

If allowed in your installation, you can also add pages, either for an unplanned visit or other.

> **Note:** If a filter is applied, such that not all of the patient's CRFs are displayed, performing a group action affects even those CRFs which are not visible. To limit the set of CRFs you are working on, use **Search** in the CRF Review or Multi-Patient Casebook page.

Casebook Spreadsheet

The Patient Casebook spreadsheet in the single patient view displays the visits in rows and the expected, visit-related CRFs in columns. To reach the desired data you can use the vertical scrollbar to view more visits, and the horizontal scrollbar to see more CRFs.

If you have multiple patients queried, you can navigate through the list of patients by using the buttons that embed the patient number, like in the following image:
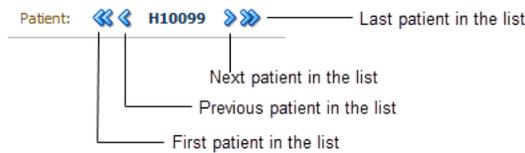
You can also open CRFs from this page and navigate through them without returning to the Patient Casebook spreadsheet.

Multiple Patient View

If this is a Flexible study, you can change the patient focus, which in turn restricts the visit selection list to those visits expected for that patient.

The Patient Casebooks tab displays by default the multiple patient view where you see a single visit for several patients. The Search pane is collapsed if you came from the Home page with a patient selection in effect. Otherwise, if you selected the Patient Casebooks tab, the Search panel is displayed to allow you to search for patients.

If a patient has not been assigned to a casebook (only possible in non-flexible studies), you can select a casebook to use for data entry for such a patient. If all patients are assigned to a casebook, changing the casebook may simply change the ordering of the CRF columns.

You can also change the visit in focus and toggle to the single patient view. Please note that the Single View always displays the first patient in the Multiple View list. You can then navigate through each of the patients in turn.

Navigating in the Multiple Patient Casebook Spreadsheet

The Patient Casebooks page in the default multiple patient view displays the patients in rows and the expected, visit-related CRFs in columns.

You can scroll up and down the list to view more patients; you can scroll across (left to right) to view more CRFs within the selected visit.

Selecting a Visit for the Multi-Patient Casebook page

When working with the Patient Casebooks in Multiple view, the Casebook, Visit Set for patient, and Visit fields work differently, depending upon whether you are working in a flexible or non-flexible study. The Visit Set for patient field does not appear for non-Flex studies.

Patient Casebooks

Casebook: DATA_BOOK2 ▾   Visit Set for patient: All ▾   Visit: VISIT 1 ▾

Selecting a Visit for Flexible Studies In a flexible study, all patients are assigned to a casebook and a different set of visits may be expected for each patient, even if the patients are all assigned to the same casebook.

The Visit Set for Patient field allows you to restrict the visit selection to the set of visits applicable to a particular patient. You can select all patients or a particular patient.

If the Patient field is set to All, then:

- The Casebook field lists the set of casebooks assigned to the set of patients currently displayed. When you select a Casebook, RDC Onsite reorders the CRF columns based on that casebook.

- The Visit field lists all the visits defined for the study. When you select a visit, RDC Onsite updates the Multi-Patient Casebooks page with the CRFs for that visit.

If the Patient field is set to a specific patient, then:

- The Casebook field displays the name of the casebook assigned to the selected patient. You cannot change the casebook.

- The Visit field lists all possible visits for the patient specified in the Patient field. Even if all the patients are assigned to the same casebook, the visits expected for each patient may be different. Therefore, by entering a specific patient in the Patient field, you can then select a visit from the set of visits relevant only to that patient.

> **Note:** The Patient field lists only the patients currently displayed in the Patient Casebooks page.

Selecting a Visit for Nonflexible Studies In a nonflexible study, patients may or may not be assigned to a casebook, but the set of expected visits is the same for any patient assigned to the same casebook. When setting the visit for nonflexible studies:

- The Patient field is not displayed. The value is automatically set to All.

- The Casebook field lists all the casebooks defined for the study. For a nonflexible study, the Casebook field:

  - Defines the order in which RDC Onsite displays the expected and entered CRFs on the Patient Casebooks page for each visit

  - Represents the casebook to use for patients not assigned to any casebook. For patients not assigned to a casebook, RDC Onsite displays the expected CRFs for the current visit based on the selected casebook.

  Note that the value of the Casebook field has little effect if all patients are assigned to casebooks.

- The Visit field lists all the visits defined for the study. Select a visit to view the associated CRFs for the currently displayed patients.

You can position the mouse over the patient icon to display the name of the casebook, if any, assigned to the patient.

Displaying the Study Interval with the Visit Name in the multiple patient view

By default, the spreadsheet heading on the Casebooks page displays only the name of the current visit.

A visit belongs to an interval in the study. An **interval** denotes the stage of a study and divides the study into logical groupings of visits. An interval can be a phase, a period, or a sub-period. For example, a study may have a screening phase, a dosing phase, and a follow-up phase.

Your sponsor can customize the spreadsheet heading to include the name of the interval along with the name of the current visit. For example:

Interval: SCREENING, Visit: Visit 1

Clicking a CRF Icon to Enter or Update Data

CRF icons appear on the Patient Casebooks page and all Review pages. See Appendix A, "Description of the CRF Icons" for a detailed description of each icon. Clicking a CRF icon opens the Data Entry window, where you can view and edit the CRF.

 Empty CRF — The Patient Casebooks page is the only page in RDC Onsite that displays the Entry Expected icon (square with a green arrow). This icon indicates that the CRF is empty and you are expected to fill in the data. Click the icon to open the CRF in a Data Entry window and begin to enter patient data.

 Entered CRF — An entered CRF contains data and is reflected in all pages. Click an entered CRF icon from the Patient Casebook spreadsheet or any Review page to open it in a Data Entry window and update data.

When the Data Entry window opens, notice that the title bar displays valuable information for the selected CRF: patient number, visit name, and CRF name, followed by study name, site name, patient number, casebook, user name, and user role.

Nonflexible and Flexible Clinical Studies

The **schedule** for a clinical study includes the intervals (phases, periods, and subperiods), the visits (also called Clinical Planned Events or CPEs), and the CRFs.

A **nonflexible study** follows the same schedule of treatments, visits, and assessments. Nonflexible studies have a relatively fixed schedule.

On the other hand, a **flexible study** can have multiple pathways through the trial for different patients. There may be entire intervals (groups of visits) that are required for some treatment groups, but are not required for others.

In addition, not all patients in a flexible study have the same assessments at every visit. For example, a subset of CRFs may be required for patients only if certain criteria are met, such as a detailed smoking history for smokers.

For a flexible study, the study designer uses Oracle Clinical to create a conditional schedule by defining decision points. The designer identifies the particular questions and the responses to those questions that determine which intervals, visits, and CRFs **are expected** for patients as they progress through the clinical trial.

About Expected CRFs and Visits

RDC Onsite displays only the CRFs and visits that are either collected or expected for each particular patient.

As you enter and update data for a particular patient, RDC Onsite automatically:

- Checks the data against the conditional rules, if any, defined in Oracle Clinical.

- Determines whether the data you entered satisfies one or more of the conditions defined in Oracle Clinical. Each condition may cause different CRFs and intervals to become expected.

Whenever you update data that triggers a conditional rule, RDC Onsite automatically recalculates what is expected for the patient and adjusts the display of the expected CRFs and intervals as necessary.

If the response to a source question meets the define rules, RDC Onsite marks the CRFs or visits as *expected* for the patient. Furthermore, if the response to the source question changes such that the defined rules are no longer met, any expected CRFs or intervals revert to the status of *not expected* for the patient.

How RDC Onsite Alerts You to Changes in Expected CRFs and Visits

As you enter, update, and save patient data in a CRF, some CRFs may become expected while other CRFs may no longer be expected. RDC Onsite displays a message if the expected CRFs have changed.

For example, when you open a CRF in a flexible study, the CRFs that are expected may have change because another user may have entered data that caused one or more CRFs or visits to become expected. In addition, when you save a CRF, the CRFs that are expected may change based on the response data you entered.

When the expected CRFs or visits change, you may notice that new CRFs were added to the Casebook Spreadsheet or that some CRFs were dropped from the spreadsheet.

As shown in Figure 3–2, the Patient Casebooks page uses the following characters to indicate which CRFs are not expected for a patient:

- **Dash (-) symbol —** Indicates that the CRF is not expected for the patient.

- **Letter N beside the CRF icon —** Indicates that the CRF is **NO** longer expected for the patient. In this case, the CRF already has data collected. However, because of an update to the data, the CRF is no longer expected (that is, not expected) for the patient.

For changes in expected visits, RDC Onsite updates the list of visits in the Set Visit Focus: Visit field on the Patient Casebooks page. The Visit field may show new or dropped visits. You can select a patient in the Patient field to display the set of visits relevant only to that patient.

Figure 3–2   Patient Casebooks Page Indicating Changes in Expected CRFs and Visits

Using the Data Entry Window

In RDC Onsite, the Data Entry window appears in a separate browser window from the application pages. You can have up to three Data Entry windows open simultaneously. Therefore, you can have up to four RDC Onsite browser windows open at a time: one for the application page, such as the Patient Casebooks page, and up to three Data Entry windows. All windows remain active and the title of each browser window is unique.

You can return to the application page you were using, execute another search, or even navigate to another page while a Data Entry window is still open. You can change the context from which the Data Entry window was originally opened. This action has no effect on the status of the Data Entry window, or on your ability to continue work in that window.

Figure 3–3 illustrates the main components of the Data Entry window.

Figure 3–3   Data Entry Window
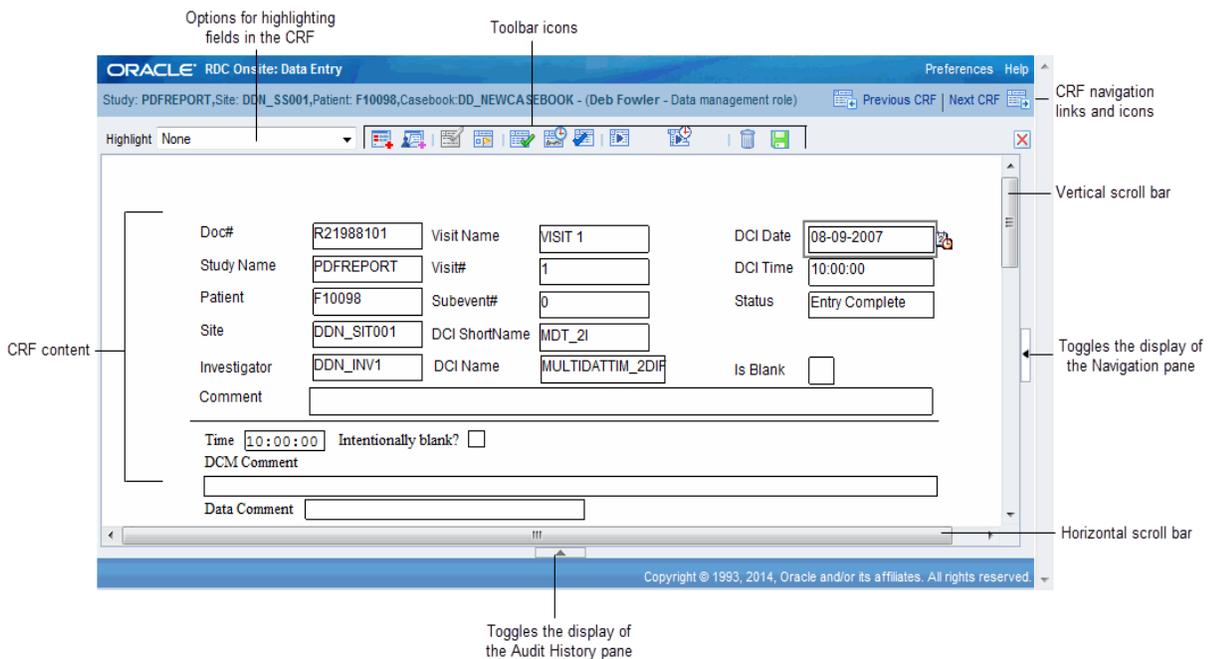
Navigating in the Data Entry Window

When you are entering and updating data in a CRF, the Data Window provides several options for:

- Navigating from Field to Field
- Navigating within the CRF
- Navigating from CRF to CRF

Navigating from Field to Field

The CRF in the Data Entry window is customized by your sponsor. For questions about the layout of the form, see the training material from your sponsor.

You can use the mouse to select and position the cursor in a field. Alternatively, you can press **Tab** to go to the next field (from left to right), or press **Shift+Tab** to go to the previous field.

When you select a field, the field comes into focus. The field in focus is outlined in gray. You can then enter or change a value in the field. RDC Onsite performs a field-level validation after you move from a field.

Navigating within the CRF

If a CRF is too long for the Data Entry window, a vertical scroll bar appears to the right of the CRF. If a CRF is too wide for the Data Entry window, a horizontal scroll bar appears at the bottom of the page.

If the CRF has multiple pages, the Data Entry window displays an additional set of page navigation tools:

The number of the current page is displayed against the total number of CRF pages. You can click the icons to navigate to the first, previous, next, or last page of the CRF.

Navigating from CRF to CRF

When you open a Data Entry window from a surround page, for example a Patient Casebook or CRF Review page, you can use the **Previous CRF** link and the **Next CRF** link to navigate from one CRF to another, without having to return to the page that you started from in order to select another CRF.

A **surround** page is any page in Oracle Clinical other than the Data Entry Window.

The surround pages impose a sequence on the CRFs, which doesn't change as long as you have a data entry window open. When you click one of these links, RDC Onsite navigates to the next or previous CRF in the sequence. These CRFs include planned CRFs with or without data, existing unplanned CRFs with data, and new CRFs that can become expected.

The **Previous CRF** and **Next CRF** links:

- Are restricted to the CRFs within a single visit for a single patient when you open the Data Entry Window from the Multi- or Single-Patient Casebooks pages.

- Are not enabled when you create an unplanned CRF from a Casebooks page. Once you close and reopen the saved CRF, the links are active.

- Are not enabled if you are viewing the first CRF (Previous CRF not active) or the last CRF (Next CRF not active).

- May be disabled when you save a CRF if the casebook is re-assigned for the patient while you had the CRF open in the Data Entry window.

You can also press **Alt+N** to open the next CRF and **Alt+P** to open the previous CRF in the Data Entry window.

Navigation in a CRF with Hidden or Grayed Out Questions

When entering data into a CRF, you may notice that some fields are grayed out and inactive. In addition, you may notice that some fields automatically become visible based on the response data you enter.

About Conditional Questions

When setting up the questions for a CRF, your sponsor can associate one or more conditions with a question. Your sponsor can define a data response value so that when you enter that value, other questions and fields become active, and the cursor automatically moves to a specified question within the same CRF. This technique is called **conditional branching.**

With conditional branching, your sponsor can define a path through the CRF based on the responses you enter. For example, suppose the CRF has the following question:

Are you pregnant?

- If the patient response is Yes, an additional set of questions are now required. RDC Onsite automatically makes the questions active and positions the cursor in the first field for the pregnancy-specific questions.

- If the patient response is No, RDC Onsite bypasses the pregnancy questions and moves the cursor to the next field.

Visual Appearance of Conditional Questions

When creating conditional questions for a CRF, your sponsor can customize how those questions appear when displayed in the Data Entry window. Your sponsor can choose one of the following options:

- Gray out the section in the CRF with the conditional questions. You can see the section, but the questions remain disabled until a response value triggers the condition defined for the source question.

- Completely hide the section in the CRF with the conditional questions. The section remains hidden until a response value triggers the condition defined for the source question.

Automatic Field Navigation and Activation

RDC Onsite controls the navigation from field to field based on whether your response value triggers the condition defined for the source question. When the trigger response value is entered, RDC Onsite automatically enables the appropriate section and positions the cursor in the next appropriate question.

Using the Toolbar Icons in the Data Entry Window

The icons in the Data Entry window toolbar facilitate working with the CRF. The toolbar icons appear active or grayed out, depending on the privileges you have, such as update, verify, or approve.

Table 3–1 describes each toolbar icon available in the Data Entry window.

Table 3–1   Toolbar Icons in the Data Entry Window

Icon	Name	Click this icon to...
	Add Discrepancy	Open the Add Discrepancy dialog box.
	Investigator Comment	Open the Add/Update Investigator Comment dialog box.
	Delete Row	Open the Delete Row dialog box.
	Blank Flag Tool	Open the CRF Blank Selection(s) Processing dialog box.
	Verify; Verification History	Open the Verify CRF dialog box.
	Approve; Approval History	Open the Approve CRF dialog box.
	Custom Review	Open the Custom Review pop-up window to view custom review history and update the current custom review status.

Table 3–1 (Cont.) Toolbar Icons in the Data Entry Window

Icon	Name	Click this icon to...
	Custom Review History	This icon appears if you have the BROWSE_REVIEW privilege, but no update privilege for a custom review type.
		Use it to open the Custom Review pop-up window to view custom review history.
	Generate CRF Report	Generate the CRF report. Once selected, the icon is animated (the arrow revolves) to show that report generation is in progress.
	CRF Report Ready	This icon appears when the CRF report has been generated and is current. Select to download the report and view it in a new window.
	CRF Report Generation Failed	This icon appears if the CRF report fails to generate. Displays a message that describes why CRF report generation failed.
	Generate CRF History	Generate the CRF history. Once selected, the icon is animated (the arrow revolves) to show that report generation is in progress.
	CRF History Ready	This icon appears when the CRF report has been generated and is current. Select to download the history and view it in a new window.
	CRF History Report Generation Failed	This icon appears if the CRF history report fails to generate. Information on why the report generation failed is stored in the PDR log file, accessible from the Reports tab.
	Delete CRF	Open the Delete CRF dialog box.
	CRF Help	Open the optional CRF Help provided by your sponsor. This icon appears only if your sponsor provided help text for the CRF.
	Save	Save the CRF.
		Keyboard Shortcut: Alt+S.
	Previous CRF	Navigate to the previous CRF. This link appears only if a CRF is opened from the Casebooks page. The link is disabled in the first CRF in a visit for a patient.
		Keyboard Shortcut: Alt+P.
	Next CRF	Navigate to the next CRF. This link appears only if a CRF is opened from the Casebooks page. The link is disabled in the last CRF in a visit for a patient.
		Keyboard Shortcut: Alt+N.
	First Page	Navigate to the first page in a CRF. This icon appears only if the CRF has more than one page.
	Previous Page	Navigate to the previous page in a CRF. This icon appears only if the CRF has more than one page.
	Next Page	Navigate to the next page in a CRF. This icon appears only if the CRF has more than one page.
	Last Page	Navigate to the last page in a CRF. This icon appears only if the CRF has more than one page.
	Close	Close the CRF and the Data Entry window.
		Keyboard Shortcut: Ctrl+W.

> **Note:** You can use combinations of keys including Ctrl on all supported devices except for iPad.

Highlighting Fields in a CRF

The Data Entry window uses color to highlight fields in a CRF that have discrepancies, investigator comments, audit history, or changes since a last verification or approval.

To highlight specific fields in a CRF:

1. Click **Highlight** in the toolbar in the Data Entry window.
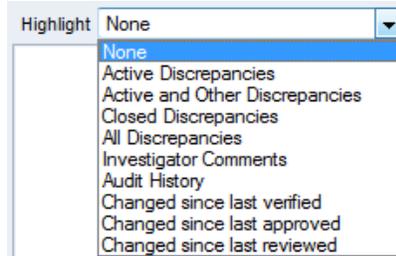
2. Select an option from the list. Your options for highlighting are:

   ■ **Active Discrepancies —** Highlights all fields associated with active discrepancies in red. Active discrepancies require action by your user role or group.

   ■ **Active and Other Discrepancies —** Highlights all fields associated with active discrepancies in red and all fields associated with other discrepancies in yellow. Other discrepancies require action by another user role or group.

   ■ **Closed Discrepancies —** Highlights all fields associated with a manually resolved (user closed) discrepancy in green.

   ■ **All Discrepancies —** Highlights all fields associated with active, other, and closed discrepancies in their respective colors (red, yellow, and green).

   ■ **Investigator Comments —** Highlights all fields that have an investigator comment in magenta.

   ■ **Audit History —** Highlights all fields that have changed since original data entry, and therefore have an audit history, in blue.

   ■ **Changed since last verified —** Available if you have the appropriate privileges. Highlights all fields that have changed since the last verification of the CRF in blue. Note that fields whose only update is an update to the investigator comment are highlighted.

   ■ **Changed since last approved —** Highlights all fields changed since the last approval of the CRF in blue. Note that fields whose only update is an update to the investigator comment are highlighted.

   ■ **Changed since last reviewed —** Highlights the fields that changed since the last Review Complete. If the CRF has or had a Review Complete status for multiple review types for which you have update privileges, highlights fields changed after the earliest of the current Review Complete status changes. If you also have browse privileges, these custom review types are ignored. If have only browse capability, highlights fields changed from the earliest of the current Review Complete status changes across all review types.

■ **None —** Highlights no fields.

Entering Data in a CRF

All CRFs, whether empty or entered, already contain basic information such as the study, site, patient, CRF name, and investigator name. You must enter responses to the remaining questions in the CRF. You enter your responses into the appropriate field.

Standard Text Fields versus Extended Text Fields

A CRF can have one or more fields into which you insert data. When designing the layout and format of a CRF, your sponsor can define the field as a standard text field or as an extended text field. In addition, your sponsor can define the maximum number of characters allowed in the field.

■ A *standard text* field can have up to 200 characters. Most fields in a CRF are standard text fields.

■ An *extended text* field can have up to 10,000 characters. In an extended text field, you can enter lengthy comments and narratives, such as patient case history or serious adverse events.

The following privileges apply to both standard text fields and extended text fields:

■ If you have browse-only privileges, you can view but not edit the data.

■ If you have update privileges, you can view and modify the data.

Yellow Note Icon Indicates an Extended Text Field in the CRF

When you open a CRF in the Data Entry window, RDC Onsite indicates an extended text field by displaying a yellow note icon to the right of the field. See Figure 3–4.

RDC Onsite always displays the Extended Text icon regardless of whether the field has any data. Once the field has data, the Data Entry window displays the beginning of your extended text followed by the ellipsis (…) character.

To view all the data associated with an extended text field, click the Extended Text icon (that is, the yellow note) to open the Show Extended Text dialog box. Alternatively, you can double-click in the field or use the right-click menu to open the Show Extended Text dialog box.

> **Note:** You can use double-click or right-click on all supported devices except for iPad.

Figure 3–4 Extended Text Field in the RDC Onsite Data Entry Window

The yellow note icon indicates the field is an extended text field. Click the icon to open the Show Extended Text dialog box, and then enter or edit data for the field.
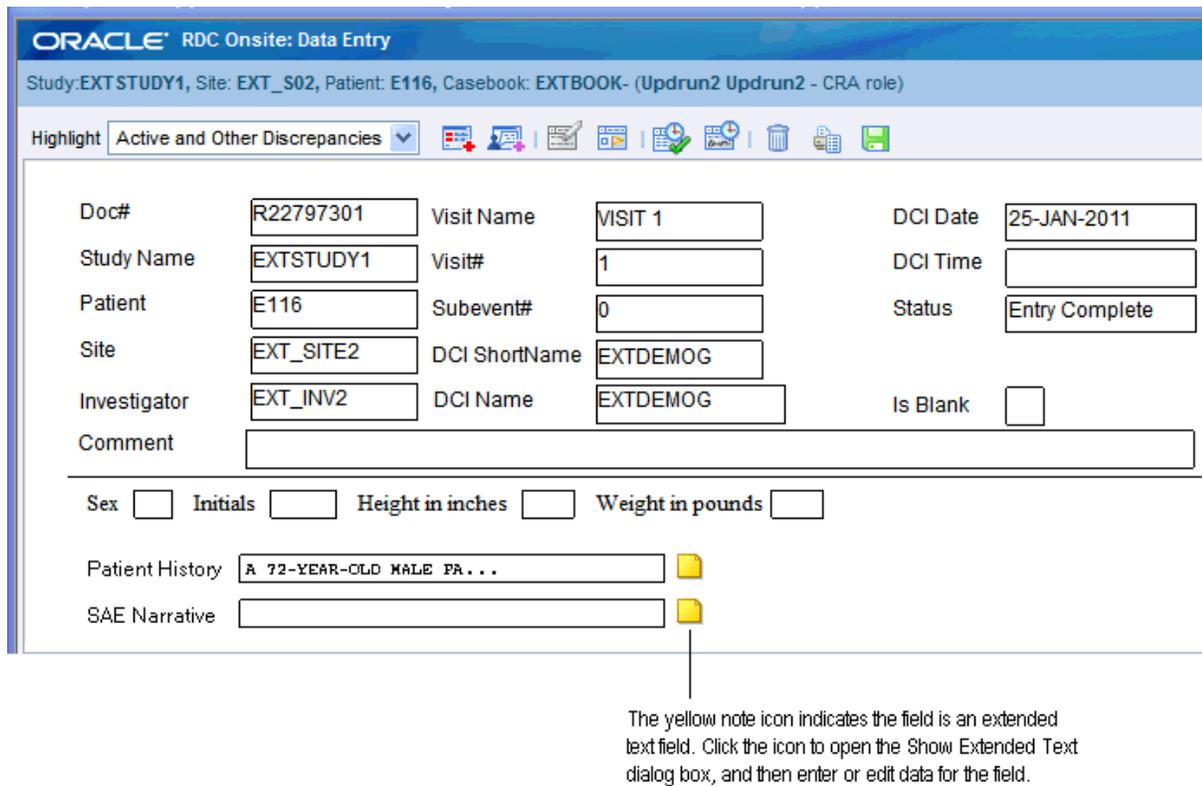
ATTACHMENT Prefix Indicates Extended Text Fields

In the Audit History pane, the Discrepancies Details pane, and the Patient Data Reports, RDC Onsite uses the following prefix to indicate that the value is an extended text value:

ATTACHMENT V *<X.Y>*:

where *X* is the version number and *Y* is the sub-version number. The system increments these numbers each time the data in an extended text field is saved.

After the ATTACHMENT prefix, RDC Onsite adds the beginning of your extended text followed by the ellipsis (…) character. For example:

ATTACHMENT V<1.1>: A 21-year-old woman presented…

Entering Data in a Standard Text Field

To enter data in a standard text field in a CRF:

1. Open a CRF in the Data Entry window.

2. Click a standard text field. Ensure that the cursor is in the correct field. Alternatively, use the Tab key to move from field to field.

3. Enter data in the field.

4. Tab or mouse-click from the field after adding or changing a value. RDC Onsite then performs a field-level validation.

The data you entered may fail a validation check and raise an error. To resolve a validation error, see "Processing Validation Errors During Initial Data Entry" on page 3-24 for more information.

Displaying the Full Text of a Standard Text Field

A standard text field may contain more information than can be displayed in the space defined on the CRF.

To view the complete text for a standard text field, you can:

- Press the left and right arrow keys to scroll through the text.

- Double-click the standard text field. The Show Full Text dialog box displays the complete text.

- Right-click the standard text field and select **Show Full Text** from the menu. The Show Full Text dialog box displays the complete text.

> **Note:** You can use double-click or right-click on all supported devices except for iPad.

You can edit text in the Show Full Text dialog box under the following circumstances:

- You have update privileges.

- The field is not display-only.

- The form is not being updated by another user.

- The patient data is not frozen.

- The CRF is unlocked. But if locked, you have update privileges to the CRF or privileged update.

After you modify text in the Show Full Text dialog box, you can either click **OK** for RDC Onsite to accept your changes, or click **Cancel** to close the dialog box without keeping your changes.

Entering Data in an Extended Text Field

In an extended text field, you can enter lengthy comments and narratives, such as patient case history or serious adverse events.

Opening the Show Extended Text Dialog Box

Before you can enter or update data for an extended text field, you must open the Show Extended Text dialog box. You cannot make changes directly in an extended text field in the Data Entry window.

To open the Show Extended Text dialog box, you can:

- Click the Extended Text icon next to the field.

- Double-click the extended text field.

- Right-click the extended text field and select **Show Extended Text** from the menu.

> **Note:** You can use double-click or right-click on all supported devices except for iPad.

Viewing or Entering Data in an Extended Text Field

To view or enter data in an extended text field:

1. Open the Show Extended Text dialog box for the field you want to modify.

2. Enter new data or update the existing data.

   - See Table 3–2 for a list of keys that are useful for entering data in the Show Extended Text dialog box.

   - See "Using Special Characters and Advanced Formatting in Extended Text Fields" for restrictions and recommendations on entering data.

3. Click **OK** to process your changes.

   If the data in the Show Extended Text dialog box:

   - Is less than 10,000 characters, RDC Onsite closes the dialog box and returns to the CRF in the Data Entry window.

   - Is greater than 10,000 characters, RDC Onsite displays an error message that the maximum number of characters allowed has been exceeded. To continue, select one of the following options:

     – To return to the Show Extended Text dialog box, click **Cancel.** You can now edit the data for the extended text field and reduce the length of the text.

     – To automatically delete all characters beyond the 10,000-character limit, click **OK.** RDC Onsite keeps10,000 characters only, closes the Show Extended Text dialog box, and returns to the CRF in the Data Entry window.

4. Click the Save icon in the Data Entry window to save your changes.

Keys for Entering Data in the Show Extended Text Dialog Box

Table 3–2 lists several keys that are useful for entering data in the Show Extended Text dialog box.

Table 3–2   Keys for Entering Data in the Show Extended Dialog Box

Key	Description
Backspace	Delete the previous character
Ctrl + A	Select all text in the dialog box
Ctrl + C	Copy text

Table 3–2   (Cont.) Keys for Entering Data in the Show Extended Dialog Box

Key	Description
Ctrl + V	Paste Text
Ctrl + X	Cut text
Delete	Delete the next character
End	Move the cursor to the end of the line
Enter	Insert a line break
Page Up	Move the cursor to the start of the text
Page Down	Move the cursor to the end of the text
Tab	Move the cursor to the OK and then the Cancel button in the dialog box

> **Note:**   You can use combinations of keys including Ctrl on all
> supported devices except for iPad.

Using Special Characters and Advanced Formatting in Extended Text Fields

Like all dialog boxes, the Show Extended Text dialog box supports a simple text editor that you use to enter and edit plain text. You can enter standard keyboard alphanumeric characters, punctuation marks, and spaces. However, extended text fields:

- Do not support special characters such as symbols, dingbats, accented letters, and ALT characters. Special characters might not display properly in all areas of the RDC Onsite application.

- Do not support advanced formatting such as font sizes and styles, alignment, automatic line spacing, automatic numbered or bulleted lists, indents, and tables. If you copy text from a document processing application, such as Microsoft Word, RDC Onsite ignores all advanced formatting.

Keep formatting plain. Use spaces to create indents; use the Enter key to create blank lines.

Selecting Data from a List of Acceptable Values

When defining the study database protocol, the sponsor specifies a list of acceptable values for some fields.

To select a value from a pre-defined list:

1. Click any header or response field. If a list of values has been defined for the selected field, a magnifying glass icon appears.

2. Click the **Magnifying Glass** icon to open a dialog box and view the list of possible values for the field. Alternatively, you can press **Alt+L.**
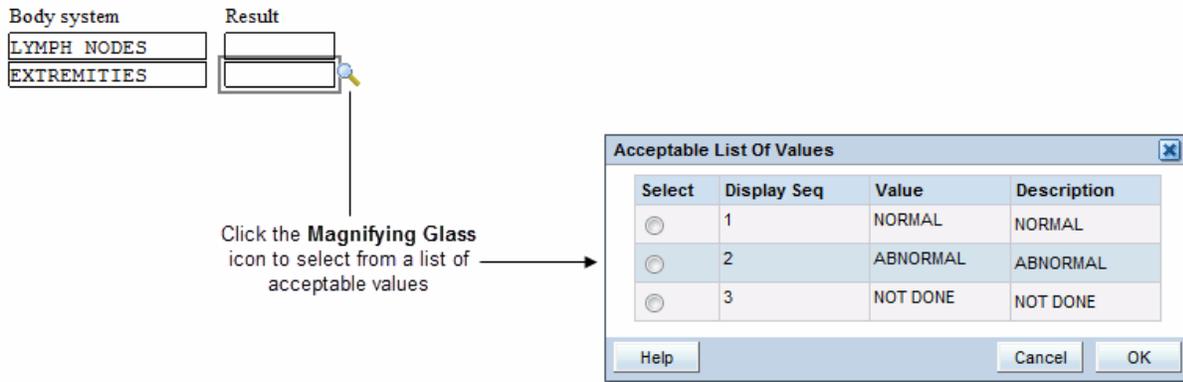
3. Select a value from the list. Use the scroll bar to scroll through the list if necessary. You can also press the up and down arrow keys on the keyboard.

4. Click **OK.** RDC Onsite inserts your selected value into the field. (The selected value may appear abbreviated in the field.)

Entering Dates

To enter a date, click the **Calendar** icon beside a date field, and then select a date from the calendar.

Keyboard shortcuts for dates are also available in RDC Onsite. To use them, place your cursor inside a date field and press one of the following keys, as needed:

- **L** — Populates the field with the date that was last entered in the current session.

- **T** — Populates the field with today's date.

- **Y** — Populates the field with yesterday's date.

Processing Validation Errors During Initial Data Entry

Your sponsor defines rules your data entries must meet. For example, you cannot enter a numeral in a field defined as requiring characters. Or, you cannot enter characters in a defined date field that requires numerals. If you enter data that conflicts with defined validation rules, RDC Onsite alerts you accordingly with a Validation Error dialog box.

To process a Validation Error, check that your entered data matches the source data and:

- Enter an explanatory comment if you want.

- Click **OK** if the entered data is correct. The Validation Error dialog box closes. You can resume data entry.

- Click **Cancel** if the entered data is incorrect or you want to navigate back to the response field. The Validation Error dialog box closes. RDC Onsite returns the previously saved values to the response field that generated the error.

> **Note:** Your configuration may suppress the Validation Error dialog box from appearing during data entry or update. In that case, you must deal with discrepancies later.
>
> If the **Highlight** field in the toolbar is set to **Active Discrepancies** or **Active and Other Discrepancies**, you see discrepant responses highlighted in red. See Chapter 4, "Managing Discrepancies" for more information routing and resolving discrepancies.

Adding and Updating an Investigator Comment

When you are entering or updating the patient data in a CRF, you may want to add an investigator comment to the response.

You can add and update investigator comments from the Data Entry window only. In addition, you can perform these actions only if you have update privileges and if your sponsor has configured RDC Onsite to allow it.

The process to add or update an investigator comment is similar. When you create an investigator comment, RDC Onsite displays an Add Investigator Comment dialog box. If you reopen a saved investigator comment, RDC Onsite displays an Update Investigator Comment dialog box.

To add an investigator comment to a field in the CRF:

1. Open the CRF in the Data Entry window.

2. Position the cursor in the field you want to add the investigator comment to, and then click the **Investigator Comment** icon in the toolbar.

   Alternatively, you can right-click a field in the CRF, and then select **Investigator Comment** from the menu.
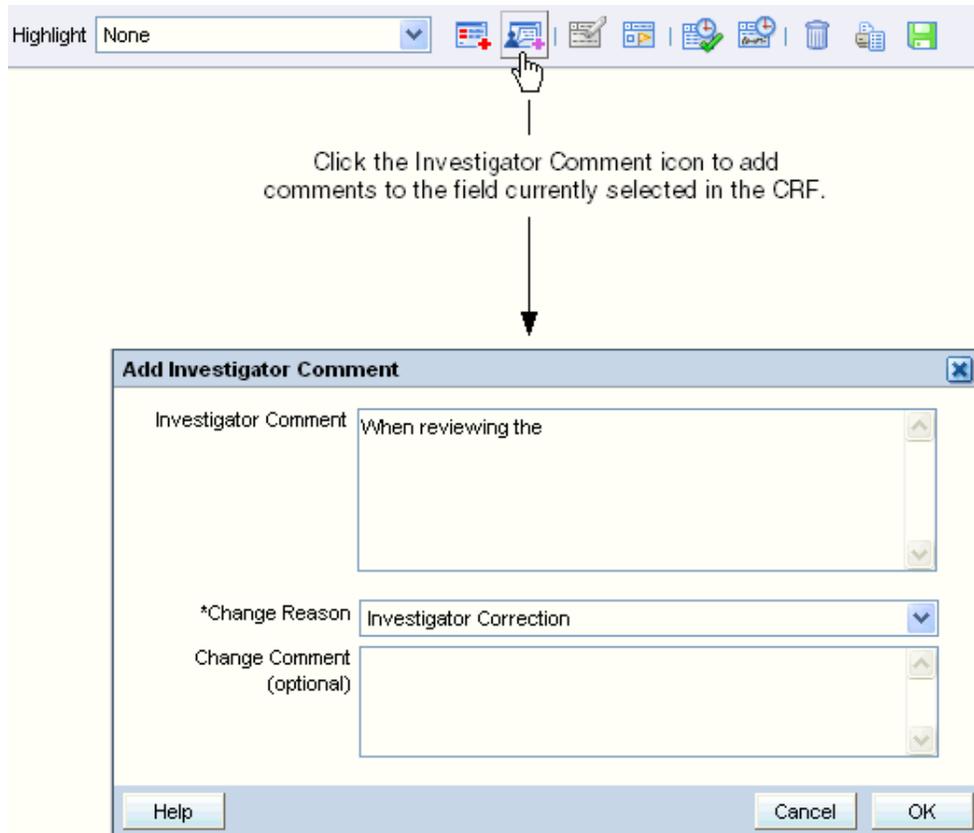
3. Add text in the **Investigator Comment** field.

4. Click the **Change Reason** field, and then select an explanation for this change from the list. Note that:

   - If the CRF status is Saved Complete, and you add an investigator comment, you may or may not need to provide a change reason as configured by your sponsor.

   - If the CRF status is Saved Incomplete, you are not required to specify a change reason when you add or update an investigator comment.

   - If you modify a previously saved investigator comment, you must enter a change reason.

5. Click the **Change Comment** field if you want to provide any additional information about your changes or comments.

6. Click **OK** to save your changes and add the investigator comment.

See Chapter 5, "Reviewing Investigator Comments" for more information on reviewing investigator comments in the Data Entry window and on working with the Review Investigator Comments page.

Changing Your Preferences for Data Entry

The Data Entry window may display a **Preferences** link if your sponsor choose to include the link when installing the RDC Onsite application.

If the **Preferences** link is available, you can customize whether RDC Onsite:

- Gives you a choice to save the CRF as complete or incomplete

■ Alerts you if a validation error occurs during data entry or update

To set your preferences for data entry:

1. Open the Data Entry window.

2. Click the **Preferences** link at the top of the window. The Preferences dialog box opens:
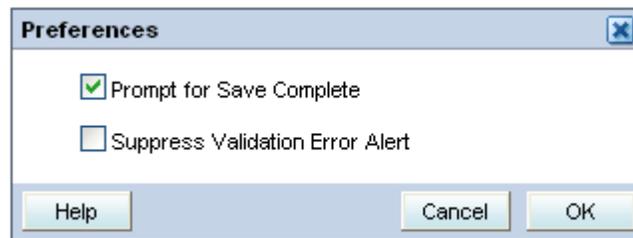
3. Select the appropriate check boxes to set your preferences for data entry.

   ■ If the **Prompt for Save Complete** check box is selected and you save a CRF, RDC Onsite prompts if you want to save the CRF as complete or incomplete.

   When you save a CRF as incomplete, its status is Entry Started. By saving a CRF as incomplete, you can:

   – Save data without raising system-generated discrepancies.

   – Continue data entry in the same CRF later, without being prompted for a change reason on every field input.

   If not selected, RDC Onsite does not prompt you with a choice of saving the CRF as complete or incomplete.

   ■ If the **Suppress Validation Error Alert** check box is *not* selected, RDC Onsite alerts you to possible validation errors that occur during data entry or data update. You then have the opportunity to correct the data before continuing to the next field.

   If selected, RDC Onsite suppresses the error message. RDC Onsite creates a discrepancy when the validation error occurs, but does not alert you to the problem.

4. Click **OK** to confirm your choices.

Viewing CRF and Field Help Customized by Your Sponsor

The content, format, and layout of CRFs used in a clinical trial vary from study to study. The information requested on each form may be unique to your study. In addition, you may need help with the type of information required in a field or have questions about a particular field.

When setting up the RDC Onsite application, your sponsor has the option of creating help information for a CRF and for each data entry field in a CRF. You can then open and view this information when you are entering or updating the data in a CRF.

To view customized help for the CRF, click the Help icon in the toolbar in the Data Entry window. This icon appears only if your sponsor provided help text for the CRF.

To view customized help text for a data entry field in a CRF:

1. Open a CRF in the Data Entry window.

2. Right-click a field in the CRF and then select **Field Help** from the menu. The Oracle Clinical Data Collection Help dialog box displays help text for the question group, help text for the question (that is, the field you selected), and details about how the field is defined in the Oracle Clinical database.

> **Note:** If visible to you, the **Help** from the browser toolbar or main menu provides information on browser related issues. It is not the RDC Onsite Online Help that appears within the application.

Updating Existing Data in a CRF

To update the existing data in a CRF, you can use any RDC Onsite page that displays CRF icons: Casebooks, Review CRFs, Review Discrepancies, and Review Investigator Comments pages. You can update data in a CRF by selecting the CRF icon for the patient, visit, and CRF you want to update.

To update a response in a CRF:

1. Open a CRF in the Data Entry window.

2. Select a response field.

3. Change the value of the response.

4. Navigate to another field. Depending on the CRF status, RDC Onsite processes your change as follows:

   - **For a CRF status of Entry Started (the CRF was previously saved incomplete):**

     – If the entry you recorded is valid, the system accepts the update.

     – If your response evokes a validation error, the Validation Error dialog box opens. See "Processing Validation Errors During Initial Data Entry" on page 3-24 for information.

   - **For a CRF status of Entry Complete:**

     – If the entry you recorded is valid, the Reason for Change dialog box opens. See "Specifying the Reason for Changing a Data Value" on page 3-28 for details.

     – If your response evokes a validation error, a change reason is also generally required for the update. In this case, a combination Validation Error and Reason for Change dialog box opens. See "Processing Validation Errors During Data Update" on page 3-29 for more information.

5. Click **Save** to save all pending CRF changes.

Specifying the Reason for Changing a Data Value

When you update a CRF previously saved as complete (**Entry Complete** status), RDC Onsite opens a Reason for Change dialog box.

To enter a reason why you changed a value on the CRF:

1. Click the **Reason** field and select an explanation from the list. The Reason field is a mandatory field.

2. Click the **Comment** field and enter additional information about why the value was changed.

3. Click **OK** to process your changes.

If the CRF was saved as incomplete (**Entry Started** status), you do not have to provide a change reason.

Processing Validation Errors During Data Update

When a validation error occurs during a data update, RDC Onsite displays a combination Validation Error and Reason for Change dialog box. See Figure 3–5.

This dialog box lets you acknowledge that the current value of the response field raised a discrepancy. In addition, and perhaps more importantly, you can use the dialog box to take immediate action on the discrepancy.

To respond to the validation error, select one of the following actions:

- Revising Discrepant Data
- Allowing Discrepant Data

Figure 3–5   Validation Error and Reason for Change Dialog Box

Revising Discrepant Data

The system lists the discrepant response in the **Description** field of the Validation Error and Reason for Change dialog box.

To revise data in the discrepant response field:

1. Click **Cancel**. The system closes the dialog box, deletes the discrepant response value, rolls back previously entered data, if any, and returns focus to the response field.

2. Revise the discrepant entry.

3. Continue to the next field.

Allowing Discrepant Data

If you feel that the entered data is correct, complete the Validation Error and Reason for Change dialog box as follows:

1. Review the **Error Message**. Ensure it has relevant information about the data entered.

2. Enter a comment in the **Comment** text box.

3. Select a **Change Reason** from the dropdown list provided in the **Reason** field. RDC Onsite also allows for user-supplied change reasons.

4. Enter an explanatory comment in the **Comment** field of the **Change Reason** section, if you want. The **OK** button becomes active.

5. Click **OK**. The dialog box closes and RDC Onsite moves the cursor to the next response field.

See "Changing Your Preferences for Data Entry" on page 3-26 for information on disabling validation error messages.

Saving a CRF

After entering data in the CRF, you must save your changes. Depending upon how your sponsor configures RDC Onsite, you can save a CRF as complete or as incomplete.

User Initiated Save

To save a CRF, click the **Save** icon in Data Entry window toolbar. Alternatively, you can press Alt+S.

When you initiate the save of a CRF, one of the following actions can take place:

-   RDC Onsite displays a *Processing...* message, and then displays a *Saved* confirmation message, indicating a successful CRF save. The CRF is always saved as Complete.

-   RDC Onsite displays a **Save Complete?** dialog box. This dialog box appears only if RDC Onsite is configured to show it. See "Changing Your Preferences for Data Entry" on page 3-26 for information on configuring this prompt.

    The Save Complete? dialog box offers you the option of saving the CRF as Save Complete or Save Incomplete. See Figure 3–6.

Figure 3–6   Save Complete? Dialog Box
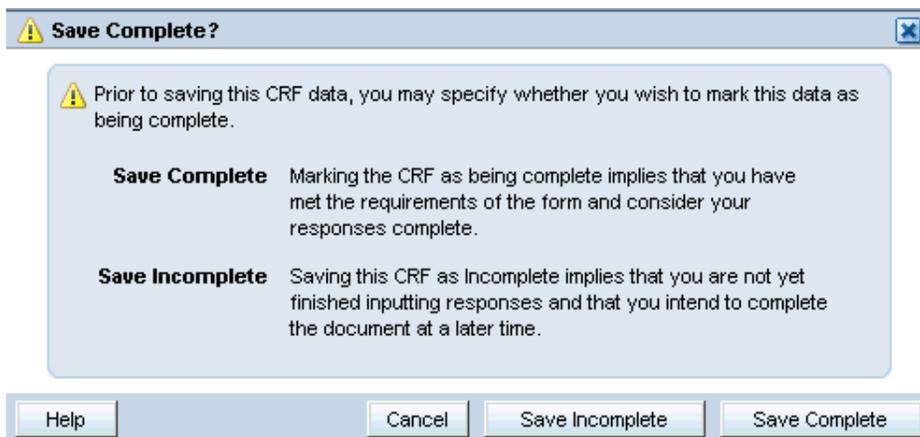
Save Complete

Click **Save Complete** if you met the form requirements and data entry is complete.

After you make a choice, the **Save Complete?** dialog box closes. The system confirms the save through a dialog box and focus returns to the CRF.

When you save complete, RDC Onsite may raise additional discrepancies. If you work with the **Highlight** option set to show **Active, Active and Other**, or **All discrepancies**, *and* you have used a Save option that does not close the CRF, newly discrepant fields are highlighted in red.

To review and address those discrepancies immediately, see "Resolving and Routing Discrepancies" on page 4-13.

When addressing all discrepancies at a later date, see "Finding CRFs with Discrepancies" on page 4-6.

Save Incomplete

Click **Save Incomplete** if data entry is incomplete, and you intend to complete the document later. Saving incomplete is possible if you at least fill in the header fields in the CRF.

When a CRF is saved incomplete, its status is **Entry Started**. By saving as incomplete, you can:

- Save data without raising system-generated discrepancies.
- Continue data entry in the same CRF later, without being prompted for a change reason on every field input.

Updates made to a CRF that has been saved incomplete are audited, as they are when a CRF is saved complete. The difference is that when a CRF is saved incomplete, the Reason for Change is PASS1 instead of a user-defined reason.

About Missing Required Header Fields

You must enter data in the header fields of a CRF before you save the CRF either as Save Complete or Save Incomplete. If you try to save the CRF without filling in the header fields, RDC Onsite highlights, and lists the required fields in a Missing Required Responses dialog box. Each field missing an entry in the CRF is highlighted with a red dashed line.

> **Note:** RDC Onsite treats non-header, mandatory response fields differently from header response fields. RDC Onsite raises a discrepancy when you save without entering a response for a non-header, mandatory question.

RDC Onsite Prompts for Saving Edits

RDC Onsite automatically prompts you to save your pending changes if you attempt any of the following actions before saving the CRF:

- Click the **Previous CRF** link (Alt+P) or the **Next CRF** link (Alt+N) if you open the CRF from the Casebooks page.
- Click the Close icon or press **Ctrl+W** to close the dialog box.

> **Note:** You can use combinations of keys including Ctrl on all supported devices except for iPad.

When you select one of these actions, RDC Onsite displays a **Save Edits?** dialog box.
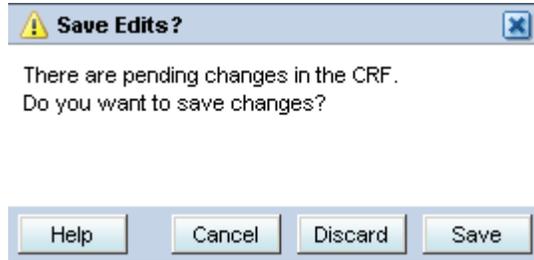
You can take one of the following actions:

- To cancel the attempted action and return focus to the CRF, click **Cancel.** Pending changes remain unaltered.

- To discard pending changes in the CRF and proceed with your selected action, click **Discard.**

- To save pending changes in the CRF and return to the CRF, click **Save.**

Effects of Discarding Changes

- If the CRF was previously saved, the system rolls back all saved values to response and information fields, maintains the current data entry status, and closes the CRF.

- If the CRF was not previously saved, the system clears values in all response and information fields, and closes the CRF. The CRF data entry status remains as *empty*.

Save and Automatic Refresh

Any time you save or delete a CRF, RDC Onsite checks the data and determines if there are any changes to the CRFs or intervals that are expected for the patient.

If new CRFs for the current visit are now expected, then RDC Onsite automatically inserts the newly expected CRFs into the Next/Prev list in the Data Entry window. Note that:

- RDC Onsite inserts the newly expected CRFs regardless of the CRF search criteria currently in effect.

- RDC Onsite inserts the newly expected CRFs only if you have the proper CRF access privileges and update privileges.

- RDC Onsite inserts the newly expected CRFs immediately after the current CRF. You can click **Next CRF** to view the newly expected CRF.

- The newly expected CRFs may include those that have been made newly expected by another user.

If CRFs with data are now no longer expected, then RDC Onsite displays the letter **N** (no longer expected) next to the CRF icon to indicate the change in status. Note that RDC Onsite indicates this change to the CRF icon on the Casebooks page only.

Upon completion of the save, RDC Onsite alerts you with a message that the expected CRFs have changed.

Changing CRF Status from Saved Incomplete

Your sponsor may instruct you to save the CRF incomplete instead of complete, after your initial data entry. Saving as incomplete lets you return to the CRF, review or update data, and then save the CRF as complete.

No data update is required to change the CRF status from **Entry Started** to **Entry Complete.**

Note: Once a document is Saved Complete, you cannot reverse CRF status from **Entry Complete** to **Entry Started**.

Removing Data from a CRF

During a clinical study, patient events may occur that require CRF sections to be marked as blank or to be deleted.

- Marking a CRF or CRF Section as Blank

- Deleting a Row from a Repeating Question Group

- Deleting a CRF

Marking a CRF or CRF Section as Blank

In certain circumstances, you may need to mark a CRF as intentionally blank; for example, if a patient fails to appear for a scheduled visit. When you mark a CRF or a CRF section as blank, its information becomes inaccessible and the section is grayed out. You can mark a CRF as blank only if you have update privileges.

For the CRF currently displayed in the Data Entry window, you can mark a CRF or CRF section blank by:

- Clicking the Blank Flag Icon

- Selecting the Blank Flag Check Box in the CRF

Note: You cannot mark a CRF or a CRF section as blank when:

- The CRF status is **Pass 2 Started, Pass 2 Pending**, **Pass 2 Complete**, or **Batch Loaded**.

- The CRF is opened in browse-only mode.

Clicking the Blank Flag Icon

To use the Blank Flag icon to mark a CRF as blank:

1. Open the CRF in the Data Entry window.

2. Click the CRF or CRF section.

3. Click the **Blank Flag** icon in the Data Entry window toolbar. RDC Onsite displays the CRF Blank Selection(s) Processing dialog box.
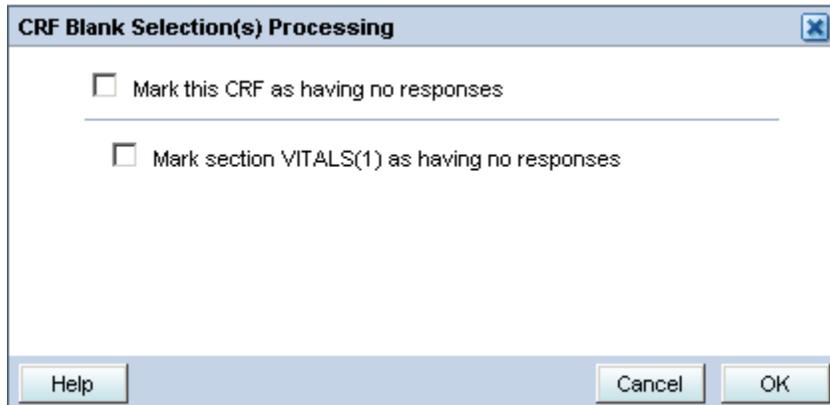
4. Select the check box for how you want to mark this data.

   ■ Mark this CRF as having no responses.

   ■ Mark section *section-name (number)* as having no responses. The system lists each section separately.

5. Click **OK**. The CRF or the related CRF section is marked blank, associated fields are grayed out, and cannot be updated. If the marked section contains data, the data remains visible until you save the CRF, but the values cannot be modified.

Selecting the Blank Flag Check Box in the CRF

Depending upon the design of the CRFs you use, select the **Blank Flag** check box in the CRF header or CRF section header. The **Blank Flag** check box option may not be available to you.

To use the Blank Flag check box to mark CRFs as blank:

1. Click the CRF or CRF section.

2. Select the **Blank Flag** check box in either the CRF header or CRF section header. A CRF Blank Selection(s) Processing dialog box appears with these choices:

   ■ Mark entire CRF as having no responses.

   ■ Mark section *n* as having no responses. The system lists each section separately.

   RDC Onsite grays out the CRF or the CRF section that you marked blank. If the marked section contains data, the data remains visible but cannot be modified.

Changing Between Blank and Non-blank Status

If you mark a CRF or CRF section blank, and then unmark and save the CRF, the previous values appear in the CRF without being grayed out.

To enter or modify data after marking a section blank:

1. Open the CRF that you marked blank in a Data Entry window.

2. Click the CRF or CRF section.

3. Deselect the **Blank Flag** check box.

If a CRF of status **Entry Complete** was marked blank (sectionally or fully), and you undo the blank selection, you must provide a change reason.

When you save changes after marking the CRF or a CRF section as blank, RDC Onsite deletes any existing responses in the marked sections or CRF. However, header field information is maintained.

Deleting a Row from a Repeating Question Group

The response fields of a repeating question group appear in many rows in the CRF. If necessary, you can delete a row from a repeating question group from within the CRF in the Data Entry window.

To delete a row, you can:

- Right-click a field in the row and select **Delete Row** from the menu.

- Click a field in the row and then click the **Delete Row** icon in the Data Entry window toolbar.

If the CRF status is **Entry Complete**, RDC Onsite prompts you for a change reason.

Deleting a CRF

You can delete a CRF only under certain circumstances. You can delete a CRF even if changes to it are pending.

You cannot delete a CRF if:

- Your sponsor has disabled the Delete CRF icon.

- You do not have update or batch update privileges

- The CRF is locked and you do not have the privileges to work with locked CRFs.

- The CRF data is frozen.

- The CRF is being updated by another user.

To delete a CRF:

1. Open a CRF in a Data Entry window.

2. Click the **Delete CRF** icon (trash can) in the toolbar. RDC Onsite opens the Delete CRF dialog box.

3. Click the **Change Reason** field and select an explanation from the list.

   The Change Reason field and the Change Comment field appear only if the CRF status is Entry Complete or Blank. These fields do not appear if the CRF status is Entry Started, or Saved as Incomplete with header data entered.

4. Enter a **Change Comment** if the field appears.

5. Select the check box if you want RDC Onsite to remember and reuse your comment information for subsequent CRF deletions.

6. Click **Delete** to proceed with the action. RDC Onsite prompts for confirmation that you want to delete the CRF.

   - To delete the CRF, click **OK.** RDC Onsite deletes the CRF and closes the Data Entry window.

   - To cancel the delete operation, click **Cancel.** The CRF remains at the same status.

Generating a CRF Report or a CRF History Report

The Data Entry Window allows you to generate two reports that are specific to the current CRF, the CRF Report and the CRF History Report.

The purpose of the CRF History report is to provide audit information that is not otherwise available in the data entry window. This includes:

- CRF Creation information (user, user role, date and time)

- History for fields not displayed in the CRF

- Deleted rows and prior history

- Prior history if the CRF was ever deleted

The CRF Report is a single-CRF Patient Data Report that includes the CRF representation itself, followed by all available ancillary data, including discrepancies, audit history and approval history.

Both reports are generated in a background process, and the 'download' icon appears when the report completes. You select that icon to open the PDF in a separate window. If data is updated for the CRF after the report has been generated, the 'download' icon changes to a 'stale' icon, indicating that you can no longer view the latest report. You can generate a new report if needed.

Viewing the Audit History of a CRF Field

The Audit History pane, which appears at the bottom of the Data Entry window, provides a history of the field currently selected in the CRF.

By default, the Audit History pane is collapsed. To open the pane, click the arrow on the horizontal splitter bar at the bottom of the window.

The audit history records the date of change, the content of the field before and after change, the person who made the change, the reason for the change, and the change comment.

To view the audit history of a CRF field:

1. Open a CRF in the Data Entry window.

2. Click the arrow on the horizontal splitter bar at the bottom of the window to open the Audit History pane.

3. Click the **Highlight** field in the toolbar and then select **Audit History** from the list. RDC Onsite highlights all fields that have an audit history in blue.

4. Click a highlighted field. The **Audit History** pane displays a complete audit trail for the selected field.
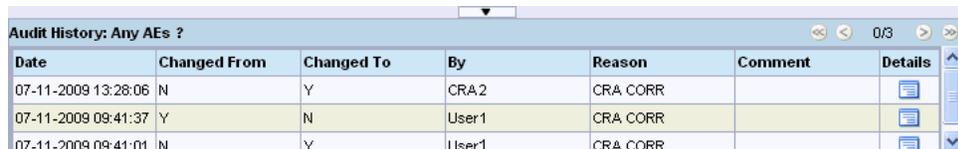
Audit History: Any AEs ?							
Date	Changed From	Changed To	By	Reason	Comment	Details	
07-11-2009 13:28:06	N	Y	CRA2	CRA CORR			
07-11-2009 09:41:37	Y	N	User1	CRA CORR			
07-11-2009 09:41:01	N	Y	User1	CRA CORR			

To view more information in the Audit History pane, you can:

- Click the arrow icons to navigate to the first, previous, next, or last entry in the list.

- Click the **Details** icon if any of the fields in an entry are truncated. The Audit History Details dialog box displays the full text for each field.

If the Audit History pane is already open, click a field to view its audit history.

Alternatively, you can right-click a field and then select **Show Audit History** from the menu.
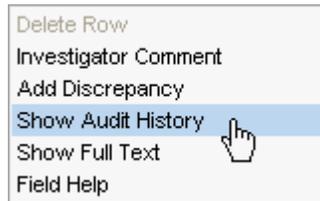
RDC Onsite automatically opens the **Audit History** pane and displays a complete audit trail for the selected field.

Audit History for Extended Text Fields

Because an extended text field can have up to 10,000 characters, the information and the layout of the information in the Audit History pane is different from the layout of other fields. Specifically, the Changed From field displays only the ATTACHMENT prefix and the truncated response text.

In addition, the Changed To, and Comment fields may be lengthy for an extended text field. To display the full text for each field, click the **Details** button in the Audit History pane.

Using the Navigator Pane for Discrepancies and Investigator Comments

The Navigator pane appears at the right edge of the Data Entry window. You use this pane to review, in list format, all discrepancies or investigator comments for a CRF.

When you are entering and updating data in a CRF, you can use the Navigator pane:

- To view detailed information about a discrepancy or an investigator comment
- To view the history of a discrepancy or an investigator comment
- To update a discrepancy or an investigator comment
- To route or resolve a discrepancy

For detailed information on using the Navigator pane for discrepancies and investigator comments, see Chapter 4, "Managing Discrepancies" and Chapter 5, "Reviewing Investigator Comments."

Opening, Closing, and Resizing the Navigator Pane

When you open the Data Entry window for the first time in a session, the Navigator pane is collapsed. Upon subsequent openings of the Data Entry window, the Navigator pane displays as you left it in the previously opened Data Entry window. The Navigator pane reverts to its default state (collapsed) when you log out or when you change to another study.

- To open the Navigator pane, click the arrow on the right edge of the Data Entry window.
- To close the Navigator pane, click the arrow on its left edge.
- To resize the Navigator pane, drag the vertical and horizontal splitter bars to adjust the width and length of the opened pane.

Selecting a Navigator Tab

- To view, update, and take action against discrepancies, click the **Discrepancy** tab in the Navigator pane. By default, the Navigator pane opens with the Discrepancy tab in view.

- To view and update investigator comments, click the **Investigator Comment** tab in the Navigator pane.

Working with the List Pane and the Details Pane

In the Navigator pane, the List pane and the Details pane organize information and facilitate navigation in the CRF.

The **List pane** lists the fields in the CRF that have either a discrepancy or an investigator comment, depending on the currently selected tab. The **Details pane** displays more information about the discrepancy or investigator comment.

When you select an item in the List pane, RDC Onsite:

- Scrolls the CRF, if necessary, to display the associated field. The associated field is outlined with a blue dashed line.

- Outlines the associated field with a blue dashed line.

- Refreshes the information in the Details pane.

When working with the List or Details pane:

- To expand or collapse a pane, click the **+** or **–** icon in the title bar.

- To view long lists, use the scroll bar at the edge of the pane.

- To select an item in the List pane, use the mouse or press the up and down arrow keys. In addition, you can click the navigation icons in the List pane to go to the first, previous, next, and last item in the list.

Adding Pages

The Patient Casebooks page provides options for:

- Adding an Unplanned Visit Page
- Adding An Other Page

Adding an Unplanned Visit Page

From the Patient Casebooks page, you can add an unplanned page to a visit using a CRF that has already been used once for the visit. The **Add Visit Page** button is active only if you have update privileges.

You can add an unplanned visit page when:

- There is no space in the initial CRF planned for the visit, and additional information needs to be added, using the same form. In this case, RDC Onsite assigns unique sub-visit numbers to identify each of the CRF instances.

- The patient makes an unscheduled visit. In this case, the sub-visit number correlates to a visit that happens after Visit X and before Visit Y. (You add the Visit pages to Visit X.) You can add Visit pages multiple times to include all the required CRFs for the unscheduled visit.

To add a visit page:

1. Navigate to the Patient Casebooks page.

2. Enter the search criteria for your patient and click **Search.**

3. Click the **Visit** field and select a visit number from the list.

4. Select the row with your patient.

5. Click the **Add Visit Page** button. The Add Visit Page dialog box opens, listing all the planned CRFs for the current visit, patient, study, and site.

   a. Select the CRF that you want to add to the visit and then click **Continue.** RDC Onsite prompts you to select a sub-visit to add to the current visit.

   b. Select the sub-visit number from the list. The new CRF is identified accordingly. For example, if the sub-visit is 1 and the CRF is PE, the new visit page is PE.1.

   If you have previously added visit pages, there may be more than one choice for a sub-visit. If you are adding a page for lack of space in the first CRF, accept the default.

   Otherwise, the sub-visit number may represent actual unscheduled visit numbers, and you should choose accordingly.

   c. Click **Continue** to add the new page to the current visit.

6. Return to the Patient Casebooks page to view the new, empty CRF icon in the designated patient row and CRF column of the Casebook Spreadsheet.

   Notice that a new CRF column may have been inserted, labeled with both the CRF name and the sub-visit number.

7. Click the newly inserted CRF icon to open the CRF in a Data Entry window.

8. Enter data and save the CRF.

Note: The Add Visit Page dialog box lists the set of planned CRFs for the selected visit and patient. However, during the study design, one or more of these CRFs may have been identified as a CRF that cannot be used for unplanned use. Such CRFs do not appear in the selection list.

Adding An Other Page

From the Patient Casebooks page, you can add a page to a visit, using CRFs not already planned for the current visit, with the Add Other Page function. The **Add Other Page** button is active only if you have update privileges.

To add an Other page to a casebook:

1. Navigate to the Patient Casebooks page.

2. Enter the search criteria for your patient and click **Search.**

3. Click the **Visit** field and select a visit number from the list.

4. Select the check box for your patient.

5. Click the **Add Other Page** button. The Add Other Page dialog box opens and lists the CRFs that you can add to the current visit for the selected patient. The dialog box also displays the study and site name.

6. Select the CRF and then click **Continue.**

If one or more sub-visits are already added to the visit, RDC Onsite prompts you to select a sub-visit number. Select the sub-visit number and click **Continue.**

RDC Onsite closes the dialog box and returns to the Patient Casebooks page. If necessary, a new CRF column is added to the spreadsheet. A new, *empty* CRF icon appears in the appropriate column.

7. Click the newly inserted CRF icon to open the CRF in a Data Entry window.

8. Enter data and save the CRF.

RDC Onsite numbers the new CRF based on the total number of planned CRFs for the visit, and the existence of other unplanned pages. For example, if the current visit has three planned pages, and you add your first unplanned page with a CRF called AE, after the third CRF, then the system numbers it as 3 U1.

Note: The Add Other Page dialog box lists all CRFs in the Oracle Clinical casebook definition that are checked for unplanned use. The list excludes CRFs planned for the current visit.

Validating Patient Data

The sponsor designs validation checks to prevent data entry errors and to streamline responses in CRFs. If you enter or update a response that does not meet specified criteria, RDC Onsite prompts you for clarification.

In addition, your sponsor defines complex validation checks as well as the ones that execute when you navigate from a field after entering a value. These complex checks are executed by the **Validate** patient(s) option provided on the Patient Casebooks page.

According to instructions from your sponsor, you can validate patient data on completion of data entry for a visit. RDC Onsite only validates CRFs of status **Entry Complete**, and CRFs currently not being updated by another user.

The **Validate** option is available only if you have update privileges.

To validate patient data after data entry is complete:

1. Navigate to the Patient Casebooks page.

2. Select one or more patients.

3. Click the **Action** menu in the table bar and select **Validate** from the list.

4. Click **Continue.** RDC Onsite prompts for confirmation that you want to validate the selected patients.

5. Click **Continue.** A dialog box confirms the validation of the selected patients.

6. Click **Close** to close the dialog box and return to the Patient Casebooks page.

   RDC Onsite refreshes the patient and CRF icons in the casebook spreadsheet to reflect the validated CRFs.

4

Managing Discrepancies

A **discrepancy** is any data that falls outside of an expected range of values or is otherwise flagged during the edit check process as an error. Examples of a discrepancy are an invalid date, an age greater than the maximum age for the study, and inconsistent information across CRFs.

RDC Onsite provides several ways for you to review, resolve, and route discrepancies. This chapter includes the following topics:

- Understanding Discrepancies and the Management Process
- Types of Discrepancies
- Discrepancy Status
- Finding CRFs with Discrepancies
- Reviewing Discrepancies
- Resolving and Routing Discrepancies

Understanding Discrepancies and the Management Process

Discrepancy management is the process that systematically addresses discrepancies generated within a study. Correcting and managing discrepancies ensures that the data is complete, accurate, and compliant with the study protocol.

Discrepancies Raised in the Validation Process

RDC Onsite checks and validates patient data at the following times:

- As you enter data or when you save a CRF, RDC Onsite executes simple edit checks and then flags any data entry errors. You can choose to correct these discrepancies immediately during the data entry process.
- During the patient validation process, RDC Onsite executes complex edit checks, typically relating to values that do not correlate across CRFs. You can conveniently execute patient validation after you complete the data entry for a visit.

> **Note:** Edit checks, depending on how they are configured, can:
>
> - fire when the CRF is saved
> - fire when running the patient validation job
> - fire outside of your RDC session
>
>   If a CRF shows a red icon on the surround but upon opening shows no active discrepancy then it is likely the data has been modified but is associated with a Multivariate discrepancy that is still current / was created by an offline procedure. In this case the regular study-wide batch validation will pick up the discrepancy and obsolete it. Once the discrepancy has been closed then the CRF icon will no longer appear as red.

- If patient validation is not executed, regular nightly study-wide batch validation raises the discrepancies that would ordinarily be caught by patient validation. In addition, batch validation executes edit checks that are even more complex and are not efficient to execute in an online session.

Manual Discrepancies Added by Users

In addition to the discrepancies that RDC Onsite generates, you can identify discrepancies by a visual review of the data. Users with the proper privileges can question information in a CRF and create a manual discrepancy for others to review.

Your Goal: Resolve All Discrepancies and Ensure Clean Data

For each discrepancy assigned to you, you must identify the cause, assess the error, and determine the appropriate action.

You can choose to immediately resolve the discrepancy as it is raised, or you can defer the resolution for later. In addition, you can route a discrepancy to another user. Your goal is to resolve all discrepancies associated with every CRF and to ensure clean data.

You use the following general procedure to manage discrepancies:

- Search for CRFs with discrepancies
- Open the CRF in the Data Entry window
- Use the tools in the Data Entry window to resolve a discrepancy, route a discrepancy, or create a manual discrepancy

Types of Discrepancies

RDC Onsite has two types of discrepancies:

- System-generated discrepancies
- Manual discrepancies

You can choose to resolve discrepancies as they are raised, or you can defer their resolution for later.

System-Generated Discrepancies

System-generated discrepancies are those discrepancies that are automatically created by RDC Onsite. These discrepancies alert you to a possible problem with a response value, or a group of response values.

Your sponsor builds edit checks into the study database. RDC Onsite executes these edit checks and raises discrepancies at various points in the data entry process, including when you update data in a CRF, save a CRF, or validate a patient. In addition, RDC Onsite creates discrepancies during complex edit checks executed on a nightly basis.

There are two types of system-generated discrepancies:

- Univariate (simple)

- Multivariate (complex)

Univariate Discrepancies

A **univariate discrepancy**, which is also called a **simple discrepancy**, is a discrepancy that depends on the value of a single data point. For example, demographics such as gender, age, weight, and birthdate are values with a single data point.

When you enter data into a field and then exit from that field (by pressing the Tab key or clicking another field), RDC Onsite checks the data you entered. If the data is not valid for the field, RDC Onsite raises a univariate discrepancy. For example, if the current study is for patients older than 50 years of age and you enter an age of 40, RDC Onsite raises a univariate discrepancy to alert you to the problem.

Univariate discrepancies typically relate to the format of the data entered, or to a value that does not meet pre-defined rules for the field. You can either resolve the discrepancy immediately, or allow the discrepancy temporarily and resolve it later.

Multivariate Discrepancies

A **multivariate discrepancy**, which is also called a **complex discrepancy,** is a discrepancy that is dependent on two or more data points. These data points can be within a single CRF or across multiple CRFs and visits.

RDC Onsite raises multivariate discrepancies in the following cases:

- **Save a CRF.** When you save a CRF by selecting **Save Complete**, RDC Onsite validates the patient data. If data is missing or if data does not correlate across CRFs, RDC Onsite raises a multivariate discrepancy.

- **Validate a patient.** Upon completion of data entry for a visit, RDC Onsite validates the data. If values do not correlate across CRFs, RDC Onsite raises a multivariate discrepancy.

- **Run regular batch validation.** If patient data is not validated upon completion of data entry for a visit, nightly batch validation ensures that discrepancies ordinarily raised by patient validation are detected. Batch validation may also execute complex edit checks that are too time-consuming for an online session.

Manual Discrepancies

A **manual discrepancy** is a discrepancy that is generated by a user, rather than by RDC Onsite. You can add a manual discrepancy to a CRF section or to a field. You can resolve discrepancies as they are raised, or defer their resolution for later.

Typically, CRAs and data managers enter manual discrepancies (or queries) and route them to site users or other user groups for a response. Investigators and other site users may also create manual discrepancies. However, to enter a manual discrepancy, you must be assigned either update or update discrepancies privileges.

If you have the appropriate privileges, you can enter the following types of manual discrepancies:

- Manual field discrepancies

- Manual section discrepancies

- Manual internal discrepancies

Manual Field Discrepancies

You can enter a manual discrepancy in association with a specific response field in a CRF. Note that only one manual discrepancy can be associated with a response field regardless of discrepancy status.

RDC Onsite processes manual field discrepancies as follows:

- You enter a manual discrepancy against a response field in the CRF.

- During the study, you resolve this manual discrepancy.

- Once the manual discrepancy is resolved, RDC Onsite lets you add a second manual discrepancy to the same response field. When you save the second manual discrepancy, RDC Onsite overwrites the *first resolved manual* discrepancy with the second discrepancy because only one manual discrepancy can be associated with a response field regardless of discrepancy status.

- You can continue to enter and resolve discrepancies for the same response field. RDC Onsite overwrites the previous resolved discrepancy with the new one you add.

> **Note:** The discrepancy history maintains a complete audit for the discrepancy, even when RDC Onsite overwrites previously entered and resolved discrepancies.

Manual Section Discrepancies

You can enter one or more discrepancies in association with CRF sections. You can use a section discrepancy to communicate CRF-related issues among site personnel, data managers, and monitors. Unlike a field discrepancy, you can associate multiple discrepancies with a CRF section.

Internal Manual Section Discrepancies

Section discrepancies can be routed to an internal or **hidden** status. If your discrepancy management system is configured to use the hidden status, you can create a manual section discrepancy, and route it to another user group with an internal status. It is hidden from other user groups who need not be involved in the communication. Typically, this is configured for use by various user groups internal to the sponsor or CRO, not by site users.

Discrepancy Status

The **discrepancy status** is a designation that describes the current state of a CRF with regard to discrepancies. The discrepancy status describes the way a discrepancy appears to a user of a particular role. The same discrepancy at the same point in time can therefore appear differently to different users.

RDC Onsite uses the following statuses to track the discrepancies in a CRF:

- Active

- Other

- Hidden
- Closed
- None

Active and Other Discrepancies

Active discrepancies are those discrepancies that are assigned to you or your user role for action. Your action may be to resolve the discrepancy or to route the discrepancy to another user for resolution.

Other discrepancies are those discrepancies that are assigned to another user role for action. A discrepancy that appears as **Active** to your user role appears as **Other** to another user role and vice versa.

An **open** status refers to CRFs that have active discrepancies, other discrepancies, or both. Open discrepancies require action and resolution.

The status of a discrepancy changes when you either resolve it or route it. If you resolve a discrepancy, its status changes from open to closed. However, if you only update the discrepancy, for example, by editing comments, its status does not change.

Hidden Discrepancies

A **hidden** discrepancy is a discrepancy that you cannot see because of your user role.

Closed Discrepancies

A **closed** discrepancy is a resolved discrepancy. To close a discrepancy, you must specify a resolution reason that is saved as part of the discrepancy record.

A system-generated discrepancy becomes obsolete if you update data in conformance with the edit checks. Specifically, the discrepancy becomes obsolete whenever the edit check that originally raised the discrepancy is executed again: upon updating the field, saving the CRF, validating the patient, or running batch validation. RDC Onsite does not display obsolete discrepancies but does maintain an audit history for the field.

You can manually resolve, and thereby close, both system-generated and manual discrepancies. You can resolve a discrepancy by correcting the data, updating the data, responding to a monitor's query, or re-confirming data veracity.

A **clean** status refers to CRFs that have either no discrepancies or only closed discrepancies (none or closed).

Colors Indicate Discrepancy Status

RDC Onsite uses color to indicate the status of discrepancies in a CRF.

For example, to alert you to an active discrepancy, RDC Onsite highlights all patient icons and CRF icons related to the particular discrepancy in red. Similarly, to mark discrepancies with a status of other, RDC Onsite highlights all icons in yellow.

See Table 4–1 for more information on the colors that RDC Onsite uses to indicate the discrepancy status.

Table 4–1   Colors Used to Indicate Discrepancy Status

Discrepancy Category	Discrepancy Status	Patient Icon	CRF Icon	Field in the Data Entry Window
Open	Active	Red	Red	Red
	Other	Yellow	Yellow	Yellow
Clean	Closed	White	White	Green
	None			

Finding CRFs with Discrepancies

Your options for finding CRFs with discrepancies are:

- Specifying Discrepancy Search Criteria
- Using a Discrepancies Activities Link
- Letting Color Guide You to Discrepancies

After you find CRFs with discrepancies, you open a CRF in the Data Entry window to take action on the discrepancies in that CRF. Your action may be to correct the discrepancy, close the discrepancy, or route the discrepancy to another user.

Note that you can use the Review Discrepancies page, the Patient Casebooks page, and the Review CRFs page to find and review the discrepancies in a CRF. However, the way in which RDC Onsite displays and groups the information about discrepancies is different on each page. Depending on your work habits, you may have a preference for which page you want to use. See "Reviewing Discrepancies" on page 4-8 for more information using each page.

Specifying Discrepancy Search Criteria

You can use the various search criteria to find discrepancies based on their status. The search options available to you depends on the page you select.

On the Home page, the discrepancy status is a patient-level search parameter.

On the Patient Casebooks page and the Review CRFs page, the discrepancy status is a CRF-level search parameter.

To find CRFs with specific types of discrepancies, you can select the following search criteria:

- **All** — Retrieves all CRFs regardless of discrepancy status. **All** is the default value.
- **Active** — Retrieves CRFs with any active discrepancies; does not retrieve CRFs that have only hidden discrepancies. Active discrepancies are those discrepancies that are assigned to you or your user role for action.

- **Other —** Retrieves CRFs with other discrepancies; does not retrieve CRFs that have only hidden discrepancies. Other discrepancies are those discrepancies that are assigned to another user role for action.

- **Open (Active & Other) —** Retrieves CRFs with active or other discrepancies; does not retrieve CRFs that have only hidden discrepancies.

- **Clean (None or Closed) —** Retrieves CRFs with no discrepancies or with closed discrepancies, as well as CRFs that have only hidden discrepancies.

  On the Review Discrepancies page, the **Clean** option is replaced by **Closed.** If you select **Closed,** the search does not retrieve hidden closed discrepancies.

  Note: On the Review Discrepancies page, the **Active, Other,** and **Open** options do not retrieve hidden discrepancies.

To find CRFs that have discrepancies:

1. Open one of the following pages:
   - Review Discrepancies page
   - Home page
   - Patient Casebooks pages
   - Review CRFs page

2. Click the ▷ button to expand the Search pane. Note that the set of search fields available to you depends on the page you selected.

3. Select the type of discrepancy that you want to find.

4. Use the other search fields to specify one or more additional criteria and further restrict the search. For example, you can:
   - Search only for CRFs that have a discrepancy status of active.
   - Search only for CRFs that have a discrepancy status of active AND are in the patient range from 1 to 100.
   - Search only for CRFs that have a discrepancy status of active AND are in the patient range from 1 to 100 AND have a CRF name of Vitals.

5. Click **Search** to execute the search. RDC Onsite displays the CRFs or patients that match your search criteria.

You can click on any CRF to open the CRF in the Data Entry window and update the discrepancies for that CRF. See "Resolving and Routing Discrepancies" on page 4-13 for more information.

Note that from the Home page, you first select the patients with discrepancies that you want to review. You can then drill down to the Review Discrepancies page or the Patient Casebooks page to open a CRF in the Data Entry window.

Using a Discrepancies Activities Link

The Activities section on the Home page can include links to some of your common tasks. Your sponsor creates, customizes, and labels all the links in the Activities section. These links, if defined, are valuable shortcuts to your *daily activities.*

Your sponsor may choose to include one or more links to help you review discrepancies. For example, your sponsor can create a **Review _n_ Active Discrepancies** link, where _n_ represents the number of discrepancies that are your responsibility.
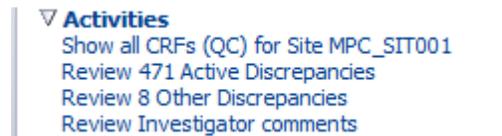
When you click the **Review _n_ Active Discrepancies** link, RDC Onsite automatically:

- Executes the search that your sponsor defined when creating the link

- Opens the Review Discrepancies page

- Lists all the active discrepancies across all the patients and CRFs for the current site

If custom review types are defined and used in the current study and site, the Activities links allows you to filter CRFs based on your review types privileges. For example, if you have safety review privileges, you can use the links to filter new, non-blank or verified CRFs that require safety review.

Your sponsor can name the link differently or customize links to filter discrepancies according to different criteria.

Note that after you click a customized link, you always have the option to expand the Search pane and specify a smaller subset of patients or CRFs to review or update.

Letting Color Guide You to Discrepancies

RDC Onsite uses color to indicate the status of the discrepancies, if any, in a CRF. For the patient icons and the CRF icons, RDC Onsite uses:

- Red to indicate active discrepancies

- Yellow to indicate other discrepancies

- White to indicate no discrepancies

You can let these colors be your guide to finding CRFs with discrepancies.

Reviewing Discrepancies

To find, order, organize, and review CRFs with discrepancies, you can use the Review Discrepancies page, the Patient Casebooks page, or the Review CRFs page.

The way in which RDC Onsite displays and groups the information about discrepancies is different on each page. Depending on your work habits, you may have a preference for which page you want to use.

The following sections describe the advantages and details for using each page:

- Working with the Review Discrepancies Page

- Using the Patient Casebooks Page to Review Discrepancies

- Using the Review CRFs Page to Review Discrepancies

Working with the Review Discrepancies Page

The Review Discrepancies page provides a list of discrepancies that you can scroll through and sort. See Figure 4–1.

Each *row* contains the information for one discrepancy. If a CRF has more than one discrepancy, RDC Onsite lists each discrepancy for that CRF in its own row.

The *columns* display the following information about each discrepancy:

- The patient number

- The visit name and date

- The CRF name, the question or section in the CRF, and the response that caused the discrepancy

- The review status for the discrepancy

- A description of the discrepancy

Figure 4–1   Review Discrepancies Page

The Review Discrepancies page is especially useful for managing discrepancies because you can glance at the discrepancies across CRFs and look for patterns. You can view a brief description of each discrepancy without opening the CRF.

Other advantages of using the Review Discrepancies page to manage your discrepancies include:

- You can sort discrepancies by any column, such as by CRF name or by description. Sorting lets you organize your work.

- You can examine the details and history of a discrepancy without opening the CRF.

- You can preview discrepancies to organize them, determine priorities, and assess which ones to resolve or route.

Navigating to the Review Discrepancies Page

To navigate to the Review Discrepancies page, you can use any of the following methods:

- Select a customized activity on the Home page.

- Open the Review Discrepancies page directly and then search for CRFs with discrepancies.

- Drill down to the Review Discrepancies page with a patient selection from the Home page or the Patient Casebooks page.

- Drill down to the Review Discrepancies page with a CRF selection from the Review CRFs page.

Once you navigate to the Review Discrepancies page, you can:

- Review the information displayed on the Review Discrepancies page and sort the columns before deciding on which discrepancies to address.

- Click a CRF icon to open the CRF in the Data Entry window and work on the selected discrepancy.

- Click **Reset** to remove the current search criteria and then re-enter a different search.

Sorting Discrepancies

Before you begin to resolve or route discrepancies, you may want to sort the list of discrepancies to help you organize your work.

By default, the Review Discrepancies page lists discrepancies in ascending order by patient number. However, you can click any column header to sort the list by the contents of that column.

You can sort the list in ascending order or descending order. An up arrow in the selected column indicates the list is sorted in ascending order; a down arrow indicates the list is sorted in descending order. You can click the same column heading to toggle between an ascending and a descending sort.

Sorting the list may also provide clues about CRF questions that often produce a discrepancy or about common data entry problems that need to be addressed. For example, you can:

- Sort by **Description** to find any preponderance of a particular type of discrepancy.

- Sort by **Question/Section** to see those questions that often produce a discrepancy.

- Sort by **Review Status** to group discrepancies according to their current status.

- Sort by **Visit Date** to view discrepancies by the date of the visit.

> **Note:** Depending on how you prefer to work or what your current task involves, limiting the search may be more useful than sorting the columns.
>
> For the patient number, the visit name, and the CRF name, you can sort the list of discrepancies on those columns. Alternatively, you can enter Search criteria into the corresponding fields (Patient Range, Visit, and CRF Name) to limit the number of discrepancies found.
>
> For example, you can search only for discrepancies in the CRFs for Visit 3. In this case, you would not need to sort the list by Visit Name because the list would only include CRF discrepancies for Visit 3.

Viewing the Details of a Discrepancy

On the Review Discrepancies page, click the **Detail** icon in the Detail column to review any related values and a discrepancy history without having to open the CRF. See Figure 4–2.

For multivariate discrepancies, the Review Discrepancies page also displays a **MULTI** link in the Question/Section column and the Response column. You can click either the **MULTI** link or the **Detail** icon to view more information about a multivariate discrepancy.

Viewing additional details is especially useful when a multivariate discrepancy involves more than one CRF. For example, suppose the birthdate in the Demography CRF indicates the patient is 84 years old, but the Inclusion/Exclusion CRF indicates the patient is between 30 and 55 years. The discrepancy appears for the primary CRF, which is the Inclusion/Exclusion CRF in this example.

To view details and then take action on a multivariate discrepancy:

1. Open the Review Discrepancies page.

2. Sort by **Description** to find a group of the same type of multivariate discrepancy.

3. Select the **Detail** icon for a discrepancy.

4. Review the **Related Values** section of the Discrepancy Details pane. This section lists the CRFs involved with the discrepancy.

   The Related Values section does not display entries for related values from any CRFs that are hidden based on your user role.

5. Select one CRF icon after the other, to view both the contributing CRFs in adjacent windows. Decide on your course of action, perhaps updating data in one or the other of the CRFs.

Figure 4–2   Viewing the Details of a Discrepancy

Discrepancies and Extended Text Fields

You can add discrepancies to an extended text field. However, discrepancy listings for such fields do not display the complete extended text. Instead, a discrepancy listing displays the ATTACHMENT prefix followed by a truncated response text. The system reserves 24 characters of the defined field length for the ATTACHMENT prefix.

Therefore, the number of characters in the truncated response text is calculated as follows:

```
Characters in Truncated Reponse Text = Defined Field Length – 24
```

Extended text fields support the following types of discrepancies:

- Manual discrepancies.

- Multivariate discrepancies. Note that RDC Onsite runs this against the truncated response text, not the complete extended text.

- Hidden discrepancies.

In the Discrepancies Details pane, you can view only the ATTACHMENT prefix and the truncated response text.

Using the Patient Casebooks Page to Review Discrepancies

The Patient Casebooks page organizes CRF icons in patient rows and CRF columns in casebook order. This organization can be useful in finding discrepancies on a patient-by-patient or visit-by-visit basis.

Managing discrepancies from the Patient Casebooks page has another advantage. When you open a CRF from the Patient Casebooks page, the Next CRF and Previous CRF links are available in the Data Entry window. You can use these links to cycle through the CRFs and discrepancies for the selected patient, without having to return to the Patient Casebooks page.

Using a Filtered Casebook Spreadsheet View

When you use the Next CRF and Previous CRF links along with search criteria, you can filter the casebook and display only the CRFs needed for your work. For example, you can search for and display only CRFs with active discrepancies.

In this case, clicking the **Next CRF** link in the Data Entry window navigates only to the CRFs with active discrepancies, skipping empty CRFs and CRFs with no active discrepancies, without having to return to the Patient Casebooks page.

Furthermore, the Patient Casebooks page displays only those CRFs that have active discrepancies for the filtered patients, resulting in a sparsely populated spreadsheet. For this example, the Patient Casebook spreadsheet:

- Displays all red CRF icons. (Icons are red because of the **Active** discrepancy search criteria. The display changes based on the specified search criteria.)
- Does not display CRF icons where data is expected, or where data has been entered, but the CRF has no active discrepancies.

Using a Non-filtered Casebook Spreadsheet View

If you prefer to see CRF icons for all entered data, select **All** in the Discrepancy field in the Search pane. When you execute the search, RDC Onsite refreshes the spreadsheet on the Patient Casebooks page. The spreadsheet still displays only patients with discrepancies, but you see all entered CRFs for those patients, with or without discrepancies. You can then select any CRF icon to open it in the Data Entry window and take action on the discrepancies.

Using the Review CRFs Page to Review Discrepancies

The Review CRFs page displays CRFs with discrepancies in a list format that you can scroll through and sort.

Similar to the Patient Casebooks page, you can use the Review CRFs page to identify all CRFs with discrepancies. The Review CRFs page provides additional information about each CRF, including the dates on which the CRF was last modified, verified, approved, and locked. You can sort the CRF list by any of the date fields. For example, sort by the Modified Date to work on the oldest CRFs first.

> **Tip:**   Select the **Show Timestamps** check box to view time stamps in the date fields.

Resolving and Routing Discrepancies

After you search for and identify CRFs with discrepancies, you can click a CRF icon to open the CRF in a Data Entry window and take action on a discrepancy. While the

Data Entry window is open, you can decide to work on one, some, or all the discrepancies for that CRF.

Topics in this section include:

- Highlighting the Discrepancies in a CRF
- Reviewing Discrepancies in the Navigator Pane
- Taking Action on Discrepancies
- Creating and Routing Manual Discrepancies

Highlighting the Discrepancies in a CRF

The Data Entry window uses the following colors to highlight the different types discrepancies in a CRF:

- **Red** highlights fields with active discrepancies
- **Yellow** highlights fields with other discrepancies
- **Green** highlights fields with closed (manually resolved) discrepancies

---

> **Note:** RDC Onsite highlights fields according to the discrepancy that takes precedence. If a field has various discrepancies, then active discrepancies take precedence over other and closed discrepancies, and other discrepancies take precedence over closed discrepancies. For example, if a field has both active and other discrepancies, then RDC Onsite highlights the field in red.
>
> In addition, RDC Onsite does not highlight fields that have only hidden discrepancies.

To highlight the fields that have one or more discrepancies:

1. Click **Highlight** in the toolbar in the Data Entry window.
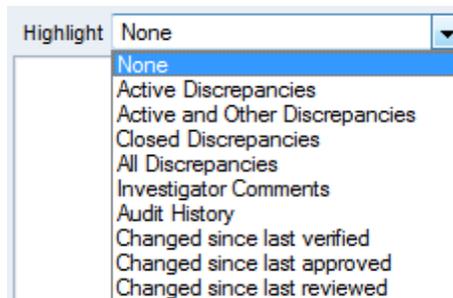
2. Select an option from the list. Your options for highlighting discrepancies are:

   - **Active Discrepancies —** Highlights all fields associated with active discrepancies in red. Active discrepancies require action by your user role or group.

   - **Active and Other Discrepancies —** Highlights all fields associated with active discrepancies in red and all fields associated with other discrepancies in yellow. Other discrepancies require action by another user role or group.

   - **Closed Discrepancies —** Highlights all fields associated with a manually resolved (user closed) discrepancy in green.

- **All Discrepancies —** Highlights all fields associated with active, other, and closed discrepancies in their respective colors (red, yellow, and green).

- **None —** Highlights no fields.

Reviewing Discrepancies in the Navigator Pane

The Navigator pane, shown in Figure 4–3, displays on the right side of the Data Entry window. You use the Navigator pane to review, in list format, all discrepancies for a CRF. As you navigate through the list of discrepancies, the cursor simultaneously navigates through the associated fields in the CRF.

Figure 4–3   Reviewing Discrepancies in the Navigator Pane
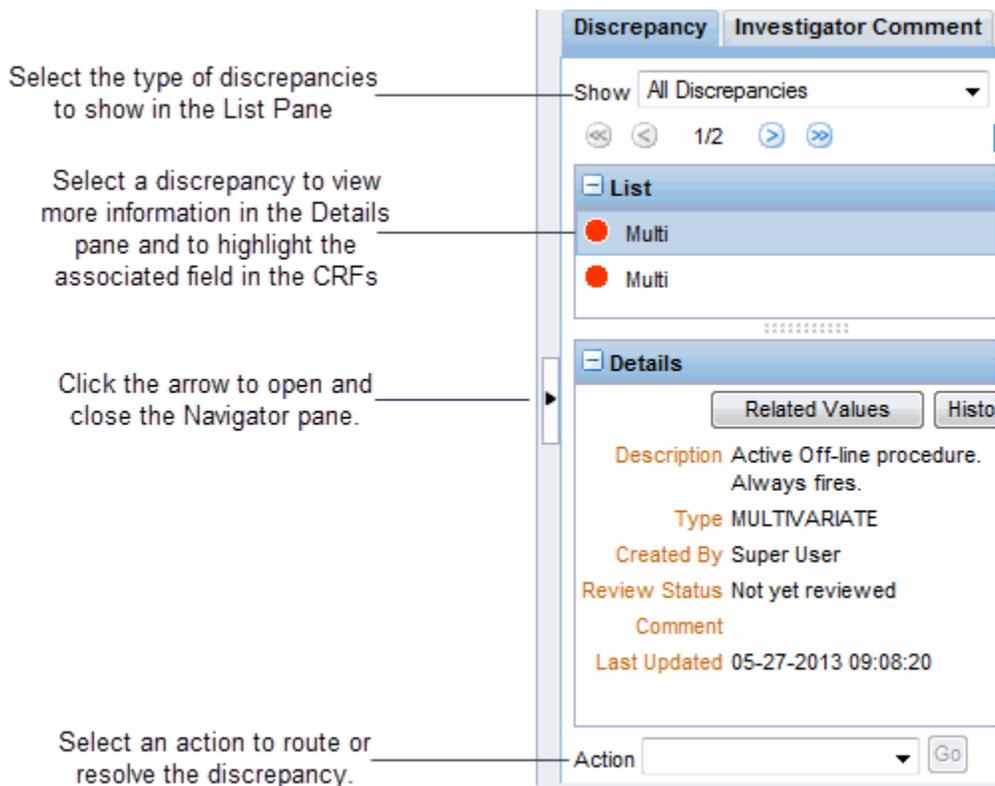
Opening, Closing, and Resizing the Navigator Pane

- To open the Navigator pane, click the arrow on the right edge of the Data Entry window.

- To close Navigator pane, click the arrow on its left edge.

- To resize the Navigator pane, drag the vertical and horizontal splitter bars to adjust the width and length of the opened pane.

Showing and Selecting Discrepancies in the Navigator Pane

You can use the List and Details panes in the Navigator to review, highlight, and update particular discrepancies in a CRF.

To use the Navigator pane to display and review discrepancies:

1.   Click the **Show** field and select a filter from the list. You can select to show:

- Active Discrepancies

- Active and Other Discrepancies

- Closed Discrepancies

- All Discrepancies

Based on your filter selection, the List pane displays the discrepancies for the current CRF. Note that:

- Discrepancies associated with multiple fields display as **Multi**.

- Hidden discrepancies do not display regardless of the filter you select.

- The total count displayed in the Navigator pane does not include hidden discrepancies.

2. Select the discrepancy you want to work with from the list. Note that:

- The Details pane refreshes and displays more information about the discrepancy.

- The discrepancy you selected in the List pane is highlighted in blue, and the associated field (or fields if multiple fields are associated with the discrepancy) in the CRF is outlined with a blue dashed line.

- If you also selected a Highlight option, then the discrepant field is additionally highlighted.

For long lists, use the scroll bar to view additional information in the List pane. In addition, click the **+** or **-** icon in the title bar to expand or collapse the pane.

Reviewing Discrepancy Information in the Details Pane

Once you select a discrepancy in the List pane of the Navigator, the Details pane displays additional information about the selected discrepancy.

The information, which varies depending on the current status of the discrepancy and on how your sponsor customized RDC Onsite, can include:

- **Description —** A description of the discrepancy.

- **Type —** The type of discrepancy, for example, manual or univariate.

- **Created By —** The name of the user who created the discrepancy. If this is a manual field or section discrepancy, the user role is included after the user name.

Note that this entry displays the name of the user who *created* the discrepancy. For the name of the user who last updated the discrepancy, click **History** to view the Discrepancy History dialog box.

- **Review Status —** The current review status of the discrepancy.

- **Reason —** The reason for the discrepancy. Note that the reason does not display if this is a multivariate discrepancy.

- **Comment —** Additional comment information, if entered when creating the discrepancy.

- **Resolution —** The resolution reason and the resolution comment, if the discrepancy was closed.

- **Last Updated —** The date and time the discrepancy was last updated.

- **Discrepancy ID —** The ID for the discrepancy. This information displays only if your sponsor customized RDC Onsite to include the ID.

If necessary, use the scroll bars to view additional information in the Details pane. In addition, click the **+** or **-** icon in the title bar to expand or collapse the pane.

Viewing the History of a Discrepancy

Click the **History** button in the Details pane to view the history of the currently selected discrepancy.

The Discrepancy History dialog box displays the Date, Description, Updated by, Review Status, Comment, Resolution Reason, and Resolution Comment.

Viewing Related Values for Multivariate Discrepancies

A multivariate discrepancy is a discrepancy that is dependent on two or more data points, or values. These data values can be within a single CRF or across multiple CRFs and visits.

When you select a multivariate discrepancy, you can click the **Related Values** button in the Details pane to list all reported values associated with the multivariate discrepancy.

For each value, the Related Values dialog box displays the CRF Name, the Visit, and the Question/Variable.

The Question/Variable column displays either the Question name or the Validation Procedure variable name associated with the discrepancy. A Validation Procedure variable is a calculated value. The variable might be used to process a validation check or to provide relevant information for discrepancy review.

For repeating groups, the Row Number displays in parenthesis next to the Question/Variable name.

Reviewing the Audit History for a Discrepancy

If the discrepancy you selected in the Navigator pane has an audit history, you can view the audit trail by opening the Audit History pane at the bottom of the Data Entry window.

If a selected discrepancy is associated with multiple fields in the CRF (as with multivariate discrepancies), then the Audit History pane displays no information.

Updating Discrepancy Comments

While reviewing a discrepancy in the Data Entry window, you can update its associated comment.

To update a discrepancy comment:

1. Open the Navigator pane.

2. Click the **Discrepancy** tab.

3. Select the discrepancy you want to work with from those shown in the List pane.

4. Click the **Update** icon. The Update Discrepancy dialog box opens.

5. Update the comment with your changes. In addition, you can update the discrepancy description in the following situations:

   - If the discrepancy is either a manual field discrepancy or a manual section discrepancy, you can modify the description text by typing in the field. You can enter up to 2000 characters. When you click **OK,** RDC Onsite verifies the number of characters in the field. If you entered more than 2000 characters, RDC Onsite forces you to shorten the description before continuing.

   - If the discrepancy is a system-generated discrepancy and more than one standard text exists for the category and type of discrepancy, you can select from a list of values containing the standard text.

6. Click **OK** to save your changes.

Taking Action on Discrepancies

You can use the Navigator pane in the Data Entry window to take action on the accumulated discrepancies for a CRF. These discrepancies include those raised during the validation process, as well as queries manually raised by monitors and data managers also using RDC Onsite.

Types of Discrepancy Actions

There are two types of discrepancy actions: routing and resolution.

Routing actions assign the discrepancy to the members of another user group (that is, users with a certain role). For example, the **Send to site** action assigns the discrepancy to the Site user role. When you route a discrepancy, you can include a comment that RDC Onsite saves with the discrepancy.

In contrast, **resolution actions** immediately close the discrepancy. When you close a discrepancy, you must provide a resolution reason. In addition, you can enter a resolution comment.

By default, RDC Onsite provides the following standard routing and resolution actions that you can take to process a discrepancy:

- Send to site

- Send for classification

- Closed - resolved

- Closed - no resolution

However, your sponsor can customize and rename these default actions, assign the actions to particular user roles, and add other discrepancy actions.

Acting on Active versus Other Discrepancies

Open discrepancies require action and resolution. An **open** discrepancy can have a status of active or other.

By default, RDC Onsite does not prevent you from taking action against any open discrepancy, regardless of whether the status is active or other.

Your sponsor, however, can customize RDC Onsite so you can only take action on active discrepancies. In this case, you can view discrepancies with a status of other, but you cannot route or resolve these discrepancies.

Routing Discrepancies

You alert a different user group (users with a certain role) to the presence of a discrepancy by routing it. Routing causes discrepancy status to change from active to other. If the appropriate highlight option is chosen, RDC Onsite then highlights the associated other discrepancy icons in yellow.

To route a discrepancy:

1. Click a CRF icon to open it in the Data Entry window.

2. Open the Navigator pane and select a discrepancy from the list.

3. Click the **Action** field and select an action from the list.

   The available actions are specific to your role. For example, a CRA can send a discrepancy to site (**Send to Site**) or to a manager (**Send to Data Manager**).

4. Click **Go**. A Discrepancy Action dialog box opens and displays your selected action in its title. The **Review Status** displays the future selected status of the discrepancy.

5. Modify, if required, the description of a user-entered discrepancy, or select a value from the list, if available.

6. Enter a **Comment** if you want, explaining why the discrepancy is being routed.

7. Click **OK** to route the discrepancy.

If you route a discrepancy to a *hidden* status, RDC Onsite removes it from the list and the discrepancy is no longer visible.

Resolving Discrepancies

As you use the Data Entry window and its Navigator pane to review discrepancies, you may find discrepancies that you can resolve.

To resolve a discrepancy:

1. Click a CRF icon to open it in the Data Entry window.

2. Open the Navigator pane and select a discrepancy from the list.

3. Click the **Action** field and then select an action to close or resolve the discrepancy. Actions are appropriate and specific to your role.

4. Click **Go.** A Discrepancy Action dialog box opens and displays your selected action in its title. The Review Status displays the future selected status of the discrepancy, for example, RESOLVED.

5. Click the **Resolution Reason** field and select a reason from the list. If no default values exist, the list is empty. You must enter a resolution reason into this mandatory field.

6. Enter a comment in the **Resolution Comment** text box if you want to provide more information about why you are resolving the discrepancy.

7. Select the check box if you want RDC Onsite to remember your comment for subsequent use. Select this option only if you intend to reuse the same comment.

8. Click **OK** to resolve the discrepancy.

When you resolve a discrepancy, RDC Onsite changes the color of its associated icons to green, if the appropriate highlighting option is selected. After you resolve or close a discrepancy, it cannot be updated nor can you perform any action on it.

> **Note:** RDC Onsite remembers the **Resolution Reason** you specified and the **Resolution Comment** you entered (provided you selected the remember comment check box), until you:
>
> ■ Enter a different reason or comment
>
> ■ Change your study
>
> ■ Log out of RDC Onsite

If you get the following message upon saving a change to a discrepancy or blanking outone or more sections of the CRF: *All responses in one or more sections have been deleted. If this is the desired action, please delete the entire document, or contact your help desk to change the status of the document*, the problem is that the Save logic detected that the CRF was either batch loaded or in status Pass 2 Started, Complete, or Pending and all responses have been deleted in one or more sections. This is not allowed for CRFs that are either batch loaded or in status Pass 2 Started, Complete, or Pending.

Click **OK** in response to the message. The system displays the document with your changes to the discrepancy status or blanked fields. You can either delete the CRF or close it, using the option to discard changes -- and then contact your help desk to change the status of the document.

■ For new documents that have status PASS 2 and need to have their Blank flag set to Y, the workaround is to:

1. Update the blank flag via RDCI key changes in Oracle Clinical.

2. Migrate the documents so they can be opened again in RDC Onsite.

■ For documents that already have the problem, the workaround is the following:

1. Create a RDCI Key change in Oracle Clinical to change the Blank flag from N to Y for the documents affected.

2. Create a second RDCI Key change to change the Blank flag from N to Y N for the documents affected (the same ones updated in the first key change).

3. Migrate the documents changed. After that it will be possible to open the blank documents in RDC Onsite.

Creating and Routing Manual Discrepancies

With the appropriate privileges, you can create a manual discrepancy for a response field or a CRF section.

You can create only one manual discrepancy for a field in a CRF.

Note that if a field has an existing manual discrepancy *and* the review status is CLOSED, then you can create a new manual discrepancy on the field. In this case, RDC Onsite re-opens the existing manual discrepancy.

However, if any of the following conditions exist, RDC Onsite grays out the Field Discrepancy option in the Add Discrepancy dialog box:

■ If a non-closed manual discrepancy already exists on a field, you cannot create another manual discrepancy on the same field. You can view the existing discrepancy, but you cannot create a new manual discrepancy.

■ If a hidden, non-closed manual discrepancy exists on a field, you cannot create another manual discrepancy on the same field. In this case, you cannot see the hidden manual discrepancy associated with the field.

■ If your user role has update discrepancy privileges only and the CRF is not Pass 1 complete, you cannot create a manual discrepancy.

To create and route a manual discrepancy:

1. Open the CRF in the Data Entry window.

   ■ To add a manual discrepancy to a field, select the field.

   ■ To add a manual discrepancy to a section, either select a response field in the section or click the section discrepancy bar to select the section.

2. Click the **Add Discrepancy** icon in the toolbar. Alternatively, you can right-click the field and then select **Add Discrepancy** from the menu.

Add Discrepancy

⊙ Field Discrepancy   ○ Section Discrepancy

*Reason   Data Entry Comment

Description

Comment
(optional)

Action

Review Status **Not yet reviewed**

Help   Cancel   OK

3. Select **Field Discrepancy** or **Section Discrepancy** depending on the type of manual discrepancy you are adding.

4. Click the **Reason** field and then select a reason from the list. You must specify the reason why you are entering this manual discrepancy. A reason is mandatory.

5. Enter a **Description** of the discrepancy in the text field.

6. Enter a **Comment** if you want.

7. Click the **Action** field and then select an option for routing the discrepancy for review, if you want. Your selection is reflected in the Review Status field.

8. Click **OK** to add the discrepancy.

   If the highlight option is selected, RDC Onsite highlights the field discrepancy in the CRF, in red, if not routed after initiation.

   ■ If you click **Highlight** in the toolbar and select **All Discrepancies,** the RDC Onsite highlights the discrepancy in the CRF according to its current status.

   ■ If you click the **Show** field in the Navigator pane and select **All Discrepancies,** the List pane displays and highlights the discrepancy according to its current status.

5

Reviewing Investigator Comments

During the data entry process, you can add an investigator comment, such as an observation or an assessment note, to a CRF response. For example, a physician may include the following notation next to the diastolic blood pressure on a patient's chart: "This BP is in the normal range for this patient."

Investigator comments provide a way for you to enter such notes or observations. Oracle Clinical Remote Data Capture Onsite (RDC Onsite) stores the comment with the response data.

Note: If your sponsor has configured RDC Onsite to allow investigator comments, all users can display and review all entered comments. However, you can add and modify investigator comments only if you have update privileges.

This chapter includes the following topics:

- Working with the Review Investigator Comments Page
- Reviewing Investigator Comments from the Data Entry Window
- Adding and Updating an Investigator Comment

Working with the Review Investigator Comments Page

The Review Investigator Comments page provides a list of investigator comments that you can scroll through and sort.

Each *row* contains the information for one investigator comment. If a CRF has more than one investigator comment, RDC Onsite lists each comment for that CRF in its own row.

The *columns* display the following information about each investigator comment:

- The patient number
- The visit name and date
- The CRF name
- The question and response that required an investigator comment
- The text of the investigator comment
- The date the comment was last modified

Navigating to the Review Investigator Comments Page

To navigate to the Review Investigator Comments page, you can:

- Use the page tabs for direct access

- Select a custom Activities link, if available

- Drill down to the page with a selection of patients or CRFs from the Home page, the Patient Casebooks page, or the Review CRFs page

Accessing the Review Investigator Comments Page Directly

To open the Review Investigator Comments page directly:

1. Click the **Review** tab, and then click the **Investigator Comments** tab.

2. Expand the Search pane.

3. Click **Search** to display all the CRFs that have at least one investigator comment.

Using a Custom Activities Link

The Activities section on the Home page can include a link for reviewing investigator comments. Your sponsor creates, customizes, and labels all the links in the Activities section. These links, if defined, are valuable shortcuts to your *daily activities.*

When you click the **Review Investigator Comments** link, RDC Onsite automatically:

- Executes the search that your sponsor defined when creating the link

- Opens the Review Investigator Comments page

- Lists all the investigator comments across all the patients and CRFs for the current site

Your sponsor can name the link differently.

Note that after you click a customized activities link, you always have the option to expand the Search pane and specify a different set of patients or CRFs to review.

Drilling Down to the Review Investigator Comments Page

You can drill down to the Review Investigator Comments page with a patient selection from the Home page or the Patient Casebooks page, or with a CRF selection from the Review CRFs page.

To drill down to the Review Investigator Comments page:

1. Open the Home page, the Patient Casebooks page, or the Review CRFs page.

2. Enter your search criteria to find the patients or CRFs for your work.

3. Continue as follows:

    - On the Home page or Patient Casebooks page, select one or more patients. Click the **Action** menu, and then select **Review Investigator Comments** from the list.
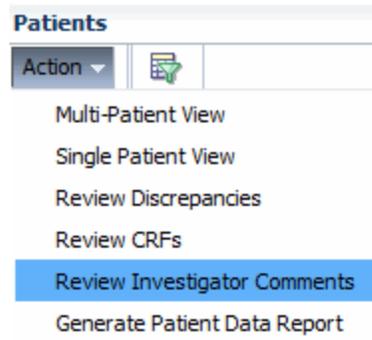
- On the Review CRFs page, select one or more CRFs. Click the **Action** menu, and then select **Review Investigator Comments** from the list.

The Review Investigator Comments page opens and displays the investigator comments for the selected patients and CRFs.

Tools for Reviewing Investigator Comments

Use the following tools on the Review Investigator Comments page when reviewing investigator comments:

- To sort comments by the content of a column, click a column header.

- To show the time that the investigator comment was last modified, select the **Show Timestamps** check box. RDC Onsite adds the time stamp to the date in the Last Modified column.

- To update a comment, click the CRF icon to open the CRF in the Data Entry window.

- To limit or expand the number of CRFs displayed on the Review Investigator Comments page, use the options in the Search pane. You can click **Reset** to remove the current search criteria and then re-enter a different search.

Reviewing Investigator Comments from the Data Entry Window

In addition to the Review Investigator Comments page, you can use options in the Data Entry window to review investigator comments while you are entering and updating data in the CRF.

You can review investigator comments in the Data Entry window by:

- Using Highlighting to Identify Fields with Investigator Comments
- Using the Navigator Pane to Display and Update Investigator Comments

Using Highlighting to Identify Fields with Investigator Comments

To highlight the fields in a CRF that have investigator comments:

1. Open the CRF in a Data Entry window.

2. Click the **Highlight** field in the toolbar, and then select **Investigator Comments** from the list.

   All fields with an investigator comment are highlighted in magenta.

3. Click a field that has an investigator comment and then click the **Investigator Comment** icon to review the existing comment.

   Alternatively, you can right-click a field and then select **Investigator Comment** from the menu.

Using the Navigator Pane to Display and Update Investigator Comments

To use the Navigator pane to review investigator comments:

1. Open the CRF in a Data Entry window.

2. Click the arrow at the right edge of the CRF to open the Navigator pane, if it is closed.

3. Click the **Investigator Comment** tab. The List pane displays the name of each CRF field that has an investigator comment. See Figure 5–1.

4. Click an entry in the list. Note that the Details pane displays the full text of the investigator comment. In addition, the associated field in the CRF is now highlighted with a blue dashed line around it.

   - To make changes to the investigator comment, click the **Update** icon in the List pane.

   - To view update information for the comment, click the **History** button in the Details pane.

Figure 5–1   Using the Navigator Pane to Review and Update Investigator Comments
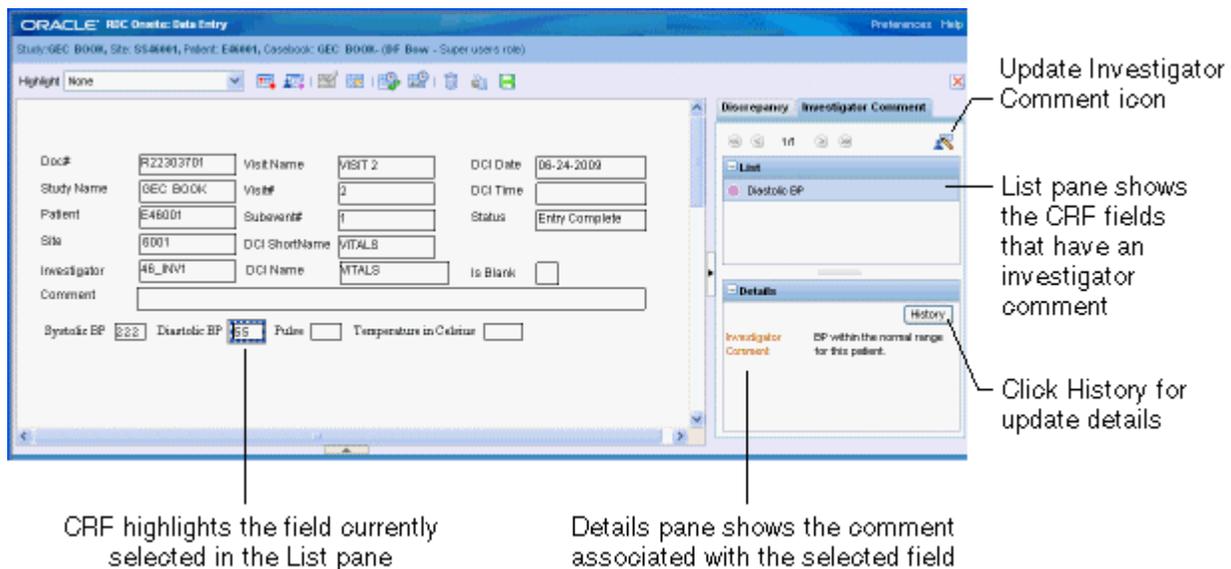
Updating Investigator Comments

While reviewing investigator comments in the Data Entry window, you can update a comment if you have update privileges.

To update an investigator comment:

1. Open the Navigator pane.

2. Click the **Investigator Comment** tab.

3. Select the comment you want to update from those shown in the List pane.

4. Click the **Update** icon. The Update Investigator Comment dialog box opens.

5. Update the existing comment with your changes.

6. Click **OK** to save your changes.

Alternatively, you can click a field that has an investigator comment and then click the **Update** icon to modify the comment. Note that when you can click **Highlight** in the toolbar and select **Investigator Comments,** RDC Onsite uses magenta to highlight those fields that have an investigator comment.

Viewing the History of an Investigator Comment

Click the **History** button in the Details pane to view update information for the currently selected investigator comment.

The Investigator Comment History dialog box displays details about the comment including the date of the update, the investigator comment text, the name of the individual who made the update, the reason for the update, and any additional comments.

Adding and Updating an Investigator Comment

When you are entering or updating the patient data in a CRF, you can add and update investigator comments associated with a response value (that is, a CRF field).

You can perform these actions:

- Only from the Data Entry window

- Only if you have update privileges

- Only if your sponsor has configured RDC Onsite to support investigator comments

To add or update an investigator comment:

1. Open the CRF in the Data Entry window.

2. Position the cursor in a field and then click the **Investigator Comment** icon in the toolbar.

   Alternatively, you can right-click a field in the CRF, and then select **Investigator Comment** from the menu.

   RDC Onsite opens either the Add or the Update Investigator Comment dialog box depending on the selected field.

3. Click the **Investigator Comment** field.

   - If the field does not have an investigator comment, enter new comment text.

   - If the field already has an investigator comment, review and modify the existing text. You can add, edit, and delete comment text.

4. Click the **Change Reason** field, and then select an explanation for this change from the list. Note that:

- If the CRF status is Saved Complete, and you add an investigator comment, you may or may not need to provide a change reason as configured by your sponsor.

- If the CRF status is Saved Incomplete, you are not required to specify a change reason when you add or update an investigator comment.

- If you modify a previously saved investigator comment, you must enter a change reason.

5. Click the **Change Comment** field if you want to provide any additional information about your changes or comments.

6. Click **OK** to save your changes.

6

Reviewing Special Listings

The Review Special Listings page displays additional information, such as adverse events (AEs) and concomitant medications (ConMeds), for a patient.

> **Note:** The Review Special Listings page is available in RDC Onsite only if the Oracle Thesaurus Management System (TMS) is installed and integrated with the Oracle Clinical database.

You review a special listing for one patient at a time. You select the type of listing to review from the Review Special Listings page, the Home page, or the Patient Casebooks page, only in the multiple patients view.

This chapter includes the following topics:

- About Special Listings
- About the Review Special Listings Page
- Displaying a Special Listing

About Special Listings

Using the Oracle Thesaurus Management System (TMS), your sponsor configures and customizes special listings for RDC Onsite by mapping CRF questions to a dictionary in TMS.

The types of special listings available in RDC Onsite are based on **verbatim terms.** Verbatim terms require codification in TMS. Adverse events (AEs) and concomitant medications (ConMeds) are types of verbatim terms, but your installation may include other types as well.

Although the CRF questions are mapped to dictionaries, the full name of the special listing also includes the name of the CRF section that includes the mapped question.

By default, the name of a special listing uses the following format:

TMS-Dictionary-Name/CRF-Section-Name

For example, MedDRA/AES.

In addition, when you view the list of available special listings from the Home page or the Casebooks page, RDC Onsite precedes the name with the word **Review**. For example, you may see the following entries:

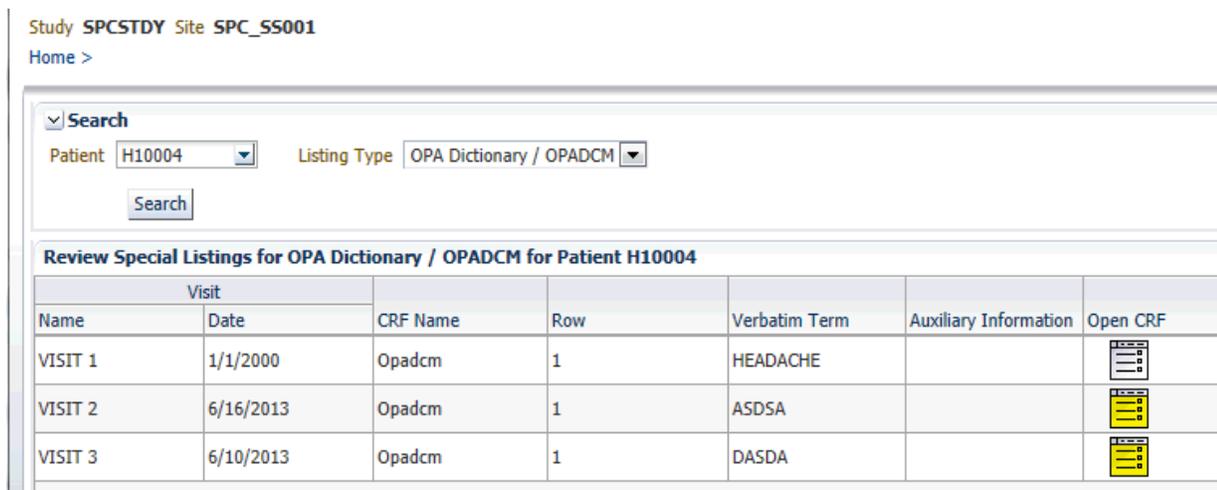- Review MedDRA/AES
- Review WHO/ConMeds

Finally, your sponsor can further customize the name of a special listing by substituting the dictionary name for a text string that may be more meaningful to you. For example:

- Review Adverse Events/AES

- Review Concomitant Meds/ConMeds

About the Review Special Listings Page

Figure 6–1 shows a sample of the Review Special Listings page for a patient.

Figure 6–1   Review Special Listings Page

Study **SPCSTDY** Site **SPC_SS001**
Home >

☑ Search
Patient H10004 ▾   Listing Type OPA Dictionary / OPADCM ▾

Search

Review Special Listings for OPA Dictionary / OPADCM for Patient H10004

Visit		CRF Name	Row	Verbatim Term	Auxiliary Information	Open CRF
Name	Date					
VISIT 1	1/1/2000	Opadcm	1	HEADACHE		
VISIT 2	6/16/2013	Opadcm	1	ASDSA		
VISIT 3	6/10/2013	Opadcm	1	DASDA		

The Review Special Listings page displays the following information:

- **Visit** — Displays the name and date of the visit.

- **CRF Name** — Displays the name of the case report form.

- **Row** — Displays the number of the row that contains the response. This value is useful if the question group is repeating. Note that if the question is non-repeating, the row number is always **1.**

- **Verbatim Term** — Displays the exact wording entered in response to the special question in the CRF section.

- **Auxiliary Information** — Displays the set of all other questions and responses related to the special question.

- **Open CRF** — Displays an icon that you can select to open the CRF and view complete information about the special question.

Displaying a Special Listing

To navigate to the Review Special Listings page and display a special listing, you can:

- Click the page tabs to access the Review Special Listings page directly

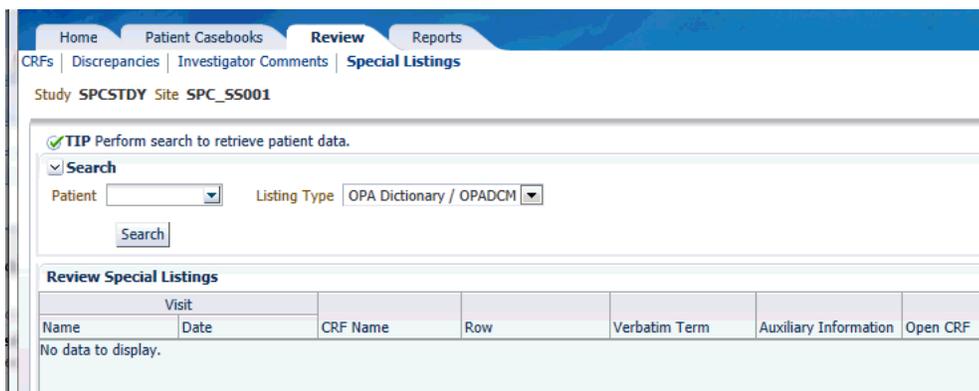- Drill down from either the Home page or the Casebooks page with a patient selected

> **Note:**   You can review a special listing for only one patient at a time. RDC Onsite displays a message if you select more than one patient and then try to view a special listing.

To display a special listing from the Review Special Listing page:

1. Click the **Review** tab, and then click the **Special Listings** tab.

2. Click the **Patient** field and enter the unique number (ID) for your patient. Alternatively, you can click the **Magnifying Glass** icon and then select a patient from the list.

3. Click the **Listing Type** field and select the *special listing* you want to review.

4. Click **Search** to display the listing for the selected patient.

To drill down to a special listing:

1. Open the Home page or the Patient Casebooks page.

2. Use the Search pane, if necessary, to retrieve data for one or more patients.

3. Select one patient.

4. Click the **Action** menu and then select the **Review** *special listing* entry that represents the type of data you want to review.

7
Performing Custom Reviews

Using Oracle Clinical, your sponsor can create custom review types to be used in RDC Onsite similar to the way verification and approval are used. These review types are configured for use by users with specific roles, such as data manager or safety expert. See the chapter "Configuring Custom Review Types" in the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for more information.

If your account has privileges to either update or browse the CRF review status for one or more custom review types, you may see Activities on the Home page specific to your review type(s), and you have the ability to perform group updates of CRF review status, depending on how these features are configured. Custom review search filters are available on all pages and in the Data Entry Window you can also update or view history of the CRF's review status for the review type(s) you have privileges for.

To start reviewing CRFs, your Home page Activities may have been configured to help you identify CRFs that require review by you. Next, you can search for all CRFs with the status Review Required and update their status to Review Complete after you complete your review.

This chapter includes:

- Finding CRFs to Perform Custom Reviews
- Finding CRFs that Require Re-review
- Reviewing CRFs from the Data Entry Window
- Completing CRF Review from the Data Entry Window
- Group Update for Custom Review Status

Finding CRFs to Perform Custom Reviews

To find the patient CRFs that need a custom review, you can:

- Use customized Activities links on the Home page.
- Select patients and navigate to the Review CRFs page or Patient Casebooks page.

Using a Customized Activities Link on the Home Page

In Oracle Clinical Remote Data Capture Onsite (RDC Onsite), you can use the **Review non-blank CRFs ready for your_review_type** activity link for each type of custom review for which you have the update privilege. This link retrieves all the CRFs with the status Review Required and with no open discrepancies; CRFs intentionally marked blank are not retrieved.

Your sponsor can also customize the Activities links. They can choose to create additional links, define different search criteria for links, rename links, or make some links unavailable. The links available to you depend on how your sponsor customized the RDC Onsite application.

To use the default Activities links to find CRFs for review:

1. Select the activity you want to work with, for example **Review non-blank CRFs ready for your_review_type**, in the Activities section on the Home page.

2. Optionally modify the search criteria for the Activities link:

   a. Expand the Search pane to view the criteria in effect as a result of selecting the activity.

   b. Click **Reset** to specify different search criteria, if needed.

   c. Click **Search** to refresh the page according to your new criteria.

3. Proceed to review CRFs with the status Review Required.

Selecting Patients and Reviewing CRFs

You can select specific patients for review on the Home page, and then navigate to the Review CRFs page to view the CRFs ready for custom review.

To select patients and view CRFs ready for custom review:

1. Open the Home page and expand the Search pane.

2. Specify patient search criteria. For example, you can specify a patient range, patients assigned to a particular casebook (study protocol), or patients with no open discrepancies.

3. Click **Search** to refresh the patient list according to your criteria.

4. Select one or more patients for review from the Patients list. In order to do this you can click one row and then use the **Ctrl + A** keys to select all the patients displayed.

   Alternatively, you can click on the table header for the patient icon to select all the patients.

   > **Note:** You can use combinations of keys including Ctrl on all supported devices except for iPad.

5. From the **Action** list, select **Multi-Patient View**, **Single Patient View**, or **Review CRFs**.

   Depending on your selection, the Review CRFs page opens, displaying all entered CRFs for the selected patients, or the Patient Casebooks page opens, displaying all entered and expected CRFs for the selected patients in tabular format. Each row of icons represents data for a single patient. See "Using the Patient Casebooks Page" on page 3-4 for information on navigating in the Patient Casebooks page.

6. Expand the Search pane to specify CRF-level criteria, including CRF status for your review type (such as Review Required or Awaiting Re-review) and others (such as verification status, entry status, or discrepancy status).

7. Click **Search** to refresh the CRF list after selecting additional criteria.

   To reset your patient selection entirely and specify a different search, click **Reset.**

Finding CRFs that Require Re-review

Data can be updated even after you set the CRF status to Review Complete. When this happens, the CRF automatically acquires a verification status of **Awaiting Re-review**.

> **Tip:** CRFs with the status **Awaiting Re-review** are not retrieved when you search by the status **Review Required**.

To find CRFs that require re-review:

1. On the Home page, select patients you want to work with and navigate to either the Patient Casebooks page or the CRF Review page.

2. Expand the Search pane on either the Review CRFs page or the Patient Casebooks page.

3. In the CRF Status group of filters, select the applicable **Review Type** if not already selected, then for Review Status select **Awaiting Re-review**.

4. Click **Search**.

5. Continue to "Reviewing Changes Since Latest Review Complete" on page 7-4.

Reviewing CRFs from the Data Entry Window

After identifying CRFs that require review, you can review them individually to ensure they meet your requirements for stating that your review is complete. Your review of CRFs can include:

- Reviewing Data
- Reviewing Discrepancies
- Viewing Review History
- Reviewing Changes Since Latest Review Complete
- Reviewing Audit History

Reviewing Data

To review entered data for errors:

1. Open a CRF in the Data Entry window.

2. Review data in the CRF fields.

3. Create a manual discrepancy if you find a problem with data entered in the CRF.

> **Tip:** To add a discrepancy, you can right-click on the field to select Add discrepancy from the pop-up menu, or you can position the cursor in the discrepant field and select the Add Discrepancy icon from the toolbar.

4. Save the CRF if you created a discrepancy.

> **Tip:** Click the **Next CRF** link to navigate through all CRFs for a patient visit without having to return to the Patient Casebook page or the CRF Review page.

Reviewing Discrepancies

Your role may require that you review discrepancies before you complete your review. See Chapter 4, "Managing Discrepancies" for more information.

Viewing Review History

RDC Onsite lets you view custom review history for a CRF, if any.

> **Note:** Changes in review status that were applied as a result of changes to the custom review type requirements, not as a result of user action do not appear in the review history. However, administrators can retrieve this information by querying the columns crt_list and allow_crt_rn in the DCIS and DCIS$JN tables.

To view the custom review history of a CRF:

1. Open the CRF in a Data Entry window.

2. Click the **Custom Review** icon in the toolbar. The upper pane of the Custom Review dialog box displays the following information about the review history, if any, for the CRF.

   Date — Displays the date and time of the CRF custom review status change.

   Operation — Displays the action that caused a change in review status: either an explicit change in custom review type status to Required, Not Required, or Complete, or a CRF Update, resulting in a new status of Awaiting Re-Review.

   Changed By — Displays the full name of the user who changed the review status or updated the CRF.

   Comment — Displays additional information about the Verify or Undo Verify action.

3. Close the CRF Review dialog box.

Reviewing Changes Since Latest Review Complete

If data in the CRF is entered or updated after you complete your review, RDC Onsite automatically changes the status of the CRF to **Awaiting Re-review.** You must review the changes in such a CRF before you set its status to **Review Complete** again.

To review the changes to a CRF since the latest review:

1. Search for CRFs awaiting re-review. See Finding CRFs that Require Re-review.

> **Note:** If you search for Review status of **Requires Review**, the search does not include CRFs with an **Awaiting Re-review** status.

2. Open a CRF in a Data Entry window.

3. Click the **Highlight** field in the toolbar, and select **Changed since last reviewed** from the list. Fields updated since the last review are highlighted in blue. Note that fields whose only update is an update to the investigator comment are highlighted.

4. Right-click a field highlighted in blue, and select **View Audit History.** The Audit History pane opens at the bottom of the Data Entry window, displaying the complete audit history for the field.

5. Review the history of changes for the selected field.

6. Continue to review the changes to other fields in the CRF since the last review.

Finding Non-highlighted Changes in a CRF

When you select **Changed since last reviewed** in the **Highlight** field in the Data Entry window, RDC Onsite does not highlight fields for which updates were restricted to discrepancies. To find such changes:

1. Click the **Custom Review** icon in the Data Entry window toolbar to establish the date of the latest review complete status change.

2. Review the Discrepancy History to identify any updates since the last review complete status change.

Reviewing Audit History

The Audit History pane provides comprehensive information on the changes to each field in a CRF.

To view the history of the changes to a field:

1. Open a CRF in a Data Entry window.

2. Right-click a field and then select **View Audit History.** The Audit History pane opens at the bottom of the Data Entry window.

3. Review the history of changes for the selected field.

The Audit History pane does not include those changes made to discrepancies or investigator comments. You can, however, use the Navigator pane to view the Discrepancy History and the Investigator Comment History for information on those updates.

Generate the CRF History report to view CRF history not available in the audit pane, such as the CRF creation, prior history for any deleted data rows, and/or history prior to the CRF being deleted.

Completing CRF Review from the Data Entry Window

If you have update privileges for one or more custom review types, you can change the review status for one CRF at a time from within the Data Entry window.

To change the CRF status for a custom review type:

1. Open a CRF in a Data Entry window.

2. Click the Custom Review icon in the toolbar.

3. In the CRF Review window, the History pane appears in the upper half of the window, and the Update pane in the lower half.

The History pane includes the review history of the CRF, if any, for the custom review types that you have the privilege to browse or update. By default, the history shown is for the first review type you have access to.

4. In the lower pane, you can choose a new status for the CRF from the drop-down list. This can be any of the following, excluding the current status of the CRF, if any.

- Review Complete

- Review Required

- No Review Required

Note: If you have access to multiple review types, the upper pane can display the history of one review type, while the lower pane allows you to change the CRF status for another.

---

5. Click **Apply Status**.

Group Update for Custom Review Status

If allowed in RDC Onsite, you can change the review status for a group of CRFs simultaneously from the multi- or single-patient casebook page or the CRF Review page.

You can set one of the following statuses: Review Not Required (RN), Review Required (RQ), Review Complete (RC).

Refer to the section *Configuration Settings for RDC Onsite* in the *RDC Onsite Administrator's Guide* for more information on configuring group actions.

To update a custom review status for multiple CRFs:

1. Depending on which page you are using in RDC, choose the CRFs for which you want to change the review status by selecting:

   ■ Patients in the Multiple Patient Casebook page

   ■ Visits in the Single Patient Casebook page

   ■ CRFs in the Review CRFs page.

2. From the **Action** list, select **Update Review Status**.

3. Choose the exclusion and inclusion criteria.

Note: The initial selection of inclusion and exclusion criteria is defined in Oracle Clinical for the Verification function.

---

4. If you have update privileges for multiple custom review types, choose the appropriate custom review type from the Review Type list. Then, from the Review Status list, select the new status you want to assign to all the selected CRFs.

5. Click **Apply Status**.

> **Note:** The review status for some of the selected CRFs may not be updated for any of the following reasons:
>
> - The CRF already had the new review status.
>
> - The CRF is being updated by another user or validation procedure.
>
> - The CRF is locked by Oracle Clinical.
>
> - You are trying to apply the review status Review not Required (RN) for a required review type and RN overrides are not allowed by the custom review requirements at the installation, study, or DCI level.

8

Verifying CRFs

In Oracle Clinical Remote Data Capture Onsite (RDC Onsite), the verification process involves checking the entered data against the source data. You can verify CRFs only if you have the VERIFY privilege. You can view the verification requirement and verification status of individual CRFs only if you have at least the BROWSE_VERIFY privilege.

You verify CRFs, one at a time, from the Data Entry window. Alternatively, your sponsor can configure RDC Onsite to make a group verification option available. Techniques for finding the CRFs requiring verification vary slightly, depending upon whether or not you have a Source Data Verification (SDV) plan in effect for the study site. If you do have a published SDV plan in place, then partial SDV is likely in effect, whereby not all CRFs require SDV. You can view the SDV plan for your site only if you have any of these verify privileges: VERIFY, BROWSE_SDVPLAN or UPDATE_ SDVPLAN. See Using Source Data Verification.

This chapter includes the following topics for sites using or not using partial SDV:

- Finding CRFs to Verify

- Finding CRFs Requiring Re-verification

- Reviewing CRFs from the Data Entry Window

- Verifying CRFs from the Data Entry Window

- Redoing CRF Verification

- Verifying Multiple CRFs

- Undoing Verification of Multiple CRFs

Finding CRFs to Verify

To review patient CRFs and verify the data against the source data, you can:

- Use a customized Activities link on the Home page

- Select patients on the Home page and navigate to the Review CRFs page

- Select patients on the Home page and navigate to the Casebooks page

If there is an active patient SDV plan, and you have the necessary privileges (BROWSE_VERIFY or higher), you can search for Patients requiring 100% SDV. The results include both patients with and without entered data. In order to retrieve only patients with data, use the **CRF Status Verification** search field, selecting *Requires Verification*. CRFs requiring source data verification have a V icon.

Using a Customized Activities Link on the Home Page

By default, the Activities section on the Home page includes a **Review non-blank CRFs ready for initial verification** link. This link has built-in search criteria that automatically finds only those CRFs that are ready for verification, and then displays those CRFs on the Review CRFs page.

Your sponsor can customize the Activities links. They can choose to create additional links, define different search criteria for links, rename links, or make some links unavailable. The links available to you depends on how your sponsor customized the RDC Onsite application.

To use the Activities link to find CRFs for verification:

1. Select the **Review non-blank CRFs ready for initial verification** link in the Activities section on the Home page.

    The link navigates to the CRF Review page, which lists all CRFs satisfying the criteria specified by the activity.

    > **Note:** The blank Verified column indicates that the CRF has not been verified.

2. Expand the Search pane to view the criteria in effect as a result of selecting the activity.

    The non-customized activity displays only CRFs with status **Entry or Pass 2 Complete** that are not verified and have no open discrepancies. If Partial Source Data Verification is implemented for your site, the CRFs page lists only those CRFs that require source data verification according to the SDV Plan in place.

3. Click **Reset** to specify different search criteria, if needed.

4. Click **Search** to refresh the page according to your new criteria.

Selecting Patient Casebooks or CRF Review Tabs Directly

You can select specific patients for review on the Home page, and then navigate to the Review CRFs page to view the CRFs ready for verification. If a patient SDV plan is in effect for your site and you have the appropriate privileges, patients requiring SDV are identified in the Home page. If desired, you can select those patients individually, or you can simply Search for Patients requiring 100% SDV.

Alternatively, select your preferred RDC page directly, using the tabs, then enter the desired CRF search criteria to retrieve all CRFs requiring verification. This may be a better approach if you have an SDV plan where some patients require 100% SDV, but the remaining patients require SDV for critical CRFs only.

To select patients and view CRFs ready for verification:

1. Open the Home page and expand the Search pane.

2. Specify patient search criteria. For example, you can specify a patient range, patients assigned to a particular casebook (study protocol), or patients with no open discrepancies or with partial SDV in place, Patients requiring 100% SDV.

3. Click **Search** to refresh the patient list according to your criteria.

4. Select one or more patients for review from the Patients list. In order to do this you can click one row and then use the **Ctrl + A** keys to select all the patients displayed.

Alternatively, you can click on the table header for the patient icon to select all the patients.

> **Note:** You can use combinations of keys including Ctrl on all supported devices except for iPad.

5. Click the **Action** menu and then select **Multi-Patient View**, **Single Patient View** or **Review CRFs** from the list.

> **Note:** If your SDV plan includes both a patient and a CRF component, this method will not necessarily retrieve all CRFs requiring verification. You will be missing patients who do not require 100% SDV but who have critical CRFs requiring verification. In this case, you should simply search for CRFs requiring verification, either using the activity link or your own search criteria.

Depending on your selection, the appropriate page opens:

- The Review CRFs page displays all entered CRFs for the selected patients.
- The Patient Casebooks page displays all entered and expected CRFs for the selected patients in spreadsheet format. See "Using the Patient Casebooks Page" on page 3-4 for information on navigating in the Patient Casebooks page.

6. Expand the Search pane to specify CRF-level criteria, such as verification status, entry status, or discrepancy status.

7. Click **Search** to refresh the CRF list after selecting additional criteria.

To reset your patient selection entirely and specify a different search, click **Reset.**

Finding CRFs Requiring Re-verification

Data can be updated even after a CRF has been verified. When this happens, the CRF automatically acquires a verification status of **Awaiting Re-Verification**.

To find CRFs that require re-verification:

1. Follow one of the methods described in "Finding CRFs to Verify" on page 8-1 to find CRFs ready for verification.

2. Expand the Search pane on either the Review CRFs page or the Patient Casebooks page.

3. Click the **Verification** field and then select **Awaiting Re-Verification** from the list.

4. Click **Search** to refresh the display.

5. Continue to "Reviewing Changes since Latest Verification" on page 8-5.

> **Note:** CRFs with an **Awaiting Re-Verification** status are not retrieved when you search for Verification status **Requires Verification**.

Reviewing CRFs from the Data Entry Window

After identifying CRFs that require verification, you can review them to ensure that they meet the requirements for verification. Your review of CRFs can include:

- Reviewing Data
- Reviewing Discrepancies
- Reviewing Verification History
- Reviewing Changes since Latest Verification
- Reviewing Audit History

Reviewing Data

To review entered data for errors:

1. Open a CRF in a Data Entry window.

2. Review data in the CRF fields.

3. Create a manual discrepancy if you find a discrepancy between source data and data entered in the eCRF.

   To add a discrepancy, you can right click on the field to select Add discrepancy from the pop-up menu, or you can position the cursor in the discrepant field and select the Add discrepancy icon from the toolbar.

4. Save the CRF if you create a manual discrepancy.

   > **Tip:** Click the **Next CRF** link to navigate through all CRFs without having to return to the Patient Casebook page or the Review page.

Reviewing Discrepancies

As a monitor or CRA, you may need to review discrepancies before you verify a CRF. See Chapter 4, "Managing Discrepancies" for more information.

Reviewing Verification History

Before you verify a CRF, RDC Onsite lets you view the CRF's verification history, if any. A CRF that has never been verified does not have a verification history.

To view the verification history of a CRF:

1. Open the CRF in a Data Entry window.

2. Click the **Verify** icon in the toolbar. The Verify CRF dialog box displays the following information about the verification history, if any, for the CRF.

   Date — Displays the date and time of the entry in the Verification History table.

   Operation — Displays the action that caused a change in verification status: Verify or Undo Verify.

   Changed By — Displays the full name of the user who changed the verification status.

   Comment — Displays additional information about the Verify or Undo Verify action.

3. Close the Verify CRF dialog box.

Reviewing Changes since Latest Verification

The data in a CRF can undergo change even after the CRF has been verified. When this happens, RDC Onsite automatically changes the status of the CRF to **Awaiting Re-Verification.**

You should always review the changes in a CRF before you verify it again.

To review the changes to a CRF since the latest verification:

1. Search for CRFs that require re-verification:

   a. Open the Patient Casebooks page or the Review CRFs page.

   b. Expand the Search pane.

   c. Click the **Verification** field and then select **Awaiting Re-Verification** from the list. In the Single Patient Casebook page select the filter **Requires Re-verification**.

   d. Click **Search** to execute the search and refresh the display.

   Note: If you search for Verification status of **Requires Verification**, the search does not retrieve CRFs with an **Awaiting Re-Verification** status.

   ---

2. Open a CRF in a Data Entry window.

3. Click the **Highlight** field in the toolbar, and select **Changed since last verified** from the list. Fields updated since the last verification are highlighted in blue. Note that fields whose only update is an update to the investigator comment are highlighted.

4. Right-click a field highlighted in blue, and select **View Audit History.** The Audit History pane opens at the bottom of the Data Entry window.

5. Review the history of changes for the selected field.

6. Continue to review the changes to other fields in the CRF since the last verification.

Finding Non-highlighted Changes in a CRF

When you select **Changed since last verified** in the **Highlight** field in the Data Entry window, RDC Onsite does not highlight fields that have undergone the following changes:

- If updates were restricted to discrepancies, RDC Onsite does not highlight the associated fields. To locate such cases:

  1. Click the **Verify** icon in the Data Entry window toolbar to find the date of the latest verification in the verification history.

  2. Review the Discrepancy History to identify any updates since the last verification.

- If the layout of a CRF was modified, the CRF status could revert to **Awaiting Re-Verification,** even without any data updates.

Follow your sponsor's instructions for re-verifying CRFs with non-highlighted changes.

Reviewing Audit History

As a monitor, you need to review the changes to a CRF, especially the changes made to a CRF that was already verified. The Audit History pane provides comprehensive information on the changes to each field in a CRF.

To view the history of the changes to a field:

1. Open a CRF in a Data Entry window.

2. Right-click a field and then select **View Audit History.** The Audit History pane opens at the bottom of the Data Entry window.

3. Review the history of changes for the selected field.

> **Note:** The Audit History pane does not include those changes made to discrepancies or investigator comments. You can, however, view the Discrepancy History and the Investigator Comment History for information on those updates.

To view other CRF creation history - Generate the CRF History report to view other CRF history not visible in the audit pane, such as the CRF creation and any deleted data rows.

1. Open a CRF in a Data Entry window.

2. Right-click a field and then select **View Audit History.** The Audit History pane opens at the bottom of the Data Entry window.

3. Review the history of changes for the selected field.

> **Note:** Generate the CRF History report as above to view other CRF history not visible in the audit pane, such as the CRF creation and any deleted data rows.

Verifying CRFs from the Data Entry Window

After identifying CRFs ready for verification as described in "Finding CRFs to Verify" on page 8-1, and reviewing CRFs as described in "Reviewing CRFs from the Data Entry Window" on page 8-4, you can verify an individual CRF from the Data Entry window. You can use a similar process to undo a verification as well as to redo the verification of a CRF.

> **Note:** You can verify a CRF only if you have verify privileges and the CRF does not have a status of Received or Entry Started.

To verify a CRF:

1. Open a CRF in a Data Entry window.

2. Click the **Verify** icon in the toolbar to open the Verify CRF dialog box.

The Verify CRF dialog box includes the verification history of the CRF, if any.

The verification actions available in the Verify CRF dialog box depends on the current status of the CRF. Based on the status of the CRF, you can:

- Click **Verify** to verify the CRF.

- Click **UnVerify** to undo the verification if the CRF was already verified.

- Click **Re-Verify** to redo the verification of a CRF. A CRF needs to be re-verified if data is updated or added since the last verification.

3. Save your changes.

See "Reviewing Verification History" on page 8-4 if you want to review the verification changes to the CRF.

Redoing CRF Verification

RDC Onsite assigns **Awaiting Re-Verification** status to a CRF, if data is updated, new data collected or discrepancies added/updated, after the CRF was verified.

To redo the verification of a CRF:

1. Search for CRFs that need to be re-verified, as described in "Finding CRFs Requiring Re-verification" on page 8-3.

2. Review changes in the CRF after verification, as described in "Reviewing Changes since Latest Verification" on page 8-5.

3. Review the audit history of changes in the CRF, as described in "Reviewing Audit History" on page 8-6, if you want.

4. Redo the verification of an individual CRF, as described in "Verifying CRFs from the Data Entry Window" on page 8-6.

5. Redo the verification of a group of CRFs, as described in "Verifying Multiple CRFs" on page 8-8.

Verifying Multiple CRFs

You can verify multiple CRFs simultaneously from the Patient Casebooks page or the Review CRFs page. The group verification option is available only if you have verify privileges, and if your sponsor has configured RDC Onsite to allow it.

To verify multiple CRFs:

1. Open the Patient Casebooks page or the Review CRFs page.

   ■ From the Multi-patient casebook page, select one or more patients whose CRFs you need to verify. Click the **Action** menu and select **Verify** from the list.

   ■ From the Single patient casebook page, select one or more visits whose CRFs you need to verify. Click the **Action** menu and select **Verify** from the list.

   ■ From the Review CRFs page, select one or more CRFs to verify. Click the **Action** menu and select **Verify** from the list.

   > **Note:** If the **Verify** option does not appear in the list, either you do not have appropriate privileges, or your sponsor has not configured RDC Onsite for group verification.

   The Group Verification dialog box opens and displays the following information:

   ■ The number of CRFs selected

   ■ The number of selected CRFs with open discrepancies

   ■ The number of patients you selected (if you started with a patient selection on the Patient Casebooks page)

   You can choose from the following options:

   ■ Exclude CRFs with discrepancies

   ■ Exclude non-migrated CRFs entered from Oracle Clinical or RDC Classic

   ■ Exclude Batch loaded CRFs

   ■ Include CRFs for this visit only (Otherwise, all visits for the selected patient(s))

   > **Note:** The above-mentioned checkboxes are enabled or disabled, checked or unchecked according to settings in Oracle Clinical. The option to include CRFs for this visit only appears when Group Verify is invoked from the multi-patient casebooks page.

2. Enter a comment in the Verification Comment field, if you want.

3. Click **Verify** to proceed with the group verification.

   RDC Onsite verifies all the selected CRFs. A dialog box reports when the verification is complete, and displays the total number of CRFs that were verified.

4. Click **Close** to close the dialog box

   RDC Onsite automatically refreshes the page and updates the verification status of the affected CRF icons.

> **Note:** The number of CRFs verified may be less than the number of CRFs selected for any of the following reasons:
>
> - Any of the optional checkboxes is selected, depending on the settings from Oracle Clinical.
>
> - The CRF is already verified.
>
> - The CRF has a database lock (another user or a validation procedure is updating the CRF).
>
> - The CRF has an Oracle Clinical lock.
>
> - The CRF is entered from another site.
>
> - The CRF is at status Received or Entry Started.

Undoing Verification of Multiple CRFs

If you unintentionally verify a group of CRFs, you can reverse the action with the Undo Group Verification option. You can undo verification of multiple CRFs simultaneously from the Casebooks page or the Review CRFs page.

The Undo Group Verification option is available only if you have the appropriate privileges, and your sponsor has configured RDC Onsite to allow it.

To undo the verification of a group of CRFs:

1. Open the Patient Casebooks page or the Review CRFs page.

   - From the Multi-patient casebook page, select one or more patients whose CRFs you need to unverify. Click the **Action** menu and select **UnVerify** from the list.

   - From the Single patient casebook page, select one or more visits whose CRFs you need to unverify. Click the **Action** menu and select **UnVerify** from the list.

   - From the Review CRFs page, select one or more CRFs for which you need to undo the verification. Click the **Action** menu and select **UnVerify** from the list.

   > **Note:** If the **UnVerify** option does not appear in the list, either you do not have appropriate privileges, or your sponsor has not configured RDC Onsite for the group undo verification.

   The UnVerify CRFs dialog box opens and displays the following information:

   - The number of CRFs selected

   - The number of patients you selected (if you started with a patient selection on the Multi-Patient Casebooks page)

   If you invoke this action from the Patient Casebooks in the multi-patient view, you see the checkbox *Include CRFs for this visit only (Otherwise all visits for the selected patient(s))*. This checkbox appears enabled or disabled, checked or unchecked according to settings in Oracle Clinical.

2. Enter a comment, if you want.

3. Click **Continue** to proceed with undoing the group verification.

   RDC Onsite undoes the verification of the selected CRFs. A dialog box reports when the unverify operation is complete, and displays the total number of CRFs

that were unverified.

4. Click **Close** to close the dialog box.

RDC Onsite automatically refreshes the page and updates the verification status of the affected CRF icons.

Verifying Deleted but Not Re-entered CRFs

You can identify and review CRFs that were deleted but not re-entered in several ways:

■ Use the **Has deleted, not re-entered CRFs** search filter on the Home page or the Multi-Patient Casebooks page to identify all patients with such CRFs. Once identified by the search, you can generate the Audit History Report, Patient Data Report, or Deleted CRFs Report for these patients to view the details of these CRFs.

9

Approving CRFs

In Oracle Clinical Remote Data Capture Onsite (RDC Onsite), an approval is the equivalent of an electronic signature. Generally, the site investigator approves CRFs. You can approve CRFs only if you have approval privileges.

You approve CRFs, one at a time, from the Data Entry window. Alternatively, your sponsor can configure RDC Onsite to make a group approval option available. Techniques for finding the CRFs requiring approval vary slightly, depending upon whether or not you have a Source Data Verification (SDV) plan in effect for the study site. If you do have a published SDV plan in place, then partial SDV is likely in effect, whereby not all CRFs require SDV. You can view the SDV requirement for CRFs only if you have the BROWSE_VERIFY or higher privilege. See Using Source Data Verification.

This chapter includes the following topics:

- Finding CRFs for Approval

- Finding CRFs Requiring Re-Approval

- Reviewing CRFs from the Data Entry Window

- Approving CRFs from the Data Entry Window

- Redoing CRF Approval

- Approving Multiple CRFs

- Undoing Approval of Multiple CRFs

Finding CRFs for Approval

To review patient CRFs and approve the data, you can:

- Use a customized Activities link on the Home page

- Select patients on the Home page and navigate to the Review CRFs page

- Select patients on the Home page and navigate to the Patient Casebooks page

Using a Customized Activities Link on the Home Page

By default, the Activities section on the Home page includes a **Review non-blank CRFs ready for initial approval** link. This link has built-in search criteria that automatically finds only those CRFs that are ready for approval, and then displays those CRFs on the Review CRFs page.

Your sponsor can customize the Activities links. They can choose to create additional links, define different search criteria for links, rename links, or make some links

unavailable. The links available to you depends on how your sponsor customized the RDC Onsite application.

To use the default Activities link to find CRFs for approval:

1. Select the **Review non-blank CRFs ready for initial approval** link in the Activities section on the Home page.

   The Review CRFs page lists all the patients and their CRFs. If the Approved column is blank, then the CRF is not approved. If Partial Source Data Verification is implemented for your site, the CRFs page lists only those CRFs that require source data verification according to the SDV Plan in place.

2. Expand the Search pane to view the criteria in effect as a result of selecting the activity.

3. Click **Reset** to specify different search criteria, if needed.

4. Click **Search** to refresh the page according to your new criteria.

Selecting Patients and Navigating to the Review CRFs Page

You can select specific patients for review on the Home page, and then navigate to the Review CRFs page to view the CRFs ready for approval.

To navigate to the Review CRFs page and view CRFs ready for approval:

1. Open the Home page and expand the Search pane.

2. Specify patient search criteria. For example, you can specify a patient range, patients assigned to a particular casebook (study protocol), or patients with no open discrepancies.

3. Click **Search** to refresh the patient list according to your criteria.

4. Select one or more patients for review from the Patients list. In order to do that, you can click one row and then use the **Ctrl + A** keys to select all the patients displayed.

   Alternatively, you can click on the table header for the patient icon to select all cells.

   > **Note:** You can use combinations of keys including Ctrl on all supported devices except for iPad.

5. Click the **Action** menu and then select **Review CRFs** from the list.

   The Review CRFs page opens, displaying all entered CRFs for the selected patients.

6. Expand the Search pane to specify CRF-level criteria, such as verification status, entry status, or discrepancy status.

7. Click **Search** to refresh the CRF list after selecting additional criteria.

   To reset your patient selection entirely and specify a different search, click **Reset.**

Selecting Patients and Navigating to the Patient Casebooks Page

You can also select specific patients for review on the Home page, and then navigate to the Patient Casebooks page, instead of the Review CRFs page, to view the CRFs ready

for approval. Navigating to the Patient Casebooks page lets you review CRFs in a casebook spreadsheet format instead of a list format.

To navigate to the Patient Casebooks page and view CRFs ready for approval:

1. Open the Home page and expand the Search pane.

2. Specify patient search criteria. For example, you can specify a patient range, patients assigned to a particular casebook (study protocol), or patients with no open discrepancies.

3. Click **Search** to refresh the patient list according to your criteria.

4. Select one or more patients for review from the Patients list. In order to do that, you can click one row and then use the **Ctrl + A** keys to select all the patients displayed.

    Alternatively, you can click on the table header for the patient icon to select all the cells.

    > **Note:** You can use combinations of keys including Ctrl on all supported devices except for iPad.

5. Click the **Action.** menu and then select **Multi-Patient View** from the list.

6. The Patient Casebooks page opens, displaying all entered and expected CRFs for the selected patients in spreadsheet format. Each row of icons represents data for a single patient. See "Using the Patient Casebooks Page" on page 3-4 for information on navigating in the Patient Casebooks page.

7. Expand the Search pane to specify CRF-level criteria, such as verification status, entry status, or discrepancy status.

8. Click **Search** to refresh the CRF list after selecting additional criteria.

    To reset your patient selection entirely and specify a different search, click **Reset.**

    > **Note:** When you specify CRF-level criteria, the *empty* CRF icons are not displayed. Ordinarily, these icons represent data that is expected according to the patient's casebook definition.
    >
    > However, when CRF-level search criteria are in effect, cells where data has not been entered are blank. If patients within the current set do not have data for a particular CRF, the column is not displayed. This feature allows for a more compressed view of patient CRFs.

Finding CRFs Requiring Re-Approval

Data can be updated even after a CRF has been approved. When this happens, the CRF automatically acquires an approval status of **Awaiting Re-Approval**.

To find CRFs that require re-approval:

1. Follow one of the methods described in "Finding CRFs for Approval" on page 9-1 to find CRFs ready for approval.

2. Expand the Search pane on either the Review CRFs page or the Patient Casebooks page.

3. Click the **Approval** field and then select **Awaiting Re-Approval** from the list.

4. Click **Search** to refresh the display.

5. Continue to "Reviewing Changes since Latest Approval" on page 9-5.

> **Note:** CRFs with an **Awaiting Re-Approval** status are not retrieved when the Approval field is set to **Not Approved.**

Reviewing CRFs from the Data Entry Window

After identifying CRFs that require approval, you can review them to ensure that they meet the requirements for approval. Your review of CRFs can include:

- Reviewing Data

- Reviewing Discrepancies

- Reviewing Approval History

- Reviewing Changes since Latest Approval

- Reviewing Audit History

Reviewing Data

To review entered data for errors:

1. Open a CRF in a Data Entry window.

2. Review data in the CRF fields.

3. Change data as required.

4. Save the CRF, if you change data.

> **Tip:** Click the **Next CRF** link to navigate through all CRFs for a patient visit without having to return to the Patient Casebooks page or the Review page.

Reviewing Discrepancies

As an investigator, you may need to review discrepancies before you approve a CRF. See Chapter 4, "Managing Discrepancies" for more information.

Reviewing Approval History

Before you approve a CRF, RDC Onsite lets you view the CRF's approval history, if any. A CRF that has never been approved does not have an approval history.

To view the approval history of a CRF:

1. Open the CRF in a Data Entry window.

2. Click the **Approve** icon in the toolbar. The Approve CRFs dialog box displays the following information about the approval history, if any, for the CRF.

    Date — Displays the date and time of the entry in the Approval History table.

    Operation — Displays the action that caused a change in approval status: Approve or Undo Approval.

    Changed By — Displays the full name of the user who changed the approval status.

> **Comment —** Displays additional information about the Approve or Undo Approval action.

3. Close the Approve CRFs dialog box.

Reviewing Changes since Latest Approval

The data in a CRF can undergo change even after the CRF has been approved. When this happens, RDC Onsite automatically changes the status of the CRF to **Awaiting Re-Approval**.

You should always review the changes in a CRF before you approve it again.

To review the changes to a CRF since the latest approval:

1. Search for a CRF that needs to be re-approved:

   a. Open the Patient Casebooks page or the Review CRFs page.

   b. Expand the Search pane.

   c. Click the **Approval** field and then select **Awaiting Re-Approval** from the list.

   d. Click **Search** to execute the search and refresh the display.

   > **Note:** If you set the Approval field to **Not Approved,** the search does not retrieve CRFs with an **Awaiting Re-Approval** status.

   ---

2. Open a CRF in a Data Entry window.

3. Click the **Highlight** field in the toolbar, and select **Changed since last approved** from the list. Fields updated since the last approval are highlighted in blue. Note that fields whose only update is an update to the investigator comment are highlighted.

4. Right-click a field highlighted in blue, and select **View Audit History.** The Audit History pane opens at the bottom of the Data Entry window.

5. Review the history of changes for the selected field.

6. Continue to review the changes to other fields in the CRF since the last approval.

Finding Non-highlighted Changes in a CRF

When you select **Changed since last approved** in the **Highlight** field in the Data Entry window, RDC Onsite does not highlight fields that have undergone the following changes:

- If updates were restricted to discrepancies, RDC Onsite does not highlight the associated fields. To locate such cases:

  1. Click the **Approve** icon in the Data Entry window toolbar to establish the date of the latest approval.

  2. Review the Discrepancy History to identify any updates since the last approval.

- If the layout of a CRF was modified, the CRF status reverts to **Awaiting Re-Approval** even without any data updates.

Follow your sponsor's instructions for re-approving CRFs with non-highlighted changes.

Reviewing Audit History

As an investigator, you need to review changes to a CRF, especially the changes made to a CRF that was already approved. The Audit History pane provides comprehensive information on the changes to each field in a CRF.

To view the history of the changes to a field:

1. Open a CRF in a Data Entry window.

2. Right-click a field and then select **View Audit History**. The Audit History pane opens at the bottom of the Data Entry window.

3. Review the history of changes for the selected field.

> **Note:** The Audit History pane does not include those changes made to discrepancies or investigator comments. You can, however, view the Discrepancy History and the Investigator Comment History for information on those updates.

Approving CRFs from the Data Entry Window

After identifying CRFs ready for approval as described in "Finding CRFs for Approval" on page 9-1, and reviewing CRFs as described in "Reviewing CRFs from the Data Entry Window" on page 9-4, you can approve an individual CRF from the Data Entry window. You can use a similar process to undo an approval as well as to redo the approval of a CRF.

To approve a CRF:

1. Open a CRF in a Data Entry window.

2. Click the **Approve** icon in the toolbar to open the Approve CRF dialog box.

The Approve CRFs dialog box includes the approval history of the CRF, if any.

The approval actions available in the Approve CRF dialog box depends on the current status of the CRF. In addition, the **Approve** button does not appear if the CRF has not been saved, if the CRF was saved as incomplete, or if you do not have approval privileges for the CRF.

Based on the current status of the CRF, you can:

- Click **Approve** to approve the CRF.

- Click **UnApprove** to undo the approval if the CRF was already approved.

- Click **Re-Approve** to redo the approval of a CRF. A CRF needs to be re-approved if data is updated or added since the last approval.

3. Save your changes.

See "Reviewing Approval History" on page 9-4 if you want to review the approval changes to the CRF.

Redoing CRF Approval

RDC Onsite assigns **Awaiting Re-Approval** status to a CRF if data is updated after the CRF was approved.

To redo the approval of a CRF:

1. Search for CRFs that need to be re-approved, as described in "Finding CRFs Requiring Re-Approval" on page 9-3.

2. Review changes in the CRF after approval, as described in "Reviewing Changes since Latest Approval" on page 9-5.

3. Review the audit history of changes in the CRF, as described in "Reviewing Audit History" on page 9-6, if you want.

4. Redo the approval of an individual CRF, as described in "Approving CRFs from the Data Entry Window" on page 9-6.

5. Redo the approval of a group of CRFs if you need to, as described in "Approving Multiple CRFs" on page 9-7.

Approving Multiple CRFs

You can approve multiple CRFs simultaneously from the Patient Casebooks page or the Review CRFs page. The group approval option is available only if you have approve privileges, and if your sponsor has configured RDC Onsite to allow it.

To approve multiple CRFs:

1. Open the Patient Casebooks page or the Review CRFs page.

- From the Multi-patient casebook page, select one or more patients whose CRFs you need to approve. Click the **Action** menu and select **Approve** from the list.

- From the Single patient casebook page, select one or more visits whose CRFs you need to approve. Click the **Action** menu and select **Approve** from the list.

- From the Review CRFs page, select one or more CRFs to approve. Click the **Action** menu and select **Approve** from the list.

Note: If the **Approve** option does not appear in the list, either you do not have appropriate privileges, or your sponsor has not configured RDC Onsite for group approval.

The Group Approval dialog box opens and displays the following information:

- The number of CRFs selected
- The number of selected CRFs with open discrepancies
- The number of unverified CRFs
- The number of patients you selected (if you started with a patient selection from the Multiple Patients View of the Patient Casebooks page.)

2. Enter a comment in the Approval Comment field, if you want.

3. In the Exclude set of options, clear the **Exclude CRFs with discrepancies** check box if you want to approve such CRFs.

   Other options you have listed in the Exclude area:

   - Non-migrated CRFs entered from Oracle Clinical or RDC Classic
   - Batch Loaded CRFs

   These two options are not checked by default.

4. Choose by clicking the checkbox corresponding to one of the options listed in the Include section, if this is the case:

   - Verified CRFs only
   - CRFs for this visit only (Otherwise, all visits for the selected patient(s)).

5. Click **Continue** to proceed with the group approval.

   RDC Onsite approves all the selected CRFs. A dialog box reports when the approval is complete, and displays the total number of CRFs that were approved.

6. Click **Ok** or on the background page to close window.

RDC Onsite automatically refreshes the page and updates the approval status of the affected CRF icons.

Note: The number of CRFs approved may be less than the number of CRFs selected for any of the following reasons:

- Any of the optional checkboxes is selected, depending on the settings from Oracle Clinical.
- The CRF is already approved.
- The CRF has a database lock (another user or a validation procedure is updating the CRF).
- The CRF has an Oracle Clinical lock.
- The CRF is entered from another site.
- The CRF is at status Received or Entry Started.

Undoing Approval of Multiple CRFs

If you unintentionally approve a group of CRFs, you can reverse the action with the Undo Group Approval option. You can undo approval of multiple CRFs simultaneously from the Patient Casebooks page or the Review CRFs page.

The Undo Group Approval option is available only if you have the appropriate privileges, and your sponsor has configured RDC Onsite to allow it.

To undo the approval of a group of CRFs:

1. Open the Patient Casebooks page or the Review CRFs page.

   ■ From the Multi-patient casebook page, select one or more patients whose CRFs you need to unapprove. Click the **Action** menu and select **UnApprove** from the list.

   ■ From the Single patient casebook page, select one or more patients whose CRFs you need to unapprove. Click the **Action** menu and select **UnApprove** from the list.

   ■ From the Review CRFs page, select one or more CRFs for which you need to undo the approval. Click the **Action** menu and select **UnApprove** from the list.

   Note: If the **UnApprove** option does not appear in the list, either you do not have appropriate privileges, or your sponsor has not configured RDC Onsite for the undo group approval.

   The UnApprove CRFs dialog box opens and displays the following information:

   ■ The number of CRFs selected

   ■ The number of patients you selected (if you started with a patient selection from the Multiple Patients View of the Patient Casebooks page.)

   You have the option to include CRFs for this visit only, by checking the check box in the Include section, under the comment text box.

2. Enter the user name and password that you specify when you log in to the RDC Onsite application.

3. Enter a comment, if you want.

4. Click **Continue** to proceed with undoing the group approval.

   RDC Onsite undoes the approval of the selected CRFs. A dialog box reports when the unapprove operation is complete, and displays the total number of CRFs that were unapproved.

5. Click **Ok** to close the dialog box.

   RDC Onsite automatically refreshes the page and updates the approval status of the affected CRF icons.

About the Approve CRFs Dialog Box

RDC Onsite prompts you to enter your username and password before you approve a CRF or undo the approval of a CRF.

The following rules apply:

■ For the first CRF approval action, enter the same user name and password that you use to log in to RDC Onsite.

■ For subsequent approvals, you only need to enter your password. However, if your session times out in between, you need to enter both your user name and password. Contact your Help Desk for information on the timeout period.

- RDC Onsite allows three attempts to enter the correct password. After three failed attempts, RDC Onsite displays a warning that the Data Entry window will close and your session will end. Click **OK** to close the window and end your session.

10

Using Search

Every page in RDC Onsite provides a Search pane that helps you locate and focus on the patients, CRFs, discrepancies, and reports that you need for your work.

Although the available search criteria varies on each page, the Search pane provides you with many search options. For example, you can:

- Search for patients by range or by whether any data has been entered
- Search for CRFs that have discrepancies, need verification, or need approval
- Search for CRFs by name or by visit

In addition, you can combine search criteria to narrow your results. For example, you can search for all CRFs that are for Visit 1 *and* have a name of VITALS *and* need to be approved.

This chapter includes the following topics:

- Selecting the Study and Site Context for a Search
- Using the Search Pane
- Using Patient Search Criteria
- Using CRF Status Search Criteria
- Using CRF Source Search Criteria
- Using Search Criteria During a Drill-down
- Clearing Your Search Criteria

Selecting the Study and Site Context for a Search

At the top-right of the Home page and the Patient Casebooks page, RDC Onsite displays the name of the study and site that you are currently using. For example:

Study FLEXSTUDY1 ▾ Site FLEX_SS001 ▾

Once you select a study and site, that context remains valid throughout your RDC Onsite session. RDC Onsite conducts all searches within the selected study and site.

The studies and sites available to you depend on the studies you are participating in, your user role, and the privileges assigned to you by the study sponsor.

Most users work exclusively on a single site in a study. If that is the case for you, the study and site you work on are your only choices. However, if you work on more than

one study or more than one site, *always* check that you are using the correct study and site *before* you execute a search.

To select a study and a site:

1. Open either the Home page or the Patient Casebooks page.

2. Click the arrow in the Study field and then select a study from the list. RDC Onsite automatically refreshes the list of sites based on the study selected and your assigned privileges.

3. Click the arrow in the Site field and then select a site from the list.

    RDC Onsite accesses the selected study and site, resets all search criteria to the default values, and then continues as follows:

    ▪   If you are on the Home page, RDC Onsite retrieves all patient data for the site and automatically displays the list of patients.

    ▪   If you are on the Patient Casebooks page, RDC Onsite retrieves *no data.* You must click **Search** in the Search pane to retrieve and display data.

Using the Search Pane

Each page in RDC Onsite provides a search pane that you can use to search for patients, CRFs, and report jobs. Figure 10–1 illustrates the Patient Search pane on the Home page.

The Search feature in RDC Onsite helps you locate the information you want from different pages of the application. Every search operation uses the same logic though the criteria may vary, for example, the patient search provides fewer criteria than the CRF search.

Figure 10–1   The Patient Search Pane on the Home Page
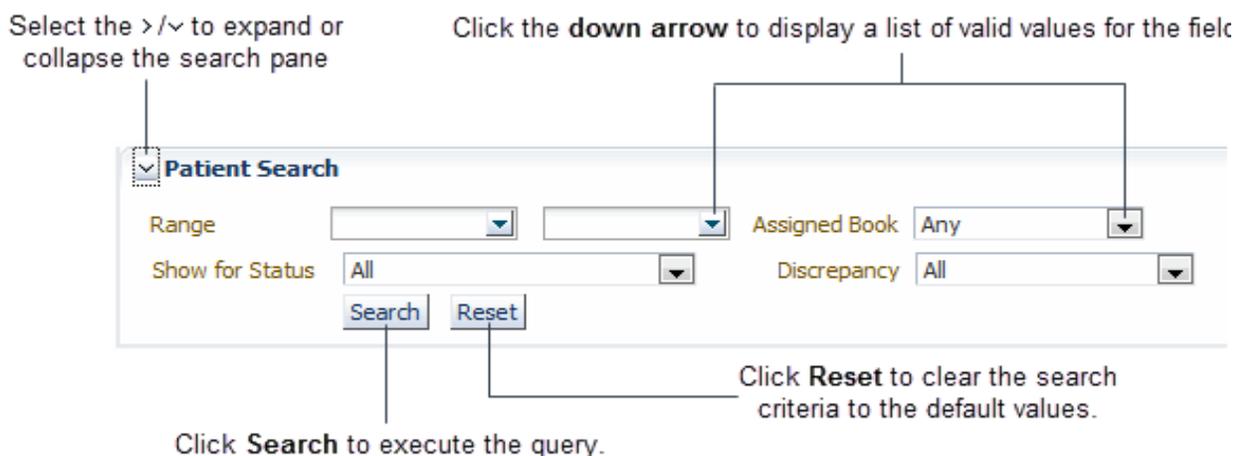
Available Search Criteria Based on Current Page

Depending on the page, RDC Onsite varies the search criteria as follows:

▪   The Home page, which displays a list of patients, provides only patient search criteria. For example, you can search for patients by number, by assigned

casebook, or by discrepancy status or if there is a published patient SDV plan, by those requiring 100% SDV.

- The Patient Casebooks page, the Review CRFs page, the Review Discrepancies page, and the Review Investigator Comments page provide both patient and CRF search criteria. You can retrieve information for a certain set of patients or CRFs, irrespective of whether you review CRFs, discrepancies, or investigator comments.

- The Reports page limits the search to finding the Patient Data Reports and the Blank Casebook Reports that you generated. You can search by job name and status. Note that when you generate a report, you can specify patient and CRF criteria for the content of the report. For more information, see Chapter 12, "Generating CRF Reports."

- The Review Special Listings page is a custom page and available only if configured by your sponsor. You can use this page to review special listings, such as adverse events or concomitant medications, for one patient at a time. You can search for the patient by number and select the special listing to view. For more information, see Chapter 6, "Reviewing Special Listings."

Search Retrieval and Hidden CRFs

Regardless of any other criteria specified:

- For searches executed from the Patient Casebooks page, the Review CRFs page, the Review Investigator Comments page, or the Review Special Listings page, the search results do not include CRFs that are hidden to the current user.

- For searches executed from the Review Discrepancies page, the search results do not include discrepancies for CRFs that are hidden to the current user.

Toggling the Display of the Search Pane

- To expand the Search pane, click the button in the title bar.

- To collapse the Search pane, click the button in the title bar.

Tools for Entering Search Criteria

- To display the list of valid values for a field:
  - Click the down arrow next to the field or click inside the field.

- To select a value for a search field:
  - Click a value in the list.
  - Press the up and down arrow keys to highlight the value you want, and then press the Enter key. If you cannot find the desired value, click on the **More...** link at the bottom of the list.

    This opens a separate window called Search and Select: Patient. Pick the patient or perform a search by entering the patient number in the text box at the top of the window and press the Enter key. Once the patient is selected, click **Ok**.

- To execute the search after you specify your search criteria, click **Search.** RDC Onsite displays the data, if any, that matches your search criteria.

- To reset the search criteria to the default values, click **Reset.**

Using Patient Search Criteria

You can locate **patients** in a particular site and study using a variety of search criteria. Patient criteria lets you search for patients:

- By number, including searching for one patient, a range of patients, or all patients

- By the book assigned to the patient

- By those with and without data entered

- By 100% SDV field if you have the appropriate privileges and a patient SDV is in effect

- By the discrepancies entered against the patient

- By a custom field defined by your sponsor

The Home page displays only patient search criteria.

The Patient Casebooks page, the Review CRFs page, Review Discrepancies page, and the Review Investigator Comments page displays both patient and CRF search criteria.

Searching for Patients by Number

Use the **Range** parameter to search for patients by their unique patient number or ID.

Range

To enter a value into the Range field, you can click the down arrow to display the list of valid patient numbers and then select a value from the list. Note that for flexible studies, the list of values displays only those patients who are assigned to a casebook.

Alternatively, you can type the exact patient number directly into the field. The Range field does not support any wildcard search characters.

You can click the **More...** link at the bottom of the list to have the entire list of patients in a pop-up window. You can also type the desired number in the text box at the top of the window.

Click the **More...** link to see the complete list of values
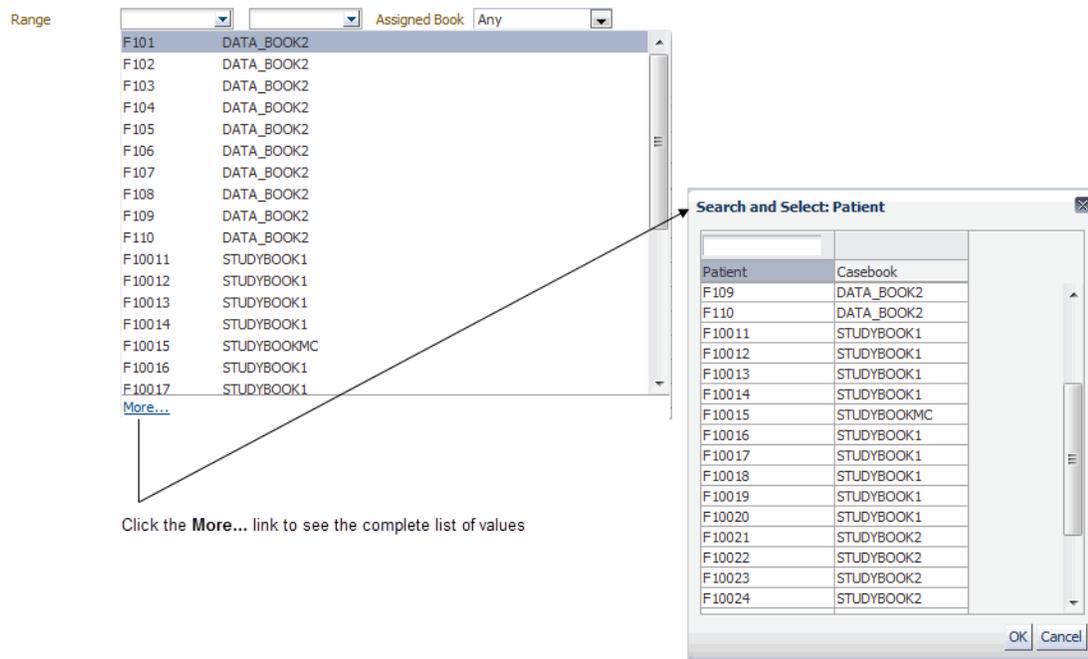
Your search options are as follows:

- To search for one patient, enter a value in only one field.

- To search for a range of patients in terms of *from* and *to,* enter a value in each field.

- To search for all patients, leave the fields blank.

Searching for Patients by Assigned Book

Use the **Assigned Book** parameter to search for patients based on whether they are assigned to a particular casebook.

RDC Onsite lists the valid values for the field in the following order:

- **Any** (default value)

- The default book for the current study

- All other books in the study, listed in alphabetical order

The Assigned Book criterion is useful if the study has multiple casebooks and if patients are explicitly assigned to casebooks. On the Home page, view the information in the Casebook column to quickly determine casebook assignments. If all patients are *unassigned* or assigned to a single book, the Assigned Book parameter may not be useful to you.

In a multiple casebooks study, use the Assigned Book parameter to work with patients assigned to a particular casebook. In the course of a multi-protocol study, multiple casebooks can be used either to introduce protocol amendments or to represent different protocols.

Searching for Patients by Data Entered

Use the **Show for Status** parameter to search for patients with or without data entered.
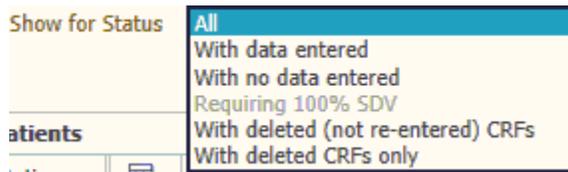
The Show for Status parameter appears only on the Home page and the Patient Casebooks page. The Review pages automatically show only those patients with data entered.

Valid values are:

- **All** — Searches for all patients, that is for patients with data entered and for patients without data entered. **All** is the default value.

- **With data entered** — Searches for any patient that has an entered CRF. The search considers a *CRF entered* even if it is entry started, batch loaded, marked blank, or saved incomplete. In addition, the search includes patients that have deleted CRFs.

  Selecting this option is useful if you want to review and update data already entered. In addition, selecting this option eliminates the placeholder rows for patient numbers with no data entered.

- **With no data entered** — Searches for all the patient numbers available for new data entry. Select this value when initiating data entry for new patients. The Home and Casebooks pages use the grayed-out patient icon with a superimposed question mark (?) to indicate patients with no data entered.

- **Requiring 100% SDV** — Searches for all the patients selected for Source Data Verification, in case there is an active SDV plan. Appears if you have the BROWSE_VERIFY privilege or higher and if a patient SDV plan is in effect.

- **With deleted (not re-entered) CRFs** — Searches for all patients that have CRFs that were deleted but not re-entered. CRFs that were deleted and later re-entered are not included for this search. Once identified by the search, you can generate the Audit History Report, Patient Data Report, or Deleted CRFs Report for these patients to view the details of these CRFs.

- **With deleted CRFs only** — Searches for all patients that have CRFs that were deleted and later re-entered.

CRF Search Criteria and the Show Search Parameter

On the Patient Casebooks page, you can specify **CRF search criteria** in addition to patient search criteria. When selecting a value for the Show parameter, note that:

- If you select **Patients with no data entered** *and* also specify one or more CRF search criteria, the search ignores all CRF criteria. These values are not relevant in this case.

- If you select **All** *and* also specify one or more CRF search criteria, the CRF search criteria applies only to patients with data entered. Patients without data are not retrieved.

Hidden CRFs and the Show Search Parameter

- If you select **Patients with data entered,** the search is not restricted to only data that you can see. Therefore, the search may retrieve patients where all patient CRFs and data are hidden from you.

- The goal of searching for Patients with no data entered is to identify patient numbers that you use for new data entry. However, the search may return a patient assigned to a casebook that has no CRFs that you can see. In this case, you will not be able to enter data for such a patient.

Searching for Patients by the Patient Discrepancy Status

Use the **Discrepancy** status parameter to retrieve all patients with a specific discrepancy status across all entered CRFs.
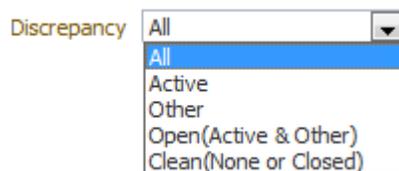
This Discrepancy status parameter appears in the patient-level search only on the Home page. In other pages, the Discrepancy status is a CRF-level search parameter.

Valid values are:

- **All —** Retrieves all patients regardless of discrepancy status. **All** is the default value.

- **Active —** Retrieves patients with any active discrepancies; does not retrieve patients who have only hidden discrepancies. Active discrepancies are those discrepancies that are assigned to you or your user role for action.

- **Other —** Retrieves patients with other discrepancies; does not retrieve patients who have only hidden discrepancies. Other discrepancies are those discrepancies that are assigned to another user role for action.

- **Open (Active & Other) —** Retrieves patients with active or other discrepancies; does not retrieve patients who have only hidden discrepancies.

- **Clean (None or Closed) —** Retrieves patients with no discrepancies or with closed discrepancies, as well as patients who have only hidden discrepancies.

> **Note:**   If a patient has discrepancies only in CRFs that you cannot see, the search does not return that patient.

Searching on the Custom *Reference* Field

Your sponsor can customize the RDC Onsite application to include an additional patient-level search field on the Home page and the Casebooks page.

By default, the field name is *Reference.* However, your sponsor can change the name of the field when setting up RDC Onsite.

The custom *Reference* field:

- Lets you search for a particular patient or a set of patients based on the contents of the field.

- Can be up to 25 alphabetic, numeric, and special characters.

- Supports wildcard searches (%).

RDC Onsite displays the patient data associated with the new field as follows:

- On the Home page, RDC Onsite adds a new column to the Patient List and displays the data defined for the customized *Reference* field. The column heading uses the same name as the field label.

- On the Patient Casebooks page, you can position the cursor over the patient icon or the patient number to reveal the data associated with the customized *Reference* field.

- On the Review CRFs page, the Review Discrepancies page, and the Review Investigator Comments page, you can position the cursor over the patient number to reveal the data associated with the customized *Reference* field.

Using CRF Status Search Criteria

RDC Onsite provides **CRF status** search criteria on all pages except the Home page. The CRF status criteria let you search for CRFs based on the **status** of their current entry, discrepancy, approval, or custom review status.

Searching by CRF Entry Status

Use the **CRF Entry Status** parameter to search for CRFs based on the status of the data entered into the CRF. In RDC Onsite, the formal stages of data entry track the progression of a CRF from no data entered to entry completed.

Valid values are:

- **All —** Retrieves all CRFs regardless of their entry status. **All** is the default value.

- **Blank —** Retrieves all CRFs that have a **blank entry status.** RDC Onsite assigns this status to a CRF that has been marked as blank. A blank CRF does not contain data. You cannot add data to a CRF while it is marked as blank.

- **Created —** Retrieves all CRFs that have a **created entry status.** RDC Onsite assigns this status to a CRF when all required CRF header data has been entered and saved, and no other data (that is, no response data) has been entered.

- **Entry Started —** Retrieves all CRFs that have an **entry started status.** RDC Onsite assigns this status to a CRF when data entry has been started but is not complete. For CRFs that are assigned this status, some required data fields are complete, while some are not. The CRF has been saved as incomplete.

- **Entry Complete —** Retrieves all CRFs that have an **entry complete status.** RDC Onsite assigns this status to a CRF when all required fields have been entered, including data in the CRF header data and response data to CRF questions.

- **Pass2 Started —** Retrieves all CRFs that have a **pass2 started status.** RDC Onsite assigns this status to a CRF that originated in the Oracle Clinical data entry system. This status indicates that the CRF requires a two-pass data entry and that at least one response has been recorded in the second pass.

- **Pass2 Complete —** Retrieves all CRFs that have a **pass2 complete status.** RDC Onsite assigns this status to a CRF that originated in the Oracle Clinical data entry system. This status indicates that the CRF required a two-pass data entry and that the second pass is complete.

- **Entry or Pass2 Complete —** Retrieves all CRFs that have either an **entry complete status** or a **pass2 complete status.**

- **Batch Loaded —** Retrieves all CRFs that have a **batch loaded status.** RDC Onsite assigns this status to CRFs with response data that is entered by electronic means, not by users performing manual data entry.

Searching by CRF Discrepancy Status

Use the **CRF Discrepancy Status** parameter to retrieve all CRFs with a specific discrepancy status.

On the Patient Casebooks page, the Review CRFs page, and the Review Investigator Comments page, the discrepancy status is a CRF-level search parameter.

On the Home page, the discrepancy status a patient-level search parameter. For more information, see "Searching for Patients by the Patient Discrepancy Status" on page 10-7.

Valid values are:

- **All —** Retrieves all CRFs regardless of discrepancy status. **All** is the default value.

- **Active —** Retrieves CRFs with any active discrepancies; does not retrieve CRFs that have only hidden discrepancies. Active discrepancies are those discrepancies that are assigned to you or your user role for action.

  On the Review Discrepancies page, **Active** does not retrieve hidden discrepancies.

- **Other —** Retrieves CRFs with other discrepancies; does not retrieve CRFs that have only hidden discrepancies. Other discrepancies are those discrepancies that are assigned to another user role for action.

  On the Review Discrepancies page, **Other** does not retrieve hidden discrepancies.

- **Open (Active & Other) —** Retrieves CRFs with active or other discrepancies; does not retrieve CRFs that have only hidden discrepancies.

  On the Review Discrepancies page, **Open** does not retrieve hidden discrepancies.

  > **Note:** If you select **Active, Other,** or **Open,** the search does not retrieve CRFs that *have only* hidden discrepancies. For example, if a CRF has a hidden manual field discrepancy and an active univariate discrepancy, then the search retrieves the CRF. However, if the CRF has only a hidden manual field discrepancy, then the search *does not* retrieve the CRF.

- **Clean (None or Closed) —** Retrieves CRFs with no discrepancies or with closed discrepancies, as well as CRFs that have only hidden discrepancies.

  On the Review Discrepancies page, **Clean** is replaced by **Closed.** If you select **Closed,** the search does not retrieve hidden closed discrepancies.

  For example, if the discrepancy is closed and hidden to your user role, the search does not retrieve the CRF.

Searching by a Custom Review Status

This search is available if any custom review types have been configured for your site and you have privileges to one or more of those review types.

If you have privileges to multiple review types, you select the review type you are working on, then select a status for that type of review.

- **Review Completed —** Retrieves CRFs that were reviewed for all your review types.

- **Explicitly set RN status —** Retrieves the CRFs for which a user marked the review as not required for any of your review types.

- **Review Required —** Retrieves the CRFs for which the review is required for at least one of your review types.

- **Awaiting Re-review —** Retrieves the CRFs that await re-review for at least one of your review types.

Searching by CRF Approval Status

This filter is available only if you have the BROWSE_VERIFY privilege or higher. Use the **CRF Approval Status** parameter to search for CRFs based on their current state of approval.

Valid values are:

- **All —** Retrieves all CRFs regardless of their approval status. **All** is the default value.

- **Not Approved —** Retrieves only CRFs that have never been approved.

- **Approved —** Retrieves all CRFs with an **approved status.** This status indicates a user with approve privileges certified that the CRF is an accurate representation of the source data. In RDC Onsite, an approval is equivalent to an electronic signature.

- **Awaiting Re-Approval —** Retrieves all CRFs with an **awaiting re-approval status**. This status indicates the CRF was approved, but one or more response values were updated since the approval. For CRFs with this status, users with approve privileges can choose to re-approve the CRF or undo the approval. Changes that cause RDC Onsite to reassign the approval status include:

  - A response value updated

  - A discrepancy updated or added

  - An investigator comment updated or added

- **Approval Undone —** Retrieves all CRFs with an **approval undone status.** This status indicates a user with approve privileges used the Undo Approval option to remove the approved status of a CRF.

Searching by CRF Verification Status

Use the **CRF Verification Status** parameter to search for CRFs based on their current state of verification. This search filter is available only if you have the BROWSE_ VERIFY privilege or higher.

Valid values are:

- **All —** Retrieves all CRFs regardless of their verification status. **All** is the default value.

- **Requires Verification —** If partial source data verification is being used, retrieves only CRFs that require verification according to the patient SDV plan.

- **Verified —** Retrieves all CRFs with a **verified status.** This status indicates a user with verify privileges checked the data in the CRF against the source data.

- **Awaiting Re-Verification —** Retrieves all CRFs with an **awaiting re-verification status**. This status indicates the CRF was verified, but one or more response values were updated since the verification. For CRFs with this status, users with verify privileges can choose to re-verify the CRF or undo the verification. Changes that cause RDC Onsite to reassign the verification status include:

  - A response value updated

  - A discrepancy updated or added

  - An investigator comment updated or added

- **Verification Undone —** Retrieves all CRFs with a **verification undone status.** This status indicates the CRF was verified but subsequently the verification was undone. This status is equivalent to the **Requires Verification** status with the exception that a verification history exists for a CRF with a verification undone status.

Using CRF Source Search Criteria

RDC Onsite provides **CRF source** search criteria on all pages except the Home page. The CRF source criteria let you search for CRFs based on their **source** casebook, visit, or name.

Searching by CRF Source Casebook

Use the **CRF Source Casebook** parameter to search based on the casebook used at the time of initial data entry into the CRF. You can search for all casebooks in the study or for one casebook. The default value is **All.**

When you select a value, RDC Onsite resets both the CRF Source Visit parameter and the CRF Source CRF Name parameter to All, and then refreshes each list with values relevant to the CRF Source Casebook you selected.

The CRF Source Casebook parameter is useful if patients whose data was entered using an earlier version of the casebook are reassigned to a new version of the casebook.

Searching by CRF Source Visit

Use the **CRF Source Visit** parameter to search for the visit during which the CRF data was collected. Note that:

- If the CRF Source Casebook parameter is **All,** RDC Onsite displays all visits defined for the study.

- If you enter a specific casebook, RDC Onsite lists only the visits defined for the selected casebook.

Searching by CRF Source CRF Name

Use the **CRF Source CRF Name** parameter to search for the name of the CRF to review.

This parameter is useful in reviewing all CRFs of a certain type, for example, all Adverse Events forms or all Concomitant Medications forms.

The list of CRFs that RDC Onsite displays in the CRF Name field depends upon the other source parameters (casebook and visit) that you already selected:

- If you specify a casebook and select all visits, RDC Onsite displays all CRF names defined for the casebook plus any CRFs that can be added as unplanned pages.

- If you specify both the casebook and the visit, RDC Onsite only displays the CRFs defined for the visit plus any CRFs that can be added as unplanned pages.

- If you select all casebooks and specify a visit, RDC Onsite displays all CRFs defined for the study.

Using Search Criteria During a Drill-down

When you set search criteria on certain pages in the application, RDC Onsite uses the same criteria as a context for subsequent actions as detailed below:

- All the Review pages inherit the patient selection from either the Home page or the Patient Casebooks page.

- The Patient Casebooks page inherits the patient selection from the Home page.

- The Review Discrepancies, and the Review Investigator Comments pages inherit the CRF selection from the Review CRFs page.

> **Note:** In a three-level drill-down, for example, from Home to Review CRFs, to Review Investigator Comments, the lowest level inherits only the CRF selection, and not the Patient selection.

About the Effects of an Inherited Patient Selection

When a page inherits a patient selection from a parent page:

- The Search pane displays a selection indicator in the following format:

  number **Patients Selected From** *page-name* **Page**

  For example: 14 Patients Selected From Home Page

- Patient search parameters are not inherited.

- Patient search parameters appear grayed out and disabled.

- If the patient selection is inherited from the Patient Casebooks page, RDC Onsite enables CRF search parameters with which you can execute a secondary search against the selected patients.

- If the Review Discrepancies page inherits a patient selection, all search parameters are enabled. You can then execute a search against the selected patients and those CRFs that fulfill CRF search criteria, if any.

About the Effects of an Inherited CRF Selection

When a CRF selection is in effect on a page selected subsequently (child page):

- The Search pane displays a selection indicator in the following format:

  number **CRFs Selected From** *page-name* **Page**

  For example: 21 CRFs Selected From Review CRFs Page

- Patient and CRF search parameters are not inherited.

- Patient and CRF search parameters appear grayed out and disabled.

- On the Review Discrepancies page, discrepancy status is inherited and enabled. In subsequent queries, RDC Onsite uses discrepancy status in a sub-query against the set of selected CRFs.

About the Effects of an Inherited Discrepancy Status Selection

The discrepancy status filter is special in two ways: first, its value is inherited by a child page during a drill-down, and second, the discrepancy status appears at patient, CRF, and discrepancy levels, depending upon the page. The discrepancy status you specify on a page can be inherited at a different level, on the page you drill down to. Scenarios of the inheritance of the discrepancy status are described below:

- If you select patient discrepancy status on the Home page, and drill down to either the Patient Casebooks, or Review CRFs, or Review Investigator Comments pages, CRF discrepancy status inherits the patient discrepancy status.

- If you select patient discrepancy status on the Home page, and drill down to the Review Discrepancies page, the Discrepancy status search criteria inherits the value specified for the patient discrepancy status.

- If you select CRF discrepancy status on the Patient Casebooks page, and drill down to the Review CRFs page, the CRF discrepancy status inherits the CRF discrepancy status specified on the Patient Casebooks page, as with other CRF search values.

- If you select CRF discrepancy status on the Patient Casebooks or Review CRFs pages, and drill down to the Review Discrepancies page, the CRF discrepancy status from the *parent* page is inherited.

- If you select CRF discrepancy status on the Patient Casebooks or Review CRFs pages, and drill down to the Review Investigator Comments page, the CRF discrepancy status is not inherited. Instead, the CRF selection stays in effect, and all CRF search criteria are disabled.

Clearing Your Search Criteria

If you want to specify a new set of search criteria, click the **Reset** button. When you use the **Reset** button, RDC Onsite:

- Resets all enabled search criteria to the default values.

- Clears the patient selection indicator, if navigation was via drill-down from the Home or Patient Casebooks pages, and enables patient parameters.

- Clears the CRF selection indicator, if navigation was from the Review CRFs page, and enables both the patient and CRF parameters.

When patient or CRF selection indicators are cleared, subsequent searches are executed against all patients or all CRFs, not just the subset previously selected.

11

Viewing Summary Reports

Oracle Clinical Remote Data Capture Onsite (RDC Onsite) summarizes information about studies, sites, and patients into one-page reports. These reports, which you can view and print, let you track your progress throughout the study or clinical trial.

This chapter includes the following topics:

- Viewing a Study and Site Summary Report
- Viewing a Patient Summary Report

Viewing a Study and Site Summary Report

The one-page Study and Site Summary Report includes up-to-date information on the total number of patients and CRFs in the entire study and at the selected site. The metrics include counts for patients and CRFs at various statuses in the study.

To view and print the Study and Site Summary Report:

1. Open the Home, Patient Casebooks, or Reports page.

   You can change the study and site before viewing the summary report from the Home or Patient Casebooks page. The Reports page has no option to change the study and site.

2. Click the **Study and Site Summary** link located on the top right of the page.

   RDC Onsite opens a new window and displays up-to-date metrics for the current study and site. Figure 11–1 shows a sample Study and Site Summary Report.

   - To print the Study and Site Summary Report, click **Print.** Use a Landscape orientation to format the report properly on the printed page.

   - To close the window and return to the previous page, click **Close.**

Figure 11–1   Study and Site Summary Report

Study and Site Summary

Study Summary: PDFRUN - PDFRUN study to facilitate QA

Total Sites	56	Sites Reported	0	Patients Created	2810
Patients Enrolled	1000	Patients With Data	259	Requiring 100% SDV	0

Study CRF Information

CRFs with Open Discrepancies	266	CRFs Approved	7
CRFs with Active Discrepancies	246	CRFs Requiring Approval	796
CRFs with Other Discrepancies	57	CRFs Requiring Approval	0

CRFs Locked 0
CRFs Not Locked 803

CRFs Verified 7
CRFs Requiring Verification 936
CRFs Requiring Re-Verification 0

☑ Study CRF Review Information

Review Type	Review Completed	Review Required	Explicitly set RN status	Awaiting Re-review
SAFETY REVIEW	4	796	1	2
DM REVIEW	8	529	3	2
INV REVIEW	5	793	3	2

Site Summary: 31301 (Site Code: 003, Site Name: 003)

Site Information

Investigator	Dr. May Fine
Investigator Address	

Site Patient Information

Patients Created	39	Requiring 100% SDV	0
Patients Enrolled	20		
Patients With Data	21		

Site CRF Information

CRFs with Open Discrepancies	15	CRFs Approved	0
CRFs with Active Discrepancies	9	CRFs Requiring Approval	47
CRFs with Other Discrepancies	7	CRFs Awaiting Re-Approval	0

CRFs Locked 0
CRFs Not Locked 47

CRFs Verified 0
CRFs Requiring Verification 47
CRFs Awaiting Re-Verification 0

▽ Site CRF Review Information

Review Type	Review Completed	Review Required	Explicitly set RN status	Awaiting Re-review
SAFETY REVIEW	2	45	0	0
DM REVIEW	2	18	1	0
INV REVIEW	0	47	0	0

ⓘ Information

This report may include counts of CRFs and discrepancies that you do not have the required access to view, depending upon your user account configuration.

Print   Close

About the Study Summary

The Study Summary section lists the overall metrics for the currently selected study. You can view metrics only for the sites to which you have privileges.

- **Study Information** — Lists the total number of sites in the study, the number of sites in the study for which you have access to view the information, and the number of patients created, patients enrolled, and patients with data entered for the study.

- **Study CRF Information** — Lists the total number of planned and unplanned CRFs for the study, and the total number of CRFs across the study with various discrepancy, verification, lock, approval statuses, and custom review statuses.

Verification and custom review metrics appear only if you have the appropriate privileges.

About the Site Summary

The Site Summary section lists the overall metrics for the current site.

- **Site Information —** Lists the address of the site, and the name and address of the site investigator.

- **Site Patient Information —** Lists the number of patients created, patients enrolled, patients with data entered for the site and patients requiring 100% Source Data Verification (SDV).

- **Site CRF Information —** Lists the total number of planned and unplanned CRFs for the site, and the sum totals of CRFs with various verification, lock, discrepancy, and approval statuses.

About the Counts in the Study and Site Summary

- The Study and Site Summary may include counts of CRFs and discrepancies that you do not have the required access to view, depending upon your user account configuration.

- The counts include the CRFs and discrepancies that you do not have the required access to view, if any, depending upon your user account configuration.

- The counts for Planned CRFs include all conditional CRFs that have become expected.

- The CRF counts in the Site Summary section are based on the CRF site assignment. If data entry takes place in two sites for the same patient, RDC Onsite apportions the CRF counts between the two sites.

Viewing a Patient Summary Report

In addition to viewing a summary report for the current study and site, you can view and print the latest overall metrics for a single patient.

To view or print a summary report for only one patient:

1. Open either the Home page or the Patient Casebooks page.

2. Search for the patient.

3. Click the patient icon to display a summary report for the selected patient.

RDC Onsite opens a new window and displays up-to-date metrics for the current patient. Figure 11–2 shows a sample Patient Summary Report.

- To print the Patient Summary Report, click **Print.** Use a Landscape orientation to format the report properly on the printed page.

- To close the window and return to the previous page, click **Close.**

Figure 11–2   Patient Summary Report
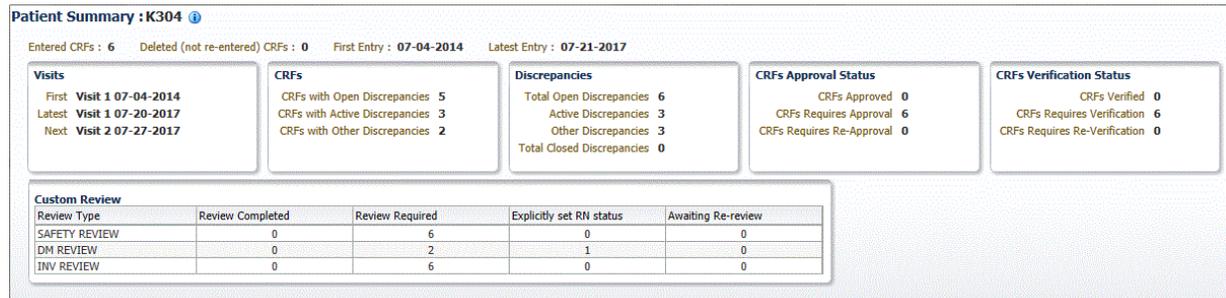
About the Patient Summary Report

As shown in Figure 11–2, the Patient Summary Report includes the following information for the selected patient:

- **Patient Information —** Lists the patient number and, if available, lists the birth date, gender, and age of the patient, and the date of the latest update to the CRF. If there is an active SDV plan in place, and the patient is selected for the verification, the title displays **100% SDV required**.

- **Discrepancies —** Lists the number of active discrepancies, other discrepancies, and closed discrepancies for the patient. In addition, lists the total number of discrepancies (active, other, and closed).

- **CRFs —** Lists the number of CRFs with active discrepancies, with other discrepancies, and with no open discrepancies. In addition, lists the total number of CRFs with discrepancies, the date of the first entry (earliest) to a CRF, and the date of the latest entry.

- **CRF Custom Review Status** - for each custom review type for which you have privileges, lists the number of CRFs with the following statuses: review completed, review required, explicitly set RN status, and awaiting re-review.

- **CRFs Verification Status —** Appears if you have the appropriate privileges. Lists the number of CRFs with the following verification statuses: verified, requires verification, and requires re-verification.

- **CRFs Approval Status —** Lists the number of CRFs with the following approval statuses: approved, requires approval, and requires re-approval.

- **Links —** Lists up to three custom links that open other Web pages and provide additional information on the patient. These links are available only if your sponsor customized the Patient Summary Report to include the links. For example, your sponsor may include a link to the Adverse Events for the patient.

About the Counts in the Patient Summary Report

- The counts include the CRFs and discrepancies that you do not have the required access to view, if any, depending upon your user account configuration.

■   The counts include for all CRFs associated with the selected patient, regardless of the patient's current site assignment.

12

Generating CRF Reports

All reports are PDF files. You can use any application that opens PDF files, such as Adobe Reader, to print the report or save a copy of the report to your PC.

You can use these reports for electronic submissions and as a printout for offline discussion and review. In addition, you can use the reports to track your progress during the clinical study.

This chapter includes the following topics:

- Working with the Reports Page
- CRF Report Content
- Generating a Patient Data Report
- Generating a Blank Casebook Report
- Generating a Standalone Deleted CRFs Report
- Searching for Report Jobs
- Monitoring the Status and Progress of Your Report Jobs
- Printing a Report

Working with the Reports Page

To open the Reports page, click the **Reports** tab.

When you open the Reports page, RDC Onsite displays all the report jobs, if any, that you have submitted for processing. Figure 12–1 shows a sample Reports page.

RDC Onsite lists the reports in a table format of rows and columns. You can search for a specific report by job name. In addition, you can click a column heading to sort the reports by that column. Clicking the column heading again toggles the sort from ascending to descending order. Both searching and sorting can help you find a report that you want to view or print.

From the Reports page, you can:

- Generate a new Patient Data Report
- Generate a Blank Casebook Report for the study or for a single patient
- Search for reports that have already been generated
- Monitor reports currently in progress
- View reports
- Print reports

> **Tip:** Some reports may require an extended time to run. You can continue to work in RDC Onsite while a report generates in the background. You can return to the Reports page at any time to view and print your report.

Figure 12–1 Reports Page
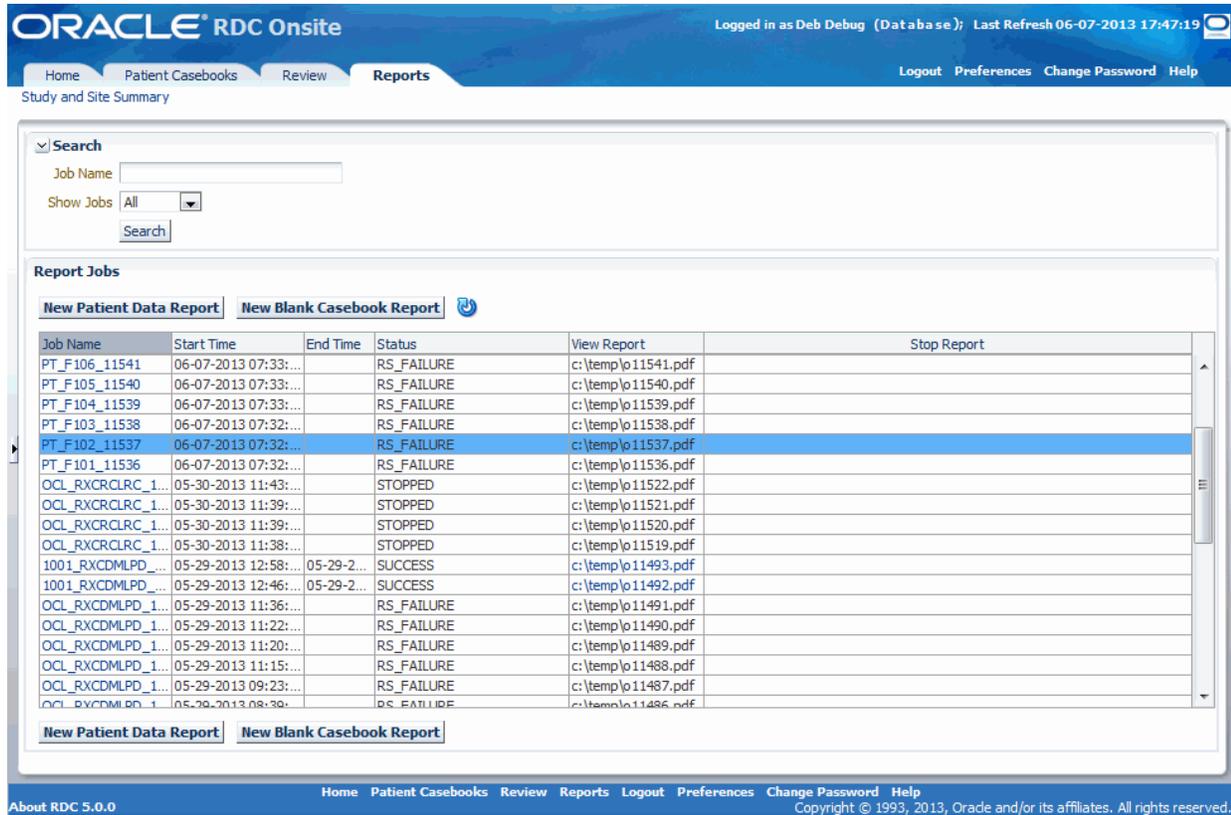
The Refresh of Status button is turned off by default. This button allows the user to toggle the auto-refresh status. Click once to start auto-refresh. Click again to turn it off.

CRF Report Content

You can generate three types of CRF reports in RDC Onsite: the Patient Data Report and the Blank Casebook Report.

This section includes the following topics:

- Content of a Patient Data Report
- Content of a Blank Casebook Report

Content of a Patient Data Report

A Patient Data Report can include any or all of the following sections, depending on the RDC page you use to request the report, which options and filters you specify, if any, and the nature of the entered data.

- A cover page
- A CRF section, including both the form and the entered data

- Ancillary pages if the CRF has any response overflow, audit, discrepancy, or investigator comment information

- A Deleted CRFs section

- An Appendix listing CRFs not included in the report. This applies to a true PDR, which is generated from the Home, Casebooks or Reports pages for a selected patient.

Cover Page in a Patient Data Report

- **Title —** The title of the report. The title uses the format `CRF Report for Study` *study-name*..

- **Report generated by** — The full name of the user who initiated the report.

- **On** — The date and time the report was generated.

- **Report Parameters** — A list of the selected parameters for the report, including:

  – The patient ID for which the report was run.

  – The search criteria in effect on the Home or Casebooks page when the report was run.

- **Legends** — An explanation of the time stamps and the superscripts shown in the report.

Every Patient Data Report, except the CRF History Report from the Data Entry Window, has a cover page that lists the following basic information:

Figure 12–2 shows a sample cover page for a Patient Data Report.

Figure 12–2   Sample Cover Page


```
CRF Report for Study  PDFRUN


Report generated by  RK  MARE          on    07-09-2009 05:21:27


Report Parameters
                          Patient:   K101
        Discrepancy status choice:   Active or Other
           Approval status choice:   All statuses
        Verification status choice:   All statuses
       Marking values changed since:   None
```

```
Notes:
1.   All reported data is current as of the time shown above under 'Report Generated'.
2.   All timestamps reflect the timezone of the database server in which the data was collected.
3.   Superscripts appear next to fields with any of the following additional information:
     -    Overflow
     -    An Investigator Comment
     -    Audit History if Include Audit History option was chosen
     -    Discrepancies if Include Discrepancy Details option was chosen
```

CRF Section

The CRFs presented in a Patient Data Report are a PDF rendering of the HTML form that was used to enter data in the RDC Data Entry Window. The PDF rendering of the form is almost exactly the same as the HTML rendering, but there can be differences of a few pixels in the placement of text and graphics. Also, in the PDR, one or more fields in the CRF may be marked with a superscript number. Superscript numbers are assigned sequentially in a CRF, based on the order of the fields.

The superscript indicates that there is additional data associated with the field, based on one of the following conditions:

- **Overflow** — The entered text is too large for the field.

- **Investigator Comment** — The field has an investigator's comment associated with the response.

- **Discrepancies** — The field is associated with one or more discrepancies. A section discrepancy is associated with the first field in the section.

- **Audit History** — The field has undergone modification since originally entered.

If a superscript appears for a field, the associated data appears in the Footnotes subsection of the Ancillary Data page(s) immediately following each CRF in the report. The CRF section appears in all reports except for the CRF History Report.

Ancillary Data Pages in a Patient Data Report

The Ancillary section can include a number of subsections, depending upon options selected for the report and the data associated with the CRF. The included subsections are listed under Content. Each subsection that can appear in a report is described below.

CRF Created Information   The Ancillary Data page includes the user name (ID) of the individual who created the CRF, and the date and time the CRF was created. For example:

Created by: RAVIKUMAR RANGARAJU

Role: DM

On: 01-31-2013 01:37:58

This subsection appears in all patient data reports.

> **Note:** The creation date and time marks when the CRF was first saved, regardless of whether it was saved as complete or incomplete. Unless audit history for a field indicates otherwise, this information represents the time when data was originally entered for each field and who entered it.

Approval Information   If the CRF is approved and if Patient Data Reports are configured to show Approval information, all reports except for the CRF History report include the name of the individual who approved the CRF, and the date and time the CRF was approved. For example:

Approved by: JOHN SMITH

Role: RXC_SITE

On: 02-02-2013 03:46:09

Approval information appears in all patient data reports except for the CRF History Report.

Content The Content subsection provides hyperlinks to each of the remaining subsections in the Ancillary pages and may include any or all of the following:

- Footnotes
- Audit History for Fields Not Displayed
- Deleted Rows for CRF abc
- Approval History
- Extended Text or Extended Text Audit History
- Deleted CRF History or Deleted CRFs Report

The Content subsection is included in all patient data reports if there is content to be listed.

Footnotes The Footnotes subsection lists each superscript number found in a CRF and outputs any additional information belonging to the corresponding field. The additional information may include any overflow text, investigator comments, discrepancy details, and audit history associated with the field. Figure 12–3 shows a sample Ancillary Data page.

This subsection is not included in the CRF History report.

Figure 12–3   Sample Ancillary Data Page in a Patient Data Report

Ancillary Information for CRF VITALS, Document Number R24812704

Created by:	Deb Smith
Role:	DM
On:	08-26-2014 11:41:44

Content

Footnotes
Audit History for Fields Not Displayed in CRF
Approval History

Footnotes

[1] **Field:** DCI Blank Flag
    Question Group: CRF Header
    Section Number: 0

Audit History for DCI Blank Flag

Changed To	On	By, Role	Reason	Audit Comment
Y	08-26-2014 11:42:36	Deb Smith, DM	CRA Correction	
N	08-26-2014 11:41:44	Deb Smith, DM	Key Change	

[2] **Field:** Systolic BP
    Question Group: VITALS
    Section: Vitals
    Section Number: 1

Audit History for Systolic BP

Changed To	On	By, Role	Reason	Audit Comment
	08-26-2014 11:42:36	Deb Smith, DM	CRF Marked Blank	
120	08-26-2014 11:41:44	Deb Smith, DM		

Deleted Rows When an entire row of data is deleted from a CRF, the CRF image does not include a superscript indicating that the row has audit history. Instead, assuming audit history is included in the report, this is reported in the Deleted Rows subsection, which includes all previous values for fields in the deleted row.

If relevant to the CRF, this subsection is included in all patient data reports.

Extended Text or Extended Text History In the CRF image itself, each extended text field displays the ATTACHMENT prefix and the truncated response text. The extended text field does not use a superscript in the CRF to indicate an overflow of text. Instead, for each extended field in the CRF that has data, the ancillary pages include a special Extended Text subsection to show the full content of the field.

If the report includes audit history, and the extended text field has been updated, this subsection is called Extended Text Audit History and includes the complete, extended content of the current and previous values for the field. Also, data for the field is presented as follows:

- A superscript does appear with the field displayed in the CRF

- Audit history appears in the Footnotes subsection as well, the same as for standard text fields. However, this audit history presents only the ATTACHMENT prefix with the truncated responses for the field.

Deleted CRF History or Deleted CRFs Report This subsection appears in all patient data reports if audit history is to be included and if it is relevant to the data.

In the reports generated from the data entry window, the CRF Report and CRF History Report, the subsection is called Deleted CRF History and is included if the CRF was ever deleted and re-entered.

In patient data reports generated for a selected patient, this section appears as an appendix at the end of the entire report. It is called Deleted CRFs Report and includes the history of any CRF that was ever deleted for the patient, whether it was subsequently re-entered or not.

In both cases described above, the section presents all CRF history prior to the delete action.

CRFs Not Included in the Report If relevant to the patient data, this section appears in patient data reports generated for a selected patient. It appears as an appendix at the end of the full report and lists the CRFs that exist for the patient but cannot be included. A CRF may not be included either because no form exists, or the data has not been migrated to a form and the option to Include CRFs entered in classic data entry is not checked. In either case, data may have been entered via Oracle Clinical data entry, Oracle Clinical Batch Data Load, or via RDC Classic.

Bookmarks in a Patient Data Report

Every Patient Data Report includes a table of contents with bookmarks to the various topics and pages in the report. See Figure 12–4. You can click the bookmarks to access pages in the report.

The report also includes two sets of bookmarks:

- The first set is organized by Visit and within the visit, the Data Domain.

- The second set is organized by Data Domain and within a Data Domain, by Visit.

For example, if an Adverse Events CRF is entered for Visit 1 and Visit 2, the report has two AE pages in the report. A bookmark would exist under Visit 1, AE as well as

under AE, Visit 1. You can click either of the bookmarks to open the first AE page entered for Visit 1.

You can navigate to the cover page of the report by clicking on the **Contents** bookmark.

Figure 12–4   Bookmarks for Reviewing the Patient Data Report

Page Numbering in a Patient Data Report

RDC Onsite numbers CRFs according to visits. Within a visit, RDC Onsite numbers the CRFs according to their assigned casebook.

If you add an unplanned page in the casebook, RDC Onsite assigns it the page number of the last expected CRF for the particular visit, appended with *U*, as well as a unique number for the unplanned page for that visit. For example, if Visit 2 includes pages 3 through 10, the second unplanned CRF entered for Visit 2 receives the number 10.U.2.

Content of a Blank Casebook Report

The Blank Casebook Report consists of a blank copy of all the planned CRFs in the casebook. Generating and printing a blank casebook is useful for sites still doing paper data entry.

> **Note:** When you generate a Blank Casebook Report for a flexible study, the report may be quite large because it includes **all CRFS defined in the casebook** even though for a given patient not all CRFs and visits will be expected.

Cover Page in a Blank Casebook Report

Each generated Blank Casebook Report has a cover page that lists the following basic information about the report:

- **Title —** The title of the report. The title uses the following format:

  CRF Report for Study *study-name*.

- **Casebook** — The name of the casebook designated for the report.

- **Report generated by** — The full name of the user who initiated the report.

- **On** — The date and time the report was generated.

- **Legends** — An explanation of the time stamps and the superscripts shown in the report.

If you specified a patient number when you generated the report, the cover page also includes the patient number (ID) for which the report was run.

CRF Data Section in a Blank Casebook Report

Most fields in the Blank Casebook Report are empty so you can hand write patient responses into the blank form. However, RDC Onsite automatically fills in the following fields when generating the report:

- Study Name
- Visit Name
- Visit Number
- CRF Name
- Short Name

In addition, RDC Onsite displays the Patient ID, Site ID, and Investigator ID on the Blank Casebook Report.

Page Numbering in a Blank Casebook Report The Blank Casebook Report retains the defined order of the planned CRFs in a selected casebook, along with their defined page numbers.

About the List of Unprinted DCIs Some DCIs do not get printed because their layout is not specified. The Blank Casebook Report lists these unprinted DCIs.

Generating a Patient Data Report

Generally, a **Patient Data Report** includes all the CRFs and data entered for a single patient. However, there are variations depending on the RDC page you use to request the report, which options and filters you specify, if any, and the nature of the entered data, as follows:

- If you request the report from the Reports, Home or Patient Casebook pages, you can request a report for multiple patients simultaneously. However, RDC Onsite will generate a separate report for each patient.

- If you request the report from the CRF Review page, you can select multiple CRFs that may or may not be for a single patient, but which will all be included in the same report.

- If you request the report from the Reports tab, you have options available that are not available when you request the report from other pages. You can include discrepancy details and audit history or include only certain CRFs based on report parameters such as visit date, casebook, and CRF status. If you request the report from the Home, Patient Casebooks, or Review pages, Discrepancy Details and Audit History are not included.

- The **Single CRF Report** is generated from the data entry window for the current CRF and includes all ancillary data associated with the CRF: discrepancy details, audit history, investigator comments and approval history.

- The **CRF History Report** is generated from the data entry window and includes all audit history for the CRF that is not otherwise available in the data entry window, including initial CRF creation data, inserted and deleted rows, and prior history if the CRF was previously deleted.

The Patient Data Report has always footnoted individual CRF fields with open discrepancies, audit history, overflow, or investigator comments. As of release 5.2, superscripts marking those fields are hyperlinked to the corresponding footnote in the Ancillary Data section, improving navigation.

To enable this feature on existing DCI forms, run the forms regeneration utility. From release 5.2 onward, new forms will automatically generate these hyperlinks. For more information, see Regenerating Forms Utility on page 12-14.

Generating a Patient Data Report from the Reports Page

A Patient Data Report includes all the CRFs and data entered against a patient. You can generate a Patient Data Report for one or more patients. For each patient that you select, RDC Onsite submits a separate job request and generates a separate report.

Optionally, you can include discrepancy details and an audit history in the report. You can also choose to include only certain CRFs in the report based on parameters such as visit date, casebook, and CRF status.

You can use Patient Data Reports for electronic submissions and as a printout for off-line discussion and review.

> **Note:** CRFs are included in the Patient Data Report that satisfy the criteria you specify in the Report Parameters. Any CRFs that are hidden based on your user role are excluded.

To generate a Patient Data Report from the Reports page:

1. Click the **Reports** tab to open the Reports page.

2. Click **New Patient Data Report.**

3. Select the report parameters that RDC Onsite uses to generate the Patient Data Report.

   You must select a Study Site, which is a required parameter. The other report parameters are optional. You can use the other parameters to include or exclude information in the Patient Data Report. See Table 12–1 for a description of each report parameter.

4. Select the job parameters for the report.

   a. Select the name of the **Report Server.**

   b. Enter up to 8 characters for the **Job Name Prefix.** RDC Onsite automatically uses a unique number as the name of a report job, and then adds your specified prefix to the beginning of the job name. You can use the prefix value to easily search for your reports in the list on the Reports page.

   RDC Onsite displays the Job Id, Job Name, and the Output File Name for your reference.

5. Click **Submit Job** to continue. RDC Onsite prompts for confirmation that you want to generate the report.

6. Click **Yes** to generate the Patient Data Reports.

   Once you submit your request to generate the Patient Data Report, you can return to the Reports page to monitor the progress of your report job. You can also stop a job in progress or check error details if the report generation failed. See "Monitoring the Status and Progress of Your Report Jobs" on page 12-18 for more information.

   After RDC Onsite successfully generates the report, you can click the link in the View Report column on the Reports page to open and print your report. See "Printing a Report" on page 12-21 for more information.

Table 12–1   Report Parameters

Report Parameter	Description
Study Site	Lists all the sites for the current study to which you have privileges. The current study is as specified on the Home page or the Patient Casebooks page.
	The Study Site is the only report parameter required. The default value is the first site listed in the study.
Patient	Specifies the patients for which you want to generate a Patient Data Report. RDC Onsite submits a separate job and generates a separate report for each patient you specify.
	You can select all patients, a range of patients, or a single patient. The default value is **All.**
CRF Date Range	Specifies whether to limit the CRFs included in the report. You can select to include only those CRFs in a certain date range. In addition, you select whether to define the range by CRF visit date or creation date. The default value is **No Limit.**
Casebook	Lists all the casebooks for the current study. RDC Onsite uses the selected casebook for CRFs not entered against a particular casebook. The following conditions apply:
	■ If not otherwise specified, RDC Onsite uses the patient's casebook.
	■ If a patient is not assigned to a casebook, RDC Onsite uses the study's default casebook.
	■ If the study has no default casebook, RDC Onsite uses the first active casebook in alphabetical order.
Mark Values	Defines whether to mark values that changed since approval, since verification, or since a specific date.
	■ If you select **Mark Values** along with the **Include Audit History** option, RDC Onsite uses the marked values as the basis of the audit history.
	■ If you do not select **Mark Values,** and only select the **Include Audit History** option, RDC Onsite creates a complete audit history for the report.
Include Audit History	Defines whether to include the audit history for each CRF in the report.
	When selected, the audit history is included in the Ancillary Data pages for each CRF. The report includes an audit history for **all** fields, even for those fields (responses) that have never been updated.
	Deleted CRFs, if any, are included in an appendix.
Include Discrepancy Details	Defines whether to include the discrepancy details for each CRF in the report.
	When selected, the discrepancy details are included in the Ancillary Data pages for each CRF. The report does not include the details for hidden discrepancies (that is, for discrepancies that are hidden from the user submitting the report).
Include CRFs entered in classic data entry	Defines whether to include the CRFs that were entered using RDC Classic or Oracle Clinical. The CRFs are included only if the DCI Form is available.
Date Format	Specifies the format to use for the report dates.
	You can select US, Standard, European, Swedish, and Dynamic.
Orientation	Defines how RDC Onsite orients pages for printing. You can select Portrait or Landscape. The default value is **Portrait.**
	This value affects only the cover page, the ancillary data pages, and the appendix pages of the report. The orientation of a CRF is always defined by its layout regardless of your selection.

Table 12–1   (Cont.) Report Parameters

Report Parameter	Description
CRF Status: Discrepancy	Defines whether to include only CRFs with a particular discrepancy status.
	You can select All, Active, Other, Open (Active & Other), or Clean (None or Closed). The default value is **All.**
	■ If you select **Clean,** the report includes CRFs with no discrepancies or with closed discrepancies, as well as CRFs that have only hidden discrepancies.
	■ If you select **Active, Other,** or **Open,** the report does not include CRFs that have only hidden discrepancies.
CRF Status: Approval	Defines whether to include only CRFs with a particular approval status.
	You can select All, Not Approved, Approved, Awaiting Re-Approval, and Approval Undone. The default value is **All.**
CRF Status: Verification	Defines whether to include only CRFs with a particular verification status.
	You can select All, Requires Verification, Verified, Awaiting Re-Verification, and Verification Undone. The default value is **All.**

Alternate Ways to Generate a Patient Data Report

In addition to the Reports page, you can generate a Patient Data Report from the Home page, the Patient Casebooks page, the Review CRFs page and the Data Entry window.

Generating a Patient Data Report from the Home or Patient Casebooks Page

When you generate a Patient Data Report from the Home page or the Patient Casebooks page, RDC Onsite:

- Submits a separate report job and generates a separate report for each patient that you select

- Orders the report by casebook visit

- Does not include audit history or discrepancy details

- Uses the following format to add a prefix to the report job name: **PT**_*patient*_

Note that if you specify CRF search criteria on the Patient Casebooks page, the report includes only the CRFs that satisfy the search criteria.

To generate a Patient Data Report from the Home page or the Patient Casebooks page:

1. Open the Home page or the Patient Casebooks page.

2. Select one or more patients. RDC Onsite submits a separate report job and generates a separate report for each patient that you select.

3. Click the **Action** menu and then select **Generate Patient Data Report** from the list to submit your request to generate the report. RDC Onsite confirms that the report job was submitted. You can click the **Reports** tab to view the status of your request.
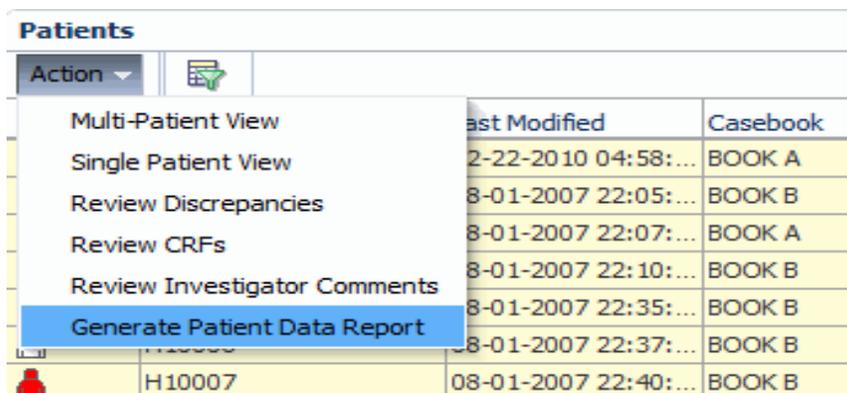
After RDC Onsite successfully generates the report, you can click the link in the View Report column on the Reports page to open and print your report.

Generating a Patient Data Report from the Review CRFs Page

When you generate a Patient Data Report from the Review CRFs page, RDC Onsite:

- Includes only the CRFs that you select in the report

- Generates a single report; the report may be across patients

- Places the CRFs in the same order as displayed on the Review CRFs page

- Does not include audit history or discrepancy details

- Uses the following format to add a prefix to the report job name: **CRFS_**

The key difference in generating a report from the Review CRFs page is that you must select each CRF to include in the report. The report orders your selected CRFs according to how they are ordered on the Review CRFs page. Although the CRFs do not follow the order of the casebook they were entered against, they do reflect the page numbers from the casebook.

To generate a Patient Data Report from the Review CRFs page:

1. Open the Review CRFs page.

2. Select one or more CRFs that you want to include in the report.

3. Click the **Action** menu and then select **Generate Patient Data Report** from the list to submit your request to generate the report. RDC Onsite confirms that the report job was submitted. You can click the **Reports** tab to view the status of your request.

4. After RDC Onsite successfully generates the report, you can click the link in the View Report column on the Reports page to open and print your report.

Generating a Report from the Data Entry Window

When you generate a Patient Data Report from the Data Entry window, RDC Onsite:

- Includes only the current CRF

- Uses the following format to add a prefix to the report job name: **HTMLDE**

You can generate a CRF History Report and a complete PDR for the current CRF, called CRF Report, by choosing the corresponding icons in the toolbar. See "Using the Toolbar Icons in the Data Entry Window" on page 3-16 for details.

Any reports generated from the Data Entry window also appear in the Reports tab, so you can view the associated log file there.

Regenerating Forms Utility

Any DCI form you generate on an ad hoc basis will be enabled for CRF field hyperlinks. However, it is also important to regenerate pre-existing DCI form versions for any study where you expect PDRs to be generated for formal use. Otherwise, PDR results are mixed, as described below. By (re)generating DCI forms, you enable the PDR to create field-level hyperlinks as needed for any CRF using that form.

You do not have to regenerate DCI Form Versions for one DCI at a time. Instead, you can use Oracle Clinical's utility to regenerate all forms for a study, following the instructions below.

PDR Results When DCI Forms Do Not Have Field Hyperlinks Enabled

If you generate a PDR with a mix of forms with and without field hyperlinks enabled:

- For CRFs against DCI forms without field hyperlinks enabled, superscripts in the CRF section will appear to be hyperlinked (with blue text), but, in fact, hyperlinks will not be enabled.

- For CRFs whose DCI Forms have field hyperlinks enabled, one-way hyperlinks will be enabled from the CRF Page to footnotes in the ancillary page.

- Superscripts in the footnotes sections are not enabled for ANY CRF page in the report–whether the DCI form is hyperlink-enabled or not.

If you generate a PDR where no forms have hyperlinks enabled, then no superscripts are enabled with hyperlinks, either in the CRF or ancillary page sections.

The PDR generates warning messages for each CRF that does not have a form with field hyperlinks enabled. The following message appears in both the PDR Log file and the Ancillary page for each affected CRF:

```
WARNING: Form Version <n> for DCI <dci_name> requires migration/regeneration to
enable hyperlinks on superscripts in the CRF. (Note: if the DCI form version for
any CRF in the report requires regeneration, return hyperlinks in the Footnotes
section are disabled for all CRFs.)
```

Instructions for Regenerating DCI Forms to Enable Field Hyperlinks

Refer to Appendix B in the *Oracle Clinical Remote Data Capture Administrator's Guide* for instructions to regenerate PDR and Data Entry templates for all form versions in a study.

> **Note:** When you use the form generation utility to regenerate form versions, the form is updated in place. No new form version number is created. Therefore, there is no need to migrate existing patient data to a new form version.

When you generate a new form version using Oracle Clinical's Maintain DCIs form, the DCI form version is updated and you need to migrate existing CRFs to use the new form. (Use the Oracle Clinical menu option, Migrate Form Version by Book.)

In most circumstances, you should execute the utility in FULL mode, but there may be circumstances where you should use INCREMENTAL mode, as described below.

Issue with Studies Having Many DCI Form Versions

When there are many, many DCI Form versions in a study, the utility may hang without completing all form regenerations. To provide a recovery mechanism:

1. Before executing the ocdcitemplate utility in FULL mode, mark all existing form versions by setting NUM_PAGES = NULL:

   a. Connect to SQL*Plus as `rxc` user:

      ```
      sqlplus rxc/password
      ```

   b. Execute the following update statement, responding to the prompt with the study for which you are about to regenerate form versions:

      ```
      update dci_form_versions
        set NUM_PAGES = NULL
        where clinical_study_id in (select clinical_study_id
            from clinical_studies
            where upper(study) like upper ('&&StudyName%'));
        commit;
      ```

2. Using the ocdcitemplate utility, regenerate all forms in FULL mode for your study. The utility will populate the NUM_PAGES field for each regenerated DCI Form version.

3. If you suspect the process may be hung, check the log file, l<job_id>.log; for example l19736.log. If there is an error message of the form, ORA-29516 Aurora assertion failure, contact Oracle Support. Otherwise, proceed with the next step.If processing has hung with no error message in the log file, run the utility in INCREMENTAL mode. In incremental mode, forms are regenerated only for those DCI Form versions with NUM_PAGES still null. To run in INCREMENTAL mode:

   a. In Oracle Clinical, navigate to Admin, Reference Codelists, Local Codelists, and find the OCL_STATE codelist.

   b. Find the Short Value UPD_FV_INCREM and set its Long Value to N.

   c. Don't forget to reset the value when you complete the study.

Generating a Blank Casebook Report

A Blank Casebook Report lets you create hard copies of all the planned CRFs in the casebook you specify. You can generate a Blank Casebook Report from the Reports page.

When you generate a Blank Casebook Report, you have two options:

- You can generate a *generic* blank casebook. The CRFs in the report include no CRF header information and no response data.

- You can generate a *patient-specific* blank casebook.

  In this case, the CRFs in the report include header information specific to the selected patient, but do not include response data. In addition, if the selected casebook is for a flexible study, the report includes all CRFs, whether they are expected for the patient or not.

  With this option, you can print a casebook for a particular patient.

To generate a Blank Casebook Report:

1. Click the **Reports** tab to open the Reports page.

2. Click **New Blank Casebook Report.**

New Blank Casebook Report

* Indicates required field

Cancel Submit Job

Report Parameters

* Casebook BOOK B ▼   Date Format mm-dd-yyyy(US) ▼

Patient ▼   Orientation ● Portrait
                                 ○ LandScape

Job Parameters

Report Server REPORT_SERVER ▼

Job Name Prefix BOOK B

Job Id 11591

Job Name BOOK B_11591

Output File Name c:\temp\o11591.pdf

3. Click the **Casebook** field, and then select a casebook from the list. You must select a casebook. The Blank Casebook Report consists of all the planned CRFs for the selected casebook.

4. Specify whether you want to create a *generic* or a *patient-specific* Blank Casebook Report as follows:

   ■ To generate a *generic* blank casebook, do not specify a value in the **Patient** field. The CRFs in the report include no header data and no response data.

   ■ To generate a *patient-specific* blank casebook, click the **Patient** field and enter the ID of the patient. Alternatively, you can click the down arrow and select a patient ID from the list.

     In this case, the CRFs in the report include header data specific to the selected patient, but do not include response data. In addition, if the selected casebook is for a flexible study, the report includes all CRFs, whether they are expected for the patient or not.

5. Select the **Date Format** to use. Your options are US, Standard, European, Swedish, and Same as in Log-In header.

6. Select the **Orientation** of the report. Your options are Portrait or Landscape. This value affects only the cover page of the report. The orientation of a CRF is always defined by its layout regardless of your selection.

7. Select the job parameters for the report.

   a. Select the name of the **Report Server.**

   b. Enter up to 8 characters for the **Job Name Prefix.** RDC Onsite automatically uses a unique number as the name of a report job, and then adds your specified prefix to the beginning of the job name. You can use the prefix value to easily search for your reports in the list on the Reports page.

   RDC Onsite displays the Job Id, Job Name, and the Output File Name for your reference.

8. Click **Submit Job.** RDC Onsite prompts for confirmation before continuing.

9. Click **Yes** to generate the Blank Casebook Report.

Once you submit your request to generate the Blank Casebook Report, you can return to the Reports page to monitor the progress of your report job. You can also stop a job in progress or check error details if the report generation failed. See "Monitoring the Status and Progress of Your Report Jobs" on page 12-18 for more information.

After RDC Onsite successfully generates the report, you can click the link in the View Report column on the Reports page to open and print your report. See "Printing a Report" on page 12-21 for more information.

Generating a Standalone Deleted CRFs Report

The Deleted CRFs Report lists the details and audit history for those CRFs of the selected patients that were deleted, but not re-entered. If a CRF was deleted but later re-entered, it is excluded from this report, as opposed to the deleted CRFs information provided in the Patient Data Report, CRF History Report, or CRF Report.

The Deleted CRFs Report is patient-specific and can be invoked from the Home page or from the Single or Multi-Patient Casebooks page

To generate the Deleted CRFs Report:

1. On the Home page or the Multi-Patient Casebooks page, select one or more patients for which you want to review deleted but not re-entered CRFs. See Verifying Deleted but Not Re-entered CRFs for instructions on identifying patients with such CRFs.

2. From the Actions list, select **Generate Deleted CRFs Report**.

3. Go to the Reports page to open the report.

Searching for Report Jobs

You can search for a report job by name, search for report jobs currently in progress, search for report jobs already completed, or search for all report jobs. RDC Onsite displays the results of your search on the Reports page.

> **Note:**   RDC Onsite searches for and displays only the report jobs that you have submitted. These jobs include jobs you submitted from Oracle Clinical. In addition, the Reports page only lists report jobs. It does not list print jobs, scheduled jobs, or jobs under preview.

By default, RDC Onsite displays the most recent report job at the top of the list. You can click a column heading to re-sort the list based on the text in the column. You can click the column heading again to toggle between an ascending and descending sort.

To search for one or more report jobs:

1. Click the **Reports** tab to open the Reports page.

2. Search for the report job you want to view.

Using the options in the Search pane, you can:

- Click **Job Name** and then type the name of the report job. You can use the percent sign (%) as a wildcard character in the search.

- Click **Show Jobs** and then select one of the following options from the list:

  - Click **All** to search for both current and previous jobs.

  - Click **Current** to search only for the jobs currently being run.

  - Click **Previous** to search only for the jobs that already finished running.

- Specify no additional search information. In this case, RDC Onsite searches for all the report jobs that you have submitted (the default).

3. Click **Search** to execute the search. RDC Onsite refreshes the Reports Jobs list 5.0: and displays the results of your search.

   For each report job, RDC Onsite displays valuable information about each job including its name, start time, end time, and status.

You can use this information to monitor jobs currently in progress. See "Monitoring the Status and Progress of Your Report Jobs" on page 12-18 for more information.

Your other options include:

- To view details about the job, click its link in the Job Name column. See "Viewing the Details of a Report Job" on page 12-20 for more information.

- To stop a job currently in progress, click the **Stop** icon in the Stop Report column. The icon appears only if the job is still running. See "Stopping a Report Job in Progress" on page 12-19 for more information.

- To open and view the report, click its link in the View Report column. The link is active only if RDC Onsite successfully generated the report. Once you open the report, you have options to print the report and save the report to your computer. See "Printing a Report" on page 12-21 for more information.

Monitoring the Status and Progress of Your Report Jobs

Certain reports may require extended time to run. You can continue to work in RDC Onsite while the report runs in the background.

In addition, you can monitor the progress of report jobs, stop a report job currently in progress, or display details about the report job.

To monitor the status and progress of report jobs:

1. Click the **Reports** tab to open the Reports page. RDC Onsite lists all the report jobs that you have submitted starting with the most recent jobs.

2. Search the list to find the report jobs you want to monitor. For each report job, RDC Onsite displays the following information:

    ■   **Job Name —** Displays the name of the report job. You can click the link to view additional details for the job.

    ■   **Start Time —** Displays the date and time that RDC Onsite started to generate the report. No time is listed if you stopped the generation of the report.

    ■   **End Time —** Displays the date and time that RDC Onsite finished generating the report. No time is listed if RDC Onsite failed to generate the report or you stopped the generation of the report.

    ■   **Status —** Displays the progress of the report generation:

        –   RS_FAILURE: The report server failed to generate the report.

        –   RS_SUBMITFAILED: The submit request to the report server failed.

        –   SCHEDULED: Your request to generate the report has been scheduled for a specific day, date, and time.

        –   STARTED: The report server has started to generate the report.

        –   STOPPED: You stopped the generation of the report.

        –   SUBMIT_TO_RS: Your request to generate a report was submitted to the report server.

        –   SUCCESS: The report was successfully generated.

    ■   **View Report** — Displays the path name of the report file. You can click the link to open, view, and print the report. The link is active only if the report generated successfully.

    ■   **Stop Report** — Displays a Stop icon that you can click to halt the execution of a report job currently in progress. The Stop icon does not display if the job is complete.

Stopping a Report Job in Progress

You can stop the execution of a report job currently in progress. You cannot stop a job after it is complete.

Click the **Stop** icon to halt the execution of a report job currently in progress.

Status	View Report	Stop Report
STARTED	c:\temp\o11481.pdf	

To stop a report job currently in progress:

1. Click the **Reports** tab to open the Reports page.

2. Search for all report jobs that are currently running.

    a. Click **Show Jobs** and then select **Current.**

   b. Click **Search.**

3. Click the **Stop** icon in the Stop Report column for the job you want to stop. The Stop Job confirmation dialog box opens.

4. Click **Yes** to stop the job. RDC Onsite confirms the action in the confirmation dialog box.

Alternatively, you can click a **Job Name** link to open another page and view details about the selected report job. If the report job is currently in progress, the page includes a Stop button so you can cancel the generation of the report.

Viewing the Details of a Report Job

There may be times when you need additional information on the status or progress of a report job. You may need to troubleshoot why RDC Onsite did not generate the report or why the process failed.

The Reports: Job Details page, as shown in Figure 12–5, provides a summary of the job executed. By viewing the details for a report job, you can:

■ View the error text if the job ended in error.

■ View the command line that RDC Onsite sent to the report server.

■ Click a link to open the log file for the report job. Note that RDC Onsite:

   – Creates the log file and provides an active link to the file only after the status of the job has changed to STARTED.

   – Does not create the log file if the job is still being submitted to the report server (Status = SUBMIT_TO_RS) or if the submit request to the report server failed (Status = RS_SUBMITFAILED).

Figure 12–5 Details of a Report Job

To view additional details about a report job:

1. Click the **Reports** tab to open the Reports page.

2. Click a link in the Job Name column. As shown in Figure 12–5, the Reports: Job Details page displays the following information for the selected job:

    - The job name, and the starting time, ending time, and status of the report generation. The Reports page displays the same information.

    - The error text, the command line executed, and the path name of the log file. You can click the active link to open the log file for the job. This information is helpful when troubleshooting why a report failed to generate.

      Note that RDC Onsite provides an active link to the log file only after the status of the job has changed to STARTED. In addition, RDC Onsite does not create the log file if the job is still being submitted to the report server (Status = SUBMIT_TO_RS) or if the submit request to the report server failed (Status = RS_SUBMITFAILED).

    - The name of the report server.

    - The path name of the report file. You can click the link to open, view, and print the report. The link is active only if the report generated successfully.

    - A Stop button, if the job is currently running. You can click the button to halt the execution of a report job currently in progress. The Stop icon does not display if the job is complete.

Printing a Report

The Patient Data Reports and the Blank Casebook Reports are PDF files. You can view a report using any application that opens PDF files, such as Adobe Reader. In addition, you can print the report or save a copy of the report to your PC.

To print a report:

1. Click the **Reports** tab to open the Reports page.

2. Search for the report you want print.

3. Click the link in the View Report column to open and print the report.

13

Using Source Data Verification

In order to implement partial source data verification (PSDV) for a study site, the site must have a published SDV Plan. Default SDV plan selections for the study are made in Oracle Clinical in the DCI Form Local Study Settings form and in the Maintain Study DCIs form. You can then simultaneously create and publish SDV plans for each site in the study based on those default values, or you can create and publish an SDV plan for each site individually, using the Source Data Verification Plan page in RDC. In either case, you can use this page to make updates to the Study Site SDV Plan through the course of the study. For more information see *Setting Up Partial Source Data Verification* in *Oracle Clinical Creating a Study*.

In Oracle Clinical Remote Data Capture, you can access the Source Data Verification (SDV) Plan page if you have either the BROWSE_SDVPLAN or UPDATE_SDVPLAN privilege. For an overview, see "Source Data Verification Plan Page" on page 1-10.

> **Note:** The Source Data Verification Plan tab is not available in RDC Test Mode.

An SDV Plan can have two parts: a patient plan and a critical forms plan. The patient plan identifies a subset of patients that require 100% SDV, and the forms plan identifies forms that should be verified across all patients. For each type of plan, it is possible to have a published version, a draft version, and one or more obsolete versions.

This chapter includes the following topics:

- Section , "Published, Draft, and Obsolete SDV Plan Versions"
- Section , "Patient Plan"
- Section , "Critical Forms Plan"
- Section , "Obsolete Plans"
- Section , "Using 100% Source Data Verification"
- Section , "Using Empty SDV Plans"

Published, Draft, and Obsolete SDV Plan Versions

The Source Data Verification Plan tab includes four links to view the published and draft versions of both patient and forms SDV plans. A fifth link provides access to all obsolete plan versions. A link is inactive if your site doesn't have that type of SDV plan. For example, if you don't have any draft patient plans for the current study site, the Patient Plan: Draft link is inactive.

Below are common workflows that include descriptions of how the links become active and inactive in the course of creating and updating SDV plan versions.

Updating a Published SDV Plan

Published plans cannot be updated directly. In order to make changes to a published SDV plan, you must first create a draft copy of the current plan, make your changes in the draft version, then publish the new version.

> **Note:** You may want to make changes soon after the initial SDV plans are published using the Oracle Clinical option to Publish SDV Plans for all Sites. In this case, when you select the Source Data Verification Plan tab in RDC, links for the published versions of both the patient and critical forms plan are enabled. The Draft plan links are disabled.

Follow these steps to update a published SDV plan:

1. Open the published patient or critical forms plan you want to update.

2. Click on **Create a New Version** to create a draft version of the plan.

   - A copy of the published plan is created with an incremented version number.

   - RDC navigates to the Draft plan page so that you can edit the draft copy.

   - The published plan version remains in effect while you work on the draft version. At this point, both the Published and Draft links for the plan are enabled.

3. In the draft version, make the required updates. You can save the draft version without having to publish it.

4. When you are satisfied with your updates, select the **Publish** option from the Actions drop-down.

   With publication, the Draft plan link is disabled, and RDC navigates back to the Published plan page where the newly published plan version is displayed. The previously published version of the plan is automatically obsoleted and can be viewed in the Obsolete Plans page.

Creating a New SDV Plan

You may want to create and publish SDV plans for each study site individually, instead of using the Oracle Clinical option to Publish SDV Plans for all Sites. In this case, when you first select the Source Data Verification Plan tab in RDC, the Draft plan links for both Patient and Critical Forms plans are enabled, and the Published and Obsolete plan links are disabled.

Follow these steps to create and publish a new SDV plan:

1. Select the **Draft** link for either the patient or critical forms plan.

   At this point, the upper right corner of the page displays either *No Patient SDV Plan created* or *No Forms SDV Plan created*, depending on the page you have selected. The Draft Patient Plan page shows the default values that have been

specified for the study in Oracle Clinical: *Number of initial patients*, *Patient auto-select rate*, *Exclude batch-loaded CRFs?*, and *Exclude non-migrated CRFs?*. The Draft Critical Forms Plan page identifies the CRFs that were identified in Oracle Clinical as critical for the study.

2. You can save the plan in its current state with the default values in place, override default selections, or make additional selections.

3. When you are satisfied with your plan, select the **Publish** option from the Actions drop-down.

   With publication, the Draft plan link becomes disabled, and RDC navigates to the Published plan page, where the newly published plan version 1 is displayed.

Patient Plan

The Patient Plan panel includes the following sections:

- Initial patient count and/or auto-select rate (auto-select section).

- Patient SDV selection status — In both the draft and published patient plan pages, this table of patients reports the current SDV eligibility and SDV selection status for each patient. In a draft plan version patients can be manually selected for SDV, and the Pending Action column shows your new selection or exclusion. The draft version of the plan lists all patients assigned to the site. The published version of the plan only lists the patients that are selected for SDV.

- Active SDV Patients report — This report shows the number of patients that are both SDV Eligible and selected for SDV (active SDV patients) and gives the breakdown of this count by selection type (Initial, Auto-Selected, Imported, or (manually) Selected).

Patient Plan Draft

You use the draft patient plan page to create the initial patient SDV plan for a site or to make changes to the published plan version. You can perform the following actions in a draft patient SDV plan:

- Change the initial patient count and the auto-selection rate, or both — If no patients require 100% SDV for this site, set both the auto-select rate and initial number of patients selected to 0. This is an *empty* plan. See "Using Empty SDV Plans" on page 13-7 for more details.

- Choose between CRF options — You can exclude batch-loaded or non-migrated CRFs from the SDV requirement even for patients requiring 100% SDV.

- Patient selection actions — You can manually select patients for SDV using the Patient Selection table. To do so, first select a patient by clicking anywhere in the patient row. You can use Shift+click or Ctrl+click to select multiple patient rows. Then choose **Select** from the Actions drop-down list for this table. Your selection, if valid, is saved in the Pending Action column for each patient affected. If the action was not valid for one or more patients, you are notified to go to the action log to view the error message(s). Other actions are available and valid for a selected patient as follows:

  - **Select** is valid for any patient with a selection status of null or excluded.

  - **Exclude** is valid for a patient having any status except excluded.

  - **Undo select** is valid for a manually selected or imported patient.

  - **Undo exclude** is valid for an excluded patient.

  Other patient selection actions are also available. The **Clear Pending** action can be used to undo a previous action. This has an effect only for patients which have a value in the Pending Action column. **View Action Log** allows you to view any errors resulting from the last action.

- Plan actions — You can validate the changes and publish the plan after changing the plan parameters using the **Validate** and **Publish** actions, respectively. If the validation returns error messages, they are added to the Validation log. You can view the log by selecting **View Validation Log**. When you publish the plan without getting any errors, the Published plan page comes into focus.

  In addition to the **Refresh**, **Save** and **Cancel** actions, if you have the ADMIN_ SDVPLAN privilege for the study or site, you can also **Unlock** an SDV plan. This situation can occur if several users simultaneously open a Draft plan for update.

- Review current patient SDV status — In the Patient Selection table, the columns Selection Status, SDV Eligibility, Proc Vers, and Active SDV? all provide you with information about the current SDV status of each patient.

  The Selection Status column can contain any of the values listed below:

  - null — The patient is not selected for 100% SDV.

  - Initial — The patient was auto-selected for SDV as one of the first n patients to become SDV-eligible for this site, where n was specified in a published patient SDV plan.

  - Auto-Selected — The patient was auto-selected for SDV based on the auto-select rate specified in the published patient SDV plan.

  - Selected — You manually selected the patient for SDV using this page.

  - Imported — The patient was selected for SDV as part of a patient list imported using Oracle Clinical's Load Patient SDV Attributes job.

  - Excluded — You manually excluded the patient for SDV using this page.

  - Import Excluded — The patient was excluded from SDV as part of a patient list imported using Oracle Clinical's Load Patient SDV Attributes job.

  The SDV Eligibility column can be null, show an eligibility date, or specify *failed* plus the date when the patient became ineligible for SDV.

  The Active SDV? column can contain the following:

- Active — The patient is both eligible and selected for SDV. These are the patients that are retrieved when an RDC user searches for patients requiring 100% SDV.

- Not eligible yet — Indicates that the patient was manually selected or imported for SDV, but is not yet eligible for SDV. Patients with this status are not retrieved when an RDC user searches for patients requiring 100% SDV.

- Failed eligibility — Indicates that the patient was manually selected or imported for SDV, but failed SDV eligibility. Patients with this status are not retrieved when an RDC user searches for patients requiring 100% SDV.

Patient Plan Published

The published version of the plan cannot be edited, so neither the Action drop-down list or Pending Action column are visible. You can press the **Create a New Version** button to copy the plan and create a draft version which you can edit. See "Updating a Published SDV Plan" on page 13-2 for more information on how to do this. If you already have a draft version, you have the option to overwrite it.

Critical Forms Plan

The Critical Forms Plan panel (Critical Forms for All Patients) includes the list of forms (DCIs) defined for the study, which in a draft plan can be selected for SDV.

Critical Forms Plan Draft

You use the draft critical forms plan page to create the initial forms SDV plan for a site or to make modifications to the current published plan version.

Review Exclusion Options

The settings Exclude batch-loaded CRFs? and Exclude non-migrated CRFs? can only be updated in the Patient SDV Plan, but are displayed in the Forms plan, because they apply to both plans. In other words, if you have a form X that requires source data verification across all patients, and the setting for Exclude batch-loaded CRFs? is checked, the form X will not be identified as requiring SDV in any case where the form content is batch-loaded.

If you are not using a Patient SDV plan, you can create an otherwise empty patient plan specifically to check or uncheck the Exclusion options. See "Using Empty SDV Plans" on page 13-7 for details.

Select Critical Forms for SDV

You can select critical forms that require SDV across all patients for the site using the Form Selection table. First select a CRF by clicking anywhere in the CRF row, then Shift+click or Ctrl+click to select multiple CRF rows. Then choose **Select** (or **Undo select**) from the Actions drop-down list for this table. Your selection is saved in the Pending Action column for each CRF you selected. If you want to renounce the selection, use the **Clear Pending** action. This only affects CRFs with a value in the Pending Action column.

Review the Current CRF SDV Selection Status

In the Form Selection table, the columns Selection Status and Selection Source are presented to provide you with information about the current SDV status of each form, based on the currently published plan. The selection status can be either null or selected. The Selection Source column indicates whether the selection was made in Oracle Clinical for the study as a whole, or in the site-specific forms SDV plan, using this page.

Critical Forms Plan Published

In the published version of the critical forms plan, the Action drop-down list and Pending Action column are not available because this is a read-only version. You can press the **Create a New Version** button to copy the plan and create a draft version which you can edit. See "Updating a Published SDV Plan" on page 13-2 for more information. If you already have a draft version, you have the option to overwrite it.

Obsolete Plans

In this tab you can find a list of all the previously published SDV plans, both patient plans and critical form SDV plans. When you select the row of a patients plan from the table, the Patients panel opens, showing the plan metrics from when that version became obsolete. If you select a critical forms plan, the Critical Forms panel expands, showing the forms that were selected for SDV at the time that plan version became obsolete.

Using 100% Source Data Verification

If all of your sites require 100% SDV, it is not required that you publish any type of SDV plan. With no published SDV plan, an RDC search for CRFs requiring verification will retrieve all CRFs, but you cannot search for patients requiring 100% SDV.

To enforce 100% SDV only for some sites, create a patient SDV plan for those sites and set the patient auto-selection rate to 100%. That way your intentions are explicit and you have access to search and filtering options. You do not also need a critical forms SDV plan in this case because all CRFs must be verified for all patients.

Using Empty SDV Plans

RDC allows you to publish a patient SDV plan without a critical forms SDV plan, and the other way around. This might produce unintended consequences that you can avoid by using empty SDV plans. An empty patient SDV plan is one in which both the initial patient count and the auto-select rate are zero and no individual patients are manually selected or imported. An empty critical forms SDV plan is one in which no forms are selected.

Consider using empty SDV plans in the following circumstances:

- If you want to be explicit about not having SDV requirements, you can publish a blank patient SDV plan, a blank critical forms SDV plan, or both. Publishing empty plans ensures that search is available in the RDC search pane and that the appropriate review data is displayed in the Single Patient Casebook Page, even if these values are zero.

- If you do not require 100% patient SDV and do not have a patient SDV plan, but want to exclude batch-loaded or non-migrated CRFs from the critical forms SDV plan, you can create an empty patient plan to set the CRF exclusion options. See "Review Exclusion Options" on page 13-5 for details.

- If no patients require 100% SDV, but critical forms do require SDV across all patients, publish an empty patient plan to maintain consistency in the RDC search pane from one site to the next. Otherwise, the option to search for *Patients requiring 100% SDV* is not available for the site, but is available for other sites where a patient plan is published.

- If none of your sites require a selection of patients for 100% SDV, you can publish a critical forms SDV plan for each site with no accompanying patient SDV plan. This means that no patients require 100% SDV at any site, and RDC users will not have the option to search for *Patients requiring 100% SDV* at any site.

A

Description of the CRF Icons

This appendix describes the CRF icons that appear on the Casebooks page and the Review pages in Oracle Clinical Remote Data Capture Onsite (RDC Onsite).

This appendix includes the following topics:

- Data Entry Status Icons

- Discrepancy Status Icons

- Verification Status Icons

- Approval Status Icons

- Custom Review Status Icons

- Multiple-Status Icons

- Summary of Colors and Symbols Added to CRF Icons

About the CRF Icons

RDC Onsite uses colored icons with various symbols and graphics to represent the current status of each CRF. For example, by looking at a CRF icon, you can determine:

- If data entry for the CRF has started, is complete, or is on a second pass

- If the CRF has any active discrepancies or other discrepancies

- If a custom review or re-review is required, not required, or completed

- If the CRF has been verified or if it needs re-verification

- If the CRF has been approved or if it needs re-approval

- If the CRF is locked

Figure A–1   CRF Icons

Data Entry Status Icons

RDC Onsite uses a series of icons to indicate the formal stages of data entry and to track the progression of a CRF from no data entered to entry complete.

Table A–1 describes the icons that RDC Onsite uses to indicate the various stages of data entry in a CRF.

Table A–1   Data Entry Status Icons

Icon	Label	Description
	Placeholder	No information has been entered into the CRF.
	Created	All required *header* information has been entered and saved for the CRF. However, no response data has been entered yet.
	Blank	A user has intentionally marked the CRF as blank. A blank CRF contains no data. You cannot enter data into a CRF while it is marked as blank.
	Entry Completed	All required fields have been entered, including CRF header fields and responses to all data points. All required CRF header and section information is complete and at least one question area response field is completed. In addition, a CRF with this icon has no discrepancies, is not yet verified, and is not yet approved. RDC Onsite adds color and symbols to the Entry Complete icon to indicate discrepancy, verification, and approval status.

Table A–1   (Cont.) Data Entry Status Icons

Icon	Label	Description
	Pass 2 Started	The second pass of data entry has started.
		This record originates from an Oracle Clinical operation, but your sponsor might create an activity that displays records with this status.
	Pass 2 Completed	The second pass of data entry is completed.
		This record originates from an Oracle Clinical operation, but your sponsor might create an activity that displays records with this status.
	Batch Loaded	The data for the CRF was loaded during an automatic batch operation configured by your sponsor.
		The response values were entered into a CRF by electronic means, as opposed to manually entered by a user performing data entry.

Discrepancy Status Icons

A discrepancy is any data that falls outside of an expected range of values or is otherwise flagged during the edit check process as an error. Table A–2 shows the discrepancy status icons.

The discrepancy status icons indicate whether you (or a member of your user group) or another group needs to correct some of the information in a CRF.

To indicate the status of discrepancies in a CRF, RDC Onsite adds the following color to the Entry Completed icon:

- Red to indicate active discrepancies.
- Yellow to indicates other discrepancies.

If a CRF contains both active discrepancies and other discrepancies, the icon remains red until you address all active discrepancies in the CRF. At that point, if one or more discrepancies with a status of other are still open, the icon changes from red to yellow. If a CRF has no discrepancies or if all discrepancies are closed, the icon is white.

Table A–2   Discrepancy Status Icons

Icon	Label	Description
	Entry Completed (and no open discrepancies)	There are no open discrepancies (active or other) associated with the CRF. There may, however, be closed discrepancies associated with the CRF.
		Note that this icon is the Entry Completed icon. RDC Onsite adds color to the Entry Completed icon to indicate the status of discrepancies.
	Active Discrepancies	The red color added to the Entry Completed icon indicates that the CRF has one or more active discrepancies that must be addressed by you or by a member of your user group.
	Other Discrepancies	The yellow color added to the Entry Completed icon indicates that the CRF has one or more other discrepancies that must be addressed by a user in a role other than yours.

Verification Status Icons

As shown in Table A–3, RDC Onsite adds symbols to the Entry Completed icon to indicate the verification status of a CRF. CRF Verification Status is only visible in the CRF icon if you have the appropriate privileges.

Table A–3   Verification Status Icons

Icon	Label	Description
	Entry Completed (but not yet verified)	The CRF has not been verified. Note that this icon is the Entry Completed icon. RDC Onsite adds symbols to the Entry Completed icon to indicate the verification status.
	Verified	The check mark added to the Entry Completed icon indicates that the CRF has been verified (that is, checked).
	Awaiting Re-Verification	Note that RDC Onsite adds a red arrow next to the check mark to indicate that the verification process must be repeated. The CRF is awaiting re-verification. At least one data point in the verified CRF has been modified since verification. The CRF must be verified again.
	Verification Required	This icon is used only if partial source data verification is in effect. Otherwise, all CRFs are assumed to require verification.

Approval Status Icons

As shown in Table A–4, RDC Onsite adds signatures and symbols to the Entry Completed icon to indicate the approval status of a CRF.

Table A–4   Approval Status Icons

Icon	Label	Description
	Entry Completed (but not yet approved)	The CRF has not been approved. Note that this icon is the Entry Completed icon. RDC Onsite adds symbols to the Entry Completed icon to indicate the approval status.
	Approved	The signature added to the Entry Completed icon indicates that the CRF has been approved.
	Awaiting Re-Approval	The CRF is awaiting re-approval. At least one data point in the approved CRF has been modified since approval. The CRF must be approved again. Note that RDC Onsite adds a red arrow next to the signature to indicate that the approval process must be repeated.

Custom Review Status Icons

If your study has Custom Review Types defined, the status of a CRF can be one in the following Table A–6, depending on your privileges. You can have privileges for multiple review types.

Table A–5   Custom Review Status Icons

Icon	Description
RC	**RC**: Review is complete for all your review types.
RQ	**RQ**: Review for at least one of your review types is required.
RN	**RN**: The CRF does not require review for any of your review types. Only appears if the Review not Required (RN) status was applied by a user. It does not appear if the status was applied by custom review requirements.
RR	**RR**: At least one of your reviews was reversed due to data update and it's awaiting re-review.

Multiple-Status Icons

RDC Onsite adds color and graphics to the Entry Completed icon, the Pass 2 Completed icon, and the Batch Loaded icon to further indicate the status of a CRF.

Some CRFs can have more than one status. Table A–6 provides a few examples of CRF icons that have a combination of statuses.

Table A–6   Multiple-Status Icons

Icon	Description
	Indicates the CRF: ■ Has been batch loaded (disk) ■ Has been approved (signature) ■ Is awaiting re-verification (red arrow next to check mark) ■ Is locked (padlock) This is a sponsor operation, but might reflect in an activity that shows records with this status.
	Indicates the CRF: ■ Has data entry completed (form with fields) ■ Has one or more active discrepancies (red background) ■ Has been verified (check mark) ■ Has been approved (signature)

Table A–6   (Cont.) Multiple-Status Icons

Icon	Description
	Indicates the CRF: ■ Has had a second pass of data entry (form with the number 2) ■ Has one or more active discrepancies (red background) ■ Is awaiting re-verification (red arrow next to check mark) ■ Is awaiting re-approval (red arrow next to signature) This record originates from an Oracle Clinical operation, but your sponsor might create an activity that shows records with this status.
	Indicates the CRF: ■ Has data entry completed (form with fields) ■ Has one or more other discrepancies (yellow background) ■ Has been verified (check mark) ■ Is awaiting re-approval (red arrow next to signature) ■ Is locked (padlock) This record originates from an Oracle Clinical operation, but your sponsor might create an activity that shows records with this status.
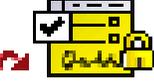
Summary of Colors and Symbols Added to CRF Icons

Table A–7 summarizes the colors and graphics that RDC Onsite adds to the Entry Completed icon, the Pass 2 Completed icon, and the Batch Loaded icon to further indicate the status of a CRF.

Table A–7   Graphical Elements that RDC Onsite Adds to the Basic CRF Icons

Added Graphic	Description of Added Graphic	Example of CRF Icon	Indicates that the CRF…
Red color	Red color		Has one or more active discrepancies that must be addressed by you or by a member of your user group.
Yellow color	Yellow color		Has one or more other discrepancies that must be addressed by a user in a role other than yours.
White color	White color		Has no open discrepancies (active or other). There may, however, be closed discrepancies associated with the CRF.
	Check mark		Has been verified (that is, checked).
	Red arrow next to the check mark		Is awaiting re-verification. At least one data point in the verified CRF has been modified since the last verification. The CRF must be verified again.
	Signature added to bottom of icon		Has been approved.

Table A–7   (Cont.) Graphical Elements that RDC Onsite Adds to the Basic CRF Icons

Added Graphic	Description of Added Graphic	Example of CRF Icon	Indicates that the CRF…
	Red arrow next to the signature		Is awaiting re-approval. At least one data point in the approved CRF has been modified since the last approval. The CRF must be approved again.
	Padlock		Is locked.

B

Patient Auto-Selection in Partial Source Data Verification

This appendix describes the process by which patients are automatically selected for Partial Source Data Verification (PSDV).

You can set RDC to automatically select patients for 100% SDV based on an initial count, auto-select rate, or both. This quota of patient data to be verified can be specified in your study site patient SDV plan.

In order for auto-selection to work, the following conditions must be met:

- A study site patient SDV plan must be published in which an initial patient count, an auto-select rate, or both are specified. For more information, see "Using Source Data Verification" on page 13-1.

- The Pending Patient Updates job must be scheduled, at an interval of your choosing, to check for newly eligible patients and to process those patients marked for auto-selection. For more information, see Schedule Pending Patient Updates in the *Oracle Clinical Administrator's Guide*.

For more information, also see Setting Up Partial Source Data Verification in *Oracle Clinical Creating a Study.*

SDV Patient Pools

Conceptually, SDV auto-selection uses patient pools that correspond to a patient's current SDV selection status and eligibility status. You can see the current Selection and Eligibility statuses for each patient in the published version of the SDV plan.

You can also see current patient statuses in a draft version of the patient SDV plan if there is one in progress and you also have a published patient SDV plan. The draft version lists all patients assigned to the site, while the published version lists only those patients already selected for SDV.

Patient pools and their corresponding patient statuses are as follows:

Exclusion Pool — Contains patients explicitly excluded by the patient SDV plan, which may have been excluded individually or through an import list. These patients may or may not be eligible. The Selection status in the patient SDV plan can be either *Excluded* or *Import Excluded*.

Manual Pool — Contains patients explicitly selected in the RDC Onsite SDV Plan, either individually or in an import list. These patients may or may not be eligible. The Selection status in the patient SDV plan can be either *Selected* or *Imported*.

Newly Eligible Pool — Contains patients that became eligible since the last time auto-selection was executed. For a patient to be included in this pool, SDV Eligibility must show a valid date. The Selection status in the patient SDV plan can be null, an Exclusion Pool status, or a Manual Pool status.

Initial Pool — Contains patients which have been auto-selected for SDV as one of the first patients to have become eligible at the site. The number of patients to be included in this pool is specified in the patient SDV plan as the Number of Initial Patients. For a patient to be included in this pool, SDV Eligibility must show a valid date. The Selection status in the patient SDV plan is *Initial*.

Auto-selected Pool — Contains patients which have been auto-selected based on the auto-select rate specified in the published patient SDV plan. For a patient to be included in this pool, SDV Eligibility must show a valid date. The Selection status in the patient SDV plan is *Auto-Selected*.

Discard Pool — Contains SDV-eligible patients that went through auto-selection, but were not selected. The Discard pool is revisited if the auto-select rate is increased while the study is in progress. There is no information in the patient SDV plan that can certainly distinguish a discarded patient from a newly eligible patient that is not in the Exclusion or Manual pools because in both cases the Selection status is null and a valid eligibility date is present. While not always accurate, you can assume a patient is discarded if it has a null Selection status and the eligibility date precedes the last run of the Pending Patients Updates job.

> **Note:** Depending on your methodology for populating patient eligibility dates, you could have a patient become eligible after the last run of the Pending Patient Updates job with a date in the past.

Active SDV Pool — Contains patients in the combined Auto-selected and Initial pools, plus those patients in the Manual pool which are SDV-eligible. These patients are further called out in the patient SDV plan with a value of *Active* in the Active SDV? column of the patient SDV plan. The Active SDV Patients table in the patient SDV plan reports the total count of Active SDV patients, broken down by selection type. These are the patients that are retrieved in RDC Onsite when a search for Patients Requiring 100% SDV is conducted. Patients in this pool must have a valid SDV Eligibility date. Patients in the Active SDV pool can have a Selection status of *Auto-Selected*, *Initial*, *Selected*, or *Imported*.

Auto-select Processing

Auto-selection runs whenever a patient SDV plan is published and each time the Pending Patient Updates job runs. RDC auto-selection processes the newly eligible patients that are not already manually selected or excluded. Therefore, take note that when you use a combination of manual and automatic selection, the effective percent of patients selected for SDV exceeds the auto-select rate you specify.

Patients are processed in order by their SDV eligibility date. If there are multiple patients with the same eligibility date, the processing order is based on the Oracle RDBMS row ID for the patient. The first patients are added to the Initial Pool until the initial count is reached, if specified. Patients are then selected in a round-robin fashion, based on the auto-select rate specified in the plan. The round-robin cycle number is derived as 100 divided by the auto-select rate. For example, if the auto-select rate is 20%, every 5th patient is selected for SDV. Fractional cycle numbers are rounded down to a whole number.

Patient Eligibility is Reversed

It is possible for a once eligible patient to become un-eligible. In this case, the patient Eligibility Date and Selection status are updated to null.

When patient eligibility is reversed, auto-selection compensates the Initial or Auto-selected pool as needed. If the patient was in the Initial pool, auto-selection looks at both the Discard and Auto-selected pools to select the patient with the earliest SDV Eligible date. If a patient is selected from the auto-select pool, then that pool is compensated with a patient from the discard pool.

All Data for a Patient is Deleted

If all data for a patient is soft-deleted or hard-deleted, all eligibility fields for the patient (Eligible Date, Ineligible Date, Proc Vers) are nulled. If the patient was formerly SDV eligible, this change triggers the auto-selection process described in Patient Eligibility is Reversed.

If the patient is manually selected for, or excluded from, SDV then the selection status remains as is.

Patient SDV Plan is Updated

You can publish a new patient SDV plan version with an increased or decreased initial count or auto-selection rate. When you do this, RDC adjusts the Initial and Auto-selected pools as needed.

- If the Initial pool needs to be increased, compensation selection(s) are made from the combined Discard and Auto-selected pools.

- If the Auto-selected pool needs to be increased, compensation selection(s) are made from the Discard pool.

- If the Initial pool needs to be decreased, patients with the most recent SDV eligibility date are removed from the Initial pool and added to the Discard pool and their Selection status changes to null.

- If the Auto-selected pool needs to be decreased, patients with the most recent eligibility dates are removed from the Auto-selected pool and added to the Discard pool. Their Selection status changes to null.

Patient Transferred from One Site to Another

When a patient's study site is updated, the Pending Patient Updates job automatically updates the SDV plans at the old and new sites as follows:

1. If there is a patient SDV plan in place at the old site, the patient is removed from the old site's plan.

2. If there is a patient SDV plan in place at the new site, the patient is added to the draft SDV plan for the new site with a null Selection status.

3. If the new site has a published SDV plan that includes an initial count or auto-select rate and the patient is eligible, the patient is processed for auto-selection at the new site.

Data Transferred from One Patient to Another

When Patient Transfer is used to transfer data from one patient ID to another (Oracle Clinical, Conduct, Security), eligibility and SDV plans may be affected as follows:

- For the target patient ID, SDV eligibility field values are transferred along with data. This may trigger auto-select processing as described above.

- For the source patient ID, all data is soft-deleted, and processing is performed as described above, unless this is an ongoing transfer. This is to prevent a subsequent operation from transferring artificially nulled eligibility data.

Patient ID Is Updated in a CRF (Key Changes or Mass Key Changes)

When the patient ID for one or more RDCIs is updated, the source patient is treated as if the CRF has been deleted. A check is made to see if all data for the patient is deleted and, if so, the patient is processed as described above. For the target patient, there is no immediate change. However, if the new patient requires 100% SDV, this CRF appears in RDC as requiring SDV.

DCI or Other Date Is Updated in a CRF

If you have an eligibility validation procedure which populates a patient's eligible date field, ineligible date field, or both, based on a date field in the CRF, an update to the field will result in an update to the eligibility date. However, if you use the DCI date for this purpose, the date change is not detected.

Index

visits
  adding pages to, 3-39
  shown with interval name, 3-11
  unplanned, 3-38

W

Web site links
  in Links section on Home page, 2-15
work space, 1-8