Oracle® Clinical Remote Data Capture Classic

Data Entry User's Guide

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Preface

This guide describes how to use the Oracle Clinical Remote Data Capture Classic (RDC Classic) application. The content that it covers and the manner in which it is structured are designed to provide substantive and applicable information for all users.

This preface contains the following topics:

- Audience on page xxv
- Documentation Accessibility on page xxv
- Finding Information and Patches on My Oracle Support on page xxvi
- Finding Oracle Documentation on page xxviii
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Audience

This documentation is intended to address the requirements of all RDC Classic users. It includes descriptions of the tasks that are typically performed by data managers, site monitors, CRAs, and investigators.

The manual assumes a basic understanding of Microsoft Windows terminology and usage, as well as a general background in clinical trials processes.

The documentation is also intended to be used by system administrators, in conjunction with the *Oracle Clinical Administrator's Guide*.

Documentation Accessibility

Our goal is to make Oracle products, services, and supporting documentation accessible to all users, including users that are disabled. To that end, our documentation includes features that make information available to users of assistive technology. This documentation is available in HTML format, and contains markup to facilitate access by the disabled community. Accessibility standards will continue to evolve over time, and Oracle is actively engaged with other market-leading technology vendors to address technical obstacles so that our documentation can be accessible to all of our customers. For more information, visit the Oracle Accessibility Program Web site at http://www.oracle.com/accessibility/.

Accessibility of Code Examples in Documentation

Screen readers may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, some screen readers may not always read a line of text that consists solely of a bracket or brace.

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This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/us/support/contact-068555.html or visit http://www.oracle.com/us/corporate/accessibility/support/index.html 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 Classic is Oracle Support's self-service Web site My Oracle Support (formerly MetaLink).

Before you install and use Oracle Clinical Remote Data Capture Classic, 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 Documentation

The Oracle Web site contains links to all Oracle user and reference documentation. You can view or download a single document or an entire product library.

Finding Oracle Health Sciences Documentation

To get user documentation for Oracle Health Sciences applications, go to the Oracle Health Sciences documentation page at:

http://www.oracle.com/technetwork/documentation/hsgbu-154445.html

> **Note:** Always check the Oracle Health Sciences Documentation page to ensure you have the latest updates to the documentation.

Finding Other Oracle Documentation

To get user documentation for other Oracle products:

1. Go to the following Web page:

   http://www.oracle.com/technology/documentation/index.html

   Alternatively, you can go to http://www.oracle.com, point to the Support tab, and then click **Documentation.**

2. Scroll to the product you need and click the link.

3. Click the link for the documentation you need.

Related Documents

This section lists the documents in the Oracle Clinical Remote Data Capture Classic documentation set, followed by their part number. The most recent version of each guide is posted on the Oracle Web site; see "Finding Oracle Health Sciences Documentation" on page xxviii.

- *Oracle Clinical Installation Guide* (Part E18817)

- *Oracle Clinical Administrator's Guide* (Part E18818)

- *Oracle Clinical Getting Started* (Part E18819)

- *Oracle Clinical Creating a Study* (Part E18820)

- *Oracle Clinical Conducting a Study* (Part E18821)

- *Oracle Clinical Application Programming Interface Guide* (Part E18866)

- *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* (Part E18823)

- *Oracle Clinical Remote Data Capture Onsite User's Guide* (Part E18822)

- *Oracle Clinical Remote Data Capture Classic Data Entry User's Guide* (Part E18824)

The release notes and the release content document are also posted in the Oracle Health Sciences documentation library.

In addition, Oracle Clinical Remote Data Capture Classic customers can request a copy of the *Oracle Clinical Stable Interface Technical Reference Manual* from Oracle Support.

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.

Part I

RDC Classic Concepts and Conventions

This part of the guide consists of sections that provide a conceptual overview and descriptions of general functionality for basic RDC Classic features. It includes information about system requirements, the components of CRFs, discrepancy management, and reports. The sections are:

- Introduction on page 1-1
- CRFs on page 2-1
- RDC Classic Discrepancy Management on page 3-1
- Reports in RDC Classic on page 4-1

1

Introduction

Oracle Clinical is a clinical data management system that provides a full suite of capabilities that facilitate study design, development of validation procedures, data entry, replication, discrepancy management, and handling of laboratory data. In Oracle Clinical, data entry activities generally occur at the sponsor site via workstation computers that are linked directly to the hardware on which the Oracle Clinical application reside.

Remote Data Capture Classic (RDC Classic) is an electronic data capture (EDC) application that is tightly integrated with Oracle Clinical and allows you to move data entry activities investigator sites, where you collect and work with patient data. When you record the data in RDC Classic and save it to the Oracle Clinical database, it is immediately available to all other users, as well as to any procedures and post-processing activities that are set up to ensure clean data. Using RDC Classic, you also have the capability to view and work with data that was collected either through Oracle Clinical or other investigator sites using RDC Classic.

The following sections describe topics that are fundamental to working with Oracle Clinical RDC Classic:

- RDC Classic and Electronic Data Capture on page 1-1
- System Requirements on page 1-3
- Security — Roles and Privileges on page 1-14
- RDC Classic Workflows on page 1-18

RDC Classic and Electronic Data Capture

A primary goal of a clinical study is to collect high quality data. The combination of Oracle Clinical and RDC Classic allows users to improve the quality of the data by providing a mechanism to record patient data at the location where it is collected. This section provides an overview of EDC, discusses how RDC Classic accomplishes EDC, and describes how RDC Classic interacts with Oracle Clinical.

EDC allows you to perform data entry, verification, approval, and data management at the investigative site, that is, remotely, using a network to communicate with study database, which is usually located at a sponsor facility. RDC Classic provides this capability with the added assurance that all updates to patient data are saved immediately to a single, centralized database that is managed by database administrators (DBAs).

RDC Classic provides real-time access to and interaction with the database where the clinical data for a study is collected, as well as communication with other study workers. By utilizing secure, online access across the Internet (or an Intranet), RDC

Classic facilitates immediate transfer of all data changes to the database and it provides direct feedback, in the form of queries or discrepancies, about patient data and related information, which allows such issues to be dealt with in a timely manner.

Because you have access to the study database from within your RDC Classic **session**, you can use RDC Classic to run reports for any set of patient data that has thus far been collected (subject to the privileges assigned to your user name). You can also use the RDC Classic report feature to generate reports comprised of all CRFs in a casebook, with or without patient information in the header areas.

Discussion

The model for gathering, collating, resolving, and managing clinical trial data has been to send paper Case Report Forms (CRFs) from study sites to a central location. The data contained in the paper CRFs was then manually transferred to the study's database by data entry operators. Any questions about the information contained in a CRF, such as those arising from typographical errors or ambiguous values, had to be routed through a data manager and resulted in a letter being sent to the study site, via postal mail or fax. At the study site, the investigator had to research the problem from medical charts that may have been completed months before, come to a conclusion, draft a response to the query, and send it back, again via postal mail. The entire process may have taken months to complete for a small set of questionable data. This delay is a cause of the lengthy amount of time that clinical trials took to complete. It also resulted in significant data management hurdles.

Oracle Clinical and RDC Classic solve the problems related to time delays and miscommunication by allowing direct access between users at clinical sites and the Oracle Clinical system. This allows users to complete tasks at investigator sites that previously were done via the post or directly at the location where the study database computer resided. It also facilitates direct communication, within the application, between sponsor and site personnel, which enhances accuracy and streamlines the entire data entry process.

How RDC Classic Works

RDC Classic is designed to run on the computer in your office. The primary requirements are a connection to the Internet or an intranet, several basic software applications, and several RDC Classic -specific add-ons to those applications. (Refer to "System Requirements" on page 1-3 for more information.)

When you launch RDC Classic and initiate a session, the application connects to a computer at the study sponsor's location. The two computers communicate with each other and you are given access to existing patient information and data that is relevant to your assigned role in the study. Among the tasks you can complete, with the appropriate security settings, from within your RDC Classic session are:

- Add new data

- Edit existing data

- Assign patients to the study

- Identify, initiate, and resolve discrepancies

- Verify CRFs

- Approve CRFs

- Lock and unlock CRFs

- Run reports

Interaction with Oracle Clinical

RDC Classic connects via the Internet to an Oracle Clinical installation on the sponsor's computer, which is usually at a different location. Data that you update in RDC Classic is immediately saved to the study database. Using RDC Classic, you can access data that was collected in Oracle Clinical. Similarly, Oracle Clinical users can access data that you collect in RDC Classic.

System Requirements

This section describes the hardware and software that you need to run RDC Classic. It includes the following topics:

- System Requirements for All Users on page 1-3
- Software Settings for Required Applications on page 1-4
- Required Information on page 1-5

System Requirements for All Users

While most of the software you need to work in RDC Classic resides on the computer at the sponsor site, there are several requirements that your computer must meet in order to properly initiate and run an RDC Classic session.

The following sections detail the system requirements for all computers you use to run RDC Classic:

- Hardware Requirements
- Network Access
- Software Requirements

Hardware Requirements

This section describes the hardware requirements for running RDC Classic on end user computers.

Processor RDC Classic is certified for computers with Pentium III and Pentium 4 CPUs.

Network Connection At the minimum, RDC Classic requires a 56 KB modem.

Network Access

The type of network connection you have determines, to a great extent, how quickly RDC Classic is able to communicate with the study host's computer. RDC Classic can operate over any local area network, intranet, or internet connection, including dial-up. For details, refer to the release notes that accompanies this version of RDC Classic release.

Software Requirements

Oracle certifies the software described in this section to be necessary or suitable for running RDC Classic.

> **Note:** To view, print, and/or save patient data reports Adobe Acrobat or Reader 5.1 or 6.0 must be installed on your computer.

Operating Systems RDC Classic is certified to run on computers with the following operating systems:

- Microsoft Windows 2000, Service Pack 4

- Windows XP, Service Pack 2

JInitiator RDC Classic requires the installation of Oracle JInitiator 1.1.8.24. You can download it and access installations instructions from the Downloads hyperlink on the RDC Classic Launch page.

Internet Browser RDC Classic is certified to run on Microsoft Internet Explorer version 6, Service Pack 1.

Software Settings for Required Applications

This section lists the configuration settings for the applications that RDC Classic uses.

- Microsoft Internet Explorer on page 1-4

- Adobe Reader or Acrobat on page 1-5

> **Note:**   In order to ensure the functionality of the Date Selection Window, Microsoft's ActiveX Calendar Control file (mscal.ocx) must be installed on your computer. Refer to Microsoft documentation if you have difficulty with the Data Selection window.

Microsoft Internet Explorer

Ensure that Microsoft Internet Explorer, version 6, is configured according to the following sections.

Default Browser Microsoft Internet Explorer must be designated as the default browser on your computer. To ensure this:

1. Open Microsoft Internet Explorer 6.

2. Select **Tools**, then **Internet Options** menu command.

3. Select the **Programs** tab.

4. Select the check box for the **Internet Explorer should check to see whether it is the default browser** setting.

When you next access an Internet browser, if the system displays a message window that states Internet Explorer is not the default browser, select the check box that sets it as the default.

Configuration Settings Ensure that the following configuration settings are present in your Microsoft Internet Explorer 6 installation.

To view these settings:

1. Open Microsoft Internet Explorer 6.

2. Select the **Tools**, then **Internet Options** menu command.

3. Select the **Advanced window** tab.

   a. In the Browsing section, ensure that the **Reuse windows for launching shortcuts** option is selected.

    b. In the Security section, ensure that the **Do not save encrypted pages to disk** setting is not selected.

Third-party Browser Software If there is third-party add-on software designed to block pop-up advertisements installed on the computer, you must disable its functionality. "Pop-up Blocker" application do not allow RDC Classic to function correctly.

Firewall Software If a firewall application is installed on the RDC Classic computer, you must either disable it or configure it for RDC Classic to function correctly. Refer to the firewall application documentation and/or your system administrator for assistance.

Adobe Reader or Acrobat

In order to properly view CRFs in either Adobe Reader or Acrobat, certain configuration options must be set in a particular way.

Reader 5.1 Ensure that the following configuration settings are present in your Adobe Reader installation.

1. Choose **Edit**, then **Preferences**, select **Options** in the Category pane.

   - Ensure that **Display PDF in Browser** is selected.

   - Ensure that **Certified Plug-ins Only** is clear.

   - Ensure that **Use Page Cache** is clear.

2. Choose **Edit**, then **Preferences**, select **Forms** in the Category pane and ensure that **Keep Forms Data Temporarily on Disk** is clear.

   The application may display a message window that asks you to confirm this choice. Click **OK** to confirm the setting.

   > **Note:**   Adobe Reader 5.1 selects this check box by default each time the application opens. Therefore, you must clear this check box when you start an RDC Classic session.

Required Information

This section describes the information that you must know before you can initiate an RDC Classic **session**. The information that you should gather is:

- Web Site Information
- User Name
- Password
- Database Name

Web Site Information

Your sponsor or administrator will provide you with a **URL** that points to the RDC Classic site where you will work. Use this URL to navigate to a site's RDC Classic Launch Page.

User Name

Your user name is a unique text string that identifies you to the database. You must use the user name that is assigned to you, since this will help to ensure that you have been granted the necessary database role to complete your work in RDC Classic.

OPS$ Prefix When you type your user name in the appropriate Logon window field, ensure that you include the "OPS$" prefix, if it is required.

Case-insensitive Your user name, and the OPS$ prefix, can be typed in upper, lower, or mixed case. As long as the characters are typed correctly, your user name is valid.

Password

Your password goes with your user name: you must correctly type both and the database name into the appropriate fields of the window in order to successfully log into the RDC Classic system.

Your system administrator typically gives you your password at the same time as your user name. It is your responsibility to keep your password private so as to prevent unauthorized access to the Oracle Clinical databases.

Case-sensitive Remember that your password is case-sensitive and must be typed into the password field of the Logon window just as it was given to you.

Database Name

Your system or database administrator will provide you with the name of the database that you will work in when you receive your user name and password.

The database name that you use in the Logon window must match the name of the database in which you have been granted sufficient rights to complete your work. For this reason, you must carefully type the name in the database field.

The database name that you enter in the Logon window determines:

1. What data you will work with in your RDC Classic session

2. If you will even be able to access data

General Concepts and Terms

This section provides basic information about how certain terms are defined and used in RDC Classic. Its purpose is also to put these terms in context with the entire application.

> **Note:** You should also consult the Glossary for definitions of terms that are used throughout this guide and in the application.

The terms are discussed in the following sections:

- RDC Classic Session on page 1-7
- Default Study on page 1-7
- Initial Study Selection on page 1-7
- RDC Classic-enabled Studies on page 1-8
- Source Data on page 1-8
- Saving Data on page 1-8
- Auditing Data on page 1-10

RDC Classic Session

An RDC Classic session is the period that starts when you successfully log in to RDC Classic and ends when you exit RDC Classic. An RDC Classic session is constricted by the following requirements:

- Only one user name is granted access to a session

- The role and privileges assigned to the user name determine the patient data and functionality that is available within a session

- Only one database can be accessed during a given session – if you want to access a different database, you must initiate a new RDC Classic session

- Only one study can be open at a time during a session, however, unlike the restriction on the active database, you can change to another study within an RDC Classic session – if you want to access a different study you must close the current study and select another

- Only one book can be active at a given time, however, you can change to another book within an RDC Classic session

- One or more sites can be active during a given session and the privileges assigned to the user name may vary from site to site

Default Study

The default study is a parameter the system uses to determine which study opens when you start an RDC Classic session.

The presence (or absence) of a value for the default study determines if the Change Study window is displayed during RDC Classic session startup. If a default study value does not exist, the Change Study window is displayed, which provides a mechanism for you to choose a study. This situation is most likely to occur the first time you start an RDC Classic session with a particular database and the system administrator has not defined a default study value.

If a default study value is defined, RDC Classic does not present the Change Study window. Instead, it proceeds to the step in the process in which you select the workset that is displayed in the RDC Classic Spreadsheet, which uses either the Search window or the Activity List window.

Initial Study Selection

In order to streamline the workset selection process, the system attempts to automate initial study selection. When you successfully initiate an RDC Classic session, a study is chosen, if possible, based on your study access, your previous RDC Classic session, or the specification of the system administrator. The following list describes how a study is chosen and when you must manually select a study.

- If you have access to one study, that study is automatically selected and you are not provided with the option to change the study during your RDC Classic session.

- If you have access to more than one study and a default study **is not** defined, the system displays the Change Study Window, which you use to choose a study for the RDC Classic session. This case is relevant during your first RDC Classic session in a given database if a default study is not defined by the system administrator.

- If you have access to more than one study and a default study **is** defined, the system does not display the Change Study Window. Rather, the default study is automatically selected and, subsequent to the News window (if applicable), the Activity List window or the Search window is displayed (depending on RDC Classic Configurator settings).

RDC Classic-enabled Studies

In order to initiate an RDC Classic session, you must have access to at least one RDC Classic-enabled study. An RDC Classic-enabled study is one for which a book is defined. So, while all studies can be opened in Oracle Clinical, only those for which at least one book is defined can be opened in RDC Classic.

This condition has implications for users who have access to more than one study.

- If a user has access to more than one study, but only one of that set of studies has a book defined, the user will not have the option to change studies during an RDC Classic session.

- If a user has access to more than one study and some, but not all, of those studies are RDC Classic-enabled, the list of values associated with the Select Study window will include all studies to which the user has access. When the user chooses a study for which a default book is not defined, the system displays a message window that describes why the study cannot be opened in RDC Classic and instructs the user to select another study.

Source Data

Source data is the true representation of the results of a patient's clinical visit. It can be the handwritten "chart" that the doctor completes as a visit proceeds or it can be data recorded directly into RDC Classic.

The purpose of RDC Classic is to facilitate the accurate collection of the information contained in a source data document to the appropriate CRF in the application. By moving this process to the investigator's site, a more efficient and accurate process is assured. Also, if there are any questions about the source data, they can be answered immediately by the person who collected and recorded the information.

Saving Data

You use RDC Classic to send data to the study database that you specify when you initiate an RDC Classic session. Data that you enter in RDC Classic, but which has not been sent to the Oracle Clinical database is termed a "pending change." That is, the data is recorded in RDC Classic, but it has not yet been transmitted to the database. Therefore, an important aspect of your workflow is to understand which data has been saved and which is pending and how to commit pending changes to the database.

Saving Changes

The system automatically saves pending changes under certain circumstances. This is referred to as implicit saving. In other cases, you take an action that saves pending changes. This is referred to as explicit saving.

Explicit Saves Whenever there are pending changes, you can choose to explicitly save the data. There are several methods you can use:

- Press the F10 key.

- Open the File menu, and then select Save.

■ Click the Save button on the toolbar.

In addition, certain other actions cause a confirmation window to be displayed, which allows you to decide if you want to save all pending changes or not (you can also choose to cancel the action and go back to the pending data). The actions that will cause a confirmation window to be displayed are:

■ Click the "X" in the upper right-hand corner of the Data Entry window to close the window.

■ Click the "X" in the upper right-hand corner of the Main Application window.

■ Click the Exit button on the toolbar.

> **Note:** You are also prompted with a confirmation window when you select the Blank check box in the CRF header.

Methods There are several methods to effect an explicit save of pending changes from the Data Entry window:

■ Press the F10 key.

■ Click the Save button on the toolbar.

■ Open the File menu, and then select Save.

Each of these actions causes RDC Classic to immediately save pending changes.

Data in Required Header Fields Only All required fields in the CRF header and CRF section header(s) must contain data before you can explicitly save pending changes.

If all required CRF header and CRF section fields contain data and you have not entered response data, when you manually save the CRF, RDC Classic assigns it the Created entry status. RDC Classic then audits any subsequent updates to CRF header or CRF section header data, using a pre-configured change reason. RDC Classic does not audit changes to response data until the CRF, or CRF section, reaches the Entry Complete data entry status.

> **Note:** You can view the current entry status of a CRF in the CRF view of the Summary task tab.

Question Area When data has been entered in a response field and you manually save the CRF, the entry status of the CRF progresses to either Entry Started or Entry Complete, depending on how many sections comprise the CRF and the current status of each. However, the current CRF section is assigned the Entry Complete status and RDC Classic audits subsequent changes to its data.

Data Entry Status The entry status of a CRF provides information about the level to which the CRF has progressed in the workflow. RDC Classic also uses it as a trigger for auditing. Although all changes to a CRF are audited after the CRF is saved the first time, the system does not prompt you to enter a change reason and optional comment until the CRF is assigned the Entry Complete data entry status.

Implicit Saves There are a large number of instances in which pending changes are saved by the system. While these are based on user actions, a confirmation window is not displayed to prompt you to save pending changes.

There is no warning popup, however, if there is pending data change that requires a user-provided change reason, the Change Reason window is displayed before the Data Entry window is closed.

The actions that will cause the system to automatically save pending changes include:

- Initial data entry — Press the Enter or Tab key when focus is in the last response datapoint in the last CRF section (with all required header data entered).

- Data update — Click the Save button in the Audit Information window.

- Open the Search window, in either New or Modify Search mode.

- Change the Page Grouping tab.

- Insert a patient.

- Use the Validate menu to validate the page, patient, site, or study.

- Approve or verify a CRF.

- Click the Show/Hide Unplanned Pages button on the Spreadsheet.

- Click another CRF icon.

- Click another CRF Section tab.

- Click another patient in the List of Current Patients.

Auditing Data

This section discusses how RDC Classic audits data. It discusses what is audited and the circumstances under which data is audited.

Although response data is of primary importance, auditing also includes changes to CRF and CRF section information, as well as changes in status (for example, approval status), and the discrepancy records.

Why Data Changes Are Audited

In order to ensure compliance with regulatory agencies, RDC Classic keeps track of the changes that a particular datapoint undergoes by noting the important information that describes the change to the data. This allows reviewers to track all of the changes that occurred to the data over time and it helps to ensure the integrity of the data.

This information is saved to the database along with the new data, which allows personnel interested in the security and validity of the study to look at the history of each datapoint and ascertain how, when, and why it changed.

What Information Is Audited

Each time a data change occurs, which the system audits, a set of related information is also saved to the database. Table 1–1 describes the audit information saved.

Table 1–1   Audit Information

Information	Description
Username	The name of the user who changed the datapoint. When an RDC Classic user changes data, the system logs the user name associated with the session and includes it as part of the audit record.

Table 1–1 (Cont.) Audit Information

Information	Description
Timestamp	The date and time that the change took place. his records the time and date that the data was updated. The system uses the timestamp of the database server, however, if your Preferences window settings are configured appropriately, the timestamp you view in RDC Classic is converted to the local time that your computer uses.
Data change	Describes how the datapoint changed. It includes the original value, the last value, and the new value.
Change Reason	The system- or user-specified reason that the data changed.
	This is either a system- or user-selected value that describes why the data was updated. Until a CRF reaches the entry complete data entry status, the change reason is system-selected. After the CRF is at the entry complete status, the system presents an audit information window, which prompts you to select a change reason. You also have the option to include a explanatory comment, which allows you to provide additional information about the data change.
Comment (optional)	A user-supplied textual description that further explains the data change

Using Status Information

RDC Classic provides you with detailed information through the use of status information that is displayed in several specific areas of the RDC Classic GUI. This section highlights how you can use this information to ensure that the data you enter, update, or verify is associated with the correct patient or other study level criteria.

This section includes the following topics:

- Main Application Window Title Bar
- Spreadsheet Status Line

Main Application Window Title Bar

The Title Bar of the Main Application Window provides you with key information, such as the:

- full name associated with the user name that is logged in
- role associated with the user name that is logged in
- database name
- log in date
- name of the study
- name of the site
- name of the active book

> **Note:** The site name is not displayed in the title bar if, in the Search Window, you select either:
>
> - the default site, or
> - "ALL" sites.

Spreadsheet Status Line

The Spreadsheet status line displays information that reminds you what criteria settings you selected in the Search window.

Default Status Line

The default status line, which is displayed when the default values for all Search window criteria are selected, has the following message:

All patients, all pages

Figure 1–1   Spreadsheet Status Line with Default Search Window Criteria
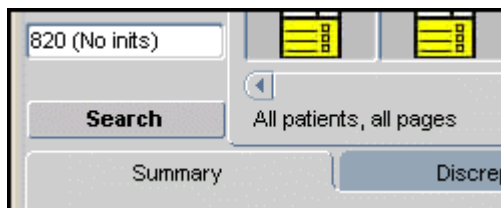
Use this status information as confirmation that you have selected the default criteria in the Search window.

Typical Status Line Information

When you make choices in the Search window that are more restrictive than the default criteria, the Spreadsheet status line is a useful feature because it:

- Helps you verify that you have retrieved the data that you intended

- Reminds you that you are looking at a subset of the data

Figure 1–2   Spreadsheet Status Line with Non-default Search Window Criteria
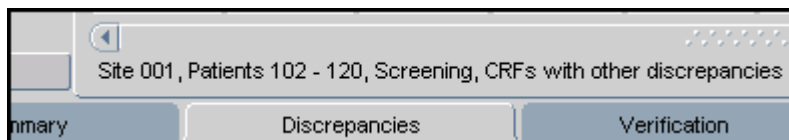
You may notice that the Search window gives you text feedback, located adjacent to the relevant criteria label, when you make changes to the parameters of that criteria. If you make changes to more than one criteria, these non-default settings are each listed in the Search window. The status line is simply a compilation of these notices, placed in the Spreadsheet to help you work.

Using the Keyboard to Assist RDC Classic Tasks

There are many features in RDC Classic that are implemented with the mouse that can also be invoked from the keyboard. The benefit to using the keyboard is efficiency: you can keep your hands stationary while you navigate to and use different features in RDC Classic. This is especially relevant to data entry, which is generally a keyboard-oriented task.

This section provides an overview of how you can use the keyboard to streamline your work in RDC Classic. The topics covered are:

- Accessing Menu Commands

- Using the Function Keys

- Navigating in the Data Entry Window

Accessing Menu Commands

Every menu command can be implemented from the keyboard, as well as by using the mouse cursor. One letter of each menu item is underlined. You can view all of the commands associated with a particular menu item by pressing the Alt key and the letter that is underlined in the desired menu item name.

One letter in each menu command is also underlined. When you expand a menu item, you can then press the key of the letter that is underlined to activate a particular command.

Example 1–1   Using the Insert Menu

The following graphic illustrates using the mouse to activate the Preferences window command on the Insert menu.

To use the keyboard to accomplish this task:

1. Press **Alt+i** to display the commands in the Insert menu.

2. Press **m** to insert a manual discrepancy for a CRF page.
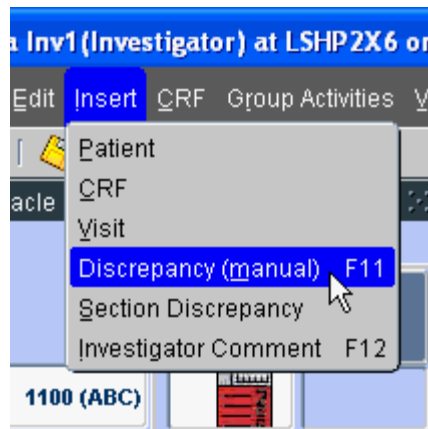
Using the Function Keys

You can accomplish several tasks more efficiently by using the function keys described in Table 1–2.

Table 1–2   Function Keys in RDC Classic

Function Key	Description of Associated Action
F1	Opens the context-sensitive help topic, if available, for the currently active GUI component.
F7	Reads the screen for acceptance of query parameters/values.
F8	Executes a query using the values provided.
F9	Displays the List of Values (LOV) for a field, if available.
F10	In the Data Entry window, this activates an explicit save of all pending changes.

Navigating in the Data Entry Window

Use the Tab or the Enter key on the keyboard to navigate from one field to the next in the Data Entry window. Use the Shift+Tab key combination to move back one field.

Verifying the Name of the Current Study

The name of the currently active study is displayed in the Title Bar of the Main Application Window. It also displays your user name, user role, and the name of the currently active book.

Security — Roles and Privileges

This section discusses roles and privileges in RDC Classic. It is important to understand how the role to which you are assigned and the privileges granted to your user name affect the tasks that you can perform in the application.

Roles

RDC Classic uses **roles** to manage the **discrepancy action** the user is allowed take and the status of discrepancies for that user. The sponsor assigns a role to each user based on the tasks required of that user.

RDC Classic provides a set of user roles by default. Your sponsor may:

- Use these roles, as is

- Edit the roles

- Add new roles

Table 1–3 describes the default user roles.

Table 1–3   Default RDC Classic Roles

Role	Abbreviation	Description
Data Manager	DM	Data manager
CRA	CRA	Clinical Research Associate
Site Coordinator	SITE	Site Coordinator or Monitor
Investigator	INV	Principal Investigator, Clinical Nurse, Data Entry personnel

Privileges

Privileges are statuses that are assigned to each user name that give the user access to certain data and CRFs, as well as permission to perform certain tasks. Privileges are independent of roles (which are described in "Roles" on page 1-14), however, sponsors often assign the same set of privileges to all users in a particular role.

The system administrator assigns each user name a set of privileges through RDC Classic Administration. Most privileges can be assigned at the study- or site-level, however, several can only be assigned at the site-level. Table 1–4 describes the privileges that are available in RDC Classic.

Table 1–4   Privileges in RDC Classic

Privilege (Short)	Privilege (Long)	Scope (Study or Site)	Description
BROWSE	Browse	Both	User can open a non-batch loaded CRF and view its data.
BRW_BATCH	Browse Batch Data	Both	User can open a batch loaded CRF and view its data.
UPD_DISCREP	Update Discrepancy	Both	User can modify the discrepancy records in a CRF.
UPD_BATCH	Update Batch Data	Both	User can update batch loaded CRFs.
UPDATE	Update Data	Both	User can update non-batch loaded CRFs.
VERIFY	Verify CRF	Both	User can change the **verification status** of a CRF.
APPROVE	Approve CRF	Site	User can change the **approval status** of a CRF.
LOCK	Lock CRF	Both	User can lock any CRF.
UNLOCK	Unlock CRF	Site	User can assign to users the ability to access and update a CRF in locked status.

Minimum Requirement

In order to have access to RDC Classic, all users must, at a minimum, be assigned the browse privilege for a study or a site. If the system determines at login that the user is not assigned at least this privilege, it will not permit the RDC Classic session to start.

As described in "Inclusion" on page 1-15, all other privileges include the browse privilege. This means that all RDC Classic users must be assigned at least one privilege in order to start a session.

Batch Loaded CRFs

Batch loaded CRFs are a distinct type of CRF for which separate privileges must be assigned to your user name in order to view and update data. These two privileges, browse batch and update batch, allow you to access and update batch loaded CRFs. Note that the other actions that change the status of a CRF are the same for batch loaded as for non-batch loaded data. That is, a user with the verify, approve, lock, or unlock privilege is able to take action on batch and non-batch loaded CRFs. However, whereas the browse privilege is included in these privileges, the browse batch privilege is not. Therefore, a user with one of these privileges must also have the browse batch (or update batch) privilege in order to open and view a batch loaded CRF.

The update batch privilege gives you access to update data in a batch loaded CRF. However, unlike the update privilege, which includes the update discrepancy privilege, update batch only permits you update response data and investigator comments. In order to update discrepancies in a batch loaded CRF, the update discrepancy privilege must be assigned to your user name.

Inclusion

Certain privileges include the permissions that comprise another privilege, in addition to different permissions. The browse privilege is the primary example of this kind of

inclusion. As discussed in "Minimum Requirement" on page 1-15, all RDC Classic users must be assigned the browse privilege in order to start a session. However, all other privileges include the permissions in browse. Consequently, if your user name is assigned to any privilege other than browse, it is not necessary that the browse privilege is also assigned to you.

The only situation in which the browse privilege must be assigned to your user name (in order to start a session) is if no other privileges are assigned.

For example, if a user is assigned the update privilege, it is not necessary to also assign the browse privilege to the user. The update privilege includes permission to open a CRF and view response data.

Table 1–5 defines the privileges that are included in other privileges.

Table 1–5   Privileges Included in Other Privileges

Privilege	Included in...
Browse	Browse batch, update discrepancy, update batch, update, verify, approve, lock, unlock
Browse batch	Update batch
Update discrepancy	Update

Precedence

All privileges except approve and unlock can be assigned at the site- and the study-level. However, the set of privileges that are assigned at the site-level take precedence over those that are assigned at the study-level. In situations where the administrator assigns privileges to users on a site basis only, precedence between the site and study levels has no affect. Similarly, when privileges are assigned on a study basis only, the permissions that are granted are not altered because no site-level privileges have been assigned. However, for those users who are assigned privileges at both the study- and the site-level, it is important to review how RDC Classic processes the permissions that each privilege grants.

You can use the method in which RDC Classic applies privileges at the site- and study-level to either ensure a user has access to all study-level privileges at all sites. Refer to Example 1–2, "Assigning Site- and Study-level Privileges to Provide Full Access" for an illustration of this use.

Alternatively, you can use precedence of site- over study-level privileges to limit the access a user has to individual sites. Refer to Example 1–3, "Using Site- and Study-level Privileges to Limit Access" for an illustration of this use.

Using precedence to provide full access to privileges If a user is granted one set of study-level privileges and a different set of site-level privileges at one or more sites in that study, the site-level privileges take precedence over the study privileges at those sites. This means that the study-level privileges are not in affect at those sites. For all other sites, that is, those for which site-level privileges are not assigned, the study-level privileges are in affect.

Example 1–2   Assigning Site- and Study-level Privileges to Provide Full Access

For a study that is comprised of sites Site001 through Site006, if a user is assigned the update privilege at the study level, the user is allowed to update data and discrepancies at all sites in the study. If that user is assigned the approve privilege (only) at Site001 and Site003, the user still has update permission at all sites except those sites. At Site001 and Site003, the user would be able to browse data (refer to

"Inclusion" on page 1-15) and approve CRFs, but not update data. In order to allow the user to update data at all sites in the study, the administrator would have to also assign the user site-level update, as well as approve, at Site001 and Site003.

Essentially, if you require a certain privilege (PrivilegeA) at all sites in a study and a different privilege (PrivilegeB) at some smaller set of sites (Site2 and Site4), your user name must be assigned:

- PrivilegeA at the study-level, and

- PrivilegeA and PrivilegeB at Site2 and Site4.

An exception to this requirement is where privileges are included in other privileges. For example, if, in the preceding scenario, Privilege A is the browse privilege, only Privilege B must be assigned at the relevant sites because all privileges include the browse privilege.

Using precedence to limit access to privileges You can also use the precedence of site- over study-level privileges to restrict the access a user has to specific sites. The situation described in Example 1–3 illustrates how an administrator can limit the privileges of a user for a specific site.

Example 1–3   Using Site- and Study-level Privileges to Limit Access

For a study that is comprised of sites Clin001 through Clin006, if an administrator wants a user to have permission to update data at all sites, except Clin003, the following privileges should be assigned to that user:

- study-level update, and

- site-level browse at Clin003.

Because privileges at the site-level take precedence over study-level, browse is the only privilege that has affect at Clin003. This effectively limits the user to view-only access to all CRFs associated with patients assigned to Clin003.

Site-level Privileges and Search Criteria

The **site criterion**, which is a constituent of the **search criteria**, can either be <ALL>, that is, all sites to which you have access, or a single site to which you have access. As illustrated in Table 1–4, " Privileges in RDC Classic", the approve and unlock privileges can only be assigned at the site-level. These site-level only privileges are directly impacted by the setting of the site criterion. In order to have access to tasks that these privileges provide, the search criteria must be a site for which the relevant privilege has been assigned to you user name.

Example 1–4   Effect of Search Criteria on Access Site-level Privileges

For a study that is comprised of sites Clin001 through Clin006 and a user with the following privileges:

- Study-level: update

- Site-level: approve at Clin003.

If the site criterion is set <ALL>, either through the Search window or by selecting a study node task in the Activity List window, the system will not allow the user to alter the approval status of any CRFs, including those for patients assigned to Clin003. In addition, the user will only be able to browse CRFs for patients assigned to Clin003.

If the site criterion is set to Clin003, the RDC Classic Spreadsheet displays only those CRFs that are associated with patients assigned to Clin003. In this case, the system will give the user access to change the approval status of any CRF in the workset.

RDC Classic Workflows

This section describes typical workflows in RDC Classic that must be completed. Although the RDC Classic documentation is structured in a manner that is not role-specific, there are certain assumptions made about the tasks that must be completed as part of a clinical study which are mimicked in the manual and the online help system.

Initial Data Entry

This section discusses the process of initial data entry.

General Workflow for Initial Data Entry

Although variations in protocols and CRF design preclude all but the most general workflow description, it is instructive to define a "typical" initial data entry sequence of events. This typical case assumes that at least a portion of the source data required to complete the CRF, or the CRF section, is available.

In such a case, the general sequence proceeds from clicking a CRF cell, which opens the Data Entry window, entering all required header data, and completing response data fields. When you save this CRF, RDC Classic assigns it the Entry Complete status.

Table 1–6 lists the steps and outlines a general sequence of events for initial data entry.

Table 1–6   General Workflow for Initial Data Entry

Data Entry Status	Step	Description/Comment
Created	Open the CRF	RDC Classic assigns a provisional data entry status of Created. "Initiate Data Entry" on page 8-2
Created	Complete all required CRF header fields	Focus automatically moves to either the first required CRF section header field (for example, "Visit Date") or, if the CRF section header is not present, the first response field in the question area. "Initiate Data Entry" on page 8-2
Created	If CRF section header is present, complete all required fields	Focus automatically moves from last CRF section header field to first response field. "Initiate Data Entry" on page 8-2
Entry Started	Enter response field data	When the CRF is saved with any response data (including investigator comments), the data entry status changes to Entry Complete
Entry Complete	Save the CRF	You can save the CRF explicitly, for example, by pressing the F10 key; or implicitly, by closing the CRF and choosing to save changes when RDC Classic prompts you. RDC Classic audits subsequent changes to the CRF header fields (both required and optional).

Scenario 1 — Save CRF in Created Status

In this case, you collect only the minimum data that the system requires to save the CRF. Once you save it, RDC Classic assigns it the Created data entry status. By implication, response data is not collected in the process.

Note that for multi-section CRFs, each section is assigned an entry status that is independent of the CRF and the other sections. However, when you initially open the CRF, the CRF and all of its sections are simultaneously assigned the Created data entry status.

This process differs slightly for single- and multi-section CRFs because all required section header fields must be complete before you can save the CRF. In most cases, a section header is not present in single-section CRFs, and if present, RDC Classic automatically places focus in the required section header fields when you complete the required CRF header fields. However, for multi-section CRFs, after you complete any required section header fields in the first section, you must navigate to other sections to collect required header fields before you can save the CRF to the study database.

The workflow described in Table 1–7, " Workflow to Save CRF in Created Status – Single-section CRF" describes the general process of opening a single-section CRF, collected required header fields, and saving the CRF in Created data entry status.

Table 1–7   Workflow to Save CRF in Created Status – Single-section CRF

Data Entry Status	Step	Description/Comment
Created	Open the CRF.	RDC Classic assigns the CRF a provisional data entry status of Created "Initiate Data Entry" on page 8-2
Created	Complete all required CRF header fields	Focus automatically moves to either the first required CRF section header field or, if CRF section header is not present, the first response field in the question area. "Initiate Data Entry" on page 8-2
Created	If CRF a section header is present, complete all required fields in the section.	Focus moves from last CRF section header field to first response field. "Initiate Data Entry" on page 8-2
Created	Save the CRF	You can save the CRF explicitly, for example, by pressing the F10 key; or implicitly, by closing the CRF and choosing to save changes when RDC Classic prompts you. In either case, RDC Classic saves the data entry status with the CRF. RDC Classic prohibits the save action if there are required header fields that are not collected. RDC Classic audits subsequent changes to the CRF header fields (both required and optional).

The workflow described in Table 1–8, " Workflow to Save CRF in Created Status – Multiple-section CRF" describes the general process of opening a multi-section CRF, collecting all CRF and CRF section header data, and saving the CRF in Created data entry status.

Table 1–8   Workflow to Save CRF in Created Status – Multiple-section CRF

No	Step	Description/Comment
1	Click the CRF cell to open the CRF.	Focus moves from last CRF section header field to first response field in the section.
		"Initiate Data Entry" on page 8-2
2	Complete all required CRF header fields	Focus automatically moves to either the first required CRF section header field or, if CRF section header is not present, the first response field in the question area.
		"Initiate Data Entry" on page 8-2
3	If CRF a section header is present, complete all required fields in the section.	Focus moves from last CRF section header field to first response field in the section.
		"Initiate Data Entry" on page 8-2
4	Navigate to each section header and complete required fields.	In each section, focus moves from last CRF section header field to the first response field in the section.
		"Initiate Data Entry" on page 8-2
5	Save the CRF	You can save the CRF explicitly, for example, by pressing the F10 key; or implicitly, by closing the CRF and choosing to save changes when RDC Classic prompts you. In either case, RDC Classic saves the data entry status with the CRF.
		RDC Classic prohibits the save action if there are required header fields that are not collected.
		RDC Classic audits subsequent changes to the CRF header fields (both required and optional).

Note that the Created data entry status is not actually assigned until you save the CRF. Prior to that, if you close the CRF without saving changes, the CRF reverts to the Not Created status.

Scenario 2 — Create CRF and Proceed to Data Entry

In this case, you complete the tasks required to create the CRF and then continue to collect response data. There are significant differences between the workflow for single-section CRFs, which represents the simpler case, and that for multi-section CRFs.

The sequence described in Table 1–9, " Workflow to Create a CRF and Proceed to Data Entry – Single-section CRF" assumes that you complete all required header fields and initiate data entry in the Question section prior to saving the single-section CRF.

Table 1–9   Workflow to Create a CRF and Proceed to Data Entry – Single-section CRF

No	Step	Description/Comment
1	Click the CRF cell to open the CRF.	RDC Classic assigns the CRF a provisional data entry status of Created
		"Initiate Data Entry" on page 8-2
2	Complete all required CRF header fields	Focus automatically moves to either the first required CRF section header field or, if CRF section header is not present, the first response field in the question area.
		"Initiate Data Entry" on page 8-2

Table 1–9   (Cont.) Workflow to Create a CRF and Proceed to Data Entry – Single-section

No	Step	Description/Comment
3	If the CRF section header is present, complete all required fields.	Focus automatically moves from last CRF section header field to first response field.
		"Initiate Data Entry" on page 8-2
4	Enter response data in the Question area.	Use the Tab or Enter key to navigate to subsequent response fields.
5	Save the CRF	You can save the CRF explicitly, for example, by pressing the F10 key; or implicitly, by closing the CRF and choosing to save changes when RDC Classic prompts you. In either case, RDC Classic saves the data entry status with the CRF.
		RDC Classic audits subsequent changes to the CRF header fields (both required and optional) and response data.

Data entry for a multi-section CRF is more involved than for a single-section CRF. Several points are pertinent to the process:

- You must complete all required section header fields for a given section before RDC Classic allows you to initiate data entry in the Question area of that section.

- You must complete all required section header fields for all sections before RDC Classic allows you to save the CRF.

- RDC Classic assigns a data entry status to the CRF that is based on the data entry status of its sections:

    – If all sections are at the same status, that is, either Created or Entry Complete, the RDC Classic assigns that status to the CRF

    – RDC Classic assigns the CRF the data entry status Entry Started under the following conditions:

        * One section is at Created and all others are at Entry Complete

        * One section is at Entry Complete and all others are at Created

The sequence listed and described in Table 1–10, " Workflow to Create a CRF and Proceed to Data Entry – Multi-section CRF" outlines a procedure to complete the required header fields and start collecting response data in the Question area.

Table 1–10   Workflow to Create a CRF and Proceed to Data Entry – Multi-section CRF

No	Step	Description/Comment
1	Open the CRF	RDC Classic assigns the CRF a provisional data entry status of Created
		"Initiate Data Entry" on page 8-2
2	Complete all required CRF header fields	Focus automatically moves to either the first required CRF section header field.
		"Initiate Data Entry" on page 8-2
3	Complete all required CRF section header fields for the section in which you want to enter data.	Focus automatically moves from last CRF section header field to first response field.
		To initiate data entry in a given section, only the required section header fields for that section must be complete. However, all required section header fields must be complete in order to save the CRF.

Table 1–10   (Cont.) Workflow to Create a CRF and Proceed to Data Entry – Multi-section

No	Step	Description/Comment
4	Enter response data in the Question area of the first section.	RDC Classic automatically navigates from last data entry field in current section the first required section header field in the next CRF or the first response field in the Question area.
5	Complete required CRF section fields in next section.	When focus moves to next section, RDC Classic assigns the Entry Complete data entry status to the first CRF section and Entry Started to the entire CRF.
6	Enter response data in the Question area of the next CRF section.	Repeat this step until all sections are complete.
7	Save the CRF	You can save the CRF explicitly, for example, by pressing the F10 key; or implicitly, by closing the CRF and choosing to save changes when RDC Classic prompts you. In either case, RDC Classic saves the data entry status with the CRF.
		RDC Classic audits subsequent changes to the CRF header fields (both required and optional).

When a CRF or CRF section is saved in the Entry Complete data entry status, all mandatory fields in the Question area(s) that do not contain data generate a "Missing Mandatory Field" discrepancy. RDC Classic will close these type of discrepancies with a reason of "Resolved" when data is collected for the missing field.

Run a Report

RDC Classic gives you the capability to generate either a patient data report (PDR) or a workbook report. The PDR can incorporate the patient data that is present in the current workset or you can specify a different workset. You can generate the workbook report either with or without information for a specific patient included in the CRF and CRF section header areas. Table 1–11 outlines the basic workflow for this task.

Table 1–11   Workflow to Run a Report

No.	Step	Comment	Reference
1	In the RDC Classic Workspace, select **File**, then **Reports**.	If you want to run a PDR using current selections, you should ensure the search criteria is correct and that workset has been refreshed before you open the Reports window.	"Refresh the Workset" on page 5-12
2	In the Reports window, select the type of report you want to run.	You can choose to run a PDR or a workbook report.	"Running Reports" on page 10-1 "Blank CRFs Report" on page 10-5
3	If desired, you can resume working in RDC Classic while the report runs.	The report may take an extended period of time to run, depending on the number of CRF s and the amount of data it contains.	"Continue Work while a Report Runs" on page 10-6
4	Check the progress of the report process.	You can periodically monitor the progress of the report.	"Monitor the Progress of a Report" on page 10-6
5	Review the report and print it, if desired.	The report is generated as a PDF document that you can save locally or print.	"View and Print a Report" on page 10-6

Unlock a CRF for Update

This section presents a general workflow scenario that illustrates how the **unlock** privilege may be used. Essentially, the unlock procedure is designed to provide a mechanism to make discrete updates to CRFs that have been locked.

Refer to "Unlock a CRF" on page 5-16 for specific information about the unlock procedure.

Table 1–12   Workflow to Unlock a CRF for Update

No.	Step	Comment	Reference
1	The data manager assigns to one or more users the capability to modify a locked CRF.	The DM must be assigned the **unlock** privilege at the current site. Only users who can update the CRF should be given access to the locked CRF.	"Assign the Capability to Update a Locked CRF" on page 5-16
2	A designated user (with appropriate privilege) opens the CRF.	The user must know the correct CRF to open, since the icon continues to reflect locked status.	"Update Response Data" on page 9-3 "Update Response Data for a CRF" on page 9-5 "Update CRF and/or CRF Section Header Data" on page 9-4 "Update an Existing Investigator Comment" on page 9-5
3	The data manager removes all names from the list of users who can update the CRF.	When no users are listed, the CRF is locked and cannot be updated.	"Remove User Names from List to Lock CRF" on page 5-17

2

CRFs

In Oracle Clinical and RDC Classic, the term "CRF", which is an acronym for **C**ase **R**eport **F**orm, refers to the form that is used by investigators to collect information and data about a patient in the clinical trial. This form can be either paper or electronic.

In a paper-based clinical trial, a CRF is a printed document that investigators use to collect handwritten identification information and response data about a patient during the course of a visit.

In a clinical trial in which patient data is collected electronically, the CRF is represented the user interface of a computer application. In Oracle Clinical and RDC Classic, this interface is an Oracle Form with fields that you use to record data.

It is not necessary for a study to be strictly paper-based or electronic. More commonly, studies use both paper- and electronic data entry to collect patient data

Although CRF design varies based on such factors as the nature of the intervention, the type of data collected, the study protocol, or the type of clinical trial, certain aspects or components of CRFs are constant. The purpose of this section of the guide is to describe each component and discuss how to best work with it in RDC Classic.

Each CRF has an area, usually at the top of the form, in which certain identification information is collected; this includes such items as the patient's ID number, the visit date, investigator's name, site name, visit number, etc. The rest of the form is used to collect data about the patient. Usually, this area consists of a series of questions, or prompts, to which the investigator records the responses that are particular to the current patient.

This section describes the structure of CRFs and discusses how you work with CRFs in RDC Classic. Because the term "CRF" has different meanings in different contexts and for different organizations, it is important to understand what a CRF is when you work with RDC Classic. This includes the components that must be present in every CRF and those that are optional. It also includes a discussion of the statuses that RDC Classic uses to classify a CRF in various ways.

This section consists of the following topics:

- Discussion on page 2-2
- CRFs on page 2-3

Discussion

Each CRF consists of questions, to which the investigator records responses for the current patient.

Usually, the protocol for a clinical study is divided into clinical planned events (CPEs). Each clinical planned event corresponds to an individual visit in RDC Classic. A visit is a discrete occurrence in time during which data about the patient (or subject) is collected. Each visit, in turn, is comprised of one or more CRFs, which are the instruments used to collect the data. Usually, a CRF will be used to collect related data, using The CRF is a discrete component that you use to collect patient data as part of a visit. In general, one copy of each CRF is assigned to each patient in the protocol.

Each CRF is comprised of one or more sections. In turn, each section is comprised of one or more questions. The purpose of the CRF is to provide a means of standardized data collection, so that the same type of data is collected for each patient in a study.

Types of CRFs

Like paper CRFs, in which similar questions are grouped together to facilitate accurate and efficient collection of data, the Data Entry window can represent CRFs with only one section and it can also display CRFs that are comprised of two or more sections. These two types of CRFs are referred to as single-section and multi-section CRFs, respectively.

No matter how many sections comprise a CRF, you view and work on one section at a time. By dividing a CRF into sections, the Data Entry window is able to present you with one group of questions at a time, which simplifies both data entry and update operations.

Each CRF section is comprised of a section header and a question area.

- The CRF section header collects information about the section, such as "time since dose" or "Lab Name", in addition to the information collected in the CRF header.

- A section header is required to be displayed for each section of a multi-section CRF.

When the section header is displayed, it is displayed as a tab. In multi-section CRFs, the tabs facilitate easy identification of each section and provide ready navigation between the sections (refer to Figure 16–2, "Example of a Multi-section CRF Data Entry Window").

Although a CRF may consist of more than one section, the connection between RDC Classic **GUI** components is always maintained: the intersection of a CRF Column and one row of the Current Patients list defines a CRF Cell; there is one CRF cell in the RDC Classic Spreadsheet associated with a single CRF, no matter how many sections comprise it; and the Data Entry Window always displays the CRF Header and only one CRF section at a time.

Components of CRFs

CRFs can be designed to collect a wide variety of patient data and information. However, certain components can be identified which are used consistently across the various types of CRFs.

Header and Footer

Each CRF includes a header and, in most cases, a footer. These are areas at the top and bottom of each CRF page, respectively. These areas are used to collect and display information about the:

- CRF
- Patient
- Visit
- Investigator
- Site

CRF Sections

A CRF section is comprised of one or more sets of related questions. Each CRF is comprised of at least one section. Although there is not a limit to the number that it can include, most CRFs consist five or less sections.

Each section includes a question.

CRF Statuses

RDC Classic uses CRF statuses to provide you the means to quickly assess where a given CRF is in the progression to completion. This section describes each status and explains the circumstances that cause a CRF to be assigned to it.

There are five categories of CRF status. Each category addresses a different aspect of CRF disposition in RDC Classic. The CRF icons can represent all of these statuses, however the examples used in this section show one status at a time.

CRFs

This section consists of the following topics:

- CRF Header on page 2-3
- CRF Sections on page 2-5
- CRF Status on page 2-8
- Blank Flag on page 2-7
- Overview of the Data Entry Process on page 2-15

CRF Header

A CRF header contains information about the CRF itself, which allows it to be placed in the proper context and to be accurately identified. This information is crucial to the integrity of the response data that is collected in the Question Area of the CRF.

RDC Classic maintains and tracks a significant amount of information about each CRF. A portion is defined by session and study settings. This information is consistent for all CRFs associated with the patients at a given site for the current study. This includes:

- Study name
- Site name
- Site location
- Principal investigator

A portion of this information is collected automatically by context when you open the CRF. This includes:

- Patient number

- Visit designation

- Planned or unplanned

- CRF name

Other information, such as visit date, visit time, and CRF comment, must be collected manually through your input when you initiate the CRF in data entry.

Complete the CRF Header

The CRF header is located at the top of the Data Entry window. When you open a CRF, RDC Classic places focus in the first required field in the CRF header. You must complete all required fields in the CRF header before RDC Classic assigns the entry status "Created" to the CRF.

Refer to "Section Header" on page 2-5 for a complete description of the CRF header.

The CRF header collects and stores information about the CRF, such as the patient name, visit number, visit date, etc. RDC Classic automatically collects a portion of this information based on the CRF cell you click to open the CRF. However, you may be required to provide certain other information that RDC Classic cannot automatically discern, for example, the date that the visit took place.

The CRF header area of the Data Entry window contains fields that collect required information about the CRF. It may also contain fields that collect optional information, for example, a Comment field.

All required fields in the CRF header must be complete before you can begin to enter response field data in the CRF question area.

Use the instructions in the following sections to complete the CRF header fields in a CRF.

Visit Date Field The Visit Date field may or may not be present in a CRF header and, if present, can either be required or optional. If it is present, the functionality is identical in the required and optional cases. When focus is in the Visit Date field, there are several methods you can use to choose a date.

Table 2–1   Method and Description to Select Visits

Method	Description
Type value	Use the current date input format to type the correct visit date in the field. (Refer to "Date Format" on page 14-26 for information about this Preferences Window setting.)
Shortcut Key	Type - "T" for today's date - "Y" for yesterday's date - "L" for the last entered value

Table 2–1   (Cont.) Method and Description to Select Visits

Method	Description
LOV	Open the List of Values window, which displays:
	■ all previously entered visit dates
	■ Today (the current date)
	■ Yesterday (the previous day's date)
	■ Last Entered (the most recently entered date in the current session)

After the correct date is displayed in the field, use either the Tab or Enter key to navigate to the next field, which is:

■   The next required CRF header field, if present, or

■   The first response field in the Question area of the first CRF section.

Alternatively, you can use the mouse to navigate to another CRF header field. This is necessary if you want to complete an optional CRF header field because RDC Classic does not automatically navigate to such fields.

Comment field To insert the comment, put focus in the Comment text field and type the message you want to include. The maximum length available for the comment is 200 characters.

You can also use the RDC Classic Field Editor to type the comment. This is particularly useful if the text of the comment exceeds the viewable portion of the field.

Select Edit, then Field Editor from the option list (or the Alt+e, e quick key combination) to open the Field Editor Window.

CRF Sections

Section Header

Like the CRF header, a section header is a consistent location for collecting general information. However, whereas the CRF Header stores information about the entire CRF, each section header stores information about the group of questions that comprise that section.

The following information may be collected in a section header:

■   Visit date

■   Visit time

■   CPE, the event or visit designation

■   A qualifying value question pair

■   Laboratory name

■   Indication that the CRF or CRF section is blank (blank flag)

The section header is optional for single-section CRFs and it is required for multi-section CRFs.

When a discrepancy is associated with a CRF section, an asterisk is displayed adjacent to the header tab label as an indication.

Question Area

The question area is the central part of each CRF section because it is where the prompts and responses are collected. The question area is where you enter the majority of the information about the patient. The questions that are presented in this area are derived directly from the CRF that is currently active.

When you begin the data entry, you click an empty CRF cell in the Spreadsheet to begin to input data for a particular page of patient's visit, the data fields of the CRF header, the section header (if present), and the question area are all blank. The prompts, or questions, are displayed, each one adjacent to its associated data field.

Basic Data Entry In general, performing data entry is similar to working with online forms:

1. After you enter any required data in the CRF header or section header, focus automatically moves to the first data field in the question area.

2. You enter the appropriate response in the data field.

3. When you are satisfied that the data in the current field is correct, you can either:

    ■ press the Tab or Enter key, or

    ■ click in the next data field.

4. Continue entering data and navigating through the questions. When you complete data entry for the last question in the section and press the Tab or the Enter key, one of three actions occur:

    a. If you are working with a multi-section CRF and the section you completed is not the last section, focus moves to the first data field in the next section.

    b. If you are working with a single-section CRF or the last section of a multi-section CRF and the "After entry of planned CRF" checkbox is selected for CRF Progression on the Preferences Window, the CRF is saved and closed, and the next CRF in the sequence specified by the CRF Progression is opened in the Data Entry window.

    c. If you are working with a single-section CRF or the last section of a multi-section CRF and "After entry of planned CRF" checkbox is not selected, the CRF is saved and focus remains in the last data field.

ATTACHMENT Prefix in a CRF Data Field Any field in the CRF that has an ATTACHMENT prefix represents an extended text field. Note that you can enter data into extended text fields only in Oracle Clinical Remote Data Capture Onsite (RDC Onsite). For more information, refer to "View Data in Fields with an ATTACHMENT Prefix" on page 8-2.

Data Entry Validation During data entry, you may on occasion mistakenly type the wrong value for the response to particular question. That is, there may be a certain set of "acceptable" values for a question and the response that you enter may not match any of these values because of a typographical error.

If certain criteria have been established for the responses to a question and the value you enter does not satisfy those criteria, a data entry edit check generates a discrepancy when you attempt to move from that data field. The Validation Failure Window is displayed, which notifies you that the value you entered does not meet the criteria established for the responses to that question. This gives you an opportunity to correct the data value, acknowledge the discrepancy, or explain the deviation and potentially route the discrepancy for further processing.

When you dismiss the Validation Failure window, the background color of the discrepant data field is changed from white to yellow, as an indication that it may require further action. Also, until the CRF is saved, you can return to the discrepant data field and edit the response. If you change the field to a value that is not discrepant, then the discrepancy is not saved to the database.

A simple example of this is a question that requires that the patient's gender is entered as "F" for female and "M" for male. If the study designer has configured RDC Classic to accept only these two values for this question and you attempt to input "N", an edit check will generate a discrepancy for that question.

Implicit Save When you complete data entry in the last field in a CRF and press the Tab or the Enter key, the system automatically saves all of the data you entered for that CRF.

Explicit Save At any point during data entry, you can choose to save any pending changes to the database by:

- clicking the Save icon on the Toolbar

- choosing **File**, then **Save** from the option list, or

- pressing the F10 key.

Visual Cues RDC Classic is able to effectively communicate a large amount of information about your study data through the use of visual cues. The most obvious example is CRF Icons in the RDC Classic Spreadsheet, which provide you with information about the entry, discrepancy, approval, and verification statuses of every CRF currently displayed in the Spreadsheet.

The question area of Data Entry window also uses visual cues to alert you to different information associated with specific datapoints.

The background color of a response field that has a discrepancy and/or an operator comment associated with it is yellow. The text of the response is displayed in a blue font.

If both an investigator comment/discrepancy and an operator comment are associated with a response field, the background color remains yellow, but the font of the response text is red.

Blank Flag

When you mark a CRF or CRF section blank, it signifies that you do not want to enter or save data at the present time. The blank flag gives you the option to enter data in the future, and it also signifies that the CRF or CRF section has not simply been overlooked.

Each CRF header and CRF section header may contain a blank flag. This is a check box that is clear by default. You can choose to mark a CRF or CRF section blank by selecting the blank flag that is associated with the relevant component.

RDC Classic provides a mechanism to mark an entire CRF blank. The implication and meaning of a blank CRF can vary from sponsor to sponsor, however the prerequisites and the procedure are consistent. Essentially, the CRF must be at the Created entry status and a Blank check box must be present in the CRF header.

Because this task describes the limited situation of marking a CRF blank during initial data entry, it does not address the disposition of existing data, or the manner in which individual sections in multiple section CRFs are marked blank. Rather, it describes the

procedures to mark a CRF blank immediately after it is created and to mark blank a CRF that has an entry status of Created and is currently closed.

Prerequisites

RDC Classic requires that you collect certain information before you can mark a CRF or a CRF section blank.

- To mark a CRF blank, you must collect all required CRF and CRF section header fields.

- To mark a CRF section blank, you must collect all required CRF header fields. In addition, you must collect any required header fields in the CRF section that you want to mark blank.

Disposition of Existing Data

You can mark a CRF or a CRF section blank at any point during the data entry process. If the CRF or section contains data, the data is deleted, however, the system audits the data changes.

Note that all CRF header and CRF section header data, both required and optional, are unaffected by selecting and clearing the blank flag.

Cascading Between the CRF and CRF Section

There is a two-way interaction between the CRF header and its constituent CRF sections when the Blank check box is selected.

When you mark a CRF blank, by selecting the CRF blank check box in the CRF header, RDC Classic automatically marks blank all CRF sections that comprise the CRF. Similarly, when you mark a CRF not blank, by clearing the CRF blank check in the CRF header, RDC Classic automatically marks not blank all CRF sections that comprise the CRF.

In contrast, when you mark a CRF section blank, the effect of the action on the rest of the CRF depends on the status of any other CRF sections:

- if there are other CRF sections that are not blank, the CRF header is not affected

- if the CRF section you mark blank is the last section marked blank, that is, all sections are now marked blank, RDC Classic cascades the change up and automatically marks the CRF header blank.

When you mark the CRF section not blank, the functionality is similar:

- if there are other CRF sections that are marked blank, the CRF header is not affected

- if the CRF section you mark not blank is the last section to be cleared, that is, all sections are now marked not blank, RDC Classic cascades the change up and automatically marks the CRF header not blank.

CRF Status

As a CRF progresses from creation through approval and verification to locking and freezing, RDC Classic assigns certain designations to it that describe the current state of the CRF. This section describes the four different status categories that are assigned to a CRF and defines the different status designations in each category.

Discussion

There are four statuses that are assigned to a CRF. The statuses describe important aspects of the CRF that help you gauge the tasks that must be performed on a CRF. The status categories are:

- Data Entry Status
- Discrepancy Status
- Approval Status
- Verification Status

Recognition of Statuses   RDC Classic uses a combination of color and icons to continuously display the current status of CRF. The most obvious example of these visual cues is in the RDC Classic Spreadsheet, where an icon is displayed for each CRF. The icon incorporates all of the status categories in a single CRF Cell.

Refer to "RDC Classic Spreadsheet" on page 12-1 for a full discussion of CRF icons that are displayed in the Spreadsheet and to view examples of how RDC Classic combines different status categories in a single icon.

> **Tip:**   When you are working in RDC Classic, you can select Help, then RDC Help Topics from the option list to quickly display the CRF Icon Legend Window, which provides a reference guide for all of the different CRF icons.

Task Tabs   In addition to the CRF icons and colors that are used in the Spreadsheet to denote CRF status, the Task Tabs also display information about the CRF in focus that is relevant to the function of the task tab. For example, the Verification Task Tab displays the Verification Statuses of the currently selected CRF, the Approval Task Tab displays the Approval Status of the CRF.

Oracle Clinical CRFs   You can use RDC Classic to open and update CRFs that originated in the Oracle Clinical data entry system.

Data Entry Status

The entry status of a CRF describes the process of entering patient data in the CRF. Data entry proceeds from a created CRF, which is the initial stage of data entry, to the point where all data is entered and the CRF is saved.

The data entry status to which a CRF is assigned tracks its progress through the workflow. Because it tracks CRF progress, RDC Classic uses the data entry status as a trigger for certain business rules, in particular, it can control audit, approval, and verification behavior.

The data entry status is assigned at the CRF section level and, based on certain factors, the CRF takes its entry status from its constituent sections. For single-section CRFs, there is a direct correlation: the data entry status of the section is the same as that of the CRF.

The situation for multi-section CRFs is not as straightforward. There is a provision in RDC Classic that allows an entry status to be assigned to each CRF section. In the case where all CRF sections are assigned the same data entry status, the CRF is also assigned the same status. However, in the case of a multi-section CRF with individual sections at different data entry statuses, RDC Classic assigns the CRF to the earliest data entry status assigned to any section.

It is important to note that it is possible to open CRFs in RDC Classic that were originally created in Oracle Clinical.

RDC Classic-generated Data Entry Status   Table 2–2 lists and describes each of the data entry status that are present in RDC Classic.

Table 2–2   RDC Classic-generated Data Entry Statuses

Icon	Name
	Blank - The CRF has been marked as blank.
	Created - The CRF has been opened and required CRF header and Section header data has been entered and saved, but no response data has been entered.
	Entry Started - Multi-section CRFs only - All required CRF header and Section header fields are completed and at least one Question area response field in one section is completed.
	Entry Complete:
	Single-section CRFs - All required CRF header and Section header information is completed and at least one Question area response field is completed.
	Multi-section CRFs - All required CRF header and Section header fields are completed and at least one Question area response field in each section is completed.

There are four entry statuses that can be generated by working in RDC Classic. These are listed and described in Table 2–2. However, RDC Classic also supports viewing and working with CRFs that are processed in Oracle Clinical. Because Oracle Clinical allows more entry status designations, RDC Classic provides information about these statuses and displays icons that reflect all of the statuses that are available in both RDC Classic and Oracle Clinical.

Oracle Clinical Generated Entry Status   CRFs that are initiated in Oracle Clinical are accessible and may be updated in RDC Classic. Consequently, data entry statuses specific to Oracle Clinical are represented in the collection of CRF icons that symbolize data entry.

Oracle Clinical has the capability to use multi-pass data entry. This means that the same data is recorded in a CRF more than once, usually by different data entry personnel, in order to increase efficiency. Therefore, the entry statuses in Oracle Clinical refer "first pass" and "second pass" data entry. CRF icons that originate in Oracle Clinical may have the number "1" or "2" to designate the current data entry stage.

Table 2–3 describes the entry statuses that can be generated in Oracle Clinical.

Table 2–3   CRF Entry Statuses Generated Externally

Status	Description
Pass 2 Started	The second pass of data entry has started.
Pass 2 Complete	The second pass of data entry is completed.

Table 2–3   (Cont.) CRF Entry Statuses Generated Externally

Status	Description
Batch loaded	The data has been entered electronically via batch data load.

General Data Entry Status Progression   This section discusses how a CRF progresses from 'not created' to Entry Complete.

Data Entry Statuses   The process of initial data entry starts with a new CRF and extends until the CRF or CRF section contains at least some response data, which is then saved to the study database. However, this process may not occur during a single session. Rather, RDC Classic permits you to open a new single-section CRF, collect the required header fields, save pending changes, and close the CRF with a data entry status of Created. At some later point, either in the same session or subsequent session, you can re-open the CRF to enter response data. This is still part of the initial data entry process. When you save the CRF with pending changes to response data, RDC Classic alters the data entry status of the CRF to Entry Complete and all subsequent changes that are made to the CRF are considered part of the data update process.

The workflow for multi-section CRFs can be somewhat different. Because RDC Classic essentially handles each section as a separate CRF, different sections can be assigned different data entry statuses. Consequently, one section in a CRF may have only section header data collected, so it is assigned the Created status and the initial data entry process is applicable to it. Another section in the same CRF may have response data collected, so it is assigned the Entry Complete status and the data update process is applies to it. The data entry status of the CRF remains at Entry Started until all CRF sections progress to Entry Complete.

Refer to "Data Review and Update" on page 9-1 for further information about the data update process.

CRF Lock/Unlock

RDC Classic allows authorized users to lock one or more CRFs. The significance of the lock status is that, under normal circumstances, the data in the CRF cannot be updated.

Before a CRF can be locked, all pending changes in the CRF must be saved to the database. This ensures that all status changes and change reasons are captured and the audit history is complete prior to locking the CRF.

Discrepancy Status

The discrepancy status of a CRF describes the presence or absence of discrepant data in the CRF and specifies if you, or someone in your user role, is responsible for taking action on it.

RDC Classic differentiates between actionable and non-actionable discrepancies to highlight and make immediately obvious those discrepancies that require your attention. This type of discrepancy is referred to as "Active." Discrepancies that require the attention of users in a role(s) other than yours are referred to as "Other." Discrepancies that have been resolved, either by the system or manually, are given the status, "Closed." Closed discrepancies do not require further attention, however, all discrepancies, once created, are tracked in the Discrepancy task tab.

The distinction between an "Active" discrepancy, that is, one that is actionable by you (or someone in your user role) and an "Other" discrepancy, one that is not actionable by you, is important in RDC Classic. It is the basis for two of the discrepancy statuses.

It also means that the discrepancy status of a CRF that one user sees may be different than that which another user (in another role) sees. Of the four CRF status categories, only discrepancy status is dependent on the role of current user.

RDC Classic uses color to display the discrepancy status of a CRF in the Spreadsheet, the Discrepancy Task Tab Procedure, and relevant discrepancy windows. There are three discrepancy statuses that can be assigned to a CRF, which are listed and described in Table 2–4. Each status is rated in importance, with Active discrepancies considered more important that Other, and Other discrepancies considered more important then Closed discrepancy. This ranking takes into account a CRF that has more than one discrepancy associated with it.

Color-coded Response Fields

The background color of a response field that has a univariate discrepancy and/or an operator comment associated with it is yellow. The text of the response is displayed in a blue font.

If both an investigator comment/univariate discrepancy and an operator comment are associated with a response field, the background color remains yellow, but the font of the response text is red.

Table 2–4   Discrepancy Statuses in RDC Classic

Icon	Name
	None - There are no other or active discrepancies associated with the CRF. (Note that there may be closed discrepancies associated with the CRF.)
	Active - There is at least one actionable discrepancy in the CRF.
	Other - There is at least one discrepancy that must be addressed by a user in a role other than yours.
	Closed - All discrepancies in the CRF have been closed and or resolved, either by the system, as the result of an update of data to non-discrepant value, or by a user.

As stated above, the discrepancy status that is assigned to CRFs is dependent on the role of the current user. A discrepancy that is "Active" for all users in the Investigator role, may be an "Other" discrepancy for Data Managers, with the CRF discrepancy status changing accordingly.

Approval Status

The approval status of a CRF describes whether or not the CRF is currently approved and what has occurred, with respect to approvals, if the CRF has ever been approved. Once a CRF is approved, all changes to the approval status of the CRF are reflected in the Approval Task Tab.

There are four approval statuses, which are listed, along with the corresponding CRF icon, and described in Table 2–5.

The CRF icons that represent the approval statuses are identified in Table 2–5.

Table 2–5   Approval Statuses in RDC Classic

Icon	Name
	Not Approved - The CRF has never been approved or approval has been undone.
	Approved - The CRF is currently approved.
	Approval Undone - The CRF was approved but a user undid the approval.
	Requires Re-Approval - The CRF was updated after being approved, it must be re-approved.

There are a limited number of events that can cause the approval status of a CRF to change. These are described in Table 2–6, " Changes in Approval Status Based on Events or User Actions".

Table 2–6   Changes in Approval Status Based on Events or User Actions

Original Approval Status	Event or Action	Resultant Approval Status	Comment
Not Approved	User enters password in Password text box and user name in Windows Associated with CRF Approval	Approved	Undo Approval button and the approval history are displayed in the Approval task tab and the CRF icon and the task tab status line are updated.
Approved	User clicks the Undo Approval button and completes the Undo Approval Password Confirmation Window	Approval undone	The approval history is displayed with two records: the timestamp of initial approval, and the timestamp of the "undo approval"
Approved	Response data in the CRF is updated (modified)	Awaiting re-approval	The Password text box is displayed to facilitate the re-approval of the CRF and the Undo Approval button is displayed to facilitate undoing the Approval.

Table 2–6   (Cont.) Changes in Approval Status Based on Events or User Actions

Original Approval Status	Event or Action	Resultant Approval Status	Comment
Approval undone	User enters password in Password text box and user name in the Windows Associated with CRF Approval	Approved	The status line and the approval history are updated. The Undo Approval button is displayed.
Approval undone	Response data in the CRF is updated (modified)	Approval undone	No change
Awaiting re-approval	User enters password in Password text box and user name in the Windows Associated with CRF Approval	Approved	The status line and the approval history are updated. The Undo Approval button is displayed.
Awaiting re-approval	User clicks the Undo Approval button and completes the Undo Approval Password Confirmation Window	Approval undone	The status line and the approval history are updated. The Password text box is displayed to facilitate approval of the CRF.

Verification Status

The verification status of a CRF describes whether or not the CRF is currently verified and what has occurred, with respect to verification, if the CRF has ever been verified. Once a CRF is verified, all changes to the verification status of the CRF are reflected in the Verification Task Tab.

The CRF icons that represent the verification status are identified in Table 2–7.

Table 2–7   Verification Statuses in RDC Classic

Icon	Name
	Not Verified - The CRF has never been verified.
	Verified - A user has verified the CRF.
	Verification undone - The CRF was verified but a user undid the verification.
	Requires Re-Verification - The CRF was verified but was subsequently updated.

There are a limited number of events that can cause the verification status of a CRF to change. These are described in Table 2–8, " Changes in Verification Status Based on Events or User Actions".

Table 2–8   Changes in Verification Status Based on Events or User Actions

Original Approval Status	Event or Action	Resultant Approval Status	Comment
Not verified	User clicks the Verify button	Verified	The Undo Verify button is displayed in the Verification task tab.
Verified	User clicks the Undo Verify button	Verification undone	The verification history table is updated; the Verify button is displayed in the task tab.
Verified	Response data in the CRF is updated (modified)	Awaiting re-verification	The Verify button and the Undo Verify button are displayed in the task tab.
Verification undone	User clicks the Re-verify	Verified	The Undo Verify button is displayed in the task tab.
Verification undone	Response data in the CRF is updated (modified)	Verification undone	No change
Awaiting re-verification	User clicks the Verify button	Verified	The Undo Verify button is displayed in the task tab.
Awaiting re-approval	User clicks Undo Verify button.	Verification undone	The Verify button is displayed in the task tab.

Overview of the Data Entry Process

The first step in the RDC Classic workflow is termed **initial data entry**. It entails opening a CRF for the first time, creating it, and starting to collect CRF information and patient data. An important distinction between initial data entry and the next step in the workflow, data update, is that, while all data changes are audited throughout the workflow, once a CRF (or CRF section) is at Entry Complete status, the data update process requires that all audited data changes include a user-supplied change reason.

This section consists of the following subsections:

- Discussion

- Adjust Data Entry Preferences

Discussion

The sequence that a CRF follows as it progresses through the workflow depends on several criteria. Among them are:

- Availability of the source data

- Number of sections in the CRF

- Necessity of marking one or more sections, or the entire CRF, blank

The simplest, most straightforward example of data entry occurs when all of the source data are collected and available: you can open the new CRF, enter all header data, enter all response data, and save the CRF by closing it.

However, all of the source data may not be available during initial data entry, particularly when the CRF consists of multiple sections. If you do not collect all of the data for the CRF, the minimum requirement for RDC Classic to assign the Created data entry status to CRF is that all required header fields are collected. This entails completion of required CRF header fields and, if present, CRF section header fields.

Background Information   Many of the procedures in this section presume certain knowledge that is necessary to complete a task. For example, most data entry tasks assume that you can locate and open a particular CRF for a specific patient.

You may also find it helpful to review the RDC Classic QuickStart Guides, which provide concise descriptions of most tasks. These are available on the My Oracle Support Web site.

Auditing   Changes to a CRF are not captured in the audit trail until the pending changes are saved to the study database. The save action, which may be implicit or explicit, cannot occur until all required header data is collected, may be triggered manually (explicitly) or by the system (implicitly). In either case, once all required header fields are collected and you save the CRF, its data entry status progresses to Created. From that point, RDC Classic audits all changes to datapoints.

All data changes that RDC Classic audits while the CRF or CRF section is in Created or Entry Started data entry status include a system-generated **change reason**. When the CRF progresses to the Entry Complete data entry status, the system prompts you to select a change reason for all subsequent changes.

Saving Changes   A primary benefit of RDC Classic is the ability to transmit newly collected data across the Internet or your intranet to the study database in real-time. This transfer is initiated by the save action. During initial data entry, RDC Classic requires that certain information is collected before the system permits the CRF, and its data, to be saved to the database. However, when you collect this minimum amount of information and save it to the study database – essentially all CRF and CRF section header fields – RDC Classic promotes the CRF data entry status to Created. Similarly, when you collect at data for at least one response field and save the CRF, RDC Classic promotes the CRF or CRF section (in the case of a multi-section CRF) to Entry Complete. This progression of data entry status can serve as a check that the data you collect is added to the study database.

The following subsections discuss the prerequisites for saving a CRF during initial data entry and how focus changes when the CRF is saved, either explicitly or implicitly.

Prerequisites for Saving during Initial Data Entry   The CRF must contain certain data before RDC Classic allows you to manually save the CRF. The requirements depend on the design of the CRF.

Table 2–9   CRF Component Requirements for Manual Save

Component	Details	Resultant Data Entry Status
CRF header	All required fields in the CRF header must contain data.	Created
CRF section header	All required fields in each CRF section header must contain data.	Created

Table 2–9 (Cont.) CRF Component Requirements for Manual Save

Component	Details	Resultant Data Entry Status
Response fields	At least one datapoint in the CRF or CRF section must be collected.	Entry Complete
	Mandatory response fields are not required to contain data, however, an explicit save will generate discrepancies for any uncollected mandatory fields.	

Check on the Mandatory response field row.

Automatic progression During initial data entry, RDC Classic interprets an explicit save to mean that you are finished working with the current CRF or CRF section.

- If automatic progression is set to trigger after entry of a planned CRF, an explicit save causes the following sequence of events:

    1. RDC Classic saves all pending changes and closes the current CRF.

    2. It then opens the next CRF in sequence. The sequence is specified in the CRF Progression of the Preferences Window.

- If automatic progression is not selected for data entry, RDC Classic saves all pending changes and places focus in the first response field of current CRF or CRF section.

Marking blank During initial data entry, you have the option to mark a CRF or CRF section blank after required header information is collected.

Refer to "Blank Flag" on page 2-7 for further information about the general process of marking a CRF or CRF section blank.

Adjust Data Entry Preferences

Refer to "Preferences Window" on page 14-24 for information on changing the settings that affect data entry.

3

RDC Classic Discrepancy Management

The process of discrepancy management entails all of the tasks that are related to working with discrepancies. This process is critical to successful clinical data management because it allows you to ensure that the collected patient data is as free of errors and inaccuracies as possible.

This section describes what discrepancies are, how discrepancies are classified, and how you use RDC Classic to manage discrepancies. It includes these topics:

- Discrepancies in RDC Classic on page 3-1
- Discrepancy Classifications on page 3-8
- Managing Discrepancies on page 3-14

Discrepancies in RDC Classic

A discrepancy is a query, or question, that calls attention to one or more datapoints in a CRF or a **CRF section**. The goal of discrepancies is to ensure that all data collected in a CRF is accurate. RDC Classic permits users and the system to take various actions on a discrepancy, with the goal of *resolving* all discrepancies to ensure *clean* data. For each occurrence of a discrepancy, a user has the ability to address the issue the discrepancy raises and take action on it.

In addition to alerting users to a potential problem with the data, a discrepancy facilities communication between users. By focusing communication on a single issue, the narrow scope of a discrepancy allows users to perform discrepancy management and safety reviews in an orderly, item-by-item basis.

Some examples of situations that result in a new discrepancy are:

- An edit check of a response field where the recorded value is eight characters long and the question definition specifies a maximum of six characters
- A validation procedure identifies that the value for the systolic pressure is less than the value for the diastolic in a given CRF
- A user wants to include a note with the response field that describes a legibility problem with the source data.

Each of these situations causes the system to initiate a new discrepancy. When a discrepancy is raised, RDC Classic users can take actions on it until it is resolved. These actions comprise the process of discrepancy management. The goal of discrepancy management is to satisfactorily close all discrepancies that are raised.

Each discrepancy is described by a discrepancy record, which maintains the pertinent information necessary to uniquely identify it. The contents of the discrepancy record provide the specific reasons the discrepancy was raised, the user responsible for its

initiation or update, the timestamp of each action, and related information that is necessary for users to perform discrepancy management tasks.

The section is comprised of the following topics:

- Types of Discrepancies on page 3-2
- System-generated Discrepancies on page 3-2
- User-generated Discrepancies on page 3-7

Types of Discrepancies

At the most general level, the discrepancy is described based on how it originates. In RDC Classic, a discrepancy can be initiated in one of two ways:

1. System-generated – also referred to as a data discrepancy
2. User-generated – also referred to as a manual discrepancy

Each type is described in the following subsections:

- System-generated Discrepancies on page 3-2
- User-generated Discrepancies on page 3-7

System-generated Discrepancies

The purpose of a system-generated discrepancy is to alert users that there may be a problem with a response value, or a group of response values. This may be related to the values recorded in the CRF(s) or it could be due to responses for which data has not been collected.

Table 3–1 describes the three types of system-generated discrepancies. This table also lists the scope of the each discrepancy and when the system initiates each.

Table 3–1   Types of System-generated Discrepancies

Type	Scope	Initiated	Description
Univariate	Single response value	Field-to-field navigation/save action	A validation error based on the value of a response field.
Multivariate	One or more response values in one or more CRFs	Validation	A sponsor-defined, system-executed validation procedure error based on the values of one or more response fields, across one or more CRFs.
Indicator Question	Indicator question group	Save action	A system error based on incongruity between an indicator question and the presence/absence of data in the remaining question group fields.

How the System Generates Discrepancies

The system generates, or raises, a data discrepancy based on the value of one or more response fields. It may also use derived fields that are based on the value of fields collected through data entry. The system alerts you to the presence of a discrepancy at different times, depending on the type of discrepancy that is generated.

Note that a system-generated discrepancy must be associated with a response field, not the CRF or CRF header fields that collect information about the CRF. When you are recording data in these fields, the system prevents you from recording an invalid value in a these fields, therefore, discrepancies are not necessary.

Impact of Study Design on Discrepancies

The system generates a discrepancy based on a difference between the response data in a CRF and some criteria specified in the study. The purpose of the criteria may differ, for example, the goal of certain question definitions is to guard against typographic errors, while a validation procedure may identify combinations of data across CRFs between seemingly unrelated data, such as age, weight, and blood pressure. However, the goal of setting discrepancy criteria in the study design is set triggers that cause the system to initiate discrepancies when certain data is recorded.

Univariate Discrepancy

A univariate discrepancy is based on the data in a single response field. The system may raise a univariate discrepancy because the value recorded for the response does not meet certain criteria or it may raise the discrepancy because no value is recorded for a response. When the data is recorded in the field, either during data entry or batch data load, the system assesses if the value meets the validation criteria. If the value does not meet a criterion, the system raises a univariate discrepancy.

The system initiates a univariate discrepancy, also called a validation error, based on the data that is recorded in a single response field, either during data entry or batch data load.

As part of the question definition, validation criteria can be specified for a response or a group of responses. The criteria describe what represents valid response values and what does not. During data entry, the system uses the validation criteria to analyze if a recorded response value meets the criteria. If a recorded value does not meet the criteria defined for a response, the system presents the user with a validation error.

Each criterion is based on a single parameter. If a question definition includes more than one validation criteria, each is assigned an order of precedence. When the system evaluates the value you record in a response field, it checks each criterion in turn, in the order specified by the precedence. When the response value violates a criterion, the system does not check any further and it raises a validation error. If a response value violates more than one criterion, the system uses the criterion with the highest precedence to initiate the discrepancy.

Table 3–2 describes the more common parameters that are used to set each criterion.

Table 3–2   Parameters that Define Univariate Discrepancy Criteria

Parameter	Description	Example of discrepant response
Data type	Specifies the kind of data that can be recorded in the field. This can be either: ■ Number ■ Character ■ Date ■ Time	If the Data type is set to TEXT and the response value is a number.
DVG	Specifies that the value recorded in the response field is one of the choices in a **list of values**.	If the LOV consists of the choices, "Yes" and "No", and the response value is "Not Sure".
Length	Specifies the maximum number of characters that a response value can use.	If the Length is set at a maximum of 6 characters and the response value is "Very Good".
Lower Bound	Specifies that the response value must be above a certain minimum.	If the Lower Bound is set to "150" and the response value is "127".
Mandatory	Specifies that the response field must contain data. Note that discrepancies based on this criterion are not generated until the CRF is saved.	If response field is set to Mandatory and the CRF is saved with no value in the field.
Upper Bound	Specifies that the response value must be below a maximum.	If the Upper Bound is set to "60" and the response value is "68".

> **Note:** In regard to the Mandatory parameter in Table 3–2, the system cannot evaluate a response for this parameter until you save the CRF. Therefore, the validation error is not raised when you navigate to a different response. On a save action for a CRF with a missing mandatory response:
>
> The system displays the validation error before it commits the save action. This allows you to navigate to the mandatory response value and record a value.

During data entry, the system raises the univariate discrepancy when you navigate from the response field or when you initiate a save action. It alerts you to the discrepancy by displaying the Validation Error window. Because the system raises the discrepancy before the response data is committed to the study database, you have the opportunity to review, and, if appropriate, change the response value before it and the discrepancy are saved. The Validation Error window provides information that allows you to evaluate both the recorded value and the reason the system raised the discrepancy.

■ If the value is inaccurate, you have the option to return to the response field and correct the discrepant value before the discrepancy record is committed to the study database. This is beneficial if the discrepancy is based on a typographical or other kind of data entry error.

- If the recorded value is accurate, that is, it matches the source data, you use the validation error window to acknowledge the discrepancy, include any comments that are necessary, and proceed with other data entry tasks. The system saves the discrepancy and assigns it the active status for the current user.

Each time the response is updated, that is, its value is changed, the system re-evaluates the response:

- If the value is different, but still discrepant, the system closes the current discrepancy (makes it obsolete) and raises a new discrepancy, even if the new value is discrepant due to the same criterion

- If the value is not discrepant, the system makes the discrepancy obsolete and you can proceed with other data entry tasks; the response is considered "clean"

The sequence described in Example 3–1, "Occurrence of a Univariate Discrepancy" illustrates how the system evaluates successive updates to a response field and generates a new univariate discrepancy each time you update the field with a value that violates the validation criteria.

Example 3–1   Occurrence of a Univariate Discrepancy

The question definition may require that the value recorded for given response meets the following criteria:

- Data type of "Number"

- Lower Bound of "150"

- Upper Bound of "200"

It would evaluate the following recorded values accordingly:

- If the value recorded is "138", the system raises a discrepancy because it is does not meet the minimum value set by the Lower Bound parameter.

- If the value recorded is "JFS", the system raises a discrepancy because the text value is not satisfy the Data Type parameter.

- If the value recorded is "214", the system raises a discrepancy because it exceeds the maximum value set by the Upper Bound parameter.

If these three values were recorded in succession, the system would make the discrepancies based on the first and second values obsolete when the field is successively updated.

The recorded data that generates a discrepancy may simply be the result of a typographical error that occurred during data entry. For example, in the first case, above, the user may have meant to type "183," which is a valid entry. Or, the recorded value may have been typed in the wrong response field, as in the second case, in which the patient's initials were recorded. Alternatively, it may be that the recorded data is accurate and the source data does not fall within criteria that the question requires.

Multivariate Discrepancy

A multivariate discrepancy is based on the data in one or more response fields. The system generates this type of discrepancy by assessing one or more response fields in relation to a validation procedure. If the data violates the validation procedure, the system raises a multivariate discrepancy and flags each constituent datapoint that is defined in the validation procedure.

The system initiates a multivariate discrepancy when the data recorded in one or more response fields cause a validation procedure to fail. When a multivariate discrepancy is raised, the system flags each response that is specified in the validation procedure as discrepant.

In contrast to the edit checks associated with univariate discrepancies, the validation procedures that are the basis for multivariate discrepancies run at different times, based on the type of procedure. There are four different actions that run validation procedures:

1. On a CRF save action.

2. Select **Validate**, then **Patient** from the option list.

3. Select **Validate**, then **Site** from the option list.

4. Select **Validate**, then **Study** from the option list.

When each of these actions occur, the system may generate new multivariate discrepancies.

Example 3–2   Occurrence of a Multivariate Discrepancy

A procedure may be developed that evaluates the value of two responses:

1. The value of the question "Sex?", which is in the "Demog" CRF.

2. The value of the question "Systolic BP", which is in the "Vitals" CRF.

When both values are recorded, the system runs the validation procedure, which processes the values:

- If "Sex?" is "Female," *and*

- Systolic BP is greater than "135," then the system raises a discrepancy.

Note that this a simple example, given here to illustrate the general concept. In practice, sponsors may develop more complex procedures that evaluate response data on several CRFs and run at various intervals throughout the protocol schedule.

Indicator Question Discrepancy

An indicator question discrepancy is based on an incongruity between an **indicator question** and values recorded in one or more responses in the associated **question group**. Because it is based on the values of more than one response, it may seem that indicator question discrepancies are a type of multivariate discrepancy. However, in contrast to multivariate, which the system initiates as the result of sponsor-defined validation procedures, indicator questions, like univariate discrepancies, are based on internal processes that are initiated when you save the CRF.

The system initiates an indicator question discrepancy when the response fields associated with an indicator question either:

- Contain data when the value of the indicator requires that no data is collected

- Do not contain data when the value of the indicator requires that data is collected

The purpose of an indicator question discrepancy is to raise the possibility of a data entry error. Example 3–3, "Occurrence of an Indicator Question Discrepancy", illustrates how the system raises this type of discrepancy.

Example 3–3   Occurrence of an Indicator Question Discrepancy

One section in a CRF is comprised of questions that are specific to female patients. An indicator question, "Male or Female?" is used as a prompt to either record responses or skip the related questions, based on the response value of either "M" or "F".

- If the recorded response is "M", the set of related questions must be skipped. If data is recorded in any response field, the system raises an indicator question discrepancy.

- If the recorded response if "F", the set of related questions requires responses. If data is not recorded in each such response field, the system raises an indicator question discrepancy for missing data.

If the indicator question value is "M", but all of the related questions are recorded, it may be that value recorded for the indicator question is in error.

User-generated Discrepancies

Users initiate discrepancies when there is pertinent information that must be noted and communicated to other users. Table 3–3 describes the two types of user-generated discrepancies. This table illustrates several aspects of user-generated discrepancies, with regard to the CRF component with which each is associated and the number of open manual discrepancies that can be associated with that component.

Table 3–3   Types of User-generated Discrepancies

Type	CRF Component	Number Allowed	Description
Discrepancy (manual)	Individual response field	One	A comment that is specific to an individual response field.
Section	CRF section	Multiple	A comment that can be generalized for an entire CRF or CRF section, or specific to a particular datapoint that is a component of the CRF section.

Manual Discrepancy

A manual discrepancy is associated with a specific response field in a CRF. A primary reason that users generate a manual discrepancy for a response field is to communicate information to other users about the response value or the condition of the source data.

Only one open manual discrepancy can be associated with a particular response, however, you have the option of updating an existing discrepancy to include new information. When the current discrepancy associated with a particular field is resolved, you can initiate another discrepancy for that field.

Section Discrepancy

A section discrepancy is associated with a CRF **section**. It is often used as a means of communication, between a site and a CRA, about issues related to the relevant part of a CRF. In contrast to the response field discrepancy, more than one open section discrepancy can be associated with a CRF section. In addition, this type of discrepancy can be set to internal, which can limit the user groups who have access to it. (Refer to "Internal Discrepancies" on page 3-11 for more information.)

How Users Generate Discrepancies

You initiate a user-generated discrepancy by taking a specific action. You can associate the discrepancy with a single response field or with an entire CRF section. You place focus in the response or section where you want to initiate the discrepancy and you take actions to cause the system to display the appropriate tools that allow you to describe the reason for the discrepancy.

The primary purpose of user-generated discrepancies is to allow users to provide comments and additional information about the question or a CRF section. When you complete the task, the system displays the discrepancy as active for your user role.

Only one open, user-initiated discrepancy can be associated with a response field. If you attempt to initiate a new discrepancy in a response for which a manual discrepancy already exists, the system prompts you update the existing discrepancy. In contrast, more than one open section discrepancy can be associated with a CRF section, therefore, for a section with a pre-existing discrepancy, you have the option to update discrepancy or add a new discrepancy.

Discrepancy Classifications

This section describes the terms that are used to classify discrepancies and the actions that are used to process them. This section is comprised of the following topics:

- Discrepancy States on page 3-8
- Current Discrepancy Statuses on page 3-9
- Discrepancy Actions on page 3-9
- Discrepancy Basics on page 3-13

Discrepancy States

A discrepancy is either in the current or obsolete state. Within the current state, there are statuses that further describe the disposition of the discrepancy. All user interaction with a discrepancy occurs while it is current. Only the system can change a discrepancy from the current to the obsolete state. Once it is obsolete, no further action on the discrepancy, either by users or the system, is permitted.

Current Discrepancies

When a discrepancy is raised, either by a user or the system, it is, by definition, current. It remains current until the system takes action on it that renders it obsolete. Each discrepancy in the current state is assigned a discrepancy status, which further describes its disposition (Refer to "Current Discrepancy Statuses" on page 3-9 for further information).

While it is current, users and the system can take action on it. As users take different actions on a discrepancy, it may remain current but its discrepancy status may change. However, only the system can take action on a discrepancy to change it to the obsolete state.

Obsolete Discrepancies

The purpose of the obsolete state is to preserve a record of the discrepancy and to provide verification that the discrepancy has been processed. Unlike current discrepancies, users and/or the system are not permitted to take action on obsolete discrepancies. The only user interaction that is permitted is review of the discrepancy history.

Current Discrepancy Statuses

Each current discrepancy is described in terms of a discrepancy status. This is a designation that allows you to track a discrepancy based on the user group that is currently responsible for managing the discrepancy.

Whatever status an open discrepancy appears to you, it is the same for all other members of your user group. When the status changes, it changes for the entire user group. It is only when the discrepancy is actionable that the status is based on user role. In contrast, when a discrepancy is closed, its status is the same for all users.

Open Discrepancy Statuses

The discrepancy status of an open discrepancy specifies whether you (and other members of your user group) can take action on the discrepancy.

Two discrepancy statuses can be associated with an open discrepancy:

- Active — indicates that you can take action on the discrepancy

- Other — indicates that it is directed to a different user role

RDC Classic uses the color red to indicate that a discrepancy is active for you. It uses the color yellow to indicate that the discrepancy is open, but is not actionable by you (or other members of your user group).

Closed Discrepancy Status

The closed discrepancy status indicates that a user has resolved the discrepancy. A user resolves a discrepancy by selecting a discrepancy action that changes the discrepancy from open to closed. When a user closes a discrepancy, the system requires that the user specify a **resolution reason**, which is saved as part of the discrepancy record.

Discrepancy Actions

A discrepancy proceeds through discrepancy management by way of discrepancy actions. Certain actions, such as updating the comments in a discrepancy, help to clarify the cause of the discrepancy, with the aim of enhancing communication among users and ultimately closing the discrepancy. Other actions, such as routing, change the status of the discrepancy in order to alert other user groups and solicit input in the management of the discrepancy.

There are three actions that you can take on a discrepancy that change the discrepancy status:

- Initiate — causes the discrepancy to become current and active for your user group

- Route — change the status of an open discrepancy so that it is active for a different user group

- Resolve — change the status of the discrepancy to closed

In addition, there are other actions you can take on a discrepancy that allow discrepancy management to proceed but do not alter the discrepancy status. These include:

- Evaluate, or receive

- Respond

- Update

- Review

Users can take the same actions on manual discrepancies as they can on data discrepancies. Changes to response data do not alter the status of user-generated discrepancies.

The system also takes action on discrepancies, with these limits:

- The system only initiates a discrepancy based on data in one or more response fields. For example, the initiation of a system-generated section discrepancy is not permitted.

- When the system initiates a data discrepancy, it is assigned the **active** status for one or more user group and the **other** status for all other user groups. Generally, the discrepancy is set to active for the user group responsible for data entry tasks.

- The system does not route discrepancies.

- There are specific conditions under which the system makes a discrepancy obsolete.

The actions that the system can take on a discrepancy are:

- Initiate

- Obsolete

The only situation in which the system takes action on a manual discrepancy is when the response or the section with which the discrepancy is associated is deleted. For example, if the CRF is marked blank, the system changes all response and section-level manual discrepancies to obsolete.

Initiating a Discrepancy

A discrepancy can be initiated either by a user or the system. When a discrepancy is initiated, it is set to the active discrepancy status for at least one user group and it is set to the other status for the remaining user groups.

The initiation of a system-generated discrepancy is based on recorded data and the question definitions and validation procedures that are defined in the protocol. Users have no control over the initiation of system-generated discrepancies – it is based strictly on the data that is recorded in the CRFs.

Users can initiate a discrepancy for any datapoint or CRF section in a CRF, within certain limitations.

- The privileges assigned to the user name must permit initiation and update of discrepancies.

- Only one open user-generated discrepancy can be associated with a response field.

- The relevant CRF must be updateable, that is, it cannot be locked.

The basic procedure for initiating a manual discrepancy entails placing focus in a response field or CRF section and selecting the appropriate commands to initiate the discrepancy. When this occurs, the system displays a window that allows the user to record pertinent information about the discrepancy, including the error reason, which states the issue that is the basis for the discrepancy, and comments that provide ancillary information about the discrepancy. In addition, you also have the capability to take immediate action on the discrepancy.

Routing a Discrepancy

The purpose of routing is to alert users in a different user group to the presence of the discrepancy. Routing actions are only available to users, the system does not route discrepancies.

In order to route a discrepancy, the user selects from a set of discrepancy actions that the system presents. This set of actions is sponsor-defined and is specific to the current user's role. The set includes both routing and resolution actions.

Example 3–4   Typical Routing Action

If an investigator initiates a discrepancy for a response field in order to send a comment to the CRA, the investigator would use an action such as, "Send to CRA". This would change the status of the discrepancy for the CRA to active, which permits all users in the CRA role to then take action on the discrepancy. The CRA would then review the discrepancy, add any relevant comments, and choose the "Send to Investigator" action.

Note that the "Send to CRA" action is not available to the CRA role. Likewise, the "Send to Investigator" action is not available to the investigator role.

Internal Discrepancies Internal discrepancies are a special case of user-initiated discrepancy that allow a user to route the discrepancy to a different user group and cause the discrepancy to be hidden from other user groups. In order to facilitate this functionality, the sponsor must define a type of routing action that renders the discrepancy viewable to certain user roles and hidden to other roles. For user groups for which the discrepancy is hidden, an internal discrepancy, for all intents, does not exist. For user groups for which the discrepancy is viewable, it can either be in the active or other status and is generally indistinguishable from all other discrepancies. A typical use of internal discrepancies is to facilitate a private means of communication between specific user roles.

If an internal discrepancy is available to your user group, you can take the same actions on it as you can with any other discrepancy: you can route it to another user role, and you can resolve it. In the GUI, an internal discrepancy appears the same as any other.

Example 3–5   Internal Discrepancy

One scenario for the use of an internal discrepancy is as a means of private correspondence between sponsor personnel.

For example, a CRA generates a section discrepancy. Initially, the discrepancy is assigned a status of active for the CRA and other for all other user roles.

If the CRA then routes the discrepancy, for example, by using a discrepancy action, "Route to Data Manager – Internal," the discrepancy status for each role is:

1. INV (Investigator) – N/A; users in the INV role are no longer able to view the discrepancy

2. SITE (Site Coordinator) – N/A; users in the SITE role are no longer able to view the discrepancy

3. CRA – Other; because a CRA user routed the discrepancy to another user role, the discrepancy is now assigned a status of other for all CRAs

4. DM (Data Manager) – Active; because the discrepancy was routed to this role, it is now assigned a status of active for all DMs.

A full sequence is outlined in Table 3–4, " Example of Internal Discrepancy Routing" in which an Investigator initiates a section discrepancy and routes it to a CRA, who then routes it to the DM role as internal.

Table 3–4   Example of Internal Discrepancy Routing

Action	INV	SITE	CRA	DM
CRA initiates a section discrepancy	Active	Other	Other	Other
CRA reviews and routes to DM as internal (Send to DM – internal)	N/A	N/A	Other	Active
DM reviews/responds and routes to CRA as internal (Send to CRA - internal)	N/A	N/A	Active	Other
CRA reviews and chooses to close the discrepancy as resolved (Close – Resolved)	Closed	Closed	Closed	Closed

Discrepancy Resolution Actions

When a user closes a discrepancy, it is termed a "resolution action." When you initiate a resolution action, the system requires that you include a resolution reason, which is chosen from a sponsor-defined list and describes why the user closed the discrepancy. You also have the option to include a explanatory comment with the resolution reason.

A user may resolve a manual discrepancy after the issue that was the basis of the discrepancy has been discussed and/or clarified among the interested parties. At that point, a user would review the discrepancy and then choose a resolution action, for example, "Closed – Issue Resolved."

A user may resolve a data discrepancy after the accuracy of the recorded value has been checked against the source data. For example, if a recorded value exceed the criteria for a question and raises a validation error, a user may choose to resolve the discrepancy after ensuring the value in the CRF matches the source data.

System Obsolete

A user can close any type of discrepancy, however, even after the user has resolved the discrepancy, the system may change its status to obsolete.

The system closes discrepancies based on the following:

- The data upon which the discrepancy is based is updated such that the discrepancy no longer exists

- the responses to which the discrepancy is associated are deleted (this also applies to manual discrepancies)

- The validation procedure that caused the error is retired.

Although a user cannot take further action on a closed discrepancy, the system can change the status of a closed, resolved discrepancy to obsolete based on the criteria above.

Once a discrepancy is initiated, which means that it is in the current state, the system can take no other action on it, except to make it obsolete. This includes discrepancies that are open and closed. When a discrepancy is in the closed state, users cannot take further action on it. However, the system can alter the status of user-closed discrepancy to obsolete.

The obsolete status is assigned to a discrepancy under the following circumstances:

- The value of the data that caused the system to initiate the discrepancy is updated so that it is no longer discrepant.

- The discrepancy is a constituent of a CRF that is deleted.

- The validation procedure that raised the discrepancy is retired, that is, it is either removed from the protocol or it is replaced by another procedure.

- The discrepancy is associated with **repeating question** that is deleted.

Discrepancy Basics

This section provides a synopsis of the classification, requirements, and capabilities of discrepancies in RDC Classic.

1. There are two types of discrepancy, based on where it originates:

    a. System-generated (for example, a validation error that results in a univariate discrepancy)

    b. User-generated (for example, a section discrepancy that a user initiates)

2. Discrepancies can be associated with either a:

    a. Datapoint/response field(s) – either user- or system-generated

    b. CRF section – user-generated only

3. The system can take two types of action on a discrepancy:

    a. Initiate

    b. Obsolete

4. A user can take three types of action on a discrepancy:

    a. Initiate

    b. Route

    c. Resolve

5. A discrepancy can be in one of two states:

    - Current

    - Obsolete

6. An open discrepancy can be in one of two statuses:

    - Active

    - Other

7. A closed discrepancy can be one of two types:

    - System-closed (obsolete)

    - Resolved (user-closed)

8. No further action can be taken on an obsolete discrepancy.

9. A CRF is termed clean, if either of these conditions are present:

   ■ No discrepancy has been associated with it

     or

   ■ If any user-generated discrepancy associated with it has been resolved and/or any system-generated discrepancy associated with it has been closed

Managing Discrepancies

This section provides overview information about discrepancy management. It uses the information presented in "Discrepancies in RDC Classic" on page 3-1.

■ Evaluating and Responding to Validation Errors

■ Initiating a Manual Discrepancy

■ Reviewing Discrepancies

■ Evaluating and Taking Action on Edit Check Discrepancies

Evaluating and Responding to Validation Errors

As you enter response data and attempt to navigate to another field, RDC Classic saves the data and, in certain circumstances, compares it to criteria that the sponsor has defined for the question. When the data is outside the criteria, RDC Classic notifies you of a discrepancy by displaying the Validation Failure Window and maintains focus in the field. The purpose of this functionality is to reduce data entry errors by allowing you to analyze and compare the source data document to the value that you entered in the response field.

The Validation Failure Window provides basic information that describes why the data is discrepant. It also provides a means for you acknowledge the discrepant data, include a comment with the discrepancy, and take action on the discrepancy.

Although you have the opportunity to change the data before RDC Classic logs a discrepancy,you cannot navigate to another data point before you resolve the status of the current data point.

■ If you review the source data and, based on that, change the value of the data such that it is no longer discrepant, the system permits you to navigate to other response fields and continue with initial data entry.

■ If you review the source data and change the value of the data such that it is still discrepant, the system will display the Validation Failure window based on the new data value. In this case, you must process the discrepancy before the system allows you to proceed with data entry.

■ If the data in response field matches the source data and it is discrepant, you must process the discrepancy before the system allows you to proceed with data entry.

Therefore, when the system presents the Univariate Validation Failure window, you have the following options:

■ Correct the response data based on a review of the source data and proceed

■ Acknowledge the discrepancy and proceed

■ Acknowledge the discrepancy and route it to another role

Initiating a Manual Discrepancy

The general sequence required to initiate a manual discrepancy is:

1. Place focus in the response field with which you want to associate the discrepancy.

2. Select Insert, then Discrepancy (manual) from the option list to open the Comment for Question Window.

3. In the Comment for Question window, provide information that describes why you are initiating the discrepancy.

4. Close the discrepancy window.

The process to initiate a section discrepancy is similar. When you select **Insert**, then **Section Discrepancy** from the option list, the system opens a discrepancy for the section that contains the response field that is in focus.

Reviewing Discrepancies

The Discrepancy task tab provides a single location to review all discrepancies that are associated with the CRF that is in focus. The List of Discrepancies tab provides a prioritized display of all discrepancies and allows you to modify the Error Message and Comment text, as appropriate, directly in the tab. The Individual Discrepancy tab is particularly useful when you review multivariate discrepancies.

You can take action on a discrepancy from either sub-tab.

Evaluating and Taking Action on Edit Check Discrepancies

When the system presents the Validation Failure window, the Message section displays the system-generated reason that the data value is discrepant. The response value is included in the reason. This allows you to compare the value that you typed in the response field to the source data value. If the two values do not match, use this procedure to navigate back to the response field and correct the value you typed. This procedure avoids the creation of a system-generated discrepancy.

1. In the Validation Failure window, click the Cancel button. The window closes and the system places focus in the discrepant response field.

2. In the response field, edit the value so that it matches the source data.

3. Navigate to another response field or save the CRF.

   ■ If the new value is valid, RDC Classic permits the navigation or the explicit save.

   ■ If the new value is discrepant, the Validation Failure window displays with the new value included in the Message text box.

If the Validation Failure window displays again, which may indicate that the source data value has caused the validation failure, review the workflow in the Procedures section to assess the method you should use to process the discrepancy.

Acknowledge Discrepant Data and Include a Comment

Use this procedure if you want to acknowledge the Validation Failure window and,optionally, include a comment with that the system saves with the discrepancy record.

1. In the Validation Failure window, review the Message text box and ensure that it includes information relevant to the discrepancy. If necessary you can edit the contents of the text box, either directly within the text box or in a separate editor.

2. Use the Comments text box or the Internal Comments button to include an comment with the discrepancy.

3. When the contents of the Message and the Comments text boxes are satisfactory,click the OK button to save the discrepancy record and close the Validation Failure window.

Route the Discrepancy

This procedure describes the steps to acknowledge the discrepancy and route it to a different user group (that is, make it Active for another role).

> **Note:** The actions that are available are based on your user role.However, your system administrator is responsible for defining the entire set of actions for the study.

1. In the Validation Failure window, review the Message text box and ensure that it includes information relevant to the discrepancy. If necessary you can edit the contents of the text box, either directly within the text box or in a separate editor.

2. Use the Comments text box or the Internal Comments button to include an comment with the discrepancy.

3. In the Action drop-down list, select a routing action. The Internal Comment window displays.

4. In the Internal Comment window, type an optional comment that you want to save with the discrepancy.

5. In the Internal Comment window, click the OK button to save the comment and close the window.

6. In the Validation Failure window, click the OK button to save the discrepancy and the discrepancy action. The window closes.

Resolve the Discrepancy

This procedure describes the steps to acknowledge and resolve the discrepancy.

> **Note:** The actions that are available are based on your user role. However, your system administrator is responsible for defining the entire set of actions for the study.

1. In the Validation Failure window, review the Message text box and ensure that it includes information relevant to the discrepancy. If necessary you can edit the contents of the text box, either directly within the text box or in a separate editor.

- To edit within the text box, place the cursor focus at an appropriate point in the message text.

- To edit in a separate editor, click the Comment button adjacent to text box.

2. To include an optional comment with the discrepancy:

- Place cursor focus in the Comments text box, or

- Click the Internal Comments button adjacent to the text box

3. In the Action drop-down list, select a resolution action. The Resolution Reason window displays.

4. In the Resolution Reason window:

   ■ Select a resolution reason from the Resolution drop-down list.

   ■ Type an optional comment in the Comment text box that you want to save with the discrepancy.

5. In the Resolution Reason window, click the Save button to save the resolution reason and comment, if present, and close the window.

6. In the Validation Failure window, click the OK button to close the window and save the discrepancy and the discrepancy action.

4

Reports in RDC Classic

Reports in RDC Classic allow you to generate output that incorporates the patient data for your current workset or a different workset that you specify and collates it into a single document. Alternatively, you can produce a CRF report that includes the blank CRFs that comprise a particular workbook.

This section describes each type of report that you can run in RDC Classic, explains the different sections that can be included, and discusses how the different parameters you set can affect the report that is produced.

This section consists of the following topics:

- Discussion of the PDR on page 4-1
- Components of PDRs on page 4-3

Discussion of the PDR

The Patient Data Report (PDR), enables you to generate reports that consist of individual or sets of documents, using criteria that you determine. You can use the PDR to print out a set of blank CRFs, which you can then fill in by hand, or you can print out an entire casebook for a particular patient.

This section consists of the following topics:

- Types of Reports on page 4-1
- Requirements on page 4-3
- Format on page 4-3

Types of Reports

You use the Reports window to select the type of PDR you want to run. By selecting different options in this window, you can run several different reports.

When you run reports, you have the option to either generate a blank workbook, a blank workbook with patient information, or a report with data for a set of patients that you specify. The primary difference between these reports is that the latter includes response data. The blank workbook report either includes no data or, if you choose the Patient Workbook option, it includes only patient information in each CRF header.

Figure 4–1   Reports Window
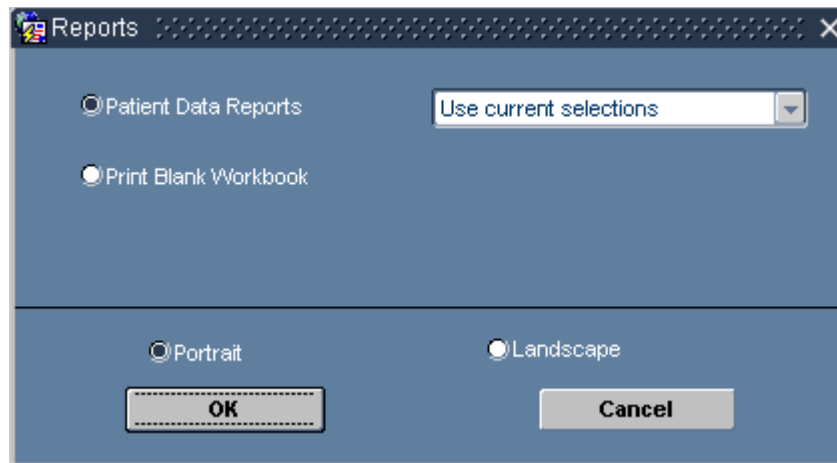
These are the types of reports that you can generate in RDC Classic:

1. Workbook Report - this type of report does not include response data.

   Blank Workbook – this option generates a Blank Case Report Form PDR that consists of all planned CRFs in the Book that you specify. It does not contain response data or CRF header information. To run this report, select **Print Blank Workbook** in the Reports window.

2. Patient data CRFs - this type of report includes the header data and the response data currently saved for all selected patients; when you run the report you have the option to:

   a. Use current selections – this option uses the search criteria that is the basis for the current workset. In this PDR, you can set parameters that display the Audit History Report Section and/or the Discrepancy Detail Report Section; set a time period that restricts the CRFs that are included; limit the time period to the last verification or approval operations; and specify the date format that is used in the report. All other aspects of the PDR are controlled by the current search criteria.

      To run this report, select **Patient Data Reports** and the "Use current selections" option.

   b. Specify Report parameters – this option gives you extensive control over the information that is included in the PDR; it allows you make selections that limit the data presented in the PDR based on a variety of parameters that are similar to those offered in the Search Window.

      To run this report, select **Patient Data Reports** and the "Specify report parameters" option.

      Note: When you run a PDR, it only includes those CRFs to which your assigned privileges allow you to view in the RDC Classic Workspace.

Requirements

This section describes the requirements for running reports in RDC Classic.

Your system administrator or the sponsor should provide you with the name of a report server to use when you run reports. You should ensure that this name is displayed in the Server/Queue field at the top of the Report Submission Window when you initiate the process to run a report.

Format

Each CRF is the same as the version that displays in the Data Entry window; the report simply combines multiple CRFs into a single PDF document. When you run reports, each CRF in the report is representative of the form that the system presents in the Data Entry window.

In addition, you have the option to set the page layout of the report to either portrait, which is the default selection, or landscape format. Each CRF is presented in the format in which it was designed. This makes it possible, in the case of CRFs with landscape layouts, to have a report with the Discrepancy Detail and Audit History sections in portrait layout, and the CRFs in landscape.

Components of PDRs

This section describes the components that may comprise a PDR. Certain components are part of every report, while others are only present in specific types of reports or when certain conditions, such as long data values, are present.

This section consists of the following topics:

- Discussion on page 4-3
- Page Numbering on page 4-4
- Cover Page on page 4-4
- CRF Data Section on page 4-5
- Audit History Report Section on page 4-7
- Discrepancy Detail Report Section on page 4-7
- Deleted CRFs Section on page 4-8

Discussion

Each PDR contains a Cover Page, which lists basic information about the report. The PDR may contain the following sections:

- Blank CRFs section
- CRF Data section
- Audit History section
- Discrepancy Data section
- Deleted CRFs section

Page Numbering

The system provides general information about the report in the header and footer areas of certain pages in the report. Pages that reproduce a CRF display the actual CRF header and footer information.

The information that may be present in non-CRF pages includes:

- The CRF number and an abbreviation of the section, with a "sub-page" number for multipage sections, is displayed in upper right-hand corner of the pages that are not part of the CRF, such as the end note pages.

    For example, the following may be present in a header:

    4.OS.2

    This indicates that the current page is the second page in the Overflow Section for the fourth CRF in the PDR.

- The page number; in the Blank CRF report, all pages in the report are numbered sequentially.

Cover Page

A cover page is generated for each PDR that RDC Classic produces. The purpose of the cover page is to provide information about the PDR. Table 4–1 describes the components that may be included in a PDR cover page.

Table 4–1   PDR Cover Page Components

Component	PDR Type	Description
Title	Both	A general description of the contents of the PDR. This may be either: - "CRF Report for Study *<study name>*" - "Blank Case Report Form for Study *<study name>*"
Report Run by	Patient CRF	The name of the user who initiated the PDR. This is the fullname that is associated with the user name.
At	Patient CRF	The timestamp that the system started to run the report.
Book	Blank Workbook	The name of the book you designated for the report.
Filter	Patient CRF	A listing of the search criteria when you choose "Use current selections" in the Reports window.
Report Parameters	Patient CRF	A listing of the parameters you selected in the Report Submission window.
Legend	Patient CRF	A display of font styles and formatting that are used in the current PDR. Its purpose is to provide a reference for reading data and information in the report.

Blank Workbook PDRs

The cover page for the blank workbook PDR includes:

- The name of the study
- The name of the book

The blank workbook for a patient also includes the patient number.

Patient CRF PDRs

The content on the cover page for the patient CRF PDR is dependent on the parameters used to define the settings for the report and the data that is included in the constituent CRFs. However, each PDR includes a title, the "Report run by" and timestamp line, and a legend.

CRF Data Section

You have the option to include CRF Data section in the PDR.

CRF Header Information

All CRF header and CRF section header information that is included in the source CRF is included in the PDR. The fields that are included in this section are:

Patient (with initials)	Frozen (if the patient is frozen)
Site name	Investigator name
CRF number	Blank flag status (Y or N)
CRF Status (data entry status)	Visit date
Visit name (CPE)	Document Number
Entry Time	Entered By
Latest Modification time	Locked status (Y or N)
Discrepancy status	Approval status
Approval time	Approver name
Verification status	Verification time
Verifier	Comment text

CRF Section Header Information

If the CRF is multi-section or single-section with a CRF section header, the PDR includes the following information:

CRF section name	CRF section number (out of total, if there is more than one section)
Blank flag status (Y or N)	CRF section status
Visit name	Visit date
Visit time (if supplied)	Entry time
Lock status (if the section is locked)	Modification time
Lab (if present)	Qualifying question (if present)

Approval and Verification Notices

There are fields at the top of the CRF that provide information about the approval and verification status. If the CRF is verified and/or approved, the PDR lists the user name of the person who performed the action and the timestamp the action occurred in the relevant fields.

Response Data

All response data is included in the PDR, however, certain aspects of the PDR format may restrict how data values that exceed the width of the data width are presented. Refer to "Long data values" on page 4-6 for further information.

Format of Data Values

The response values that are displayed in the PDR may be formatted to indicate the presence of discrepancies and/or an audit history.

- Response values associated with a univariate or manual data discrepancy are printed in bold style font

- Response values for which an audit history exists are printed in italic style font

- Response values that are discrepant and possess an audit history are printed in bold and italic style font.

End Notes

End notes are used to give complete information about response data without interrupting the formatting or flow of the CRF data section of the PDR. The end note section, if present, if placed immediately after the CRF data section.

As the name implies, end notes are located at the end of each CRF data section in a PDR. There are two sets of numbered endnotes:

1. One set corresponds to the superscripts associated with Investigator comments

2. One set corresponds to the subscripts associated with Long data values

PDRs use endnotes to display any investigator comments that are associated with response fields in the preceding CRF. Note that long data values in the PDR are displayed in-place, by wrapping the text.

Investigator comments If an investigator comment is associated with a datapoint, a superscript is inserted adjacent to the field. The superscripts start at "1" for each CRF and increment regularly for each occurrence of an investigator comment. The entire content of each investigator comment is viewable in the Investigator Comments section, which is in the End Notes.

Long data values Response data values that exceed the length of the response field in the CRF are marked with a subscript number adjacent to data field. The subscripts start at "1" for each CRF and increment regularly for each long data value in the CRF. The entire contents of the response field is included in a listing of such values in the Overflow Section, which is in the End Notes.

Links to Other Sections

If a discrepancy is associated with the CRF, the PDR inserts a hyperlink after the End Notes section that allows you to navigate to the Discrepancy Data section. Similarly, if any response value in the CRF contains an audit trail, the PDR inserts a hyperlink at the bottom of the response data section that allows you to navigate to the Response History section.

Audit History Report Section

The Audit History Report section is present in a Patient CRF PDR under two conditions:

- It has been specified in the PDR definition process, and the parameter is set to "Y" in the Report Submission Window.

- An audit history is associated with at least one datapoint in the associated CRF.

There is a separate page or set of pages for each CRF in the report that contains an audit trail. The following information is included for each CRF:

- Document number
- Patient number
- Visit number
- CRF name
- Site
- Visit Date
- CRF page
- Section name
- Qualifying prompt
- Qualifying value
- Section Visit
- Section Date

- Question Group number
- Question Group name
- Field name
- Row number
- Value Changed From
- Value Changed To
- Impact on resequence
- Change timestamp
- User who made change
- Change Reason
- Change Reason comment

Discrepancy Detail Report Section

The Discrepancy data section of the PDR lists the discrepancies that are associated with the data that is presented in the CRF Data Section. It is present in the PDR under two conditions:

- It has been specified in the PDR definition process, and the parameter is set to "Y" in the Report Submission Window.
- Discrepant data is in the associated CRF.

The discrepancies associated with a given CRF are set off in a separate subsection, however, more than one discrepancy record may be present on each page. For each discrepancy, the PDR includes the following information:

- Document number
- Discrepancy ID
- Site
- Patient number
- Visit
- Visit Date
- CRF
- CRF Section
- Qualifying value
- Response Field

- Row
- Value Text
- Type of Discrepancy
- Status
- Review Status
- Discrepancy Text
- Internal Comment Text
- Resolution Type
- Resolution Reason

Deleted CRFs Section

This section lists all CRFs that have been deleted. If the report includes CRFs that have been deleted, they are listed in this section, which is located at the end of the PDR.

Part II

Data Entry Tasks

This part of the documentation describes how to complete RDC Classic tasks. The tasks are categorized as follows:

5

Getting Started

This section describes general tasks that you perform in RDC Classic. It includes the following:

- Start Your RDC Classic Session on page 5-1

- Select a Workset on page 5-5

- Work with Patients on page 5-5

- Work with CRFs on page 5-7

- Work with Visits on page 5-9

- Validation Tasks on page 5-11

- Modify the Workset on page 5-12

- Lock and Unlock CRF Procedures on page 5-15

- Miscellaneous Tasks During an RDC Classic Session on page 5-17

- End Your RDC Classic Session on page 5-18

Many of the tasks in this chapter require you to use the RDC Classic Spreadsheet and/or the Search window. These components are described in separate sections. Refer to "RDC Classic Spreadsheet" on page 12-1 and "Search Window" on page 15-1.

In addition, refer to the Glossary for a list of RDC Classic and Oracle Clinical terms and definitions.

Start Your RDC Classic Session

To start working with RDC Classic, the first task you complete is to initiate a **session**. This entails establishing a connection to the Internet, accessing the RDC Classic Launch page, logging in to the study database, and selecting a **workset**.

The following steps list the basic workflow you follow each time you initiate an RDC Classic session:

1. Use your computer to access the sponsor site (refer to "Connect to the Sponsor Site" on page 5-2).

2. Use Microsoft Internet Explorer to display the RDC Classic Launch page (refer to "Navigate to the RDC Classic Launch Page" on page 5-2).

3. Complete the RDC Classic Login window (refer to "Log In to RDC Classic" on page 5-3).

4. Choose a study, if a default study is not defined (refer to "Select an Initial Study" on page 5-4).

5. Review news items in the News window, if your administrator has configured it and there are news items you have not yet viewed (refer to "Review News Items During Session Startup" on page 5-4).

6. (Optional) Change the default study from either the Activity List window or the Search window.

7. Choose the CRFs you want to work with in the RDC Classic session (refer to "Select a Workset" on page 5-5).

> **Note:** Refer to "System Requirements" on page 1-3 for a listing and descriptions of the hardware and software requirements to run RDC Classic.

Connect to the Sponsor Site

To start an RDC Classic session, the first step is to connect your computer to the sponsor site. This can be accomplished via the Internet or a Local Area Network (LAN), using a modem or network interface card.

Consult the sponsor's system administrator for information about how to best access the sponsor site.

Navigate to the RDC Classic Launch Page

You use the browser installed on your computer to navigate to the RDC Classic Launch page. To do this:

1. Open a Microsoft Internet Explorer browser window.

2. Type the URL provided by your sponsor in the browser's Address text box.

3. Press the Enter key.

   The RDC Classic Launch page is displayed in the browser window. The next step in the RDC Classic session startup process is described in "Log In to RDC Classic" on page 5-3.

Notes

You can use the "Bookmark" tool, which is a component of Microsoft Internet Explorer, to save the URL for an RDC Classic Launch page site. For subsequent sessions, this allows you to quickly navigate to the launch page and avoid typing the URL in the Address text box. If you work with multiple RDC Classic installations, you can uniquely identify the URL bookmarks in order to differentiate each. Refer to the Internet Explorer documentation for further information.

The RDC Classic Launch Page provides links that allow you to access other documentation and Web sites. Refer to "RDC Classic Launch Page" on page 14-2 for information.

Access login help Click the Login Help link to navigate to a help topic that provides troubleshooting information for login problems.

View extended help and manuals Click the links on the RDC Classic Launch Page to open the online help and to access documentation for other Oracle Health Sciences products.

Log In to RDC Classic

This section describes the procedure to login to RDC Classic, which you complete after you open the RDC Classic Launch Page in an Internet browser (refer to "Navigate to the RDC Classic Launch Page" on page 5-2).

Prerequisites

You must know the following information in order to login to RDC Classic:

1. Your User Name

2. Its associated Password

3. The Database Name where the study resides.

Procedure

To login to RDC Classic from the RDC Classic Launch Page:

1. Click the Launch hyperlink.

   The Logon Window is displayed.

2. In the Logon window, type your:
   - User name (using the "OPS$" prefix, if required)
   - Password
   - Database

3. Click the OK button.

Figure 5–1 depicts a typical Logon window with example input parameters for the user name, password, and database name.

Figure 5–1   Typical Logon Window
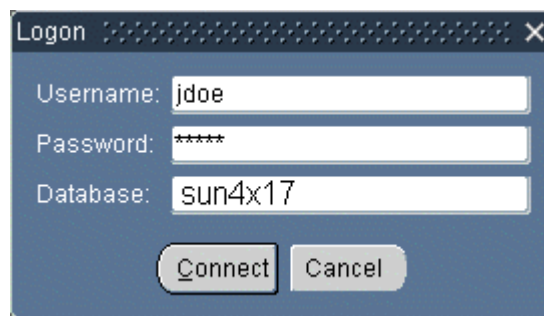
Notes

When you complete the Login window and you successfully initiate an RDC Classic session, the application starts and the Main Application Window opens. However, before you can start working in RDC Classic, you must complete one or more of the following tasks:

- Review the News window

- Choose a study

- Change the default study

- Select a workset

Change Your Login Password

The procedure to change your password requires that you know your current password and that you type the new password twice, in order to confirm it.

You should adhere to any rules or regulations that the sponsor has in place with regard to the frequency of password changes.

> **Note:** You should not be logged into RDC Classic when you initiate this task.

Procedure

To change your password:

1. In the RDC Classic Launch Page, click the **Change Password** hyperlink. The Change Password Window opens.

2. In the Change password window, type the password currently assigned to your user name in the **Old Password** text box.

3. Type the new password in the **New Password** text box and again in the **Confirm New Password** text box.

4. Click the **OK** button to close the Change Password window. The system discards the current password and saves your new password.

Select an Initial Study

In most cases, RDC Classic automatically loads the **default study** when you start a session. If this is the case, the system does not display the Change Study Window and you can skip this topic.

If no default study is defined, the system displays the Change Study window, which you use to select the study from which you want to select a workset. In this case, refer to the Usage subsection in "Change Study Window" on page 14-5 for instructions on how to locate and select a study.

To change to a different study after your session starts, refer to "Change the Study During an RDC Classic Session" on page 5-12.

Review News Items During Session Startup

The News Window consists of **news item**s that the study sponsor wants to communicate to you. RDC Classic displays the window when it contains information that you have not previously viewed. Because the news items displayed are configured and maintained by the system administrator, usage requirements and procedures are sponsor-specific and are not addressed here.

Refer to "View News Items During a Session" on page 5-18 for the procedure to access the News window after the session has started.

The News window is displayed during session startup if:

■ your system administrator configures it, and

■ you have not viewed at least one of the news items.

Procedure

The procedure to use the News window depends on the type of news items that it displays. If a new items does not contain a link, the only action available to you is to read the new item(s) and then close the News window.

If the news items contains a link or if an "Additional Information" button is adjacent to it, you can access further details about it by clicking the link or the button, as appropriate. This action generally causes a new instance of your Internet browser to start and navigates the browser to a Web page that the system administrator has specified.

Click the **OK** button to close the News window. The system closes the window and opens either the Activity List window or the Search window.

Select a Workset

After you have initiated an RDC Classic session and either you or the system have selected a study, the next step is to specify a **workset** that you want to display in the RDC Classic Spreadsheet. A workset is a subset of the data that is in the study database. In general, the workset should consist of the data that is required for you to accomplish your required tasks, such as displaying the set of patients for which you want to enter data, or display the CRFs that require verification.

Refer to "Select a Workset" on page 6-1 for a description of the ways in which you can load a useful workset into the RDC Classic Workspace.

Work with Patients

This section describes the procedures you use to work with patients in the RDC Classic Spreadsheet. These procedures are relevant only after you select a workset to display in the RDC Classic Spreadsheet.

This section includes the following tasks:

- Select a Patient

- Navigate in the Patient List

- Include a Specific Patient in the Workset

- Insert a New Patient

Select a Patient

The Patient List displays eight patients at a time. When you select a patient, RDC Classic highlights the patient cell with a light blue-colored background.

There are two methods you can use to select a patient, one direct and the other indirect.

If necessary, use "Navigate in the Patient List" on page 5-6 to display the patient in the list.

1. To select a patient directly, click in the appropriate patient cell. This places focus on the patient.

2. To select a patient indirectly, click any CRF cell in its row. This places the focus on the CRF cell, however it also selects that associated patient. Any function that requires a patient number for context, such as selecting **Validate**, then **Patient** or **Insert**, then **CRF**, uses the patient associated with the CRF.

Navigate in the Patient List

The list of current patients is divided into sets of eight, which each can be displayed in the RDC Classic Spreadsheet in turn.

With focus in a patient cell, use the following:

1. Press the Up and Down arrow keys to navigate through the list one patient at a time.

2. Press the Page Up and Page Down keys to navigate through the list one set of patients at a time.

3. Click the Patient Selection Drop-Down List to view a list of patients that are separated into sets of eight. Select the set that includes the patient whose data you wish to view.

Include a Specific Patient in the Workset

There are several methods you can use to include a patient in the workset. The method you choose depends on which data selection tool you are using (Activity List window or Search window), and on whether you want to work with one patient at a time or on a larger set of patients.

- If you use the Activity List window to define the workset, you can:

    1. choose a "Show all data" type task with a scope of either Study or the Site to which the patient is assigned, or

    2. highlight the Patient node in the Navigation pane and select a corresponding task in the Activity pane.

- If you use the Search window to define the workset, you can:

    1. use the default values for all criteria to select all available patient data for the workset, or

    2. use the Patients Subsearch Window to either select a single patient number or a range of patients

Insert a New Patient

Before you can begin data entry for a patient, the patient must be added to the List of Patients, which adds the patient to the study, assigns the patient to the currently active book, and allows you to collect data in a CRF that is associated with that patient.

You use the Insert New Patient Window to insert a new patient (i.e., a patient for which no data has previously been entered in the database) into the list of current patients. This window is accessible, either by:

- Selecting **Insert**, then **Patient** from the option list, or

- clicking an empty patient cell.

To insert a new patient:

1. Open the Insert New Patient Window.

2. In the Insert new patient window, click the drop-down arrow to display a list of all patient numbers for which no data is entered.

3. Click the patient number that you want to insert.

4. Click the **OK** button. The system inserts the new patient number in the appropriate location in the patient list sequence.

Work with CRFs

This section describes the tasks that you perform to work with CRFs.

This section covers the following tasks:

- Open a New or Existing CRF
- Add an Unplanned CRF
- Show or Hide Unplanned CRFs
- View Summary Information for a CRF
- Delete a CRF
- Add an Unplanned CRF to a Planned Visit
- Add an Unplanned CRF to an Unplanned Visit

Open a New or Existing CRF

In order to review, add, or update patient data, you must open the appropriate CRF in a Data Entry window. This section provides general information about the procedure to open a CRF.

To open a CRF, click the appropriate CRF cell. The system opens the Data Entry window specified in the Preferences Window.

Note

When you click a CRF cell, RDC Classic places focus on that CRF. This allows you to view information about the CRF in the Summary Task Tab and allows you to take certain actions on the CRF.

Add an Unplanned CRF

You use the Add Unplanned CRF window to add a CRF to an existing visit. This task is commonly used to add an Adverse Events and/or a Concomitant Drugs CRF to a visit. The system allows you to add a CRF to a visit the current patient, with the following restrictions:

- the CRF is not already part of the visit, and
- the study configuration allows the CRF to be collected more than once. For example, some studies specify that the "Demography" CRF be collected only once for each patient.

When you add a CRF to a current visit, the system inserts a new CRF column in the the Spreadsheet to accommodate the unplanned CRF. It then initiates data entry for the current patient by opening the Data Entry window.

Procedure

Use these instructions to insert an unplanned CRF in the current visit.

1. Ensure that the correct visit is selected:

   - if the Visit Spreadsheet view is active, that is, if the Spreadsheet tabs are labeled by the visit, ensure that the correct tab is selected
   - if the Phase or Study Spreadsheet view is active, ensure that a CRF that is a constituent in the correct visit is selected.

2. Ensure that the correct patient is in focus in the Patient List.

3. Select **Insert**, then **CRF** from the option list. The system opens the Add Unplanned CRF Window.

4. In the Add Unplanned CRF Window, use the drop-down list to select a CRF to add to the visit. When you make a selection, the system immediately inserts the CRF in the Spreadsheet and opens it in a Data Entry window.

Show or Hide Unplanned CRFs

An unplanned CRF may be associated with either a planned or an unplanned visit. By default, unplanned CRFs are included in the workset, but are not displayed in the RDC Classic Spreadsheet.

You can alter the display of unplanned CRFs in the Spreadsheet at the workset level or at the Spreadsheet view level.

Spreadsheet View

From the RDC Classic Spreadsheet, toggle the Show/Hide Unplanned Pages Button, which is located adjacent to the last CRF column, to display or hide the unplanned CRFs in the current Spreadsheet view.

Workset

In the Visit/Page Range Subsearch Window, which is part of the Search window, select the Show all unplanned pages? parameter check box

Refer to "Exclude Planned or Unplanned CRFs" on page 15-18 for instructions on the latter two situations.

View Summary Information for a CRF

To display summary data about a CRF:

1. Click the relevant CRF cell to put it in focus.

2. Click the Summary Task Tab label to display its contents.

3. The data about the CRF is displayed in the task tab.

Note: When a CRF is in focus, you can access any of the other Summary task tab views by using the Summary View Drop-Down List.

Delete a CRF

To delete a CRF:

1. Click the relevant CRF cell to put the document in focus.

2. Select the **Delete CRF** command on the Edit menu, which opens a confirmation message window that allows you to confirm your choice.

3. In the confirmation message window, click the **OK** button.

Add an Unplanned CRF to a Planned Visit

To add an unplanned CRF to a visit:

1. If the Spreadsheet Visit view is active, select the Visit tab of the visit to which you want to add the CRF. If either the Spreadsheet Phase or Study view is active, select a CRF Column that is part of the visit to which you want to add the CRF.

   Note that the visit can be a planned or an unplanned visit.

2. Select **Insert**, then **CRF** from the option list, which opens the Add Unplanned CRF Window.

3. In the Add unplanned CRF window, click the drop-down list arrow to view the list of CRFs that are available to add to the current visit.

4. Select the CRF that you want to add to the visit. Your selection is immediately added to the visit.

Add an Unplanned CRF to an Unplanned Visit

An unplanned visit consists of the CRFs that comprise the associated planned visit, with the exception that CRFs that are designated to be collected once in the study. This procedure describes the steps to add other CRFs to the unplanned visit.

To add an unplanned CRF to an unplanned visit:

1. Open the planned visit that is associated with the unplanned visit.

2. Put focus in a CRF that is part of the unplanned visit.

3. Select **Insert**, then **CRF** from the option list. The Add Unplanned CRF Window is displayed.

4. In the Add unplanned CRF window, use the **CRF** drop-down list to select the CRF you want to add.

5. When you make your selection, the CRF is added as the last CRF of the visit.

Work with Visits

Since visits are the most notable milestone in a study, most of your work will take place with the Visit Spreadsheet view active. In this view, each planned visit that is scheduled for the study is displayed as a tab in the RDC Classic Spreadsheet.

This section describes the tasks that are related to working with visits in RDC Classic. In includes:

- Show/Hide Unplanned Visits
- Add an Unplanned Visit to a Study

Show/Hide Unplanned Visits

Depending on your task, you may want to display all visits, both planned and unplanned, in the Spreadsheet. Alternatively, you may want to show only planned or only unplanned visits. RDC Classic permits any of these discrete views to be displayed by allowing you to either change way CRFs are displayed in the Spreadsheet or by changing the workset.

To adjust the workset so that only planned or only unplanned visits are included, you use the Visit/Pages criterion in the Search window. If unplanned CRFs are included in the workset, you can also specify that they are displayed throughout the Spreadsheet.

Since unplanned CRFs can be associated with a planned visit or an unplanned visit, you can use the Show/Hide Unplanned CRFs button to show or hide unplanned CRFs for the visits in the current Spreadsheet tab.

Show Unplanned Visits

The following are methods to show unplanned visits while also showing planned visits.

1. To show unplanned visits that are associated with the visit in focus, click the Show Unplanned CRFs button in the CRF Column Header.

2. To show unplanned visits throughout the Spreadsheet, select the "Show unplanned CRFs?" check box in the Visits/Page Range Subsearch Window.

3. To show unplanned visits only (i.e., to hide planned visits), select "Unplanned" in the CRF Status drop-down list in the Visits/Page Range Subsearch Window.

Hide Unplanned Visits

You can use the following methods to hide unplanned visits while displaying only planned visits:

- To hide unplanned visits that are associated with the visit currently in focus, click the Hide Unplanned CRFs button in the CRF Column Header.

- To hide unplanned visits throughout the Spreadsheet, ensure that the "Show unplanned CRFs?" check box in the Visits/Page Range Subsearch Window is not selected.

- To show planned visits only, that is, if you do not want the option of viewing unplanned visits or CRFs in the Spreadsheet, select "Planned" in the CRF Status drop-down list in the Visits/Page Range Subsearch Window.

Add an Unplanned Visit to a Study

RDC Classic allows you to add an unplanned visit to the study. When you add the visit, it is associated with the planned visit currently in focus and includes the same set of CRFs, except those that are designated to be collected only once during the study.

An unplanned visit is assigned an visit number that combines the planned visit number with a decimal designation. For example, the first visit that you add after Visit 6 is assigned an event number of "6.1," the second visit added after Visit 6 is assigned an event number of "6.2."

If a unplanned visit rather than a planned visit is in focus, the new unplanned visit is associated with same planned visit as the unplanned visit in focus. After you insert the unplanned visit, it is inserted in the next available position after the visit in focus.

Procedure

To add an unplanned visit to a study:

1. Select the **Visit** tab of the visit that you want to add a visit after.

2. Select **Insert**, then **Visit** from the option list, which opens a confirmation message window that allows you to confirm your choice.

3. In the confirmation message window, click either:

    a. **OK** - to insert the visit and open the first CRF in the Data Entry window

    b. **Cancel** - to revert back to the Spreadsheet without inserting the visit.

Notes

Although RDC Classic assigns event numbers to inserted visits in the order each is added, it is possible for an Oracle Clinical user to specify a non-continuous event number to an inserted visit. This may result in a set of visit numbers such as: Visit 3, Visit 3.1, Visit 3.3. In this case, if you want to insert Visit 3.2, ensure that a CRF that is part of Visit 3.1 is selected before you select **Insert**, then **Visit** from the option list. If Visit 3 is selected when you select the Visit option, then the inserted visit is designated Visit 3.4.

Validation Tasks

When you initiate a validation task in RDC Classic, the system runs the validation procedures that are defined for the study. There are three validation tasks that you can initiate. Each causes RDC Classic to run a different combination of procedures for different sets of CRFs.

Validate a Patient

The patient validation menu command runs [DCM] and [Online] validation procedures on all CRFs associated with a patient that are at Entry Complete data entry status. This may include CRFs that are not part of the current workset.

To validate the CRFs associated with a patient:

1. Place the patient in focus.

2. Select **Validate**, then **Patient** from the options list. A confirmation window displays a message that lists the patient to be validated.

3. In the confirmation window:

   - click the OK button to proceed with the task

   - click the Cancel button to discontinue the task and revert focus to the Spreadsheet.

Validate a Site

The site validation command runs validation on all CRFs in a site that are at Entry Complete data entry status. This may include CRFs that are not part of the current workset.

To validate the CRFs associated with a site:

1. Ensure that the appropriate site is part of the search criteria. Refer to "Notes" on page 5-12 for further information.

2. Select **Validate**, then **Site** from the option list. A confirmation window displays a message that identifies the site that will be validated.

3. In the confirmation window:

   - Click the **OK** button to proceed with the task

   - Click the **Cancel** button to discontinue the task and revert focus to the Spreadsheet

Notes

If you have access to more than one site, you should use either the Activity List window or the Search window to select a single site prior to selecting **Site** from **Validate** option list.

Validate a Study

The study validation process runs batch validation procedures on all eligible CRFs in the study. This can be a time-consuming process. In general, this capability to validate a study is only given to users assigned to the data manager role.

To validate the CRFs associated with a study:

1. Ensure that the appropriate study is open.

2. Select **Validate**, then **Study** from the option list. A confirmation window displays a message that identifies the study that will be validated.

3. In the confirmation window:

    -   Click the **OK** button to proceed with the task

    -   Click the **Cancel** button to discontinue the task and revert focus to the Spreadsheet

Modify the Workset

The tasks in this section describe provide methods you can use to modify the data that comprise the workset. The following tasks are included:

-   Refresh the Workset

-   Change the Study During an RDC Classic Session

-   Modify the Search Criteria

-   Change the Current Book

-   Change the Current Site

Refresh the Workset

When you use the Activity List window or the Search window to specify criteria that populates the RDC Classic Spreadsheet with a workset, the data in the Spreadsheet is synchronized with the search criteria. However, when you subsequently change data in a CRF so that it no longer satisfies the original criteria, it continues to be included in the workset. In this way, the workset may not be synchronized with the criteria. In such circumstances, the Spreadsheet status line may not be accurate.

To refresh the workset, select **File**, then **Refresh** from the option list.

Change the Study During an RDC Classic Session

If you have access to more than one study, you can change to another study within the current RDC Classic session. Ensure that you save pending changes before you begin.

Procedure

To change the current study in your RDC Classic session:

1. On the File Menu, click the Change Study menu command to open the Change Study Window.

> **Note:** If you have access to one study only, the Change Study menu command is inactive.

2. In the Select Study window, you can either:

   ■ Type the name of a study in the text box, or

   ■ Use the List of Values feature to display the studies to which you have access.

3. Click the OK button to change to the specified study.

Modify the Search Criteria

At any time during your session, you can change the workset by modifying the existing search criteria. The task is identical whether you used the Search window or the Activity List window to select the workset, when you use the Modify Search command, the Search window opens with the current search criteria selected.

Discussion

The data that is displayed in the RDC Classic Spreadsheet is the result of a query to the database that is defined by the Search window criteria or the task you select in the Activity List window (refer to "Notes" on page 5-15 for further information). You can use the Search window to modify the search criteria and so change the workset displayed in the RDC Classic Spreadsheet.

To modify the search criteria:

1. In the RDC Classic Workspace, use the **Modify Search** command on the File menu to open the Search window with the current search criteria active.

2. In the Search window, locate the criterion that you want to modify. Repeat this step for each criterion you want to modify.

3. When you have modified all criteria necessary to display the required workset in the RDC Classic Spreadsheet, click the **OK** button. The Search window closes and the system displays the new workset in the RDC Classic Spreadsheet.

Change the Current Book

There are two methods to change the current book:

■ Use the Search window

■ Select a CRF associated with a patient assigned to a book that is not active.

The first method is user-generated; the second is system generated.

Use the Search Window to Change the Active Book

To change the current book using the Search window:

1. Open the Search Window.

2. In the Book criterion area of the Search window, either:

   a. Use the drop-down list to select a Book, or

   b. Click the Default Book button to select the book that is designated as the default for the current study.

3. Click the OK button to close the Search window.

Use Data Entry to Change the Active Book

When you click a CRF icon of a patient that is not assigned to the current book, an alert window may be displayed that prompts you and provides a means to change the current book without using the Search window.

1. Click a CRF icon associated with a patient who is assigned to a book other than the current book.

    Note: The Patient Summary section of the Patients view on the Summary task tab includes a field, "Book for data entry," that specifies which book each patient is assigned to.

    ---

2. An alert window displays (refer to Figure 5–2 for an example).

Figure 5–2   Change Book Alert Window
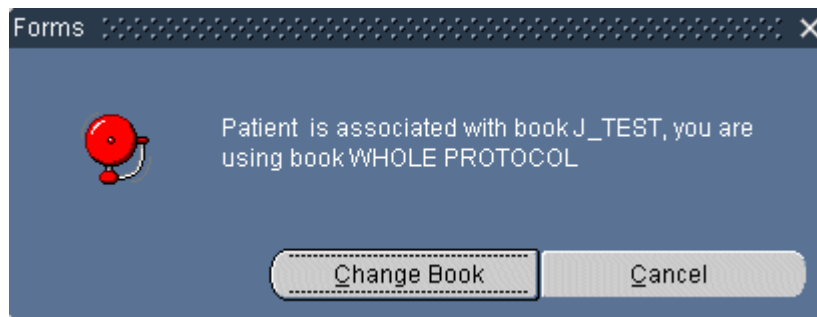
3. In the alert window, either click the **Change Book** button.

Change the Current Site

If you have access to more than one site, you can change to a different site within the current RDC Classic session. This is useful if different privileges are assigned to your user name at different sites in the study.

There are two methods available to change the current site:

■   Search Window Procedure

■   Activity List Window Procedure

Search Window Procedure

To change to another site using the Search window:

1. Open the Search Window.

2. In the Site criterion area of the Search window, either:

    ■   Use the drop-down list to select an individual site, or

    ■   Click the **All Sites** button to select all of the sites to which you have access.

3. Click the OK button to close the Search window.

Activity List Window Procedure

If the your session uses the Activity List window, you can change the current site by selecting activity from a different site node or a patient node within a different site.

1. Click the Activity List button on the RDC Classic Spreadsheet to open the Activity List Window. The node associated with the most recently selected task is highlighted.

2. Locate the node associated with the site you want to use:

> **Note:** If no patients are assigned to the site, you must choose a site-wide activity to work specifically with that site.

3. In the Task pane, select the activity you want to use in your RDC Classic session.

4. Click the OK button to close the Activity List window and populate the RDC Classic Spreadsheet with the patient associated with the task you selected.

Notes

It is possible that the privileges assigned to your user name may vary from site to site. If this is the case, you may not have access to the same set of tasks for all of the patients that are displayed in the RDC Classic Spreadsheet if they are assigned to more than one site.

Lock and Unlock CRF Procedures

This section consists of the procedures to lock and unlock a CRF.

- Lock an Individual CRF on page 5-15
- Unlock a CRF on page 5-16

Lock an Individual CRF

You can lock an individual CRF if your user name is assigned the **lock** privilege and the CRF is at the **entry complete** status.

To lock the CRF that is in focus in the RDC Classic Spreadsheet:

1. Ensure that the CRF cell associated with the CRF you want to lock is in **focus**.

2. In the CRF menu, select the **Lock** command. The system displays the Current CRF Lock Process Window.

3. In the Lock CRF window, ensure that the appropriate option check boxes are selected. Refer to the "Usage" subsection in "Current CRF Lock Process Window" on page 14-45 for information about the implications of these check boxes.

4. Click the **OK** button to close the window and lock the CRF. RDC Classic displays a confirmation window.
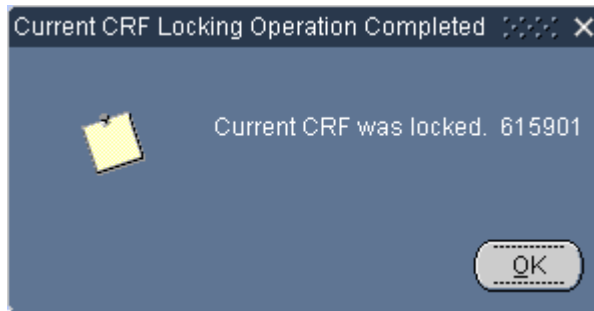
5. Click the **OK** button to close the confirmation window. The system updates the CRF icon to include its locked status.

Unlock a CRF

In contrast to the procedure to lock a CRF, which directly alters the status of a CRF, the unlock procedure requires a user with the **unlock** privilege to designate a user, or set of users, to be assigned the capability to update a locked CRF. Unlike the Group Locking Procedure, you unlock CRFs one at a time.

Each user name that is given the capability to update the locked CRF can do so, within the limitations of the privileges that are assigned to that user. For example, if a user with the **update discrepancy** privilege is given access to a locked CRF, that user is only able to work with discrepancies in the CRF. The user is not able to modify response data because **update** is not among the privileges assigned to the user.

Assign the Capability to Update a Locked CRF

To grant selected users the capability to update a CRF that is in locked status:

1. Ensure that the CRF you want to unlock is in focus.

2. In the CRF menu, select the Unlock menu command. The system displays the Users Who Can Update Window.

3. In the Users with Privileged Update window, review the list of users who currently are allowed to update the CRF. If the list is correct, skip to Step 6.

4. To add a user name to the list:

   ■ Place focus in the first empty row.

   ■ Click the Add User button.

   The system opens the Valid User Names Window, which you use to select a name to add to the list. Repeat this step until the list includes all user names you want to allow the capability to update the CRF.

5. To remove a user name from the list:

   ■ Place focus in the row that contains the name you want to remove.

   ■ Click the Delete User button.

   The system removes the user name from the list. Repeat this step until the list contains only those users you want to allow the capability to update the CRF.

6. When the list contains the correct set of users to which you want to grant the privileged update for the CRF, click the **Save** button. The system closes the window and updates the list of users who can modify the CRF.

Remove User Names from List to Lock CRF

Use this procedure after the required updates have been made to the locked CRF and you want to ensure the CRF is locked and cannot be updated further.

1. Ensure that the CRF you want to unlock is in focus.

2. In the CRF menu, select the **Unlock** command. The system displays the Users Who Can Update Window.

3. In the Users with Privileged Update window, select each listing in turn and click the **Delete User** button.

4. When the list is empty, click the **Save** button. The system closes the window and returns focus to the RDC Classic Workspace. The CRF is locked from all users.

Notes

The Unlock CRF menu command is only accessible if:

- you have the unlock privilege for a site, and

- the workset is comprised only of CRFs that are assigned to that site.

Miscellaneous Tasks During an RDC Classic Session

This section describes the following tasks that you can perform during an RDC Classic session:

- Change Preferences During a Session

- View News Items During a Session

- Use the Links Task Tab During a Session

- Access Online Help

Change Preferences During a Session

The RDC Classic administrator configures the Preferences Window settings for your RDC Classic session. However, you can modify the settings for current session. When you close RDC Classic and re-initiate a session, all settings revert to the administrator configuration.

Note also that the RDC Classic administrator may remove the **Preferences** menu command from your RDC Classic Workspace. In that situation, you cannot modify settings for your session and you can skip this section.

To change preferences during a session:

1. Select **Edit**, then **Preferences** from the option list. The system opens the Preferences window.

2. Modify the Preferences window settings.

3. Click the **OK** button. The system closes the Preferences window.

View News Items During a Session

To view the News Window during a session, select the **News** command on the File menu.

Use the Links Task Tab During a Session

The Links Task Tab provides access to the sponsor-defined information that can use the current context, such as the current study, site, patient, or CRF, to modify hyperlinks.

To use a particular link, click the Links task tab and then click the link that is of interest. If it is a contextual link, ensure that the appropriate workset is active and Spreadsheet component is in focus.

For further information, refer to "Links Task Tab" on page 13-30.

Access Online Help

There are three methods you can use to access online help in RDC Classic:

- Main Help
- Context-sensitive Help
- CRF Icon Legend

Main Help

To display Main help, click the Help menu, then the **Help** command.

Context-sensitive Help

You access GUI context-sensitive help by placing focus in the GUI fixture and pressing the F1 key. To display response field help, place focus in a datapoint in the Data Entry window and press the F1 key.

CRF Icon Legend

To display the CRF Icon Legend, select **Help**, and then select **RDC Help Topics.**

End Your RDC Classic Session

When you want to stop working with RDC Classic, there are several tasks that you should complete in order to maintain the quality and security of your data. This section outlines those tasks and provides guidance on how to exit RDC Classic.

Process Pending Changes

Before you exit RDC Classic, it is important to ascertain if there are pending changes in the system. If there are, a message window displays and provides you the options of saving changes, discarding changes, or canceling the exit RDC Classic process.

Save Pending Changes

There are several methods to save pending changes:

- Click the Save menu command.
- Click the Save toolbar button.

- Close the Data Entry window, which causes a pop-up window to display that allows you to save or discard pending changes, or to cancel the close window process and return to the Data Entry window.

Discard Pending Changes

If you wish to close RDC Classic without saving changes that are pending, simply click the No button when the message window is displayed. This prompts you to either save or discard pending changes or to cancel the "Close RDC Classic" procedure.

Exit RDC Classic

When you have dealt with any pending changes and you take action to close the application, RDC Classic will exit by closing the Main Application window. The Internet browser window that you used to start RDC Classic will remain open.

Use the following methods to exit RDC Classic:

- Click the "X" button in the upper right corner of the Main Application window.

- Select File, then Exit from the option list.

6

Select a Workset

The task of displaying patient data in the RDC Classic Spreadsheet is fundamental for all users because it is your **workset** that determines the patients and patient data that are available to you in RDC Classic. The factors that affect what is included in a workset are the security settings assigned to your user name, that is, the study and site privileges, and the CRFs that exist in the study or site(s) to which you have access.

After you select a workset, RDC Classic displays the data in the Spreadsheet:

- Patients with an associated CRF that meets the search criteria are listed in the Patient List.

- Visit tabs are aligned across the top of the Spreadsheet.

- The CRF cells associated with first visit tab and the patients in the Patient List are displayed in the matrix.

This section is comprised of the following topics:

- Discussion on page 6-1
- Using the Search Window to Select Worksets on page 6-2
- Using the Activity List Window on page 6-6
- Using Saved Searches on page 6-11

Discussion

The RDC Classic Spreadsheet is the central component in RDC Classic. It allows you to manage the patients you work with and data associated with each. This set of patients and CRFs is referred to as a workset. The workset determines what patient data are displayed in the Spreadsheet at any given time. When you initiate an RDC Classic session, one of the first tasks you complete is to choose the workset that you want to display in the Spreadsheet. There are two methods you can use to do this:

- The Search window allows you to specify parameters and criteria that narrowly define the patients and data that are presented in the Spreadsheet.

- The Activity List offers an intuitive set of tasks that allow you to choose the patients and data that are displayed in the Spreadsheet based on a description of a task.

> **Note:** The tasks that are displayed in the Activity List are highly configurable. Your system administrator is responsible for the design and implementation of the Activity List that is displayed to the participants of your study.

When you log in to RDC Classic, you are presented with one of the two windows, which allows you to specify which patients and visits you want to work on to start your session. At any time during the session, you can change the data that is displayed in the Spreadsheet by opening either of these two windows.

Default Settings

Your system administrator controls which data selection is the default for your session: the Search window or the Activity List window. This configuration setting determines which window you are presented with upon initiating an RDC Classic session. It also impacts the functionality of the Search button that is adjacent to the Spreadsheet.

Which Method to Use

If your session is setup to use either the Activity List or the Search window, the method you choose depends on the task you want to perform and the data that you need in the workset.

The tasks that are available in the Activity List window are dependent on your system administrator, however, in general, the tasks are simple and straightforward. For example: Show all data for a given site, show all discrepancies for a given patient or site, show all CRFs with active discrepancies, etc.

When you use the Search window, you choose the data that is retrieved from the study database and displayed in the RDC Classic Spreadsheet. This is because only those CRFs that satisfy the criteria you specify in the Search window are displayed in the Spreadsheet. The Search window gives you the capability to specify a very narrow set of search criteria to return a limited workset.

The implication of this is:

- Only patients with at least one CRF that meets the Search window criteria are displayed.

- Only CRF columns with at least one CRF that meets the Search window criteria are displayed.

Access

The system presents the default data selection method when you start an RDC Classic session. If the Search window is the default, your session is not configured to use the Activity List window, and it is not available in your RDC Classic session. However, if the Activity List window is the default, the system displays it at session startup and it is available throughout the session, however, you have the option to also use the Search window to specify the workset.

When either the Activity List window or the Search window is displayed immediately after session startup, you must select a task (Activity List) or criteria (Search) before the system displays the RDC Classic Workspace. Alternatively, you can change the study from either window.

Using the Search Window to Select Worksets

This section describes the various ways you can configure the Search window criteria to support the tasks you want to complete in RDC Classic.

Strategies to Best Use the Search Window

A critical point to remember when you are making selections in the Search window is that the choices you make for more general criteria usually affect the choices that are available to you in more specific criteria. This is also true for certain choices that are available within a particular subsearch window when you change more than one parameter.

The first two choices you can make in the Search window specify the Book and the Site in which you will work. Along with choosing a study, which is done when you first log on, these choices determine the framework within which you will enter, update, and review data. They also control, to a large degree, the default settings and choices that are available to you as you change other parameters in lower-level criteria.

Common Search Window Tasks

This section provides procedures for a variety of multi-criteria Search window tasks. Because the Search window allows you to define data sets that can be based on a large, discrete set of parameters, one purpose of the tasks described here is to offer general guidance about the ways you can use the Search window to construct complex searches based on multiple criteria and parameters.

This section includes the following topics:

- Find all Discrepant CRFs at a Site on page 6-3
- Find all CRFs from a Date Range for Set of Patient Numbers on page 6-3
- Find all Specific Type CRFs that Require Re-verification on page 6-4

Find all Discrepant CRFs at a Site

To define a data set that includes only those CRFs that have "Active" or "Other" discrepancies and are associated with patients at a specific site:

1. In the Search window, click the **Sites** drop-down list arrow and select the site you want.

2. Click the **Specify...** button for the CRF Status criterion to open the CRF Status Subsearch Window.

3. Click the **Discrepancies** drop-down list arrow and select, "With actionable or other discrepancies."

4. Click the **OK** button to close the subsearch window.

5. Click the **OK** button to close the Search window.

Find all CRFs from a Date Range for Set of Patient Numbers

To define a data set that includes all CRFs that were created during range of dates for a set of patient numbers:

1. In the Search window, click the **Specify...** button for the Patients criterion to open the Patients Subsearch Window.

2. In the first **Patient** drop-down list, select a patient number that starts the patient number range.

3. In the second **Patient** drop-down list, select a patient number that ends the patient number range.

4. Click the **OK** button to close the Patients Subsearch window.

5. In the Search window, click the **Specify...** button for the Date Window criterion to open the CRF/Visit Dates Subsearch Window.

6. Ensure that the values in the first two drop-down lists are "CRFs," and "were created," respectively.

7. In the first drop-down list on the second line, select the value, "Between." A third drop-down list box is displayed.

8. In the second drop-down list, select a CRF creation date that starts the date range.

9. In the third drop-down list, select a CRF creation date that ends the date range.

10. Click the **OK** button to close the subsearch window.

11. Click the **O**K button to close the Search window.

Find all Specific Type CRFs that Require Re-verification

To define a data set that contains all of the CRFs of a given type that currently require re-verification (due to data changes since verification):

1. In the Search window, click the **Specify...** button for the CRF Status criterion to open the CRF Status Subsearch Window.

2. In the **Verification status** drop-down list, select "Awaiting re-verification."

3. Ensure that all other parameters are set to default values ("<ALL>").

4. Click the **OK** button to close the subsearch window.

5. In the Search window, click the **Specify...** button for the Date criterion to open the Data Subsearch Window.

6. In the **CRF** drop-down list, select the type of CRF that you want to include (e.g., PE for all Physical Exam CRFs).

7. Click the **OK** button to close the subsearch window.

8. Click the **OK** button to close the Search window.

Worksets for Discrepancy Management

To define a workset for discrepancy management:

1. In the Search window, click the **Specify...** button for the CRF Status criterion to open the CRF Status Subsearch Window.

2. In the **Discrepancy status** drop-down list, select "With actionable discrepancies". (To include all open discrepancies, that is, both active and other statuses, select "With actionable or other discrepancies".)

3. Ensure that all other parameters are set to default values.

4. Click the **OK** button to close the subsearch window.

5. In the Search window, click the **OK** button. The system closes the window and loads a workset comprised of all CRFs with active discrepancies.

Specify a Workset for Group Procedures

Because of the nature of the group activities commands, it is generally best to select a workset that includes only those CRFs that you want to include in the group activity. Although you can undo the approval and verification actions, each action is audited in

the audit history of each affected CRF. In addition, there is not a group unlock action, so the lock option should be carefully managed.

Define a Workset to Change Verification Status of a Group

To define a workset suitable for the group verify action:

1. In the Search window, click the **Specify...** button for the CRF Status criterion to open the CRF Status Subsearch Window.

2. In the CRF Status drop-down list, select, "Entry or Pass 2 Complete". This includes in the workset only those CRFs for which data entry is finished.

3. In the Discrepancy status drop-down list, select, "Without discrepancies". This includes in the workset only those CRFs that are "clean".

4. In the Verification status drop-down list, select, "Not verified". This includes in the workset only those CRFs that are not source document verified.

5. In the Approval status drop-down list, select "Not approved". This includes in the workset only those CRFs that are not approved.

6. In the Lock status drop-down list, select "Unlocked". This includes in the workset only those CRFs that are not locked.

7. Click the **OK** button to close the subsearch window.

8. In the Search window, click the **OK** button. The system closes the window and loads a workset comprised of all CRFs that are suitable for verification.

Selecting a workset for group undo verify is similar to this, modify the parameters as necessary to define the appropriate workset.

Define a Workset to Change Approval Status of a Group

To define a workset suitable for the group approval action:

1. In the Search window, click the **Specify...** button for the CRF Status criterion to open the CRF Status Subsearch Window.

2. In the CRF Status drop-down list, select, "Entry or Pass 2 Complete". This includes in the workset only those CRFs for which data entry is finished.

3. In the Discrepancy status drop-down list, select, "Without discrepancies". This includes in the workset only those CRFs that are "clean".

4. In the Verification status drop-down list, select, "Verified". This includes in the workset only those CRFs that have been source document verified.

5. In the Approval status drop-down list, select "Not approved".

6. In the Lock status drop-down list, select "Unlocked". This includes in the workset only those CRFs that are not locked.

7. Click the **OK** button to close the subsearch window.

8. In the Search window, click the **OK** button. The system closes the window and loads a workset comprised of all CRFs that are suitable for approval.

Selecting a workset for group undo approval is similar to this, modify the parameters as necessary to define the appropriate workset.

Using the Activity List Window

The Activity List window allows you to select the task, termed an *activity*, that you want to complete during an RDC Classic session. Your choice of activity causes the system to load a **workset** that includes the CRFs necessary to complete that task.

For example, if your task is to review **active** discrepancies for a patient, you would select an activity such as, "Review 12 active discrepancies for Patient 101." The system would load a workset in the RDC Classic Spreadsheet that consisted of all CRFs for Patient 101 that contain at least one active discrepancy.

Figure 6–1 depicts a typical example of the Activity List window.

Figure 6–1   Activity List Window
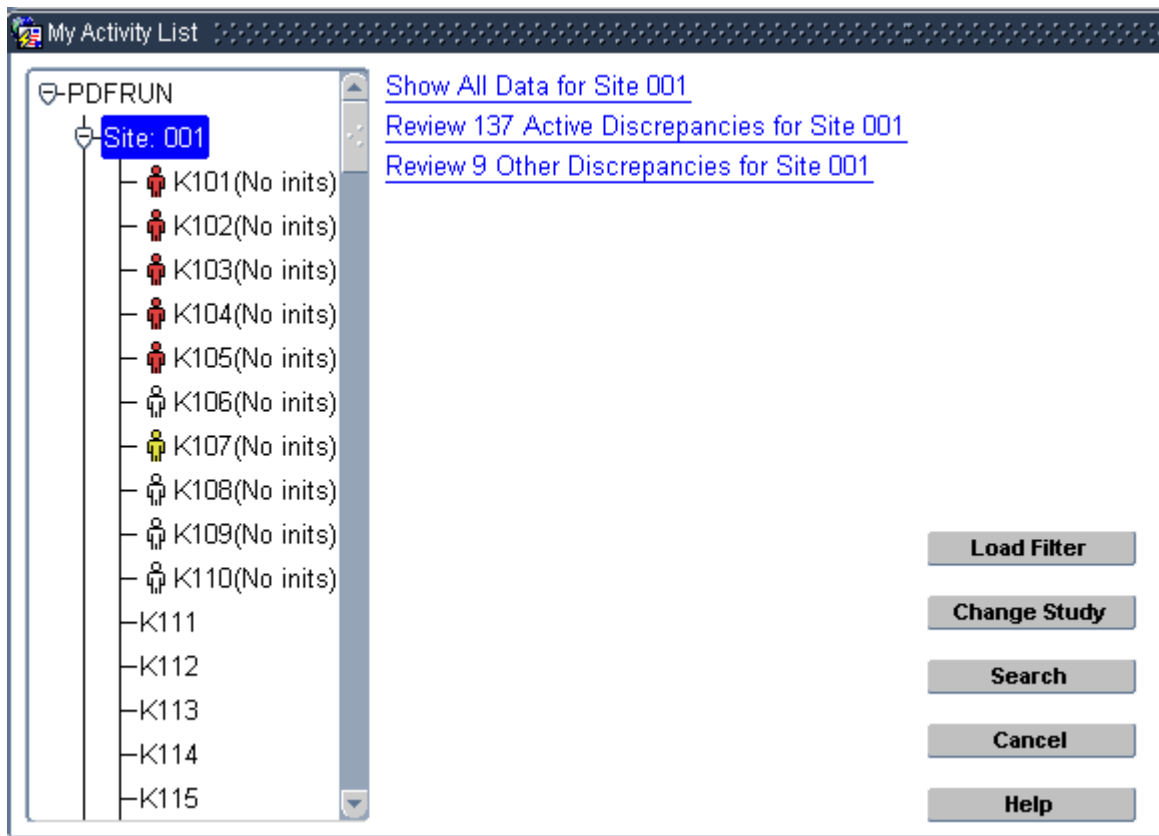
Discussion

As an alternative to the Search Window, the Activity List window offers you an intuitive method of working in RDC Classic. Each task is a descriptive statement that informs you about the data you will work with to perform the task.

The topics in this section describe the general properties of the Activity List window and discuss the variations in the tasks that appear in your Activity List; a section also describes how different RDC Classic configurations affect whether the Activity List window is accessible in your session.

Alternative to Search Window

The Activity List window is an alternative to the Search window. When your RDC Classic session is configured to use the Activity List, you can also access the Search window.

Each task that present in the Activity List corresponds to a specific set of search criteria. When you select a task, its associated search criteria are loaded into the Search window, which then causes the data that satisfies that query to be displayed in the RDC Classic Spreadsheet.

Because the Activity List uses the Search window to query and display a set of data, when you select **File**, then **Modify Search** from the option list, or click the Search button on the Activity List window, the Search window opens with the criteria that were defined by the last task you chose.

Configuration Settings

The sponsor defines a configuration setting that specifies the default data selection tool for you. This is either the Activity List window or the Search Window. In most cases, the Activity List is specified your RDC Classic session and the system presents the Activity List window when you log in to RDC Classic. However you can still access the Search window, either while the Activity List window is open or from the File menu.

If the configuration settings specify that the Search Window is the default data selection tool, the Activity List window is not available in your session. In this case, refer to "Search Window" on page 15-1.

Interaction with the Summary Task Tab

When the Activity List window is open, it is positioned just above the task tab area of the RDC Classic Workspace. The Study Summary View task tab is automatically displayed when you open the Activity List window. As you view different sets of tasks, the view in the Summary Task tab changes to either Site Summary View or Patient Summary View.

Refer to "Summary Task Tab" on page 13-2 for further information about the views that are displayed when the Activity List window is open.

Access the Activity List Window

When the Activity List window is available in your session, it is the default data selection tool. There are two situations in which you can access the Activity List window:

1. Session Startup

2. During a Session

You can also access the Search window, both from the Activity List window and through File menu commands.

Session Startup The system automatically displays the Activity List window after you complete the session startup process. When it is displayed you are logged in to the study database and a study is selected. Refer to "Start Your RDC Classic Session" on page 5-1 for information about session startup, study selection, and other windows that may display before the Activity List window displays.

During a Session You can access the Activity List window during a session by clicking the Activity List button that is below the list of Current Patients.

Accessing the Activity List Window

When your configuration is setup to use it, the system displays the Activity List window during session initiation. You can also access it anytime during the session.

Initial Display of the Activity List Window

The Activity List window is displayed automatically when you start an RDC Classic session. (Refer to "Start Your RDC Classic Session" on page 5-1 for complete information about this process.)

When the system displays Activity List window so that you can select an initial workset to display in the RDC Classic Spreadsheet, the scope of the Navigation pane is set to the study level.

> **Tip:** If you are unsure what task to choose, a good starting point is to place focus on the Site node and select the "Show all data" task. This displays all accessible patient data for the site.

The underlying requirement to these options is that you must define an initial workset to display in the RDC Classic Spreadsheet before the system allows you access to the RDC Classic Workspace.

Open the Activity List Window

You open the Activity List window during an RDC Classic session when you want to change the current workset. There are two methods you can use to open the Activity List window from a RDC Classic session:

1. Activity List command in the File menu, or

2. **Activity List** button adjacent to the RDC Classic Spreadsheet

When you open the Activity List window during a session:

- The active node is highlighted in the Navigation Pane; this reflects either:

    - The node associated with the most recently selected task, or

    - The node associated with the most recently defined Search window criteria

- The system displays the Summary Task Tab below the Activity List window. The task tab is set to the summary view associated with the active node. (Refer to "Interaction with the Summary Task Tab" on page 6-7 for further information.)

Access the Activity List Window

When it is configured for your session, RDC Classic displays the Activity List window:

1. Upon initial entry into your RDC Classic session

2. When you click the Activity List button that is adjacent to the Spreadsheet.

RDC Classic Session Startup The Activity List window is displayed after you start an RDC Classic session. (Refer to "Start Your RDC Classic Session" on page 5-1 for complete information about this process.) After you successfully log in to RDC Classic, you must use either the Activity List window or the Search Window to select a workset that the system displays in the RDC Classic Spreadsheet. The difference between these two methods is:

- The Activity List allows you to choose the task that you want to complete in RDC Classic – the search criteria is defined indirectly based on that task.

■ The Search window allows you to directly define a custom set of search criteria.

During an RDC Classic Session To use the Search window when the Activity List window is configured for your session, click the Search button, which is adjacent to the RDC Classic Spreadsheet.

Usage

The primary use for the Activity List window is load a workset in the RDC Classic Spreadsheet that contains only the data necessary for you to complete your task. You do this when you select an activity.

The most common tasks you use the Activity List window for are to select an activity, change an activity, and view patient, site, and study information. These are described in the following sections:

■ Select an Initial Activity

■ Change the Current Activity

■ View Sites and Patients in the Navigator Pane

■ View Activities Associated with a Node

■ View Summary Information

■ Change Studies from the Activity List Window

■ Access the Search Window from the Activity List Window

■ Close the Activity List Window

Select an Initial Activity

When the Activity List window displays as part of the RDC Classic session initiation, you use it to choose an activity.

1. In the Activity List window, locate and select the appropriate scope in the Navigation pane. This can be either the study name, a site name, or a patient number.

2. In the Task pane, click an activity that matches the task you want to complete. The system closes the Activity List pane, loads the workset, and displays it in the RDC Classic Workspace.

Change the Current Activity

You change the workset that is displayed in the RDC Classic Spreadsheet by either selecting another activity or modifying the search criteria. Refer to "Modify the Search Criteria" on page 5-13 for the latter option.

To change the current Activity List task:

1. In the RDC Classic Workspace, click the Activity List button. The Activity List window opens. The node associated with the current task is selected.

2. In the Navigator pane, select a node to view its set of activities in the Task pane.

3. Click an activity in the Task pane. The Activity List window closes and the workset that is defined by the task is displayed in the RDC Classic Spreadsheet.

View Sites and Patients in the Navigator Pane

When the Activity List window is open, the current study is displayed in the Navigator pane and all of the sites in the study to which you have access are listed below it. If there are patients associated with a site, the icon adjacent to the site listing contains a plus sign. To display the list of patients that are assigned to a site, click the icon, which expands the tree.

View Activities Associated with a Node

The Task pane displays the activities that are associated with the currently selected node. To view the activities for a particular node, click the node to select it and then review its associated activities in the Task pane.

View Summary Information

When the Activity List window is open, the system positions it on top of the relevant information is displayed in the Summary Task Tab, which is located can be viewed when the Activity List window is open. The particular "view" of the Summary task tab that is open depends on the node. When the Activity List window is opened, the Study node is selected and the Study view is displayed in the Summary Task tab.

When you click a Site node, the corresponding Site view is displayed in the Summary Task tab.

When you click a Patient node, the corresponding Patient view is displayed in the Summary Task tab.

Change Studies from the Activity List Window

If you have access to more than one study, click the **Change Study** button, which opens the Change Study Window.

Access the Search Window from the Activity List Window

If the activities presented in the Task pane of the Activity List window do not correspond to the data you want to use for a particular job, you can use the Search window, which allows you to narrowly define a patient workset.

When the Activity List window is open, click **Search** to open the Search window.

- If you are in the process of initial startup of your RDC Classic session, the Search window criteria will be set to default values.

- If you open the Activity List window during your RDC Classic session and then open the Search window, the parameters and criteria that were set to enable the task you most recently selected will be set in the Search window.

Close the Activity List Window

Click the Cancel Button to close the Activity List window without selecting an activity. If you opened the window during a session, the **Cancel** button closes it and focus reverts to the RDC Classic Workspace and the same workset.

If you attempt to close the Activity List window during session initiation, the system requires that you:

- Return to the Activity List window and select an activity or open the Search window

- Change the study

- Exit RDC Classic

Using Saved Searches

RDC Classic permits you to save a search so that you can use it at a later time. This adds efficiency and consistency to your workflow because it allows you to use the Search window to define a complicated set of criteria and then save those criteria for use at a later time. In this way, you can use saved searches to generate a workset based on the same criteria each time you use RDC Classic.

If you perform several types of tasks in RDC Classic, you can create a saved search that corresponds to each task and then switch between those worksets during a single RDC Classic session. Because you can use a saved search as filter, you can still use the Activity List window to load a workset.

This following topics describe various aspects of saved searches:

- Overview of Saved Searches
- Components of a Saved Search
- Scope of a Saved Search
- Default Search/Filter
- Saved Search Tasks
- Maintaining Saved Searches

Overview of Saved Searches

You can use a saved search in three primary ways:

1. You can load it into the Search window, where you have the option to further modify the criteria or generate the workset.

2. You can set it as a filter in the Activity List window, where it can limit the scope of the navigation tree and/or the number or extent of the activities available.

3. You can run it directly in the RDC Classic Workspace to immediately load the workset that is based on the criteria in the saved search.

In addition, you can designate one saved search to be a default, which means that it is automatically loaded each time you initiate an RDC Classic session. This allows you to pinpoint the workset that you want to work with each time you initiate an RDC Classic session.

Components of a Saved Search

Each saved search has associated with it certain components that:

- Uniquely identify it
- Describe its search criteria
- Specify what set of users can use it, including:
  - Who can access and use it
  - Who can modify it

The name that is associated a saved search uniquely identifies it within the study database. RDC Classic prevents you from saving a search with a name that already exists.

The description of a saved search is generally based on the search criteria. Its initial value is the same as the description that is displayed in the RDC Classic Spreadsheet

Status Line. The search criteria define how the saved search interacts with the dataset when it is loaded, either in the RDC Classic Workspace, or in the Search window or the Activity List window. For example, "Site 001, CRFs with actionable discrepancies", limits the resultant workset to patients assigned to Site 001 for which there are associated CRFs with one or more **active** discrepancies.

The scope values specify who can use the saved search and who is able to modify it. The scope of a saved search determines if it is available to you within the current study and if you are able to make changes to it.

Scope of a Saved Search

There are three parameters associated with a saved search that determine which users have access to the search and in what study the search is available for use. These parameters, which are termed *scope values*, are:

- User

- Study

- Role

You can view the scope values for a saved search in the Maintain Saved Search Window. In order to be able to use a particular saved search, the set of scope values must align with your corresponding user information.

Each scope value can be set either to its default value, "%" (percent sign), which means "ALL", or it can be set to a specific value. However, only two scope values can be set to non-default values, that is, a value other than "%", at the same time:

- Role and study can be set to specific values

- Study and user can be set to specific values

- Role and user **cannot** be set to specific values

The role scope can be set to "%", which makes the associated saved search available to all users, or it can be set to a specific role, which limits the search to all users assigned to that role for the studies in the database. However, if the study scope is also specified, the saved search is available to all users of a the given role who have access to the specified study.

The study scope can be set to "%", which makes it available in all studies in the database or it can be set to a study name, in which case it limits the availability of the search to those users who have access to that study. For example, for a given saved search with a role scope of "CRA", which makes the search available to any user assigned to the CRA role, setting the study scope to "STUDY01" limits the search to CRA users who have access to STUDY01.

The user scope can be set to "%", which makes it available to all users in the database (within the constraints of the study scope) or it can set to a user name. If the study scope is set to a specific study, the user scope can only be set to a user who has access to that study. If the User scope is set to a user name and Study scope is set to its default, the saved search is available to that user in each study to which the user has access.

Default Search/Filter

After you have created one or more saved searches, you can choose one to use as the default search/filter for the current study. In the Search window and in the RDC Classic Workspace, the default search quickly selects the criteria that define it. In the

Activity List window, the default filter can limit the activities that are displayed in the Task pane and the Site and/or Patient nodes that are displayed in the Navigation pane.

You can designate one default search/filter at a time for a given study. Even if the Study scope of the default saved search is "%" (or "ALL Studies"), which allows you to access and use the saved search in any study to which you have access, when you make that search the default, it is only the default for the current study. In order to make it the default for a different study, you open that study and then designate the search as the default in that study.

Default Search in the Search Window

When a search is specified as a default, the system loads its criteria each time the Search window opens, including at session initiation. This allows you to either use the search criteria as-is to load a workset or use the criteria as a starting point and then further modify the Search window parameters. This gives you the capability to use a "base" set of search criteria and then modify that as your various tasks demand.

> **Note:** When you select a default saved search, the system does not automatically load it. To do that, open the Search window and click OK to accept the criteria for the default search.

Default Filter in the Activity List Window

When the saved search is used as a filter for the Activity List window, its search criteria are used to limit, or filter, the patient data the is available in the Activity List window. This typically reduces the activities and/or the navigation tree scope of the Activity List window. The effect of this is that you are presented with a more restricted set of activities from which to choose in the Activity List window Task pane.

Saved Search Tasks

This section describes the tasks associated with saved searches. Some tasks are useful for selecting a workset, others describe how to create and maintain your set of saved searches.

- Save a Search on page 6-13
- Load a Saved Search on page 6-14
- Modify an Active Saved Search on page 6-15
- Load a Filter in the Activity List Window on page 6-15
- Deactivate a Saved Search or Filter on page 6-15
- Specify a Default Search or Filter on page 6-16

Save a Search

You save searches from the RDC Classic Workspace. When you save a search, the system associates the currently active search criteria, which were used to load the **workset**, with the saved search. You can view a description of the search criteria in the RDC Classic Spreadsheet Status Line or you can open the Search window (**Modify Search** command in the File menu) and review each criterion prior to starting this procedure.

All RDC Classic users are able to save searches.

To save a search:

1. Use the Search window or, alternatively, the Activity List window, to define the required search criteria.

2. Use the Save Search command in the File Menu. The system displays the Save Current Search Window.

3. In the Save Current Search window:

   a. Enter a unique title for the search in the **Name** text field.

   b. Modify the text in the Description text box, if necessary. By default, the description is the same as the text in the RDC Classic Spreadsheet status line.

   c. Select the **Save as my default...** check box if you want the search to be designated the default for this study.

   d. Click the **Save** button.

4. The system closes the Save Current Search window and saves the search criteria and associated information.

Load a Saved Search

You can load a saved search from either the RDC Classic Workspace or from the Search Window. When you load a search from the RDC Classic Workspace, the system immediately uses the search criteria to generate a workset and displays it in the RDC Classic Spreadsheet. When you load a search in the Search window, you have the option to further modify the criteria before you generate the workset.

From the RDC Classic Workspace To load a search from the RDC Classic Workspace:

1. Use the Load Search command in the File Menu. The system displays the List of Saved Searches Window.

2. Select a saved search from the list. Use the Find tool, if necessary.

3. Click **OK**. The system uses the search to generate a workset and displays it in the RDC Classic Spreadsheet.

When a saved search is loaded, the system displays its name and description in the RDC Classic Spreadsheet Status Line, using the following format:

<Name_of_Saved_Search> == <Description_of_Search_Criteria>

From the Search window To load a search from the Search window:

1. Open the Search Window.

2. Click the **Load Search** button. The system displays the List of Saved Searches Window.

3. Select a saved search from the list. Use the Find tool, if necessary.

4. Click **OK**. The system returns focus to the Search window and modifies the relevant criteria/parameters.

5. If you want to further modify the search criteria, use the subsearch windows to make changes.

6. When the criteria are set, click the **OK** button to close the Search window. The system loads the workset.

When a search is loaded, the Search window title bar displays the name of the saved search.

Modify an Active Saved Search

One of the primary purposes of a saved search is to use it as baseline search criteria that you then modify after it is loaded. You can do this when either the Search window or the Activity List window is the default workset selection tool.

> **Note:** When a saved search is active, the system displays its name in the title bar of the Search window and Activity List window. It also displays its criteria description in the RDC Classic Spreadsheet Status Line.

To modify the search criteria of a saved search or filter that you have loaded:

1. Use either the **Search** button in the Activity List window or the **Modify Search** command in the File menu to open the Search window.

2. Modify the search criteria, as necessary.

3. Click the **OK** button to close the window and load the workset in the RDC Classic Workspace.

Note that the saved search is no longer active, you have simply used it as a starting point to further modify the search criteria.

Load a Filter in the Activity List Window

To load a filter in the Activity List Window:

1. Open the Activity List window.

2. Click the **Load Filter** button. The system displays the List of Saved Searches Window.

3. Select a saved search from the List table. Use the Find tool, if necessary.

4. Click **OK**. The system returns focus to the Activity List window and adjusts the scope in the Navigation pane and/or the activities in the Task pane, as determined by the criteria of the filter.

5. Select an activity from the Task pane.

Deactivate a Saved Search or Filter

When a saved search is active, there are two methods you can use to remove it:

1. exchange it by making a different saved search active

2. remove it by specifying that no search is active

To deactivate a saved search or filter:

1. Open the List of Saved Searches Window.

2. Select an entry in the List table:

   a. To clear all saved searches, select the "<Remove Filter>" row.

   b. To make a different search active, select its row.

3. Click the OK button to close the window.

The system reverts focus to the previous window – either the RDC Classic Workspace, the Activity List window, or the Search window. If you selected a different search/filter, the system displays its name in the title bar of the active window.

You can also reset a saved search by opening the Search window with default criteria. To do this, use the **New Search** command in the **File** menu. This action opens the Search window with all criteria set to default values.

Specify a Default Search or Filter

You specify a default search in the following ways:

- Use the **Save as my default search/activity list filter for current study** check box in the Save Current Search Window

- Use the **Default** check box in the appropriate row of the Maintain Saved Search Window

For further information about these components, refer to the Components and Usage sections in "Save Current Search Window" on page 14-16 and the "Maintain Saved Search Window" on page 14-19.

Maintaining Saved Searches

The area of maintaining saved searches is one of the few in which RDC Classic makes a distinction between a user who is an **RDC administrator** and one who is not.

All RDC Classic users have the capability to manage saved searches that are available to them in the current study. In addition, each user is permitted to modify any saved search with a User scope value of that user's user name. An RDC Classic administrator also has the capability to view and maintain any saved search in the study database.

This section includes the following topics:

- General Rules for Maintaining Searches

- Maintain Save Search Rules for Non-Administrator Users

- Maintain Saved Search Rules for Administrator Users

- Change the Study Scope of a Saved Search

- Create a Copy of a Saved Search

- Delete a Saved Search

- View the Query Associated with a Saved Search

General Rules for Maintaining Searches

This section outlines the functionality of the Maintain Searches window for all users. Some areas of functionality are not covered here because the behavior differs for typical, non-administrator users as compared to RDC Classic administrator users. Refer to subsequent sections for this information.

1. When a user saves a search, the system sets the scope values as follows:

   - User = the user name of the user

   - Study = the name of the current study

   - Role = "%"

2. A saved search with a User scope of "%" can only be modified by a user with administrator privileges.

3. A saved search with a User scope of a specific user name can be modified by that user or any user with administrator privileges.

4. When the User scope is set to a specific user name, the Study scope LOV lists only those studies to which that user has access.

5. When the Study scope is set to a specific study name, the User scope LOV lists only those users who have access to that study.

6. When you create a copy of a saved search, the system assigns the following values to it:

Parameter	Value
Name	"Copy of *<saved_search_name>*"
Description	Same text as the original search
User scope	The user name of the person who created the copy.
Study scope	Same study name as the original search
Role scope	"%"

Maintain Save Search Rules for Non-Administrator Users

This section outlines the functionality of the Maintain Searches window for general users, that is, those who are not RDC Classic administrators. Use this list, in conjunction with "General Rules for Maintaining Searches" on page 6-16, to determine how you can use the Maintain Searches window to manage your saved searches.

1. The list of searches that are available in the Maintain Saved Search Window consists of those that satisfy the User/Study/Role scope values for the current user and study.

2. You can copy or set as default any saved search in the Maintain Saved Search window.

3. You can modify or delete any saved search with a User scope value of your user name.

4. You can only change the User scope to another user name; you cannot change it to its default value ("%"). You select a new User scope value from among those users who have access to the study scope for that search.

5. When you change the User scope to a different user name, which normally means the search is no longer displayed in the list, the system permits you to make further changes to it until you close the Maintain Saved Search window. This allows you to correct the parameters in case you mistakenly change the User scope.

   When you re-open the window searches with different user names in the User scope are not included in the list of searches.

6. You can change the Study scope to value selected from among the studies to which you have access. Note the limitations of this action that are described in the "Change the Study Scope of a Saved Search" on page 6-18.

7. You cannot modify the Role scope from its default value ("%").

Maintain Saved Search Rules for Administrator Users

This section outlines the functionality of the Maintain Search window for RDC Classic administrators. Use this list, in conjunction with "General Rules for Maintaining Searches" on page 6-16, to determine how you can use the Maintain Searches window

to manage both your saved searches, as well as any search that is defined in the database.

1. You can manage searches either in RDC Classic or through RDC Classic Administrator application.

2. The list of searches available in the Maintain Saved Search window consists of all saved searches in the database.

3. You can copy, modify, or delete any saved search.

4. The User and Role scopes cannot simultaneously be set to non-default values:

   ▪ For a saved search with a non-default User scope, when you modify the Role from its default value, the system resets the User to "%"

   ▪ For a saved search with non-default Role scope, when you modify the User from its default value, the system resets the Role to "%".

Change the Study Scope of a Saved Search

Certain parameters that you can modify in the Search window are dependent on data that can vary from study to study. For example, one study may designate sites as "Site_01, Site_02,...", while a different study designates sites as, "Site A, Site B,....." Search criteria based on this type of parameter is termed *study-specific*. There are certain factors to consider when you are working with saved searches that include non-default values for this type of criteria. (Refer to the Study-specific search criteria section, below.)

When you change the Study scope of a saved search to a different study, you make the saved search available in that study. However, doing so could render the search useless if its search criteria refer to information or data that does not exist in the study. For example, a Site criterion of a saved search that specifies "Site_03", cannot be used in a study that identifies sites as, "Site A, Site B...etc." For this reason, RDC Classic changes all study-specific search criteria to default values when you change the Study scope to a different name.

Figure 6–2   Changing Study-specific Saved Search
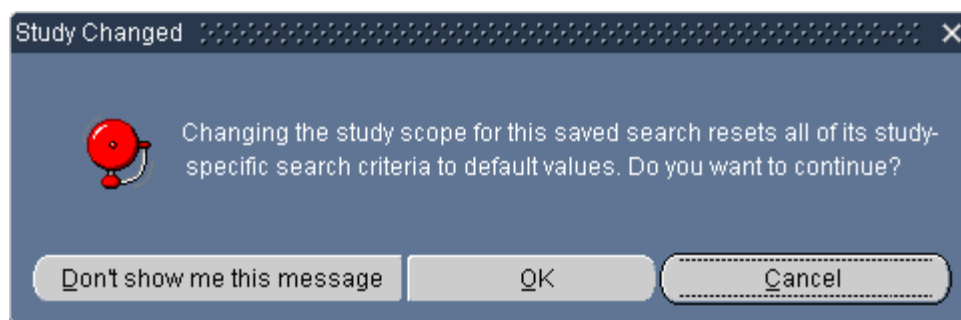
Study-specific search criteria A saved search is designated as *study-specific* if certain of its parameters are set to non-default values. These parameters are those that typically change from one study to another. These criteria/parameters are listed in the following table along with the relevant Subsearch window, where appropriate.

Criteria/Parameter	Location in Search window
Book	Search window criterion
Site	Search window criterion

Criteria/Parameter	Location in Search window
Patient (From/To)	Patients Subsearch window
Visit Date Range (Start/End)	CRF/Visit Dates Subsearch window
Visit (Phase, Visit From/To, Page From/To)	Visit/Pages Subsearch window
All Parameters	Data Subsearch window

Changing the Study Scope If you change the Study scope of saved search with study-specific criteria, the system resets those criteria to default values, after first giving you the option of canceling the action.

1. In the Maintain Saved Search window, highlight the row that contains the search you want to modify.

2. Place focus in the Study scope field for the selected row and click the LOV button. The List of Studies window opens, displaying the set of available studies.

3. Select a study and click the OK button. The window closes and the Study Changed window opens.

4. In the Study Changed window, click the OK button. The window closes and focus reverts to the Maintain Saved Search window.

> **Note:**   If you click the **Don't show me this message** button, the system does not display the window while the Maintain Saved Search window is open. If you close and then re-open the Maintain Saved Search window, the Study Changed window is displayed again.

5. Click the Save button.

Create a Copy of a Saved Search

You can make a copy of any saved search that is listed in the Maintain Saved Search Window.

> **Note:**   Refer to "General Rules for Maintaining Searches" on page 6-16 for information on the parameters the system assigns to a new copy of a saved search.

Figure 6–3   Copy Search Window

To save a copy of a search:

1. In the Maintain Saved Search window, highlight the row that contains the search you want to copy.

2. Click the **Save As** button. The system displays the Copy Search window.

3. Modify the fields in the Copy Search window as necessary.

4. Click the **Save** button. The system reverts focus to the Maintain Saved Searches window.

5. Click the **Close** button. The system closes the window and reverts focus to the RDC Classic Spreadsheet.

Delete a Saved Search

To delete a saved search:

1. In the Maintain Saved Search window, highlight the row that contains the search you want to copy.

2. Click the Delete button. The system displays a confirmation window that names the search about to be deleted.

3. Click the OK button. The system dismisses the confirmation window, deletes the saved search and reverts focus to the Maintain Saved Search window.

> **Note:** Refer to "General Rules for Maintaining Searches" on page 6-16 for information on the circumstances under which you can delete a saved search.

View the Query Associated with a Saved Search

As an RDC Classic administrator, you can use the Maintain Saved Search window as means to troubleshoot other aspects of RDC Classic administration. In particular, you use one of its tools to quickly and accurately generate the SQL statement that is associated with a saved search, which you can then analyze and use in SQL*Plus to run against the database of your choice. You may find this useful as you develop activities for the Activity List window.

To view the query:

1. Click the **View Query** button in the Maintain Saved Search Window. The system opens the SQL Query window.

2. Set the parameters that you want to use in the query:

   a. Saved Search – initially set to the name of the selected search

   b. Study – initially set to the scope value of the selected search

   c. Site – initially set to '%', can also be set to specific site

   d. Role – use the LOV to select a role

   > **Note:** A role must be specified in order to return correct metrics for 'actionable' and 'other' discrepancies, should the Search include such parameters.

3. When the parameters are set, click the **Get SQL** button. The system displays the query statement in the text box. You can select

4. You can modify any of the parameters and retrieve the resultant SQL as many times as you wish.

7
Group Activities

The majority of the functions that you use in RDC Classic affect an individual CRF. Group activities, in contrast, allow you to alter the status of multiple CRFs in a single operation. Using commands in the **Group Activities** menu, you can change the verification, approval, or lock status of the CRFs that comprise the current **workset**.

This section outlines the tasks that use group activities, discusses the factors that affect your access to the menu commands, and describes the steps to successfully complete each task. It consists of the following subsections:

- Discussion on page 7-1
- Group Verification Procedures on page 7-6
- Group Approval Procedures on page 7-9
- Group Locking Procedure on page 7-12

Discussion

This section provides general information about all of the tasks that are available using the Group Activities menu commands and discusses how other RDC Classic components can affect these tasks.

> **Note:** Refer to "Group Activities Menu" on page 11-11 for information about each menu command, including shortcut key designations.

The following subsections describe the factors that impact the group activities tasks.

- Workflow on page 7-1
- Worksets on page 7-2
- Group Activities Interaction with Other RDC Classic Components on page 7-2
- Access on page 7-5

Workflow

Use the following workflow as a starting point for the commands available through the Group Activities menu.

1. Use either Search or Activity List to specify a workset that includes the CRFs you want to include in the group activity.

2. Choose the Group Activities menu command that corresponds to the procedure you want to run.

3. In the processing window, select those CRFs that you do not want to include in the procedure, if applicable.

4. Run the procedure.

5. Review the status window and note the number of CRFs that the procedure updated.

> **Note:** After a group activity successfully runs and you close the status window, you may notice a slight delay while the system updates the RDC Classic Spreadsheet to display the current status of the CRF icons.

Worksets

Because each group activity evaluates all CRFs in the workset, the tasks that are available from the Group Activities menu may affect a large number of CRFs in a single action. Therefore, use care when employing these commands. In particular, you may want to limit the size of the workset when you use the Group Locking Procedure because, unlike the verification and approval group activities, there is no mechanism to "undo" the lock status of more than one CRF at a time.

A key factor in successfully using any of the commands in the **Group Activities** menu is to take into account that these functions act upon the entire workset. This includes:

■ CRFs that have been updated such that they no longer meet the **search criteria**

■ unplanned CRFs that are not currently displayed in the RDC Classic Spreadsheet

■ CRFs for patients that are not in the current patient list

■ CRFs that are in a RDC Classic Spreadsheet tab that is not currently visible.

Group Activities Interaction with Other RDC Classic Components

This section describes how other RDC Classic components impact a Group Activities task. Each of these factors are listed and briefly described in Table 7–1, and are more fully discussed in the relevant subsections.

Table 7–1   Factors that Affect Group Activities

Condition	Description	Comment/Recommendation
Blank Flag	CRFs or CRF sections marked blank are equivalent to entry complete data entry status.	A CRF that is marked blank or which is at **entry complete** status but contains one or more sections that are marked **blank** is eligible for inclusion in a group activity.
Multi-section CRFs	Only the status of the CRF is pertinent to inclusion/ exclusion in Group Activity tasks.	Each section in a CRF must be at entry complete status for the CRF to be eligible for inclusion in a group activity.
Spreadsheet Refresh	The workset displayed in the RDC Classic Spreadsheet maybe out of synch with the criteria used to establish it.	It is recommended that you refresh the workset to ensure that the required CRFs are available for a group activity.

Table 7–1   (Cont.) Factors that Affect Group Activities

Condition	Description	Comment/Recommendation
Spreadsheet View	CRFs that are present on other view tabs are available for a group activity.	If possible, use the Spreadsheet Study view to display all workset CRFs in a single tab.
Unplanned Visits and CRFs	Unplanned CRFs that are present in the workset are eligible for a group activity.	Use the **Hide/Show Unplanned CRFs** button to ensure all unplanned CRFs are displayed in the Spreadsheet prior to initiation of a group activity.
Patient List	Eight rows of patient data are displayed in the Spreadsheet, however, the CRFs for all patients in the workset are eligible for group activities.	Use the navigation tools to inspect the entire set of patients in the workset prior to initiating a group activity.
Open Windows	A group activity cannot proceed until all open windows are closed.	Close all open windows prior to initiating a group activity.
Pending Changes	A group activity cannot proceed if there are changes pending.	Process pending changes prior to initiation of a group activity.

Blank Flag

When the blank flag is selected, the associated CRF or CRF section is assigned an entry status of **blank**. However, for the purpose of processing, RDC Classic treats the blank status as equivalent to entry complete. Therefore:

- a multi-section CRF, with some CRF sections that are at entry complete and others that are at blank, is considered entry complete

- a CRF that is marked blank is considered entry complete.

In these cases, the CRF is eligible for inclusion in a group activity, subject to its discrepancy, verification, and approval statuses.

Multi-section CRFs

Each section in a multi-section CRF is assigned an entry status that is independent of any other sections or the CRF itself. The entry status assigned to the CRF is based on the statuses of its constituent sections.

All of the Group Activity tasks include or exclude workset CRFs based on the data entry status of the CRF. The entry status of individual CRF sections is not a factor in the inclusion or exclusion of the CRF from a given process. Consequently, a CRF that is at entry started status is excluded from Group Activity processes, even if it includes constituent CRF sections at entry complete status. Essentially, each CRF section must be at the entry complete status in order for the CRF to be assigned the entry complete status and be eligible for inclusion in a group activity. Note that, as described in "Blank Flag" on page 7-3, RDC Classic treats a CRF section that is marked blank as entry complete.

Spreadsheet Refresh

When you use the Activity List or the Search window to specify a workset, the data in the RDC Classic Spreadsheet is synchronized with the search criteria. However, when you subsequently change data so that the CRF no longer meets the original criteria, it continues to be included in the workset. In this way, the workset may not be synchronized with the criteria.

Each group activity operates on the CRFs that are currently included in the workset, not on those that simply meet the search criteria. Therefore, it is recommended that you update the workset, by choosing **Refresh** in the **File** menu, prior to initiating a group activity. This ensures that the appropriate CRFs are included in the procedure that you run.

Spreadsheet View

CRFs that are displayed in view tabs that are not currently displayed in the RDC Classic Spreadsheet are part of the workset and are eligible for inclusion in a group activity. If either the Spreadsheet Visit view or the Phase view is active, there generally will be CRFs present on other view tabs.

If the Spreadsheet View drop-down list is available, you can use the Study view to display all CRFs in the workset (for the current Patient List) on a single tab.

Unplanned Visits and CRFs

By default, unplanned CRFs in the workset are not displayed in the RDC Classic Spreadsheet. If there are unplanned CRFs associated with the current view tab, RDC Classic displays the Show/Hide Unplanned Pages Button adjacent to the CRF columns. Because all unplanned CRFs are eligible for inclusion in a group activity, it is recommended that you click the Show Unplanned Visits button to inspect unplanned CRFs prior to initiation of a group activity.

Patient List

The maximum number of patient rows that you can view in the RDC Classic Spreadsheet is eight. However, each group activity acts upon the CRFs associated with all patients in the current Patient List. Refer to "Current Patients" on page 12-4 for information on navigating the patient list.

Open Windows

You should ensure that all windows within the RDC Classic Workspace are closed prior to initiating any task that involves the Group Activities menu.

- If the Data Entry window is open and there are no pending changes, the menu commands are available; however, RDC Classic closes the Data Entry window when you activate any of the Group Activities menu commands. (Refer to "Pending Changes" on page 7-4 for a description of RDC Classic behavior when there are pending changes in the Data Entry window.)

- If a "functional" window, such as the Text Editor, is open, the Group Activities menu commands are inactive. You must close these windows in order to access any of the Group Activities commands.

Pending Changes

In order to initiate any of the functions that are available through the Group Activities menu, there cannot be pending changes.

If the Data Entry window is open when you select any of the Group Activities menu commands and there are pending changes, RDC Classic prompts you to process those changes – that is, to either save or discard them. After you have handled the pending changes, focus returns to the RDC Classic Workspace; however, you must re-initiate the Group Activities task.

Access

There are several factors that affect the presentation of the Group Activities menu in your RDC Classic session. These factors are related to:

- configuration settings defined by your system administrator

- the privileges assigned to your user name

- the workset that you specify through the Activity List window or the Search window.

Based on these factors, the Group Activities menu may not be present or, if it is, you may not have access to a particular command. When you do not have access to a command, it is said to be "inactive". RDC Classic displays inactive menu commands in light grey font. When you click an inactive menu command, the system does not respond.

RDC Classic Configurator

Your system administrator can use the RDC Classic Configurator to exclude the Group Activities menu from the RDC Classic Workspace. In this case, the menu and the commands that comprise the menu are unavailable to you. Consequently, you cannot perform any of the group activities that are described in this section.

Privilege

In order to perform any of the group activities, you must have appropriate access. This means that the privilege necessary to perform the individual function must be assigned to your user name. Table 7–2 lists the privilege that is relevant to each Group Activities menu command.

Table 7–2   Group Activities and Required User Privileges

Command	Privilege
Approve CRFs	**approve**
Undo Approved CRFs	approve
Verify CRFs	**verify**
Undo Verified CRFs	verify
Lock CRFs	**lock**

If you do not have the requisite privilege for a particular command, RDC Classic renders that command inactive in the menu.

Site Criteria

Access to the Group Activities menu commands may be dependent on the Site criterion that was used to generate the workset.

Verification and Approval Commands In order to perform tasks that use the commands that affect the verification and the approval status of CRFs, the workset that is displayed in the RDC Classic Spreadsheet must be based on an individual site and the appropriate privilege must be assigned to your user name for that site. The verification and approval Group Activities menu commands are rendered inactive if the Site criterion is set to All Sites (either in the Search window or by the scope of the task selected in the Activity List window). If this situation occurs, you must limit the site criteria to an individual site to which you have the required privilege. You do this either by:

- Changing the Site Criterion in the Search Window to a single site
- Selecting a task in the Activity List Window that is a constituent of either:
  - a Site node to which you have access, or
  - a Patient node within such a site.

Lock Command The **lock** privilege can be assigned to your user name on a site-by-site basis or on a study basis.

- If it is assigned for the current study, the value of the Site criterion that is used to generate the workset is irrelevant – the Lock CRFs menu command is always accessible.
- If it is assigned at the site level, the Lock CRFs menu command is inactive in each of the following circumstances:
  - the Site criterion is set to All Sites, and
  - the Site criterion is set to a site to which you do not have Lock privilege.

Group Verification Procedures

You use the following commands in the Group Activities Menu to change the verification status of the CRFs displayed in the RDC Classic Spreadsheet:

- Verify a Group of CRFs
- Undo Verification for a Group of CRFs

These commands are functionally equivalent to the Verify and Undo Verify tasks for an individual CRF.

Discussion

Because group activities have the potential to affect a large number of CRFs through a single user action, it is important to understand the rules that RDC Classic uses as the basis to take action on a particular CRF in the RDC Classic Spreadsheet. The following sections describe which CRFs RDC Classic automatically includes or excludes when a group verification procedure runs. Also, "Optionally Excluded CRFs" on page 7-7 describes how you can choose to exclude certain CRFs from the verify/undo verification group procedures.

Automatically Included CRFs

CRFs that meet the following criteria are automatically included in group verification procedures:

- Present in the RDC Classic Spreadsheet
- CRF entry status of entry complete, or equivalent Oracle Clinical designation (for example, Pass 2 Complete)
- Verification status other than Verified for the Verify a Group of CRFs procedure, specifically:
  - **not verified**
  - **verification undone**
  - **awaiting re-verification**

- Verification status of **verified** for the Undo Verification for a Group of CRFs procedure

- Discrepancy status of either none or **closed**

Automatically Excluded CRFs

Certain CRFs in the workset are not, by definition, included in the set that is eligible for group verification procedures. CRFs that meet the following criteria are automatically excluded from group verification procedures:

- CRF entry status that is less than entry complete

- Verification status of Verified for the Verify a Group of CRFs procedure

- Verification status other than Verified for the Undo Verification for a Group of CRFs procedure, specifically:

  - **not verified**

  - **verification undone**

  - **awaiting re-verification**

Optionally Excluded CRFs

In addition to those CRFs that are never included in a group verification procedure, the Verify CRFs procedure allows you to exclude CRFs that have open discrepancies. If you choose this option, any CRF in the workset that has one or more **active** or **other** discrepancies is not processed.

In contrast, the Undo Verified CRFs procedure does not provide the option to exclude CRFs. All CRFs that meet the inclusion criteria, as described in "Automatically Included CRFs" on page 7-6, are immediately processed.

Verify a Group of CRFs

This section describes the procedure to change the status of the workset CRFs to **verified**.

The following conditions must be present in order to initiate this procedure:

1. Your user name is assigned the **verify** privilege.

2. At least one CRF in the RDC Classic Spreadsheet is a candidate for verification, that is, its verification status is:

   - **not verified**

   - **verification undone**

   - **awaiting re-verification**

3. The **Group Activity** menu is present in the RDC Classic Workspace.

Procedure

To change the verification status of unverified CRFs in the current RDC Classic Spreadsheet:

1. In the **Group Activities** menu, select **Verify CRFs**. The Group Verification Processing Window displays.

2. In the Group Verification Processing window, ensure that the search criteria is correct. You also have the option to:

- Select the **Skip CRFs with discrepancies** check box to exclude discrepant CRFs from the procedure

- Type a comment in the **Comment** text box that you want to associate with each CRF that is verified

3. Click the OK button to close the Verify CRFs window and initiate the verification procedure.

4. When the procedure completes, the **Group Verify Update Complete** message window displays, which describes the status of the procedure. The message lists the number of eligible CRFs and the number of CRFs that were processed.

    Click **OK** to close the window.

When you close the message window, the system updates the RDC Classic Spreadsheet to reflect the change in verification status of those CRFs that were processed.

Undo Verification for a Group of CRFs

This section describes the procedure to change the verification status of a group of CRFs to **verification undone**.

The following conditions must be present in order to initiate this procedure:

1. Your user name is assigned the **verify** privilege.

2. At least one CRF in the Spreadsheet is assigned the verification status **verified**.

3. The **Group Activity** menu is present in the RDC Classic Workspace.

Procedure

To undo verification of the verified CRFs in the RDC Classic Spreadsheet:

1. In **Group Activities** menu, select **Undo Verified CRFs**. The Group Undo Verification Processing displays.

2. In the Group Verification Processing window:

    - Ensure that the search criteria are correct

    - Type an optional comment in the **Comment** text box that you want to associate with each CRF that is processed

3. Click **OK** to close the Group Verification Processing window and initiate the verification procedure.

4. When the procedure completes, the **Group UNDO VERIFY Update Completed** message window displays, which describes the status of the procedure. The message lists the number of eligible CRFs and the number of CRFs that were processed.

    Click **OK** to close the message window.

When you close the message window, the system updates the RDC Classic Spreadsheet to reflect the change in verification status of those CRFs that were processed.

Group Approval Procedures

You can use the commands in the Group Activities Menu to change the approval status of the CRFs displayed in the RDC Classic Spreadsheet. There are two commands that you can use to change the approval status:

■ Approve a Group of CRFs

■ Undo Approval for a Group of CRFs

These commands are functionally equivalent to the approve and undo approval tasks for an individual CRF.

Discussion

Because group activities can potentially affect a large number of CRFs through a single user action, it is important to understand the rules that RDC Classic uses as the basis to take action on a particular CRF in the RDC Classic Spreadsheet. The following sections describe which CRFs RDC Classic automatically includes or excludes when the group approval procedures run. Also, the Optionally excluded CRFs section describes how you can choose to exclude certain CRFs from the Approve CRFs procedure.

Automatically Included CRFs

CRFs that meet the following criteria are automatically included in group approval procedures:

■ Present in the RDC Classic Spreadsheet

■ CRF entry status of entry complete, or equivalent Oracle Clinical designation (for example, pass 2 complete)

■ Approval status other than **approved**, for the Approve a Group of CRFs procedure, specifically:

  ■ **not approved**

  ■ **approval undone**

  ■ **awaiting re-approval**

■ Approval status of Approved, for the Undo Approval for a Group of CRFs procedure

■ Discrepancy status of either None or Closed.

Automatically Excluded CRFs

Certain CRFs in the workset are not, by definition, included in the set that is eligible for group approval procedures. CRFs that meet the following criteria are automatically excluded from group approval procedures:

■ CRF entry status that is less than entry complete

■ Approval status of **approved** for the Approve CRFs procedure

■ Approval status other than **approved** for the Undo Approved CRFs procedure, specifically:

  ■ **not approved**

  ■ **approval undone**

  ■ **awaiting re-approval**

Optionally Excluded CRFs

In addition to those CRFs that are automatically excluded from a group approval procedure, the Approve CRFs procedure allows you to exclude CRFs based on:

- Discrepancies
- Verification status

The discrepancies option affects CRFs that have one or more open discrepancies. If you choose this option, any CRF in the workset that has one or more Active or Other discrepancies is not processed.

The verification option affects CRFs that are not verified. If you choose this option, any CRF in the workset that is not assigned a status of Verified is not processed.

In contrast, the Undo Approved CRFs procedure does not provide the option to exclude CRFs. All CRFs that meet the inclusion criteria, as described in "Automatically Included CRFs" on page 7-6, are immediately processed.

Password Confirmation

Both group approval procedures require user confirmation, which consists of typing your user name and password in a Password confirmation window. This step is required for each group approval procedure that you run.

Note that the system allows three attempts to type the correct user name/password combination. After a third unsuccessful attempt, RDC Classic closes the session.

Approve a Group of CRFs

This section describes the procedure to approve currently unapproved CRFs in the RDC Classic Spreadsheet.

The following conditions must be present in order to initiate this procedure:

1. Your user name is assigned the **approve** privilege.

2. One or more CRFs in the Spreadsheet are assigned an approval status other than **approved**.

3. The **Group Activity** menu is present in the RDC Classic Workspace.

Procedure

To change the approval status of the CRFs that are currently not approved in the current RDC Classic Spreadsheet:

1. In the Group Activities menu, select **Approve CRFs**. The Password Confirmation window displays.

2. In the Password confirmation window:

   a. Type your user name in the **Username** text box

   b. Type the password associated with your user name in the **Password** text box.

3. Click **OK** to proceed to the Approve CRFs window.

4. In the Group Approval Processing window, ensure that the search criteria is correct. You also have the option to:

   - Select the **Skip CRFs with discrepancies** check box to exclude discrepant CRFs from the procedure

- Select the **Skip Un-verified CRFs** check box to exclude CRFs that are not verified

- Type a comment in the **Comment** text box that you want to associate with each CRF that is processed

5. In the Group Approval Processing window, click **OK** to close the window and initiate the approval procedure.

6. When the procedure completes, a message window, entitled, "Group Approval Update Complete", is displayed that describes the status of the procedure. The message lists the number of eligible CRFs and the number of CRFs that were processed.

   Click **OK** to close the message window.

When you close the message window, the system updates the RDC Classic Spreadsheet to reflect the change in verification status of those CRFs that were processed.

Notes

If this procedure causes a CRF to be inadvertently approved, refer to "Undo CRF Approval" on page 9-11 to change it to an unapproved status.

Undo Approval for a Group of CRFs

This section describes the procedure to change the approval status of the CRFs that are currently approved in the workset. In order to initiate this procedure, the following conditions must be present:

1. Your user name is assigned the **approve** privilege.

2. One or more CRFs in the Spreadsheet are assigned an approval status of **approved**.

3. The Group Activity menu is present in the RDC Classic Workspace.

Procedure

To change the approval status of the CRFs that are currently approved in the current RDC Classic Spreadsheet:

1. In the Group Activities menu, select **Undo Approved CRFs**. The Undo Approved CRFs window displays.

2. In the Undo Approved CRFs window:

   - Ensure that the search criteria is correct.

   - Type an optional comment in the **Comment** text box that you want to associate with each CRF that is processed.

3. Type your user name in the **Username** text box.

4. Type the password associated with your user name in the **Password** text box.

5. Click **OK** to close the Undo Approved CRFs window and initiate the procedure

6. When the procedure completes, the **Group Undo Approval Complete** message window displays, which describes the status of the procedure. The message lists the number of eligible CRFs and the number of CRFs that were processed.

   Click **OK** to close the message window.

When you close the message window, the system updates the RDC Classic Spreadsheet to reflect the change in verification status of those CRFs that were processed.

Group Locking Procedure

You can use the Lock CRFs command to change the lock status of CRFs displayed in the RDC Classic Spreadsheet.

In contrast to the group verification and approval procedures, which provide a mechanism to undo the verify and approve procedures, respectively, there is not an analogous "undo lock" procedure for a group of CRFs. Therefore, the Lock CRFs procedure should be used carefully. The only mechanism in RDC Classic to change the status of a locked CRF so that it can be updated is the Unlock a CRF task, which acts on a single CRF (refer to "Unlock a CRF" on page 5-16).

Refer to "Lock an Individual CRF" on page 5-15 which describes the procedure to lock a single CRF.

Automatically Included CRFs

CRFs that meet the following criteria are automatically included in the Lock CRFs procedure:

- Present in the RDC Classic Spreadsheet

- CRF entry status of entry complete, or equivalent Oracle Clinical designation (for example, Pass 2 Complete)

- Status other than **locked**

Automatically Excluded CRFs

- CRF entry status that is less than entry complete

- Status of Locked

Certain CRFs in the workset are not, by definition, included in the set that is affected by group verification procedures. These are CRFs with an:

Optionally Excluded CRFs

In addition to those CRFs that are automatically excluded from the Lock CRFs procedure, you may choose to exclude CRFs based on:

- Discrepancies

- Verification status

- Approval status

The discrepancies option affects CRFs that have one or more open discrepancies. If you choose this option, any CRF in the workset that has one or more Active or Other discrepancies is not processed.

The verification option affects CRFs that are not verified. If you choose this option, any CRF in the workset that is not assigned a status of Verified is not processed.

The approval option affects CRFs that are not approved. If you choose this option, any CRF in the workset that is not assigned a status of Approved is not processed.

Unlock CRFs

RDC Classic does not permit multiple CRFs to be unlocked via a group activity. You can only unlock CRFs one at a time. Consequently, there is not an "Unlock CRFs" command in the Group Activities menu.

Refer to "Unlock a CRF" on page 5-16 for a description of this procedure.

Prerequisites

The following conditions must present in order to initiate the process of locking a group of CRFs:

1. Your user name is assigned the **lock** privilege.

2. One or more CRFs in the **workset** is not locked.

3. The **Group Activity** menu is present in the RDC Classic Workspace.

Lock a Group of CRFs

To lock the CRFs that are unlocked in the workset:

1. In the Group Activities menu, select **Lock CRFs**. The Group Lock Processing window is displayed.

2. In the Group Lock Processing window, ensure that the search criteria are correct. Also, you have the option to:

   ■ Select the **Skip CRFs with Discrepancies** check box to exclude discrepant CRFs

   ■ Select the **Skip Un-verified CRFs** check box to exclude CRFs that are not verified

   ■ Select the **Skip Un-approved CRFs** check box to exclude CRFs that are not approved

3. Click **OK** to initiate the locking procedure

   When the procedure completes, a message window is displayed that describes the status of the procedure. If the procedure was successful, the number of CRFs processed is also displayed.

4. Click **OK** to close the message window.

When you close the message window, the system updates the **workset** to reflect the change in lock status of the CRFs that were processed.

8

Initial Data Entry

This section describes tasks you perform during initial data entry. Just as there is a progression in data entry status that is linked to the workflow, the tasks that are considered part of initial data entry also represent steps in a progression.

The tasks that can be part of initial data entry are:

- Open a CRF on page 8-2

- Initiate an Investigator Comment on page 8-3

- Evaluate and Respond to a Validation Error During Initial Data Entry on page 8-3

- Mark the CRF Blank During Initial Data Entry on page 8-5

- Mark a CRF Section Blank During Initial Data Entry on page 8-5

- Insert a Repeating Question Groups Row on page 8-6

- Initiate a Discrepancy for a Response Field on page 8-6

- Initiate a Section Discrepancy on page 8-6

- Close a CRF on page 8-8

Certain tasks, such as "Initiate Data Entry", are limited by definition to initial data entry, while others, such as "Initiate a Section Discrepancy" and "Initiate an Investigator Comment" can occur at any point in the data entry workflow, up until the CRF is locked.

> **Note:** The procedures in this section reference various GUI components and assume knowledge of basic functionality. If you have questions about components used in the tasks, refer to the Part III, "RDC Classic GUI Reference" sections.

Open a CRF

In order to open a CRF, your user name must be assigned the **browse** privilege, at a minimum (**browse batch** privilege for **batch loaded data**). In order to record or update patient data, your user name must be assigned the **update** privilege.

To open a CRF:

1. Locate the correct CRF in the RDC Classic Spreadsheet.

   Refer to "RDC Classic Spreadsheet" on page 12-1 for information on locating a specific CRF.

2. Click the CRF cell. The system opens the CRF in the Data Entry window.

> **Note:** If the system does not open the Data Entry window when you click the CRF cell, ensure that the "Action When Clicking on a Cell" setting is selected. (For details about this setting, refer to "Preferences Window" on page 14-24.)

Initiate Data Entry

This is the first step in the data entry process. In order to perform data entry, your user name must be assigned the **update** privilege.

1. Open the CRF in the Data Entry window and place focus in the CRF header area.

2. Complete all of the required CRF header information fields. If a CRF section header area is present, place focus in it and complete all required fields there.

3. Place focus in the first response field in the Question area and begin to record data in the appropriate fields. Complete all fields in the section.

4. If there is another CRF section:

   a. Place focus in the CRF section header and complete all required fields.

   b. Place focus in the first response field in the Question area and begin to record data.

   c. Repeat these steps for all subsequent sections in the CRF.

5. When all CRF information and response fields are complete, you can:

   a. Save pending changes and proceed to the next CRF.

   b. Save pending changes and close the CRF.

When all required CRF header data is collected and you save the CRF, RDC Classic assigns it the data entry status **created**.

View Data in Fields with an ATTACHMENT Prefix

A CRF can have one or more fields into which you insert data.

- 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.

Any field in the CRF that has an ATTACHMENT prefix represents an extended text field that supports 10,000 characters instead of the normal maximum of 200 characters.

As shown in Figure 8–1, RDC Classic uses the following prefix to indicate that a field is an extended text field:

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 Classic displays the beginning of the extended text. For example:

ATTACHMENT V<1.1>: A 48-year-old woman presented

> **Note:** In RDC Classic, you can view only the beginning of the data in an extended text field. You cannot view all the data in the field. In addition, you cannot enter or update data in the field. You can enter and modify data in an extended text field only in Oracle Clinical Remote Data Capture Onsite (RDC Onsite).

Figure 8–1   ATTACHMENT Prefix in an Extended Text Field

Initiate an Investigator Comment

You use the Investigator Comment Window to add a new comment. In order to complete this task, your user name must be assigned the **update** privilege.

To insert an investigator comment in a CRF:

1. In the Question area, place focus in the relevant response field.

2. From the Insert menu, choose **Investigator Comment**. The Investigator Comment Window opens.

3. Type the comment in the text box.

4. When you are ready to close the Investigator Comment window, click **OK**. The system saves the investigator comment.

When you save the comment, focus returns to the response field. The presence of an investigator comment associated with the data field is signified by:

■   The yellow background color of the field

■   The presence of **<Inv>** appended to the contents of the Data Entry window title bar

Evaluate and Respond to a Validation Error During Initial Data Entry

As you record data in response fields and navigate to other fields, RDC Classic evaluates the value you record. When you record a value in a response field that does not meet certain criteria defined for the question, the system displays the Validation Failure Window, which indicates the presence of a **discrepancy**. When the validation error window displays while you are recording data, there are three routes you can take:

1. Return to the response field and correct the value

2. Acknowledge the discrepancy and proceed with data entry

3. Acknowledge and take action on the discrepancy

To process the validation error:

1. Ensure the response value that raised the discrepancy matches the source data.

   a. If the value is recorded correctly, skip to Step 3.

   b. If the value is not recorded correctly, click the **Cancel** button. The system closes the Validation Failure window and returns focus to the response field, where you can correct the response value.

     If the system again displays the Validation Failure window, the new value is also discrepant; proceed to Step 2.

2. If the value in the response field matches the source data, you can either:

   ■ Acknowledge the discrepancy and proceed with data entry

   ■ Acknowledge and route the discrepancy

   ■ Acknowledge and resolve the discrepancy

3. To acknowledge a discrepancy:

   a. In the Validation Failure window, review the Error Message text box.

   b. If you want to augment the error message, type a text message in the Comments text box.

   If you want to take action on the discrepancy, that is, either route or resolve it, proceed to Step 4. If you want to proceed with data entry, skip to Step 6.

4. Select an action in the **Action** drop-down list box:

   a. If you select a routing action, such as "Send to Site", skip to Step 6

   b. If you select a resolution reason, such as "Close - Resolved", the system displays the Resolution Reason window, proceed to Step 5.

5. In the Resolution Reason window,

   a. Select a resolution reason from the Resolution drop-down list

   b. Type an optional comment in the Comment text box that you want to save with the discrepancy

   c. Click **Save**; the system closes the window and returns focus to the Validation Failure Window.

6. Click the **OK** button. The system closes the Validation Error window.

   ■ If the CRF is not in entry complete status, the system returns focus to the Data Entry window and you can continue with initial data entry.

   ■ If the CRF is in entry complete status, the system displays the Audit Information Window, in which you must the change reason.

   When you complete the audit information window, the system saves the discrepancy record and the change reason, and it reverts focus to the response field.

Notes

■ The discrepancy actions that are available are based on your user role and the setup done by the system administrator.

- **Correcting the value in the response field** – When the system presents the Validation Failure window, the Message section displays the system-generated reason that the data value is discrepant. The response value is included in the reason. This allows you to compare the value that you typed in the response field to the source data value. If the two values do not match, use this procedure to navigate back to the response field and correct the value you typed.

Mark the CRF Blank During Initial Data Entry

You can mark a CRF blank in order to signify that it was not overlooked during data entry and that it was intentionally left blank. When a CRF is marked blank, you can, at a later time, clear the blank flag and proceed with normal data entry.

If data has been recorded in the CRF when you mark it blank, the system deletes all response values in the CRF.

To mark a CRF blank:

1. Open the CRF.

2. Complete all required CRF header fields.

3. If necessary, complete any optional CRF header fields.

4. Complete all required CRF section header fields, if applicable.

5. Click the **blank flag** check box. The system displays the Blank CRF Confirmation Window with the message, "Mark this CRF blank and Save?"

6. In the confirmation window, click **OK** to mark the CRF blank and save pending changes.

When you complete the task, the Blank check box is selected and the CRF question area is inaccessible for data entry.

Mark a CRF Section Blank During Initial Data Entry

This task, which is applicable to multi-section CRFs, allows you complete initial data entry for one or more CRF sections and mark one or more other CRF sections blank.

RDC Classic allows you to mark individual sections of a CRF blank when the CRF blank flag is not selected. This is useful when all of the data to be collected in the CRF is not available. In this way, you can record the data on hand, mark those sections for which data is not yet available blank, and save the CRF.

To mark one or more sections blank in a multi-section CRF:

1. In the RDC Classic Spreadsheet, locate and open the CRF you want to create.

2. Ensure that all required CRF and CRF section header fields are complete.

3. Place focus in the CRF section you want to mark blank.

4. Select the blank flag check box.

   If all other sections in the CRF are marked blank, RDC Classic displays a window that requires you to confirm your choice and save pending changes.

   If other sections are not blank, the system displays a text message in the current section, "This section has been marked as blank".

5. If another CRF section must be marked blank, navigate to it and repeat this procedure.

Note that when all other sections in the CRF are marked blank and you mark the last CRF section blank, RDC Classic automatically marks the entire CRF blank.

Insert a Repeating Question Groups Row

Under certain circumstances, you can add a row to a set of repeating question rows. This facilitates collection of additional data in a question group.

To insert a repeating question group row:

1. Place focus in the row above the one you want to delete.

2. From the CRF menu, choose **Insert Row** menu command.

3. The system adds the row, if necessary, by moving the rows below down one row.

The conditions that prevent you from inserting a row in the question group are related to how the question is defined in Oracle Clinical. The question group may be protected against the insertion and/or deletion of additional rows, or it may contain the maximum number rows specified in the definition. In these cases, the system displays a message window that informs you that a row cannot be added to the question group.

Note that if your user name is assigned privileged update, the system does not enforce these restrictions.

Initiate a Discrepancy for a Response Field

A user-generated discrepancy can provide additional information about a response field. In contrast to an investigator comment, the discrepancy can be routed to another user group and it is reflected in the color-coding of the CRF icon that is displayed in the RDC Classic Spreadsheet.

This section describes the procedure to add a discrepancy to a response field during initial data entry. One user-generated discrepancy can be associated with each response field in the question area of a CRF section.

To initiate a discrepancy for a response field:

1. Place focus in the response field of the question with which you want to initiate a discrepancy.

2. Select **Insert**, then **Discrepancy** from the option list. The system opens the Comment for Question Window. Ensure that the title bar refers to the correct question label.

3. In the discrepancy window:

    a. Ensure that the Comment Reason is correct. If it is not, use the LOV button to select an alternative.

    b. Type explanatory text in the Message pane. If necessary, click the Editor button to open the Text Editor.

Initiate a Section Discrepancy

You can use a **section discrepancy**, which is associated with the CRF section that is active when you insert it, to log comments about the questions and/or response data in that section, to facilitate communication between workers, or to use the **internal** discrepancy feature of RDC Classic.

For single-section CRFs, the procedure is straightforward, the section is active as long as the CRF is open. For multi-section CRFs, where each section is represented by a tab within the Data Entry window, the section that is active is determined by which tab is currently selected.

To insert a section discrepancy:

1. Ensure that the correct CRF is open in the Data Entry window and the section with which you want to associate the discrepancy is active.

2. Select **Data Entry**, then **Discrepancy** from the option list, which opens the Discrepancy for CRF Section Window. Refer to Figure 8–2.

Figure 8–2   Discrepancy for CRF Page Window

3. In the Discrepancy for CRF page window:

   a. Ensure that the appropriate Comment Reason is chosen for the Comment Reason field.

   b. In the Message text box, type the message that you want to associate with the discrepancy.

   c. Use the Comments text box to type an additional comment that you want to associate with the discrepancy.

4. Click the Save button. The system saves the discrepancy, closes the window, and, if you selected an action, takes the action you specified.

Notes

■ The Message text you type is displayed in the "Text" field of the List of Discrepancies Tab and as the descriptive title of the Individual Discrepancy Tab in the Discrepancy Task Tab.

■ The Comments text you type is displayed in the Comments fields of both the List of Discrepancies Tab and the Individual Discrepancy Tab in the Discrepancy Task Tab.

■ You have the option to immediately route or resolve the discrepancy. Use the Action drop-down list box to select an action, if necessary.

Close a CRF

When you close a CRF, there are several factors that determine the steps you must perform. The factors are:

■ The entry status of the CRF

■ Whether or not values for response fields were previously entered and saved

■ The presence of required fields in the CRF header

■ The presence of mandatory fields in the question area

■ The presence or absence of pending changes

In practice, these factors tend to be inter-related. For example, if the CRF is assigned an data entry status of Created, but not all required header fields are collected, RDC Classic does not allow you to close the CRF.

Required Header Fields

Essentially, RDC Classic does not assign a data entry status to a CRF until all required header fields, both CRF and CRF section header fields, are collected. If you attempt to close a CRF with required header fields uncollected, the system places focus in the first uncollected required header field, as a prompt to you.

Pending Changes

If there are pending changes, a confirmation message window is displayed that allows to save changes and close the CRF, remove pending changes and close the CRF, or remove pending changes and display the CRF with previously saved data only.

In each of these cases, if there are no changes pending, the selected action proceeds without an opportunity for you to cancel it.

Methods to Close a CRF

There are four methods you can use to close a CRF:

■ Click the X button in the top right-hand corner of the Data Entry window.

■ Click a Page Grouping tab other then the one currently in focus.

■ Click another CRF cell.

■ Exit the application.

In each case, RDC Classic closes the current CRF if:

■ There is not an uncollected required header field.

■   There are not pending changes.

9

Data Review and Update

This section provides an overview of the CRF review and data update processes and details the tasks that allow you to accomplish each. It also describes the procedures that you use for verification and for approval of CRFs.

The following topics are in this section:

- CRFs Review on page 9-1
- Update Response Data on page 9-3
- Manage Discrepancies on page 9-7
- CRF Verification Tasks on page 9-9
- CRF Approval on page 9-10

There are certain other tasks that are relevant to CRF review and data update that are documented in the Chapter 5, "Getting Started." The tasks in that section specifically related to CRF review and/or data update are:

- Validation Tasks on page 5-11
- Lock and Unlock CRF Procedures on page 5-15
- Refresh the Workset on page 5-12

CRFs Review

This section describes the procedures you use to review a CRF. These tasks help to ensure that response data, CRF information, and investigator comments are correct and complete. If you find it is necessary to modify any data, refer to the "Update Response Data" on page 9-3.

The following tasks are described in this section:

- Review the Audit Trail for a CRF
- View the Change History for a Response
- Review an Investigator Comment
- Review the Approval or Verification History of a CRF
- Review Discrepancies Associated with a CRF

In order to review CRFs, your user name must be assigned the **browse** or **browse batch** privilege. This is generally sufficient when you are verifying CRFs against the source data. In order to update data your user name must be assigned the **update** or **update batch**.

When you change the data in an existing CRF, the change is audited in all CRFs. If the CRF is at the **entry complete** data entry status, the system displays a change reason window, which you must complete in order for the data update process to proceed.

Review the Audit Trail for a CRF

The audit trail captures changes to response values, investigator comments, and CRF information. You can use the Audit Trail task tab to review all changes to a CRF and the changes that are associated with a response field. In order to review the audit trail for a CRF, at least one response value in the CRF must have changed since the CRF was created.

General Procedure

To review the audit trail for a CRF:

1. Put the CRF that is of interest in focus.

2. Click the Audit Trail Task Tab. All of the changes that have occurred in the CRF since it was created are listed in the task tab.

Procedure Based on the Approval or Verification History

You can use the Approval Task Tab or the Verification Task Tab to automatically set the "Changes since" field on the Audit task tab. This allows you to view changes to the CRF since a specific approval or verification event.

In order to do this, there must be an approval or verification history associated with the CRF.

1. Put the CRF that is of interest in focus.

2. Click either the Approval or the Verification task tab.

3. In the task tab, place focus in the history table, selecting a row that corresponds to the event you want to use in the Audit task tab.

4. Click the Show changes button. The system changes focus to the Audit Trail task tab. The "Changes since" field is set to the event in the Approval or Verification task tab.

View the Change History for a Response

You can use the Audit Trail task tab to view the changes that have occurred to a specific response field. This procedure is also applicable to audited investigator comments and CRF header information.

To view the change history for a response:

1. Put the CRF that is of interest in focus.

2. Click the Audit Trail task tab.

3. Place focus in the row that corresponds to the response field of interest.

4. Click the Show button for that row. The system opens the Audit History Window, which displays all audited changes to the response.

Review an Investigator Comment

Use this procedure to review an existing investigator comment. When focus is in a response that contains an investigator comment, the Data Entry window title bar

displays an alert, in the form of, "<Inv>". When focus is not in the response field, its value is displayed in red font color.

To review an existing investigator comment:

1. Place focus in the response field of interest. The Data Entry window title bar displays "<Inv>" if it contains an investigator comment.

2. Select **Edit**, then **Investigator Comment** from the option list. The system displays the Investigator Comment Window.

3. Review the comment.

Review the Approval or Verification History of a CRF

After a CRF has been verified or approved, its change history is displayed on the Verification and/or the Approval task tab.

To review the approval or verification history of a CRF:

1. Put the CRF that is of interest in focus.

2. Click the appropriate task tab.

Review Discrepancies Associated with a CRF

CRFs that have at least one discrepancy of either "Active" or "Other" status are displayed in the RDC Classic Spreadsheet with a red or yellow CRF icon (respectively). In addition, a CRF that is displayed with a white icon may have one or more discrepancies in the "Closed" status.

Refer to the "Review Discrepancies" section in "Manage Discrepancies" on page 9-7 for further information.

To view the discrepancies associated with a CRF:

1. Click the relevant CRF to put it in focus.

2. Click the Discrepancy Task Tab to display its contents. If there is at least one discrepancy associated with the CRF currently in focus, the List of Discrepancies Tab is displayed within the Discrepancy task tab.

3. Click an Individual Discrepancy Tab to view detailed information about a specific discrepancy.

Update Response Data

This section describes the procedures you use to modify data that has been saved in a CRF. This includes response values, investigator comments, and CRF or CRF section information.

The following topics comprise this section:

■ Complete the Audit Information Window

■ Update CRF and/or CRF Section Header Data

■ Update Response Data for a CRF

■ Update an Existing Investigator Comment

■ Mark a CRF or CRF Section Blank

■ Clear the Blank Flag and Proceed with Data Entry

Complete the Audit Information Window

RDC Classic displays an audit information window whenever you update data in a CRF or CRF section that is assigned the **entry complete** data entry status.

The procedure to complete the Audit Information is similar for all types of updates. The audit information window presents a default change reason. At a minimum, the system requires that you acknowledge the default change reason and close the window before you can continue with your data update tasks. However, you can use the Change Reason drop-down window to select an alternative change reason. Also, you have the option to include an explanatory comment, which is saved with the audit record.

Refer to "Audit Change Reason Type Codes Window" on page 16-14 for additional information on the usage of these windows.

Procedure

When you update an entry complete CRF, as described above, and attempt to save the CRF or navigate to a different field, the system displays an audit information window. To complete it and proceed with other tasks:

1. In the audit information window, review the default change reason.

2. If you want to select an alternative reason, use the LOV button to open the Audit Change Reason Type Codes Window.

3. Select an alternative change reason and close the Type Codes window.

4. In the audit information window, type a comment, if necessary, in the Comment text box.

5. Click the OK or Save button, as appropriate, to close the audit information window and proceed with your update tasks.

Update CRF and/or CRF Section Header Data

The CRF header may contain required and optional data fields. All changes to CRF header fields, with the exception of Comment fields, are audited and require you to provide a change reason and optional comment. The Comment field may or may not be audited, based on the CRF definition in the protocol.

Procedure

When you update CRF or CRF section header information, RDC Classic displays the Audit Information for CRF Change window. Refer to "Complete the Audit Information Window" on page 9-4 for information on completing this window.

1. Use the RDC Classic Spreadsheet to locate and open the CRF in the Data Entry window.

2. In the CRF header or the CRF section header area of the Data Entry window, place focus in the field you want to update.

3. Modify the existing field.

4. When you press the Tab or Enter key to navigate out of the field, or press the F10 key to save the new data, the system displays the Audit Information for CRF Change window.

5. In the Audit Information Window, either use the default change reason or select another from the LOV.

6. In the audit information window, type an optional comment that more fully explains the data update, if necessary.

7. Close the audit information window.

Notes

If you make other changes to CRF or CRF section information before you save pending changes, the system uses the same change reason and comment that you supplied for the first update.

Update Response Data for a CRF

It is often necessary to modify a datapoint in a CRF that is in the "Entry Complete" entry status, either by changing existing response data or inserting data in a previously incomplete response field. RDC Classic terms this process "data update."

Procedure

To update response data in a CRF or CRF section:

1. In the RDC Classic Spreadsheet, click the CRF icon associated with the CRF that contains the datapoint(s) you want to modify. The system opens the CRF in the Data Entry window.

2. In the Question area of the Data Entry window, place focus in the response field you want to update.

> **Note:** Any field in the CRF that has an ATTACHMENT prefix represents an extended text field. Note that you can update data in an extended text field only in Oracle Clinical Remote Data Capture Onsite (RDC Onsite). For more information, refer to "View Data in Fields with an ATTACHMENT Prefix" on page 8-2.

3. Modify the existing response value or type a new value in the field.

4. When you press the Tab or Enter key to navigate out of the field, or press the F10 key to save the new data, the system displays the Audit Information for Data Change window. The default change reason is automatically selected.

5. In the Audit Information Window, either use the default change reason or select another from the LOV.

6. In the Audit information window, type an optional comment that more fully explains the data update, if necessary.

7. Click the Save button to close the Audit information window and save the reason and comment.

Auto progression is not available during data update. When you close the Audit information window, focus moves to the first datapoint in the CRF section.

Update an Existing Investigator Comment

As part of the data update process, you may find it necessary to augment an existing **investigator comment** for a given response field. This section describes the procedure to do this.

If an investigator comment is not associated with the response field, refer to "Initiate an Investigator Comment" on page 8-3 for a description of how to associate a new investigator comment to a datapoint.

The background color of a response field that has an investigator comment associated with it is yellow. The text of the response is displayed in a green font.

If both an investigator comment **and** an operator comment are associated with a response field, the background color remains yellow, but the font of the response text is red.

Procedure

To update an existing investigator comment:

1. In the Data Entry window, place focus in the response field that contains the investigator comment you want to update.

2. Select **Edit**, then **Investigator Comment** from the option list, which opens the Investigator Comment Window. The text of the existing comment is displayed in the window.

3. You can edit the text of the comment, as necessary, in the window.

4. Click the **OK** button to close the Investigator Comment window. The system displays the Audit Information for Investigator Comment Change window.

5. In the audit information window, either use the default change reason or use the LOV to select an alternative reason.

6. If necessary, type an optional explanatory message in the Comment text box.

7. Click the **OK** button to close the Change Reason window and revert focus to the response field.

Notes

When you modify both a response value and its associated investigator comment in the same transaction, that is both changes are included in the same save action, the system uses the change reason associated with the response change for both updates.

Mark a CRF or CRF Section Blank

When you mark a CRF blank, all response values are deleted and each section, as well as the CRF, is marked blank.

When you mark a CRF section blank, the system deletes only the response values in that section and marks the section blank if there are other non-blank sections in the CRF. If there are no other non-blank sections in the CRF, marking the last section blank is the same as marking the entire CRF blank.

To mark an entry complete CRF blank:

1. In the CRF header, click the **blank flag** to select it. The system displays a confirmation window.

2. In the confirmation window, click the OK button. The system displays the Audit Information for CRF Change window.

3. Process and close the audit information window, as described in "Complete the Audit Information Window" on page 9-4.

4. The system displays the following message in the Question area of the Data Entry window of single-section CRFs:

This page has been marked as blank

In multi-section CRFs with at least one other non-blank section, the system displays the following message in the Question area of each section:

This section has been marked as blank

Clear the Blank Flag and Proceed with Data Entry

This section describes the steps necessary to clear the blank flag for a CRF or a CRF section and proceed with data entry tasks.

To clear a blank flag and proceed with data entry:

1. In the CRF or CRF section header area, click the relevant blank flag to clear it. The system displays the Audit Information for CRF Change window.

2. Process and close the audit information window, as described in "Complete the Audit Information Window" on page 9-4.

3. The system clears the blank flag and places focus in the first response field in the section.

Manage Discrepancies

The section describes the procedures you use to manage discrepancies in RDC Classic. It discusses how to review, update, and take action on discrepancies.

This section includes the following subsections:

- Review Discrepancies
- Update an Existing Discrepancy
- Take Action on a Discrepancy

Review Discrepancies

You use the Discrepancy Task Tab to review the list of discrepancies associated with a CRF. In that tab, the List of Discrepancies Tab lists all discrepancies. When you want to review a single discrepancy, either open its discrepancy window or use its Individual Discrepancy Tab.

View all Discrepancies

To review all of the discrepancies in a CRF:

1. Open the CRF in the Data Entry window.

2. Click the Discrepancy task tab.

3. If there is at least one discrepancy in the CRF, it is displayed in the List of discrepancies tab. Note the sequence number assigned to the discrepancy of interest.

4. Locate and click the individual discrepancy tab that corresponds to the discrepancy you noted in Step 3.

Access the Discrepancy Window

You can view, and update, a discrepancy record using its discrepancy window. The discrepancy window is accessible for all univariate, manual, and section discrepancies.

1. Open the CRF in the Data Entry window.

2. Place focus in the appropriate response field in the CRF:

   a. For univariate and manual discrepancies, focus must be in the related response field.

   b. For section discrepancies, focus must be in any response field in the section.

3. In the Edit menu, select the appropriate command:

   – **Discrepancy** for a data discrepancy

   – **Discrepancy** (manual) for a manual discrepancy

   – **Section Discrepancy** for a section discrepancy

   The system opens the appropriate discrepancy window.

Update an Existing Discrepancy

You can work with an existing discrepancy in either discrepancy window, such as the or the Discrepancy Task Tab. Use either interface to edit descriptive text and comments or to take an action on the discrepancy. The exception to this is multivariate discrepancy, for which you work with the Discrepancy task tab only.

Discrepancy Task Tab Procedure

To open and work with a discrepancy, you can either use with the List of Discrepancies Tab or the Individual Discrepancy Tab.

1. Ensure that the relevant CRF is in focus.

2. In the Discrepancy task tab, use the List of discrepancies to locate the discrepancy listing.

3. Either work with the discrepancy in the List of discrepancies tab or use the sequence number to identify and open the relevant Individual discrepancy tab.

Discrepancy Window Procedure

Use the procedure described in "Review Discrepancies" on page 9-7 to open the discrepancy window for a specific discrepancy. You can use the window to review and update the discrepancy. Note that if you want to modify the Error Message in a univariate discrepancy, you must do this in its discrepancy window.

Take Action on a Discrepancy

This topic covers the procedures that you follow to take an action on a discrepancy. To update a discrepancy, your user name must be assigned the **update discrepancy**, at a minimum.

Route a Discrepancy

To route a discrepancy to another role:

1. Put the discrepancy in focus, either in the Discrepancy task tab or a discrepancy window.

2. Use the Action drop-down list to select a routing action. For example, "Send to Site."

3. Save pending changes.

Resolve a Discrepancy

To resolve a discrepancy:

1. Put the discrepancy in focus, either in the Discrepancy task tab or a discrepancy window.

2. Use the Action drop-down list to select a resolution. For example, "Closed - Resolved." The system opens the Resolution Reason Window.

3. In the Resolution Reason window, use the Resolution drop-down list to select a reason. Note that you must select a resolution reason.

4. If necessary, type a comment in the Comment text box.

5. Click the Save button to save the resolution reason and the comment.

6. If you are working in a discrepancy window, click the Save button to save pending changes and close the window.

CRF Verification Tasks

You use the Verification Task Tab to review the verification history and to change the verification status of a CRF.

This section consists of the following tasks:

- Review the Verification History
- Change the Verification Status of a CRF

Review the Verification History

You can review the verification history of a CRF if its verification status has changed. Refer to Figure 9–1, "Example of the Verification Task Tab" for an illustration of the verification history for a CRF.

To review the verification of a CRF:

1. Open the CRF in the Data Entry window.

2. Click the Verification task tab. If the verification status of the CRF has changed from its original not verified, the system displays the verification history in the task tab.

Change the Verification Status of a CRF

There are three circumstances in which you can change the verification status of a CRF.

1. If it is not verified or if verification is undone, you can verify the CRF.

2. If it is verified, you can undo verification of the CRF.

3. If it is awaiting re-verification, you can either re-verify it or undo verification.

Figure 9–1, "Example of the Verification Task Tab" shows an example of the Verification task tab of the CRF that was verified when a response datapoint was updated. This causes the system to change its status from verified to awaiting re-verification. The graphic also illustrates the verification history that is included in the task tab when its status changes to verified for the first time.

Figure 9–1   Example of the Verification Task Tab

Procedure

CRFs are assigned one of four verification statuses, one of which is "Verified." To verify a CRF that is in one of the three other statuses:

1. Click the relevant CRF cell to put the document is focus.

2. Click the Verification Task Tab label to display its contents.

3. If necessary, use the Comment field to type a message that describes your actions.

4. If you are verifying multiple documents in sequence, you may want to select the "Keep comments between verifications" check box.

5. Click the Verify button.

CRF Approval

This section includes the following tasks:

- Approve a CRF on page 9-10
- Undo CRF Approval on page 9-11

Approve a CRF

CRFs are assigned one of four approval statuses. To approve a CRF that is in one of the three eligible statuses:

1. Click the relevant CRF cell to put it in focus.

2. Click the Approval Task Tab label to display its contents.

3. If necessary, use the Comment field to type a message that describes your actions.

4. If you are approving multiple documents, you may want to select the "Keep comments between approvals?" check box.

5. In the Password text box, type the password that is associated with your user name.

6. Press the Enter key. The "Approval" Password Confirmation Window is displayed.

> **Note:** If you are approving multiple CRFs within a short period of time, the Password confirmation window may not be displayed. It may be displayed after a certain period of time (e.g., 10 minutes) have elapsed.

7. In the Password Confirmation window, type your user name (with the "OPS$" prefix) in the Username text box.

8. Click the OK button.

Undo CRF Approval

CRFs are assigned one of four approval statuses.

To undo the approval of a CRF that is approved:

1. Click the relevant CRF cell to put it in focus.

2. Click the Approval Task Tab label to display its contents.

3. If necessary, use the Comment field to type a message that describes your actions.

4. If you are undoing the approval of multiple documents, you may want to select the "Keep comments between approvals?" check box.

5. Click the Undo Approval button. The Password Confirmation Window for Undo Approval is displayed.

6. In the Password Confirmation window:

   a. Type your user name (with the "OPS$" prefix) in the Username text box.

   b. Type the password associated with your user name in the Password text box.

   c. Click the OK button.

10

Study Closeout

RDC Classic Reports is a feature that allows you to generate printouts of patient data or printouts of blank CRFs. By setting certain parameters, you can view distinct subsets of patient data based on such factors as: study, site, range of patients' numbers, or dates. Alternatively, you can generate reports that use the existing Search window criteria.

This section covers the following topics:

- Locking and Unlocking CRFs on page 10-1

- Running Reports on page 10-1

Locking and Unlocking CRFs

The following related topics are described elsewhere in the documentation:

- Refer to "Lock an Individual CRF" on page 5-15 for a description of this procedure.

- Refer to "Unlock a CRF" on page 5-16 for a description of this procedure.

- Refer to "Lock a Group of CRFs" on page 7-13 for a description of this procedure.

Running Reports

This section provides instructions to successfully run reports in RDC Classic. It describes each of the windows that you use to setup, schedule, and run a report.

Reports in RDC Classic are collectively referred to as patient data reports or PDRs. Refer to "Reports in RDC Classic" on page 4-1 for information about the types of reports that are available in RDC Classic.

This section covers the following topics:

- Patient CRFs Report on page 10-1

- Blank CRFs Report on page 10-5

- Continue Work while a Report Runs on page 10-6

- Monitor the Progress of a Report on page 10-6

- View and Print a Report on page 10-6

Patient CRFs Report

When you choose to print patient CRFs, you can also choose to use the criteria currently specified in the Search Window, or you can choose to define a different set of

criteria that is independent of, and not restricted by, the current Search window criteria. The two choices are:

1. Print Patient CRFs Using Current Selections

2. Print Patient CRFs by Specifying Report Parameters

The following procedures describe the process of running a report for each option.

Figure 10–1   Reports Window
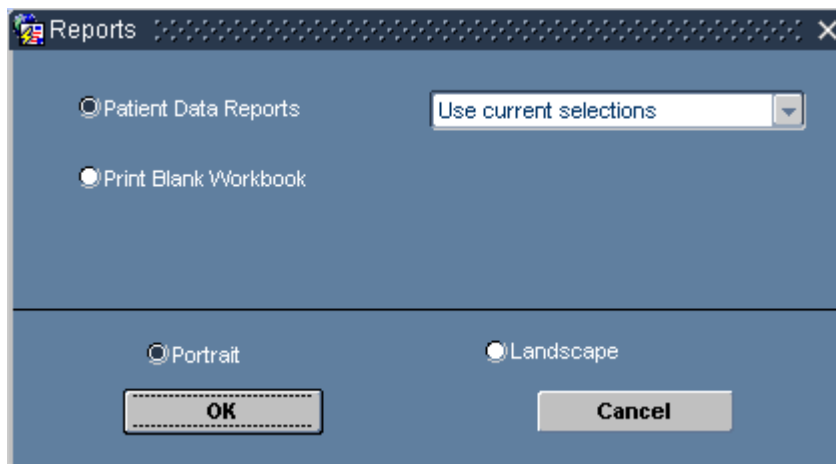
Print Patient CRFs Using Current Selections

This option uses the current Search window criteria. Because the search criteria populates the RDC Classic Spreadsheet, this report is essentially a compilation of the patients and CRFs that are currently displayed in the Spreadsheet.

To generate the report:

1. From the File menu, choose **Reports**. The Reports Window opens.

2. Select **Patient Data Reports** and the "Use current selections" option.

3. Ensure the page layout is set to your preference (Portrait or Landscape).

4. Click **OK**. The Report Submission Window opens with the heading, "Report selected patient data in CRF Format."

Figure 10–2   Report Submission Window

5.   In the window, ensure that all parameters are set correctly. Refer to "Report Submission Window" on page 14-32 for information on the parameter settings.

6.   Click the Job Details button, which opens the Submission Details for Report Window.

Figure 10–3   Submission Details for Report... Window

7.   In the Submission Details for Report... window:

   a.   Make a note of the Report Server Job number.

   b.   Ensure that the Mode of Execution field is set the value to "BATCH_ IMMEDIATE."

   c.   Ensure that the Report Server field is set to the name of your Reports Server.

d. Ensure that the Output Type field is set to "PREVIEW".

e. Ensure that the Output Format field is set to "PDF".

8. In the Submission Details window, click the Submit Job button. An acknowledge is displayed in a message window.

Figure 10–4 Job Submittal Message Window
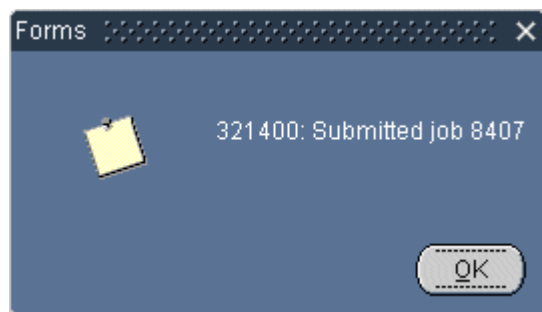
9. Click the OK button to clear the message window. The "Report selected patient data in CRF Format" window is displayed.

10. In the "Report selected patient data in CRF Format" window:

- click the Exit button to close RDC Classic Reports, or

- click the Job Details button to view the Submitted Batch Jobs Window, which lists each job and its status.

Print Patient CRFs by Specifying Report Parameters

This is the second option you can choose when you are setting up to generate a patient data report. While this option and the "Print Patient CRFs Using Current Selections" option generate reports in the same format, the latter option uses the current Search window criteria.

1. From the File menu, choose **Reports**. The Reports Window opens.

2. Select **Patient Data Reports** and the "Specify report parameters" option.

3. Click **OK**. A window with the heading, "Report patient data in CRF format," opens.

4. In the "Report patient data in CRF format" window, type the name of your Reports Server in the Server/Queue field or select it from the LOV.

5. Specify the parameters that are necessary for the report.

6. Click the Job Details button, which opens the Submission Details for Report Window.

7. In the Submission Details... window:

a. Make a note of the Report Server Job number.

b. In the Mode of Execution field, use the LOV to set the value to "BATCH_ IMMEDIATE".

c. In the Report Server field, ensure that the value is set to the name of your Reports Server.

d. In the Output Type field, use the LOV to set the value to "PREVIEW".

     e. In the Output Format field, use the LOV to set the value to "PDF".

8. In the Submission Details window, click the Submit Job button. An acknowledgement is displayed in a message window.

9. Click the OK button to clear the message window. The "Report selected patient data in CRF Format," window is displayed.

10. In the Report selected patient data in CRF Format window:

- Click the Exit button to close RDC Classic Reports, or

- Click the Job Details button to view the Submitted Batch Jobs window, which lists each job and its status.

Blank CRFs Report

To print a blank CRF report:

1. Select **File**, then **Reports** from the option list to open the Reports window.

Figure 10–5   Reports Window
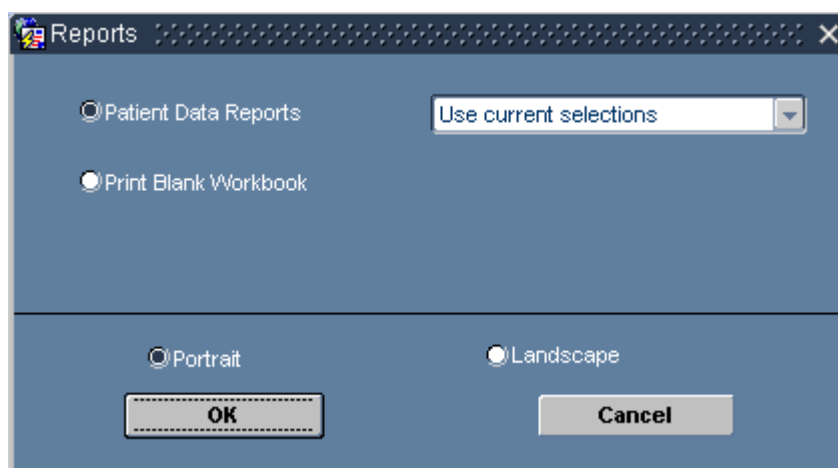
2. Select **Print Blank Workbook**.

3. Click the OK button. The system displays the Report Submission Window.

4. In the window, use the LOV to select a book.

5. Click the Job Details button The system opens the Submission Details for Report Window.

6. In the Submission Details for Report window:

     a. Make a note of the Report Server Job number.

     b. In the Mode of Execution field, use the LOV to set the value to "BATCH_ IMMEDIATE".

     c. In the Report Server field, ensure that the value is set to the name of your Reports Server.

     d. In the Output Type field, ensure the value is set to "PREVIEW".

     e. In the Output Format field, ensure the value is set to "PDF".

7. Click the Submit Job button. An acknowledgement that includes the Job Number is displayed in a message window.

8. Click the OK button to clear the message window.

9. The system opens the Report Previewer Window.

   ■ Click the Report Server Screen button to open the Report Queue Manager Window.

   ■ Click the Job Status Screen button to open the Submitted Batch Jobs Window.

Continue Work while a Report Runs

Certain reports may require extended time to run. You can continue to work in RDC Classic while the report runs. To do this, close all Reports-related windows, place focus in the RDC Classic Workspace and proceed normally. When you want to check on the status of the report, refer to "Monitor the Progress of a Report" on page 10-6.

Monitor the Progress of a Report

When you close all Reports-related windows so that you can continue work in RDC Classic, you must re-open the Submitted Batch Jobs Window to review the status of a report. To do this:

1. Select **File**, then **Reports** from the option list to open the Reports window.

2. Select the **Print Blank Workbook** radio button.

3. Click the **OK** button. The system opens the Report Submission Window.

4. In the Report Submission window, click the **Job Status** button. The system opens the Submitted Batch Jobs Window.

5. In the Submitted Batch Jobs window, locate the Job Id of the report you want to check and review its Execution Status.

View and Print a Report

In most cases, you do not have access to printers that are on the same network as the application server. For this reason, you specify the Output parameter in the Submission Details for Report Window as "PREVIEW", rather then the "PRINT" value, which sends the report directly to a printer on the same network as the application server computer.

When you chose to preview the report, it allows you to view it in Adobe Reader or Acrobat. From within either of these applications, you have the option to print the file and/or save the file to your local computer.

1. Navigate to the Submission Details for Report Window. If the Reports-related windows are closed, refer to "Monitor the Progress of a Report" on page 10-6 for information.

2. In the Submission Details window, click the View Output button. The system displays the Output File Window, which displays the location on the application server where the report resides.

3. Click the OK button. The system opens the report in Adobe Reader or Acrobat, depending on your system configuration and which application is installed.

4. When the PDF file opens, you can:

   ■ Save it locally.

   ■ Print it using a local printer.

Part III

RDC Classic GUI Reference

This part of the RDC Classic manual describes the components of the RDC Classic Graphical User Interface, how to use them, and how they interact. It includes sections that address the windows, Spreadsheet, task tabs, toolbar, and menus. All of these components are part of the RDC Classic Graphical User Interface, or GUI.

Although the main part of RDC Classic The GUI is the part of the application that you view and use through

The GUI components are categorized here by function and structure, however, certain components are important enough to require an entire chapter to discuss and describe them adequately.

You should review this section prior to working with the Task-based sections so you are familiar with the terminology used in the task descriptions.

The sections that make up this part of the manual are:

- RDC Classic Workspace on page 11-1
- RDC Classic Spreadsheet on page 12-1
- Task Tabs on page 13-1
- General RDC Classic Windows on page 14-1
- Search Window on page 15-1
- RDC Classic Windows on page 16-1

11

RDC Classic Workspace

The RDC Classic Workspace is comprised of the components that are displayed throughout your RDC Classic session. This includes the Main Application window, a menu bar, a toolbar, the RDC Classic Spreadsheet, and the task tabs. The tasks for which you use the RDC Classic Workspace include such jobs as running reports, working with group activities, and adding patients, CRFs, or visits.

The Main Application window consists of the window that encompasses the other components. The menu bar is comprised of menus, each of which contain a set of commands. The toolbar consists of a set of buttons that provide rapid access to commonly used menu commands. The RDC Classic Spreadsheet consists of the matrix of patients, CRFs, and visits. The task tabs are a set of tools, each on its own tab, that allows you to view information about the current patient data set, access sponsor defined links, and perform discrepancy management, approval, verification, or audit review tasks.

These sections discuss the RDC Classic Workspace and its components:

The two other RDC Classic Workspace components are described in these sections:

Overview of the RDC Classic Workspace

The RDC Classic Workspace is the part of RDC Classic that is present throughout your RDC Classic **session**. Unlike the various windows, such as the Reports Window, the discrepancy management windows, and Activity List Window, which are displayed while you use them and are then dismissed, the components of the Workspace are **persistent**.

The following sections describe the RDC Classic Workspace:

- Organization of the RDC Classic Workspace
- Workspace Variations

Organization of the RDC Classic Workspace

The RDC Classic Workspace is organized with the Main Application window containing the other components. The other Workspace components are arranged such that, from the top of the Main Application Window moving down, there is the:

- Menu Bar

- RDC Classic Toolbar

- RDC Classic Spreadsheet

- Task Tabs

Workspace Variations

There may be differences between the Workspace that you are presented with and that which is described in this guide. This is due to any of several factors that determine the components that are present during your session, the manner in which they are presented, and whether you are able to access, or use, a particular component. In general, this guide describes RDC Classic as it is shipped, or as it functions with certain RDC Classic Configurator settings defined in a manner that enables a description of that functionality.

The following sections describe each of the primary factors that affect the makeup of the RDC Classic Workspace in your session.

- RDC Classic Configurator Settings

- User Role

RDC Classic Configurator Settings

Because one of the goals of RDC Classic is to provide a highly configurable interface that allows study designers and system administrators to tailor the application to meet the unique requirements of each study, your RDC Classic Workspace may not include all of the components that are listed and described here. A notable example of this is the Group Activities Menu, which may be absent from the Workspace.

In addition, certain components, notably among the Task Tabs, may be labeled differently in your Workspace.

User Role

The role that is assigned to your user name determines, to large extent, what tasks you are able to perform in RDC Classic. Consequently, you may notice certain components in the RDC Classic Workspace, as well as in dialog windows, are not available to you.

RDC Classic Workspace Components

The RDC Classic Workspace is comprised of several GUI components that provide you with information about your session, various functionality tools, and access to patient data. The following sections describe each component:

- Main Application Window

- Menu Bar

- RDC Classic Toolbar

The two other RDC Classic Workspace components are described in these sections:

- RDC Classic Spreadsheet on page 12-1

■ Task Tabs on page 13-1

Main Application Window

The RDC Classic Main Application Window is the frame that contains all of the other RDC Classic Workspace components. In general, all of the windows that RDC Classic displays that allow you to complete various tasks open on top of and within the borders of the Main Application window.

Access

The Main Application window opens when you start a session and persists throughout the session. The system gives you access to the Workspace after you successfully login and use either the Activity List window or the Search window to select a workset.

> **Note:** The system may also display the News Window as part of session startup.

Title Bar

The title bar is the top border of the Main Application window. It displays information about the current session. The information displayed includes:

■ User name

■ User role

■ Name of the database you are logged into

■ Current date

■ Current study

■ Current Site (unless the search criteria is set to All Sites)

■ Current Book

Menu Bar

The Menu bar gives you access, via menu items, to the full set of commands available through the RDC Classic Workspace. It is located just below the Title Bar and above the RDC Classic Toolbar. The organization of the menus and the set of commands in each is based on a logical grouping of similar actions.

Access

You can use either the mouse or a keyboard-based "quick key" combination to view a menu. When you access a menu, the system displays its set of commands in a drop-down list from which you can then select an action.

The availability of the Group Activities Menu is dependent on a setting in the RDC Classic Configurator, which your system administrator manages. All other menus are present, by default, in all RDC Classic Workspaces.

Your access, or ability to use a particular menu command, is based on the privileges that are assigned to your user name, and the current focus in the application. When the privileges assigned to your user name do not allow you to use a particular function, the menu command associated with that function is rendered inactive.

An exception to this is selecting the **Preferences** option from the **Edit** list, which opens the Preferences Window. As with the Group Activities menu item, your system administrator can use the RDC Classic Configurator to remove the Preferences command from the Edit menu.

Components

The Menu bar consists of a set of menus that allow you to take various actions and perform different tasks in RDC Classic. The following sections describe each menu and its commands:

- File Menu on page 11-5
- Edit Menu on page 11-7
- Insert Menu on page 11-9
- CRF Menu on page 11-10
- Group Activities Menu on page 11-11
- Validate Menu on page 11-12
- Help Menu on page 11-12
- Window Menu on page 11-13

Usage

You can use menus and menu commands either through the:

- mouse, or
- keyboard.

To use a menu with the mouse:

1. Click on the relevant menu, the commands associated with it are displayed in an expanded list
2. Click the desired menu command.

To use the keyboard to open menus and activate menu commands, you must first identify the access key that is associated with the menu and the command. To use the keyboard to activate a menu command:

1. Identify the access key in the menu's title.
2. Press the **Alt** key and the relevant letter. The system opens the drop-down list of commands associated with that menu.
3. Press the key that corresponds to the underlined letter in the desired menu command.

File Menu

The File menu (Figure 11–1) consists of the commands that are related to large-scale application activities.

Figure 11–1   File Menu Commands
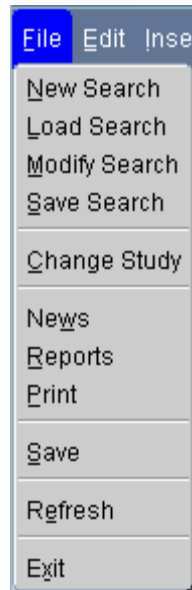
Commands

Table 11–1 describes the commands on the File menu.

Table 11–1   File Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
New Search	Opens the Search Window with all criteria set to default values.	Alt+f, n
Load Search	Opens the List of Saved Searches Window.	
Modify Search	Opens the Search Window with the current search criteria active, even if those criteria were set indirectly through the Activity List Window.	Alt+f, m
Save Search	Opens the Save Current Search Window.	
Change Study	Opens the Change Study Window, which allows you to change the active study.	Alt+f, c
News	Opens the News Window.	Alt+f, w
Refresh	Runs the current search criteria to re-query the database and updates the workset.	Alt+f, e
Reports	Opens the Reports Window.	Alt+f, r
Print	Initiates the procedure to print a screen capture of the RDC Classic Workspace.	Alt+f, p
Save	Saves all pending changes to the database.	Alt+f, s or F10

Table 11–1   (Cont.) File Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
Exit	Closes RDC Classic; if there are pending changes, RDC Classic prompts you to save or discard the changes or to discontinue the exit sequence and revert back to the application.	Alt+f, x

Usage

This section describes the functionality of certain File menu commands.

New Search This command allows you to reset the Search window to its default criteria. It is useful when you have previously modified several search criteria for the current workset and want to change the workset using a different set of criteria.

Load Search This command opens the List of Saved Searches Window, which allows you select from a list of saved searches for your session.

Modify Search This command opens the Search window with all criteria set to current values. It is useful if you want to make minor adjustments to your current criteria set. Note that this menu command has the same functionality as:

■   the Search Button that is a constituent of the RDC Classic Spreadsheet

■   the Search Button that is a constituent of the Activity List Window

Save Search This command opens the Save Current Search Window, which allows you assign a name and description to the current set of **search criteria** and then save it to the database as a saved search.

Change Study This command opens the Change Study Window, which allows you change the active study. This command is inactive if you have access to only one study.

Refresh This command runs the current search criteria so that the study database is re-queried and the **workset** is reset. It is useful to use this action prior to initiating a group activity because it ensures that the workset contains only those CRFs that satisfy the **search criteria**.

> **Note:**   When you use the Refresh command, the system may remove certain CRFs, those that no longer meet the search criteria, from the workset.

Print This command opens the Windows Print window, which allows you to specify a printer and print settings.

Save This command commits any pending changes to the study database.

Edit Menu

The Edit menu (Figure 11–2) consists of commands that are primarily meant to assist you with data entry and discrepancy management tasks. Its purpose is to allow you to record new data or update existing data.

Figure 11–2   Edit Menu Commands

Commands

Table 11–2 describes the commands on the Edit menu.

Table 11–2   Edit Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
Cut	Copies the selected text to the Windows Clipboard and deletes it from the current field.	Ctrl-x or Alt+e, t
Copy	Copies the selected text to the Windows Clipboard.	Ctrl-c or Alt+e, c
Paste	Inserts the contents of the Windows Clipboard at the insertion point. Accessible when the Clipboard contains text and the insertion point is in an editable field.	Ctrl-v or Alt+e, p
Duplicate Field	Duplicate the contents of a field from one repeating row to the next in sequence.	Alt+e, d
Delete CRF	Deletes the CRF that is currently in focus. Accessible in when a CRF icon is selected in the RDC Classic Spreadsheet.	Alt+e, d
Field Editor	Opens the Field Editor Window. Accessible when focus is in an editable text field.	Alt+e, e
Preferences	Opens the Preferences Window.	Alt+e, f

Table 11–2   (Cont.) Edit Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
Discrepancy	Opens the Comment for Question window for the field currently in focus if at least one **univariate discrepancy** exists for the field.	Alt+e, y
Discrepancy (manual)	Opens the Comment for Question window for the field currently in focus. The command is inaccessible if a **manual discrepancy** does not exist for the response field.	Alt+e, m
Section Discrepancy	Opens the Discrepancy for CRF Section window for the CRF section currently in focus. The command is inaccessible if a **section discrepancy** does not exist for the current CRF section.	Alt+e, s
Investigator Comment	Open the Investigator Comment window associated with the response field currently in focus. The command is not accessible if an investigator comment does not exist for the response field in focus.	Alt+e, i
Maintain Search	Opens the Maintain Saved Search Window that is appropriate for the current user.	Alt+e, m

Usage

This section describes basic usage of the Edit menu commands described in Table 11–2. Note that much of the functionality that is available through the discrepancy and investigator comment commands is also available through the Discrepancy Task Tab.

Cut, Copy, and Paste These commands are identical to the functions that are available in other Microsoft Windows applications.

Use the Cut command to copy the selected text to the Clipboard and remove the selection from its current location.

Use the Copy command to copy the selected text to the Clipboard and also leave the selection at its current location.

Use the Paste command to insert the contents of the Clipboard at the insertion point.

Duplicate Field This command is useful when you are working with a **repeating question** in the Data Entry window and you want to use the same value in the same field for a succession of rows. The command is active when there is a previous field in a repeating question group that contains data and focus is in the same field in the next row.

Delete CRF Use this command to delete an entire CRF. To do this, place focus in the appropriate CRF cell and select **Edit**, then **Delete CRF** from the option list.

Refer to "Delete a CRF" on page 5-8 for a full description of this task.

Field Editor This command opens the Field Editor Window, which allows you to compose a text message in a larger text box. The Field Editor also allows you search through existing text.

Preferences This command opens the Preferences Window, which allows you to change various settings that control certain functionality in your session. Note that the Preferences menu command is configurable by the system administrator. Therefore, this menu command may not be present in your RDC Classic Workspace.

Discrepancy This command opens the Comment for Question window, which displays a univariate discrepancy that is associated with the response field in focus. The command is accessible if a **univariate discrepancy** exists for the response field. If more than one univariate exists for the field, the system presents the discrepancy with the lower **sequence number**.

Discrepancy (manual) This command opens the Comment for Question window, which displays the user-generated discrepancy that is associated with the current response field. The command is accessible if an manual discrepancy exists for the response field.

Section Discrepancy This command opens the Discrepancy for CRF Section window, which displays the section discrepancy that is associated with current CRF section. The command is accessible if a section discrepancy exists for the section. If more than one section discrepancy exists, the system presents the discrepancy with the lower **sequence number**.

Investigator Comment This command opens the Investigator Comment window, which displays the investigator comment that is associated with the current response field. The command is accessible if an investigator comment exists for the field.

Maintain Search This command opens the Maintain Saved Search Window that is applicable to the privileges associated with your user name. This window allows you to modify existing saved searches and create new ones based on existing entries.

Insert Menu

The Insert menu (Figure 11–3) consists of commands that allow you to add patients, CRFs, or unplanned visits to the Spreadsheet. There are also commands that allow you initiate discrepancies and investigator comments.

Figure 11–3   Insert Menu Commands
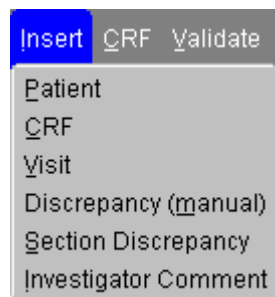
Commands

Table 11–3 describes the commands on the Insert menu.

Table 11–3   Insert Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
Patient	Displays the Insert New Patient Window, which initiates the process of adding a new patient to the Patient List.	Alt+i, p
CRF	Displays the Add Unplanned CRF Window, which initiates the process of adding an unplanned CRF to the currently active visit.	Alt+i, c

Table 11–3   (Cont.) Insert Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
Visit	Initiates the process of adding an unplanned visit after the current one.	Alt+i, v
Discrepancy (manual)	Opens the Comment for Question window, which allows you to initiate a discrepancy for the response field in focus.	Alt+i, m
Section Discrepancy	Opens the Discrepancy for CRF Section window	Alt+i, s
Investigator Comment	Opens the Investigator Comment window associated with the response field in focus.	Alt+i, i

Usage

You use the commands in the insert menu to either add to the contents of the Spreadsheet, or to add a discrepancy or investigator comment to the current CRF.

Patient This command opens the Insert New Patient Window, which allows you to add a patient to the current **case book**.

Discrepancy (manual) This command is accessible if you have the requisite privilege to update discrepancies and an open discrepancy does not exist for the response field in focus.

CRF Menu

The CRF menu (Figure 11–4) consists of commands that affect the CRF that is displayed in the Data Entry window.

Figure 11–4   CRF Menu Commands
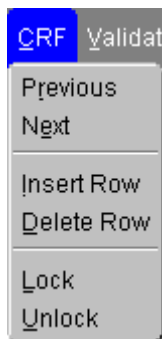
Commands

Table 11–4 describes the commands on the CRF menu.

Table 11–4   CRF Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
Previous	Moves focus to the previous CRF.	Alt+c, r
Next	Moves focus to the next CRF.	Alt+c, e
Insert Row	Adds a row in repeating question groups that do not have a qualifying value.	Alt+c, i

Table 11–4   (Cont.) CRF Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
Delete Row	Deletes a row in repeating question groups that do not have a qualifying value.	Alt+c, d
Lock	Locks the current CRF.	Alt+c, l
Unlock	Unlocks the current CRF.	Alt+c, u

Group Activities Menu

The Group Activities menu (Figure 11–5) allows you to work with multiple CRFs. Each command acts on the set of CRFs that are currently displayed in the Spreadsheet. The factors that affect the availability of the commands are:

- The privileges assigned to your user name

- Limiting the workset to a single site

- The status of the CRFs in the workset

Figure 11–5   Group Activities Menu Commands
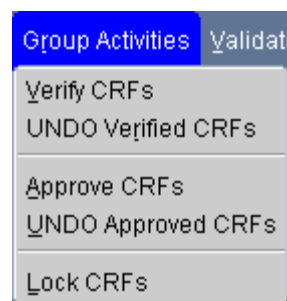
Commands

Table 11–5 describes the commands on the Group Activities menu.

Table 11–5   Group Activities Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
Verify CRFs	Initiates the procedure to verify all CRFs in the current workset.	Alt+r, v
Undo Verified CRFs	Initiates the procedure to undo verification of all CRFs in the current workset.	Alt+r, r
Approve CRFs	Initiates the procedure to approve all CRFs in the current workset.	Alt+r, a
Undo Approved CRFs	Initiates the procedure to undo approval of all CRFs in the current workset.	Alt+r, u
Lock CRFs	Initiates the procedure to lock all CRFs in the current workset.	Alt+r, l

Validate Menu

The Validate menu (Figure 11–6) consists of commands that allow you to validate data at patient, site, or study level.

Figure 11–6   Validate Menu Commands
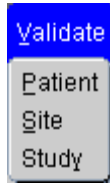
Commands

Table 11–6 describes the commands on the Validate menu.

Table 11–6   Validation Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
Patient	Runs validation on all of the CRFs associated with the patient currently in focus.	Alt+v, p
Site	Runs validation on the CRFs associated with all of the sites to which you have access.	Alt+v, s
Study	Runs validation on all CRFs associated with the current study.	Alt+v, y

Help Menu

The Help menu (Figure 11–7) gives you access to two of the three features of the RDC Classic Help system. You can access the third feature, context-sensitive help, by pressing the F1 key or clicking the Help button on the RDC Classic Toolbar.

Figure 11–7   Help Menu Commands
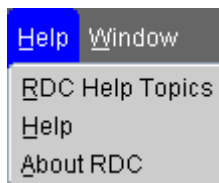
Commands

Table 11–7 describes the commands on the Help menu.

Table 11–7   Help Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut Key
RDC Help Topics	Opens the CRF Icon Legend Window.	Alt+h, r
Help	Opens the RDC Classic Online Help Window.	Alt+h, h
About RDC	Opens the About Window.	Alt+a, a

Window Menu

The Window menu (Figure 11–8) allows you to reorganize open RDC Classic windows and quickly access a window that may not be currently visible.

Figure 11–8   Windows Menu Commands
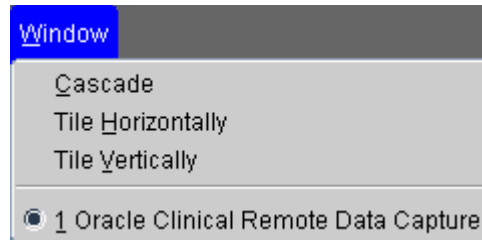
Commands

Table 11–8 describes the commands on the Window menu.

Table 11–8   Window Menu Commands: Descriptions and Shortcut Keys

Command	Description	Shortcut key
Cascade	When more than one window is open in RDC Classic, aligns the windows on top of one another, with only the title bar of each underlying window visible.	Alt+w, c
Tile Horizontally	When more than one window is open in RDC Classic, resizes and aligns all open windows by making each as wide as the Main Application window and high enough to allow each window to be displayed.	Alt+w, h
Tile Vertically	When more than one window is open in RDC Classic, resizes and aligns all open windows by making each as high as the Main Application window and wide enough to allow each window to be displayed.	Alt+w, v
Select window	When more than one window is open, provides a mechanism to navigate to other windows, which are identified in a numbered list.	Alt+w, #

RDC Classic Toolbar

The RDC Classic Toolbar allows you to perform functions quickly, using only the mouse. All of the functions that are available on the toolbar are also available through menu commands.

The toolbar, shown in Figure 11–9, consists of ten buttons. Each button contains a distinctive icon graphic, which indicates the action the button initiates when you click it.

Figure 11–9   RDC Classic Toolbar

Access

The RDC Classic Toolbar is an integrated constituent of the RDC Classic Workspace. It is displayed with all other Workspace components when a session is initiated.

Certain functions are not available while you work with a component of RDC Classic that does not use or allow the function. In these cases, the button that is associated with an unavailable function is inactive, that is the system displays it as "greyed out".

The system renders each button active or inactive based on the current task, focus, and context. For example, if there is no content in the Window Clipboard, the Paste toolbar button is inactive.

Toolbar Components and Associated Actions

Table 11–9 describes the toolbar buttons, the actions that each enables, and the equivalent menu commands.

Table 11–9   RDC Classic Toolbar Buttons

Button	Label	Description	Equivalent Menu Command
	Insert Patient	Displays the Insert New Patient Window, which initiates the process of adding a new patient to the Patient List.	**Insert**, then **Patient**
	Save	Save all pending changes.	**File**, then **Save** or press F10
	Cut	Copies the selected text to the Windows Clipboard and deletes it from the current field.	**Edit**, then **Cut**
	Copy	Copies the selected text to the Windows Clipboard.	**Edit**, then **Copy**
	Paste	Inserts the contents of the Windows Clipboard at the insertion point.	**Edit**, then **Paste**
	Previous CRF	Moves focus to the previous CRF. This button is accessible when the Data Entry window is open.	**CRF**, then **Previous Page**
	Next CRF	Moves focus to the next page. This button is accessible when the Data Entry window is open.	**CRF**, then **Next Page**
	Investigator Comment	Opens the Investigator Comment window for the response that is currently in focus. This button is accessible when the Data Entry window is open.	**Insert**, then **Investigator Comment**
	Discrepancy (manual)	Opens the Comment for Question window for the response in focus. This button is accessible when the Data Entry window is open.	**Insert**, then **Discrepancy** (manual)
	Help	Opens the RDC Classic Help system, which allows you to view more information about your current task, or browse to other information.	F1

12

RDC Classic Spreadsheet

The RDC Classic Spreadsheet is a component of the RDC Classic Workspace. It graphically displays the status of each CRF in a manner that is meaningful to each RDC Classic role by using study milestones as the basis for displaying data. It allows you to display CRFs arranged within an individual visit, within a phase, or over the entire study. You can use the RDC Classic Spreadsheet to open a CRF in a Data Entry window and to add patients, CRFs, or visits to the current book and site.

This topics in this section discuss the structure and organization of the RDC Classic Spreadsheet and describe each of its components, including how each one interacts with other RDC Classic components.

The following sections describe the RDC Classic Spreadsheet:

- Discussion on page 12-1
- Components of the Spreadsheet on page 12-2
- Navigation and Information Aids on page 12-14

Discussion

This section provides a functional context for the following description of the RDC Classic Spreadsheet components. The subsections discuss each RDC Classic role and offer some general methods to effectively use the Spreadsheet to accomplish the tasks usually associated with each role.

This section is comprised of the following subsections:

- Organization
- Purposes of the RDC Classic Spreadsheet
- Spreadsheet Focus

Organization

The RDC Classic Spreadsheet consists of a grid or matrix of cells, each of which represents a CRF (refer to Figure 12–1, "Components of the RDC Classic Spreadsheet"). Every row and column is uniquely identified with descriptive information, in the form of page numbers, visit designations, CRF names, and patient numbers.

Functionally, the Spreadsheet gives you easy access to patient and CRF data and presents information about the data in a logical and clear manner. Depending on how you choose to display the data, you view CRFs on a visit, phase, or whole study basis.

Purposes of the RDC Classic Spreadsheet

The goal of the Spreadsheet is to provide a central location for you to view, access, and work with study data. It allows you to track study progress from a variety of perspectives and provides you with visual cues that help you react to various changes in study data.

At any given time, the Spreadsheet contains all of the CRFs you have access to that satisfy your Search Window criteria. Because each CRF is uniquely defined by a patient number and a visit designation, the Spreadsheet displays the following information for each CRF:

- by looking at the row a CRF appears in, you can find out which patient number it is associated with

- by looking at the column a CRF appears in, you can find out which visit it is associated with.

Spreadsheet Focus

Certain tasks in RDC Classic depend on which RDC Classic Spreadsheet component is in focus. When there are no other windows open in the RDC Classic Workspace, focus in Spreadsheet can be in one of the following components:

- a patient in the Patient List

- a CRF Column header

- a CRF cell.

When a CRF cell is in focus, the corresponding patient and CRF Column header are also highlighted. When either a patient cell or a CRF Column header are in focus, no other component is highlighted.

Certain tasks require that a CRF cell is in focus. For example, the Lock CRF task takes action on the CRF that is highlighted in the Spreadsheet. You can click a CRF cell to place focus in it, however, in most cases this also opens the Data Entry window. Alternatively, you can place focus in a patient cell and use the Tab and the arrow keys to move focus among CRF cells.

Components of the Spreadsheet

This section names and describes the parts of the Spreadsheet. The terminology that is used throughout this manual and the application is based on the descriptions in this section and in the other GUI sections.

The spreadsheet is divided into one or more tabs. There are three types of tabs that are available, each type is linked to a Spreadsheet view: Study, Phase, or Visit.

Refer to Figure 12–1, "Components of the RDC Classic Spreadsheet" and use it as a guide as you read this chapter.

This section includes the following topics:

- Overview on page 12-3

- Current Patients on page 12-4

- CRF Column on page 12-5

- CRF Cell on page 12-7

- Spreadsheet Views on page 12-11

Overview

Table 12–1 describes the major components that comprise the RDC Classic Spreadsheet.

Table 12–1   Major Components of the RDC Classic Spreadsheet

Component	General Description
Current Patients	The set of patients for which there is an associated CRF that meets the search criteria.
CRF Column	Represents a single CRF for all patients in the Patient List.
CRF Cell	The intersection of a patient row and a CRF column, it represents the CRF, identified in the column, that is associated with the patient, identified in the row.
Spreadsheet Views	There are three types of view: Visit, Phase, Study. Each provides a different view of the CRFs that comprise the **workset**.

The functions of the other components in Figure 12–1 are related to these primary components of the Spreadsheet.

Figure 12–1   Components of the RDC Classic Spreadsheet
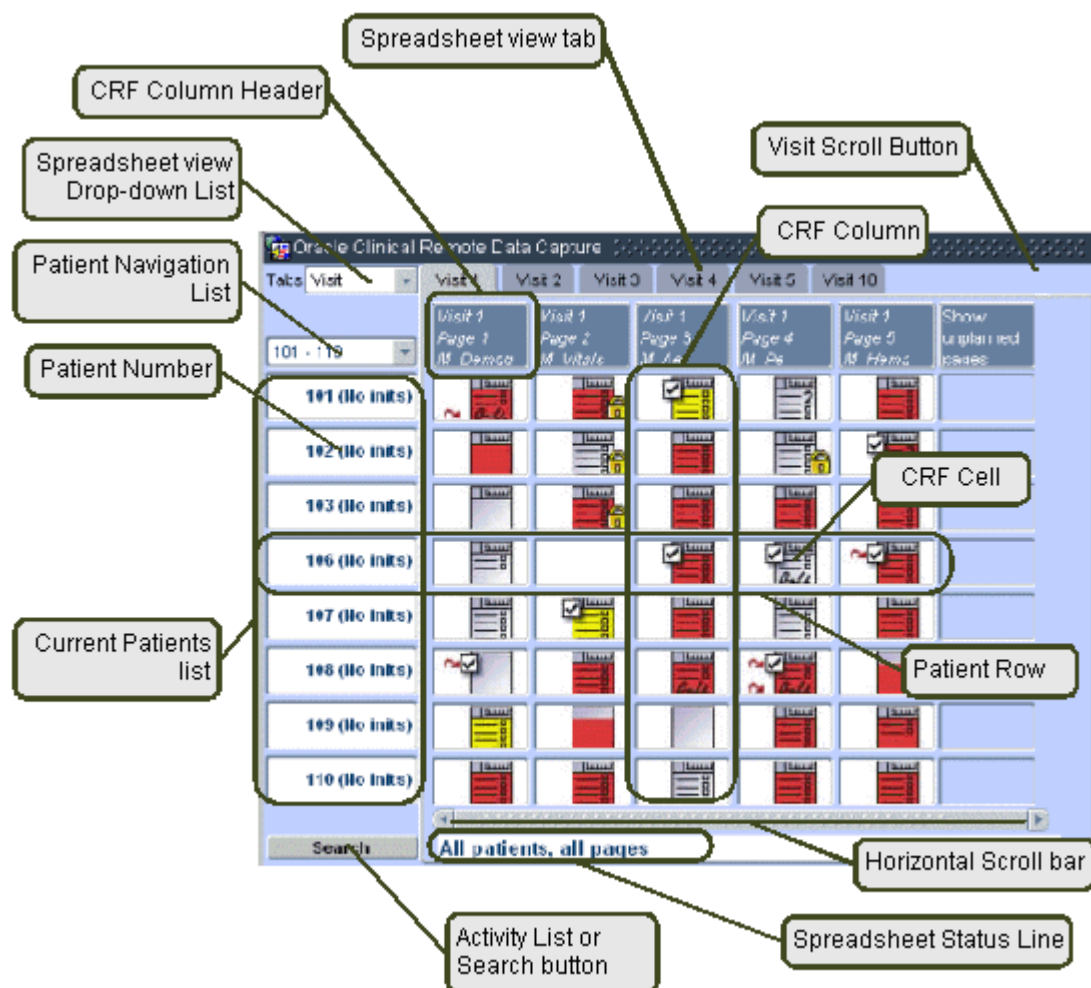
Current Patients

The patient list consists of all of the patient numbers for which at least one CRF satisfies the Search window criteria. The Spreadsheet displays up to eight patient numbers at any one time, in an area called Current Patients. The patient numbers in the Patient List act as row headers in the Spreadsheet.

Contents of Current Patients

At any given time, the patient list, and the contents of Current Patients, consists of only those patients whose data includes at least one CRF that satisfies the Search window criteria. However, if the Patient range parameter of the Patients criteria specifies a range of patient numbers for which at least one CRF is retrieved, the first (and only the first) patient number in the range is displayed in Current List.

Groups of Eight

When you select a task or specify search criteria to define a workset, RDC Classic analyzes the resultant patient list. It then:

1. arranges the list in an order that is defined by the sponsor

2. separates the list into groups of eight

How Search Window Criteria Affect the Patient List

Only those patients that contain data, i.e., for which at least one CRF has been created, are displayed in the Spreadsheet. You must explicitly add each patient number for which no data exists to the Spreadsheet.

Similarly, if you use the Patients criteria in the Search window to define a range of patient numbers, only those patients for which data exists are displayed in the Spreadsheet.

An exception to this is if you define a range that consists entirely of patient numbers for which no data exists. In this case, the first patient number in the range is displayed in the Spreadsheet. This action effectively inserts that patient number into the Spreadsheet and allows you to start entering data for that patient.

Assigned Patients

There are eight patient number boxes displayed in the current patient area. This means that, at any one time, you can view the data associate with eight patients.

A patient number box may be either be:

- empty, in which case the patient number box will not have any information displayed in it, or

- assigned, in which case the cell has a patient number and (optionally) patient initials.

Inserting a New Patient You can use an existing empty patient cell as a rapid way to add a new patient to the study. To add a new patient using an unassigned patient number:

1. Click in any empty patient cell, the Insert New Patient window is displayed.

2. Click the drop-down arrow to view the list of available patient numbers.

3. Select an appropriate patient number.

4. Click the OK button.

Figure 12–2   Insert New Patient Window
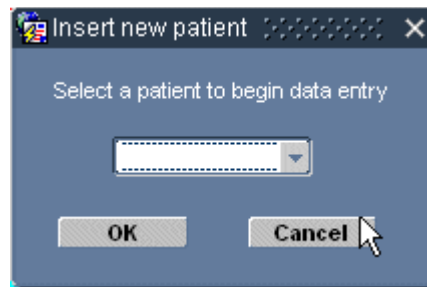
The number you select is inserted into the patient list at the appropriate location, based on where in the set of currently retrieved patient list the new number occurs. The set of eight patient that includes the new patient number are then displayed in the Patient List.

Selecting a Patient

In order to work with the set of data associated with a particular patient, you must either select that patient or a CRF cell in that patient's row. To select the patient, click the appropriate patient cell. When you do this the:

- patient cell is displayed with an aqua-colored background

- Summary Task Tab displays the Patient Summary View

- Main Application Status line lists the patient record's sequence number and the total number of patient records currently retrieved (e.g., "Record: 4/56", which means that you have selected patient record #4 of 56 records retrieved).

Viewing Patients While in Browse Mode

If you are logged into the RDC Classic system with "Browse only" privileges, the patient cells are displayed with a gray background, which is a cue that you cannot update the data in each record.

Frozen Patient Numbers

The Patient Number box of patients whose data is frozen are displayed with gray background fill color. This is an indication that the data in that record cannot be updated, it can only be viewed (browsed).

> **Note:**   Although viewing data in Browse mode and viewing frozen patient numbers may be similar, when you click a CRF for the patient, the "Protection" field in the CRF Summary Section of the CRF view for the Summary Task Tab indicates if the CRF is frozen.

CRF Column

A vertical set of spreadsheet cells is referred to as a column. In RDC Classic, only columns that can contain data are important. These columns are called Page Columns. You can easily identify page columns because there is a Column Header associated with each.

CRF Column Header

The area at the top of each page column, above the first row of CRFs, provides important information about the CRFs currently displayed in the Spreadsheet. Each column contains a header that, for planned events, displays the visit number, page number, and CRF title. The information that is displayed for unplanned events depends on several factors. In all cases, however, enough information is displayed in the page column header to uniquely identify the data in the column within the entire study.

Optional CRFs

The protocol may specify that one or more CRFs be included in a visit, but that they are not required to be collected. Each such CRF is referred to as an optional CRF. The system displays the descriptive information located in the CRF column header for optional CRFs italic font.

Visit Number

The visit number corresponds to the value that is assigned to an occurrence that is either a defined part of the study protocol, i.e., a "planned" event, or an undefined part of the study protocol, i.e., an "unplanned" event.

A visit that is planned is assigned a whole number. A visit that is unplanned is assigned a decimal number that is based on the most recently completed visit. If an unplanned visit is already part of the current planned visit, each subsequent unplanned visit is assigned the next higher decimal number (e.g., 4.2, 4.3, etc.).

Page

The Page designation is assigned to each CRF that is a part of a planned visit. This number corresponds to the page number of the CRF in the hardcopy binder. Unplanned CRF pages are not associated with a page number.

CRF

The CRF name in the Column Headers provides you with the name that is assigned to the CRF.

Color Coding

The information in each heading is displayed in a color that immediately informs you if the CRF pages in that column are associated with a planned or unplanned clinical event.

- Clinical Planned Events, i.e., scheduled visits – column heading information is displayed in black font

- Clinical Events that are not scheduled, i.e., unplanned visits – column heading information is displayed in blue font

Show/Hide Unplanned Pages Button

RDC Classic allows you to add patient data for CRFs that are not part of the visit in the case book. These are termed "unplanned CRFs." If unplanned CRFs are present, they are displayed in the Spreadsheet without a "Page" number in the heading.

Figure 12–3   Show Unplanned Pages and Hide Unplanned Pages Buttons

Figure 12–4 shows the difference between the display of planned and unplanned CRFs. The graphic depicts five CRF column headers in Visit 1. The planned pages, "Demog" and "Vitals" and "PE," are displayed in the farthest left columns. The unplanned CRFs, "AE" and "ECG," are displayed in columns after the last planned CRF.

Figure 12–4   CRF Column Header for Planned and Unplanned Pages

In addition, you can toggle the Spreadsheet between showing and hiding unplanned pages. You do this using a unique column heading that is displayed in the first column heading to the right of the last column with data.

This column heading functions as a button that toggles between two settings when you click it.

1. The column heading text is Show Unplanned Pages, when only planned pages are displayed. If you click it when it reads Show Unplanned Pages, all of the unplanned pages for the current visit are displayed and the button changes (toggles) to Hide Unplanned Pages

2. The column heading text is Hide Unplanned Pages when both planned and unplanned pages are displayed. If you click it when it reads Hide Unplanned Pages, all of the unplanned pages for the current visit are removed from view and the button changes (toggles) to Show Unplanned Pages.

Note that when unplanned pages are displayed in the Spreadsheet, any and all unplanned pages for every patient that is available to your user name are displayed. This means that if an unplanned visit is inserted for a single patient, the CRF cells for that visit are displayed for every patient in the Spreadsheet.

> **Note:**   The Show/Hide Unplanned Pages button may not be present if your criteria settings in the Search window preclude unplanned pages. Specifically, you can select parameters on the Visits/Pages subsearch window that cause only planned pages to be displayed in the Spreadsheet.

CRF Cell

The intersection of a patient row and a CRF column defines a CRF cell. Each CRF cell represents a specific CRF for a given patient. By default, when you click a CRF Cell

that is not frozen or locked, the Data Entry window opens, which allows you to initiate, update, or browse the data.

Background Color in CRF Cells

CRF cells that are not in focus are displayed with a white background. When a CRF cell is in focus, the system colors the cell background aqua. Also, the corresponding patient cell and CRF column are also highlighted, which helps you ensure you are working with the correct CRF.

The graphic in Figure 12–5, "Example of Highlighted CRF Cell, Patient, and Page Column Header" depicts an example of this behavior. In this graphic, the PE CRF for Visit 2, Page 5 for Patient K102 is in focus.

Figure 12–5   Example of Highlighted CRF Cell, Patient, and Page Column Header
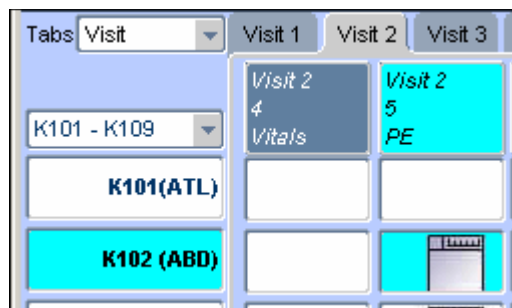
Empty CRF Cells

There are two types of empty CRF cells that may be present in the RDC Classic Spreadsheet: those that are part of the active Spreadsheet and those that are not. A CRF cell for which data entry has not yet started is referred to as an empty CRF cell. Each empty CRF cell is displayed as an all white field. Cells that are not part of the active Spreadsheet are colored blue and are not active, that is, the system does not respond when you click the cell.

When you click an empty CRF cell, the system opens the Data Entry window to facilitate initial data entry (provided your user name is assigned the **update** privilege).

Figure 12–6 displays two CRF cells and two cells that are not part of the active Spreadsheet.

- The cell in the upper left is empty, that is, the CRF associated with that Patient and CRF Column has not been created because no CRF information or response data has been collected.

- The CRF cell in the lower left-hand portion of the graphic is not empty. The CRF associated with this cell is assigned the **entry complete** data entry status.

- The two cells in the right-hand half of the graphic are not part of the active Spreadsheet because they are not associated with a CRF column.

Figure 12–6   Example of Empty and Non-empty CRF Cells

CRF Icons

The icons that are used in CRF Cells to represent CRF pages provide valuable feedback about status. At one glance, you can learn the following information about a given CRF:

- Entry status

- Discrepancy status

- Verification status

- Approval status

Entry Status Icons The entry status icons display where the CRF is in the data entry process. Table 12–2 describes each of the data entry status icons.

Table 12–2   Entry Status CRF Icons

Icon	Label	Description
	Created	The CRF has been opened and required CRF header and Section header data has been entered and saved, but no response data has been entered.
	Blank	The CRF has been marked as blank.
	Entry Started	Multi-section CRFs only - All required CRF header and Section header fields are completed and at least one Question area response field in one section is completed.
	Entry Complete	Single-section CRFs - All required CRF header and Section header information is completed and at least one Question area response field is completed.
		Multi-section CRFs - All required CRF header and Section header fields are completed and at least one Question area response field in each section is completed.
	Pass 2 Started	The second pass of data entry has started. This operation is for Oracle Clinical only.
	Pass 2 Complete	The second pass of data entry is completed. This operation is for Oracle Clinical only.
	Batch loaded	The data has been entered electronically via batch data load. This operation is for Oracle Clinical only.

Discrepancy Status Icons The Discrepancy Status Icons provide indication of the existence of discrepancies in a given CRF. Essentially, the discrepancy status is a color-coding of the existing CRF icon; the entry, verification, and approval status symbols remain unchanged. The lower section of the icon is displayed differently: red to signify at least one Active discrepancy, or yellow to signify at least one Other

discrepancy. In the case of both Active and Other discrepancies in the same CRF, the icon remains red until you address the Active discrepancy. At that point, if the discrepancy with a status of Other is still open, the icon changes from red to yellow. When all discrepancies are closed, the icon changes to white.

Table 12–3   Discrepancy Status CRF Icons

Icon	Label	Description
	None (White)	There are no other or active discrepancies associated with the CRF. (Note that there may be closed discrepancies associated with the CRF.)
	Active (Red)	There is at least one actionable discrepancy in the CRF.
	Other (Yellow)	There is at least one discrepancy that must be addressed by a user in a role other than yours.

Verification Status Icons The CRF icons that indicate the verification status of a CRF are add-ons to the Entry Complete icon (refer to "Entry Status Icons" on page 12-9 for further information).

Table 12–4   Verification Status CRF Icons

Icon	Label	Description
	None	The CRF has not been verified.
	Verified	The CRF has been verified.
	Re-verification Required	At least one data point in the verified CRF has been modified since verification. The CRF must be re-verified.

Approval Status CRF Icons The Approval Status CRF Icons provide you with feedback on the approval status of each CRF.

Table 12–5   Approval Status CRF Icons

Icon	Label	Description
	None	The CRF has not been approved.
	Approved	The CRF has been approved.

Table 12–5   (Cont.) Approval Status CRF Icons

Icon	Label	Description
	Re-approval Required	At least one data point in the approved CRF has been modified since approval. The CRF must be re-approved.

Multiple-status CRF Icons This section provides examples that are illustrative of how a single CRF icon can convey information about more than one status at a time.

Table 12–6   Examples of Multiple Status CRF Icons

Icon	Label/Description
	Batch loaded, approved, requires re-Verification
	Entry complete, active discrepancy, verified, approved
	Pass 2 complete (Oracle Clinical originated), active discrepancy, requires re-verification, requires re-approval
	Entry complete, other discrepancy, verified, requires re-approval, locked

Spreadsheet Views

The basic components of the RDC Classic Spreadsheet are the CRF cells. Each set of the same CRFs for the same visit is arranged as a CRF Column. CRF columns can be displayed in groups that are based on study intervals. Each type of interval is called a Spreadsheet view.

Spreadsheet views do not change the data in any way, they simply alter how much data is displayed in the Spreadsheet. The purpose of the different views is to give you flexibility in how you view and work with your study data.

Types of Spreadsheet Views

You can view CRFs:

- By visit
- By phase
- By study

The Spreadsheet for each type of spreadsheet view is consistent: a matrix of Page columns and Patient rows that intersect at CRF cells. Each type of Spreadsheet View provides a different view of the same data (refer to Table 12–7, " Information Displayed on Each Type of Spreadsheet View").

Table 12–7   Information Displayed on Each Type of Spreadsheet View

Spreadsheet View	Information Displayed in Each Spreadsheet View
Visit	One spreadsheet view for each visit in the study, either planned or unplanned. Each view tab contains all of the CRFs in the workset that are part of that visit.
Phase	One spreadsheet view tab for each phase in the study; each grouping contains all of the visits that are assigned to a given phase in the study design and all of the CRFs in the workset that are part of that phase.
Study	One spreadsheet view tab for the entire study, displays all of the CRFs in the workset.

Spreadsheet View Tabs

Phase and Visit views, use multiple tabs to display data, whereas the Study Spreadsheet View displays all of the data associated with the study (to which you have access) on a single tab. For Visit and Phase views, you access page groupings by clicking the tabs attached to each page, which are arrayed across the top of the Spreadsheet. Each tab is labeled with the information necessary to distinguish it from other page groupings:

- Phase spreadsheet view tabs are labeled with the name of each study phase

- Visit spreadsheet view tabs are labeled with the name of each visit.

Simply click a particular tab to display the data associated with the visit or phase in which you are interested.

Spreadsheet View Selection Drop-Down List

You use the Spreadsheet View drop-down list box to change the active spreadsheet view. This component, which is labeled "Tabs:", is located above the patient text boxes, in the upper left-hand corner of the Spreadsheet. To use it:

1. Click the drop-down arrow.

2. Select the appropriate Spreadsheet View.

Figure 12–7   Spreadsheet View Drop-down List Box
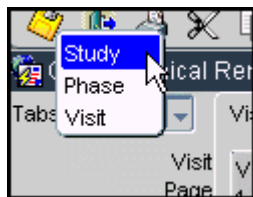
The Visit Spreadsheet View tab is active by default when you start RDC Classic. To change to the Study or Phase Spreadsheet View tab, click the drop-down arrow and then click your selection. When you use the drop-down list box to change current view, the system displays the corresponding Spreadsheet Summary View in the Summary Task Tab.

> **Note:** The availability of the Spreadsheet View Selection tool is dependent on a setting in the RDC Configurator, which is maintained by the RDC administrator. Refer to "Workspace Variations" on page 11-2 for additional information.

Visit Spreadsheet View

The Visit Spreadsheet View tab is the default spreadsheet view, which means it is displayed when you launch an RDC Classic session. When it is active, each Spreadsheet View tab is labeled with the name of a visit and each Spreadsheet View displays the information associated with that one visit. The Spreadsheet View tabs are displayed in the order that is delineated in the study design, with the first visit to occur in the study displayed "on top" and subsequent visit arrayed across the top of the spreadsheet to the right.

Figure 12–8 is an example of an RDC Classic Spreadsheet with the Visit Spreadsheet View tab selected. In this case, the Spreadsheet View tab for the first visit, Visit 1, is active (i.e., it is "on top") and subsequent Spreadsheet view tabs (Visit 2, Visit 3, etc.) are arrayed across the top of the Spreadsheet.

Figure 12–8   Example of Visit Spreadsheet View Tabs
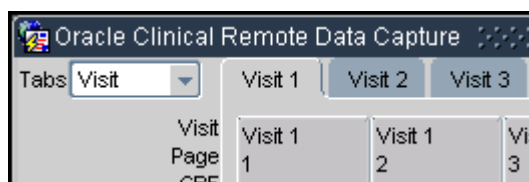
Planned and Unplanned Visits The tabs for planned and unplanned visits are displayed somewhere differently.

Phase Spreadsheet View

When Phase is selected in the Spreadsheet View Tab drop-down list, the number of Spreadsheet View tabs that are displayed depends on the number of phases that were designated for the current study in the study design. Each tab is labeled with the name of the phase, e.g., "Screening," "Dosing," "Follow-up," and they are displayed in chronological order. The Spreadsheet View associated with the initial study phase is active when you select Phase from the Spreadsheet view drop-down list.

This view is useful if you wish to gauge the progress of a study by analyzing the status on a phase-by-phase basis. With the Phase Spreadsheet View tab active, all of the planned visits and CRFs associated with a particular study phase are displayed. In addition, you can display any unplanned clinical events that have occurred within the phase.

Figure 12–9 is an example of an RDC Classic Spreadsheet with the Phase Spreadsheet View tab active. In this graphic, the names of the first three study phases, "Screening," "Dosing 1," and "Dosing 2," are displayed on the first three Spreadsheet View tabs. By default, the Screening Spreadsheet View page is displayed first, because it is associated with the first phase of the study.

Figure 12–9   Example of Phase Spreadsheet View
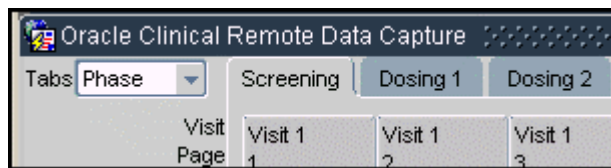
Study Spreadsheet View

When you select "Study" in the Spreadsheet View Selection Drop-Down List, the system displays just one tab. It is labeled with the name of the current study and all of the visits and CRF columns in that study, for the current book, are displayed in that tab. Use the horizontal scroll bar at the bottom of the Spreadsheet to view CRF columns not currently displayed.

This view is useful if you want to assess progress from a study-wide, cross-visit perspective because all of the visits and CRFs are available in a single tab.

Figure 12–10 is an example of an RDC Classic Spreadsheet with the Study Spreadsheet View tab active. In this case, the name of the study, STUDY02, is displayed on the lone Spreadsheet View tab and all of the page columns, starting with Visit 1, Page 1, are displayed.

Figure 12–10   Example of Study Spreadsheet View
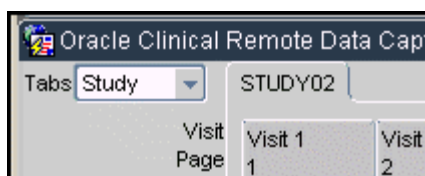
Navigation and Information Aids

There are several features in the RDC Classic Spreadsheet that help you navigate the application or provide you with information that helps you accomplish your work.

The following sections describe how to navigate to other components and how to find information about the workset.

- Spreadsheet Focus
- Horizontal Scroll Bar
- Visit Selection Button
- Spreadsheet Status Line
- Search Button
- Activity List Button
- Patient Selection Drop-Down List

Spreadsheet Focus

When a CRF cell is in focus, the CRF Column and Patient number with which it is associated are also highlighted.

Figure 12–11   Example of CRF Cell in Focus
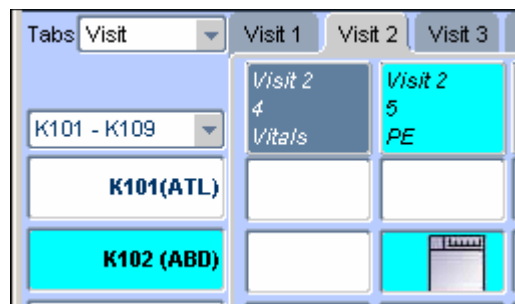
To place focus in a CRF cell:

1. Click the CRF cell. If the Data Entry window opens, close it.

    To prevent the system from opening the CRF when you click on the cell, clear the check box for the "Action When Clicking on a Cell" setting, which is in the Data Entry Tab in the Preferences Window.

2. Use the keyboard to move focus to the CRF cell:

    a. Place focus in the Patient cell that is in the same row as the CRF you want to select.

    b. Press the Tab key to move focus to one cell to the right. Repeat until the appropriate cell is in focus. (You can also use the Up and Down arrow keys to change rows.)

Horizontal Scroll Bar

The Spreadsheet provides a horizontal scroll bar, which is displayed when more than thirteen CRF column must be displayed in a given Spreadsheet view.

To use the scroll bar, you can either:

- Click-Hold the scroll box and move it to the right or the left

- Click either the left or the right scroll arrow to display visit-columns in the desired direction.

Visit Selection Button

If all of the visit tabs do not fit across the top of the Spreadsheet, a Visit selection button is displayed in the upper right-hand corner of the Spreadsheet, adjacent to the last displayed visit tab. There are two arrows on the button, a left and a right arrow.

Figure 12–12   Three Views of the Visit Navigation Button

Initially, the left arrow on the button appears inactive. This is an indication that the first visit tab is currently displayed (refer to the first graphic in Figure 12–12). If the right arrow appears inactive, it is an indication that the last visit tab is currently displayed (refer to the third graphic in Figure 12–12). If neither arrow appears inactive,

it is an indication that neither the first nor the last visit tab is currently displayed (refer to the middle graphic in Figure 12–12).

When you click the Visit Selection button, a drop-down list is displayed that contains all of the visits in the current view. The visits that are currently displayed are listed in bold font, with a round bullet list symbol adjacent to each. The visits that are not currently displayed are listed in regular font. To view the pages associated with these visits, click the visit name in the list. To display a particular visit, click the its list item.

Figure 12–13   Visit Navigation Drop-down List

Spreadsheet Status Line

Important information about your current Search window criteria selections is displayed in a status line that is to the right of the **Search Button** and just below the **Horizontal Scroll Bar**.

When you define a set of criteria in the Search Window, RDC Classic constructs a statement that describes the data set that is currently displayed in the Spreadsheet. This is the information that is displayed in the Spreadsheet status line.

In order to quickly ascertain what set of data is currently active in the Spreadsheet, you should examine the Title Bar of the Main Application Window and the Spreadsheet status line.

Figure 12–14   Detailed Views of the Spreadsheet with Status Line and Search Button
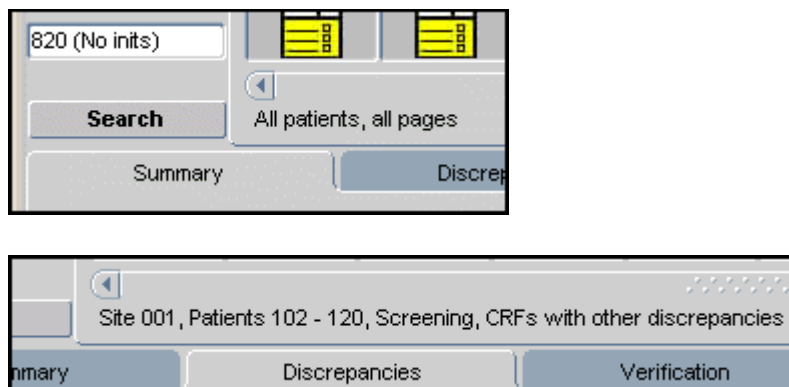
For instance, the status line displayed in the top graphic of Figure 12–14, "Detailed Views of the Spreadsheet with Status Line and Search Button" indicates that, for the specified Book and Site(s), all patients and all pages are displayed (i.e., the Search window criteria are at default settings).

The status line depicted in the lower graphic in Figure 12–14 describes the following criteria settings:

- Site criteria is set to Site 001

- Patient criteria, Patient parameter is set to 102 to 120

- Visits/Page criteria, Phase parameter is set to Screening

- CRF Status criteria, Discrepancy Status parameter is set to "With other discrepancies"

Use the Main Application Window title bar to view the current Book and Site criteria, as well as the Study, database, date, your current Role, and your name.

Search Button

You use the **Search** button that is adjacent to the RDC Classic Spreadsheet to rapidly open the Search window. It is located at the lower left-hand corner of the Spreadsheet, below the **Current Patients** and to the left of the **Spreadsheet Status Line**.

When you use this button, the Search window is displayed with all current criteria still set. This is equivalent to using the **Modify Search** command on the File menu. If you wish to "start over" with your Search window criteria settings, use the **New Search** menu command.

> **Note:**   The **Search** button is only displayed when the Search window is the default data selection method for the current RDC Classic session.

Activity List Button

You use the **Activity List** button that is adjacent to the Spreadsheet to access the Activity List Window. It is located adjacent to the lower left-hand corner of the Spreadsheet, below the **Current Patients** and to the left of the **Spreadsheet Status Line**.

When you click this button, the Activity List window is displayed with the node of the most recently selected task highlighted in the Navigation pane.

> **Note:** The Activity List button is only displayed when the Activity List window is the default data selection method for the current RDC Classic session.

Patient Selection Drop-Down List

The Patient list displays patients in sets of eight. The sets are grouped according to the assigned patient numbers, with the lower patient numbers at the top of the list and higher patient numbers at the bottom.

Figure 12–15   Patient Range Drop-down List Box
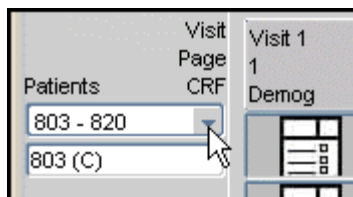
As Figure 12–15 illustrates by depicting a set of eight patient numbers that ranges from "803" to "820", patient numbers that are not yet assigned are not included in the Patient list. The first set of patient numbers that is displayed by default in the Spreadsheet includes the first eight lowest patient numbers.

To display patient numbers that are not in this first set, you can:

- Use the **Patients Subsearch Window** to retrieve only those patient numbers you wish to use

- Use the Patient Range drop-down list

The Patient Range drop-down list, which is illustrated in Figure 12–16, allows you to:

- View all of the patient ranges that are currently retrieved

- Quickly display different patient numbers

- Easily add patients using existing patient numbers (refer to "Inserting a New Patient" on page 12-4 for further information)

Figure 12–16   Using the Patient Range Drop-down List Box

13
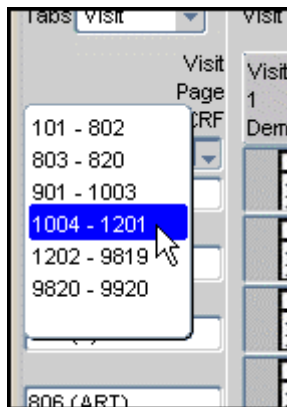
Task Tabs

This section describes the task tabs, which are located in the lower section of the Main Application Window. You use the task tabs to accomplish various processing chores that allow you manage:

- Discrepancies
- Approval status
- Verification status

You also use the task tabs to review:

- Summaries based on various views of the patient data
- Audit histories

This section is divided into seven topics: a discussion section that describes general task tab issues, and six separate sections that each describe one of the task tabs.

- Discussion on page 13-1
- Summary Task Tab on page 13-2
- Discrepancy Task Tab on page 13-14
- Verification Task Tab on page 13-21
- Approval Task Tab on page 13-24
- Audit Trail Task Tab on page 13-27
- Links Task Tab on page 13-30

> **Note:** Various settings in the Preferences Window and the RDC Configurator affect which Task tabs are displayed in the RDC Classic Workspace.

Discussion

In RDC Classic, a maximum of six task tabs are available in the RDC Classic Workspace (refer to Table 13–1).

> **Note:** The text that each task tab label contains may be configured by your system administrator to a title other than that used in the RDC Classic documentation. If your system is configured in such a manner, consult your system administrator for further information.

Five of the task tabs provide information and functionality related to the current study data. The sixth, the Links Task Tab, is a collection of hyperlinks that you use to access Web sites that you and/or the Study Sponsor feel are useful to your work.

Table 13–1   List of RDC Classic Task Tabs

Task Tab Name	Function
Summary	Provides overviews at the Event (Study, Phase, Visit), CRF, Page, and Patient levels.
Discrepancy	A central location for analyzing and managing discrepancies on a CRF basis.
Verification	A view of verification status and history, with a mechanism to verify each CRF.
Approval	A view of approval status and history, with a mechanism to approve each CRF.
Audit Trail	Provides a user-configurable view of the audit trail history of each CRF.
Links	A listing of context-sensitive hyperlinks that are configured by the sponsor.

Accessing Online Help for a Task Tab

You can access context-specific online help for each of the task tabs. However, you must first establish **focus** in a field within the task tab before you request the help topic.

Data Entry and Display of Task Tabs

The Summary and Links task tabs provide information about data and access to sites that are external to RDC Classic, respectively. The focus of the four remaining task tabs is to enable you to perform certain tasks in RDC Classic.

Task Tabs and the RDC Classic Spreadsheet

With the exception of the Links Task Tab, the information that is displayed in a given task tab is dependent on the current study, **workset**, and **focus**. As you change focus in the RDC Classic Spreadsheet, the information that is displayed in the task tabs changes so that it accurately reflects the data associated with the Spreadsheet component in focus.

In certain circumstances, a message is displayed in a task tab that prompts you to change focus in the Spreadsheet in order to display information in that tab.

Example 13–1   Typical Task Tab Prompt

When the Discrepancy Task Tab is active and focus in the Spreadsheet is not on a CRF, a message is displayed in the Discrepancy tab, "Please select a CRF to view discrepancy information," that prompts you to change the focus of the Spreadsheet to a CRF cell in order to view discrepancy information about that document.

Summary Task Tab

This section describes the purpose, components, functionality, and navigation of the Summary task tab. This RDC Classic feature provides you with ready access to useful information about Study data. You can use the Summary task tab to view information about the data that is compiled from the individual document level up to a study-wide perspective.

This topic is divided into the following subsections:

Discussion

The Summary task tab provides information about the data that is part of the current study. There are five different sets of information that can be displayed in the Summary task tab. Each set is termed a "view" and it gives you snapshot of the data at specific levels, such as study, CRF, and patient.

Summary Views

You can access five views of the Summary task tab:

1. Spreadsheet view – this view displays information about the currently active view in the RDC Classic Spreadsheet. There are three possibilities:

    a. Study – summary information about the currently active study

    b. Phase – summary information about the currently active phase

    c. Visit – summary information about the currently active visit

2. Site view

3. Patient view

4. CRF view

5. Page view

By default, the data that is displayed in the task tab is dependent on the current Spreadsheet focus.

Access

There are five specific views of the Summary task tab that are available to you. Most can be accessed

Components of the Summary Task Tab

Although each view of the Summary task tab provides a different set of information, there are components that are consistent in each summary view. The information that is displayed in the Summary task tab is generally divided into named, logical **sections**, which provide related data about one aspect of the currently active view. For example, one section may contain information about the currently active patient, while another

contains information on the number of CRFs that have been created for the currently active visit.

Summary View Drop-Down List

On each Summary task tab view there is a "Summary For" drop-down list that allows you to access the views that are available (refer to Figure 13–1). Three of the selections are static, the fourth, which is related to the current Page Grouping tab, can be one of three values.

Figure 13–1   Summary View Drop-down List
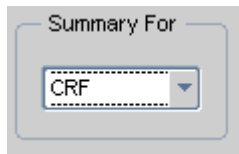
The selections on the drop-down list are:

1. Patient

2. Page

3. CRF

4. Study, Phase, or Visit.

If the Spreadsheet focus and the "Summary for" drop-down list box do not coincide, either a prompt message is displayed in the tab area or a dialogue box describes why that selected Summary view cannot be made active.

Summary Task Tab Sections

The majority of the Summary tab displays information about the current Summary view. In general, the information is arranged into categories and displayed in specific areas called sections. Each section is labeled and outlined by a thin blue-gray line.

Patient Summary View

The Patient summary tab provides information about the currently selected patient. It is divided into five sections:

1. Patient Summary Section

2. Discrepancies Section

3. CRFs Section

4. CRF Status Section

5. Visits Section

> **Note:**   If the Summary tab is blank, i.e., there are no sections displayed, it is an indication that a patient is not selected.

Patient Summary Section

The Patient Summary section provides information about the patient that is in focus. It includes these fields:

Table 13–2   Fields and Descriptions for the Patient Summary Section

Field	Description
Patient	The patient number
Initials	The initials in the patient record
Birthdate	The date of birth in the patient record
Sex	The sex in the patient record
Age	The age in the patient record
Site	The site to which the patient is currently assigned
Book for Data Entry	The book to which the patient is assigned. A patient can only be assigned to one book at a time and that book must be active in order to perform data entry for the patient.

Discrepancies Section

The Discrepancies section provides information about any discrepant CRFs that are associated with the currently active patient. The section includes these fields:

Table 13–3   Fields and Descriptions for the Discrepancies Summary Section

Field	Description
Active	The number of active discrepancies associated with the current patient, i.e., the number of discrepancies that are actionable by you or another user in your role.
Other	The number of discrepancies associated with the current patient that are assigned to another role.
Closed	The number of closed discrepancies associated with the current patient.
Total	The total number of discrepancies associated with the current patient. This field should equal the sum of the previous three fields.

CRFs Section

The CRF Status section provides information about the CRFs that are associated with the patient that is currently in focus. The purpose of this information is to give you feedback on CRFs that are at least at an entry status of "Started".

If a CRF contains discrepancies of status "Active" and "Other," the Summary tab counts it as "containing active discrepancies" until a user in your role addresses the active discrepancy(ies). At that point, if the CRF still contains an "Other" discrepancy(ies), the Summary tab counts it as "containing other discrepancies."

Table 13–4   Fields and Descriptions of the CRFs Summary Section

Field	Description
With active discrepancies	The number of CRFs associated with the current patient that contain at least one active discrepancy.
With other discrepancies	The number of CRFs associated with the current patient that contain at least one discrepancy that in not actionable by you or other users in your role.
With closed discrepancies	The number of CRFs associated with the patient that have either closed or obsolete discrepancies.
Total	The sum of the previous three fields.
Earliest entry	The date that data entry was initiated.

Table 13–4   (Cont.) Fields and Descriptions of the CRFs Summary Section

Field	Description
Latest entry	The most recent date that data entry was performed.
Latest update	The most recent date that data update was performed.

CRF Status Section

The CRFs section lists pertinent information about the CRFs associated with the currently selected patient. The fields in this section are:

Table 13–5   Fields and Descriptions of the CRF Status Section

Field	Description
Not verified	The number of CRFs that have never been verified.
Awaiting re-verification	The number of CRFs that have previously been verified, have subsequently been modified, and must be re-verified.
Verified	The number of CRFs that are currently verified.
Not approved	The number of CRFs that have never been approved.
Awaiting re-approval	The number of CRFs that have previously been approved, have subsequently been modified, and must be re-approved.
Approved	The number of CRFs that are currently approved.

Visits Section

The Visits section lists information that is useful in tracking a patient. The fields included in this section are:

Table 13–6   Fields and Descriptions of the Visits Section

Field	Description
First (visit)	The name and range of dates for the first visit in the study.
Latest (visit)	The name and start date of the currently active visit.
Next (visit)	The name and start date of the next visit.
Missing pages	The Page number, which is displayed in the CRF Column header, for each CRF that contains a section that should have been collected (according to the protocol) for the current patient.

Page Summary View

The Page summary tab provides information about the page that is currently in focus in the Spreadsheet. In contrast to the Patient Summary View, which gives you information about one patient, or row, in the Spreadsheet, the Page Summary view gives you information about one CRF Column. Note that this includes information about patients that may be in rows that are not currently displayed in the Spreadsheet.

This view is displayed in the Summary task tab when:

- you select Page in the Summary view drop-down list box, or

- focus is in a CRF Column Header.

The Page Summary view consists of three sections:

1.
2.
3.

Page Summary

The page summary section provides basic information about the CRFs that are associated with currently active page column.

Table 13–7   Fields and Descriptions of the Page Summary Section

Field	Description
Page (number)	The first number designation that is assigned to the currently active page
Visit	The visit designation to which the current page is assigned
CRF	The CRF name associated with the current page column
Sites	The site(s) specified in the Search window

CRFs Section

The CRFs section lists pertinent information about the CRFs associated with the active Page Column.

Table 13–8   Fields and Descriptions of the CRFs Section

Field	Description
With active discreps	The number of CRFs associated with the active Page Column that have at least one discrepancy with a status of "Active"
With other discreps	The number of CRFs associated with the active Page Column that have at least one discrepancy with a status of "Other"
Clean	The number of CRFs associated with the CRF Column that have either closed or obsolete discrepancies.
Total	The total number of CRFs associated with the active Page Column. This number should be the sum of the previous three fields.
Earliest entry	The date that data entry was initiated.
Latest entry	The most recent date that data entry was performed.
Latest update	The most recent date that data was updated.

CRF Status Section

The CRF Status section lists pertinent information about the verification and approval statuses of CRFs associated with the active Page column.

Table 13–9   Fields and Descriptions of the CRF Status Section

Field	Description
Not verified	The number of CRFs associated with the active Page Column that have never been verified.
Awaiting re-verification	The number of CRFs associated with the active Page Column that have previously been verified, have subsequently been modified, and so are awaiting re-verification.

Table 13–9 (Cont.) Fields and Descriptions of the CRF Status Section

Field	Description
Verified	The number of CRFs associated with the active Page Column that are currently verified.
Not approved	The number of CRFs associated with the active Page Column that have never been approved.
Awaiting re-approval	The number of CRFs associated with the active Page Column that have previously been approved, have subsequently been modified, and so are awaiting re-approval.
Approved	The number of CRFs associated with the active Page Column that are currently approved.

CRF Summary View

The CRF Summary tab provides information about the CRF that is associated with the CRF cell in focus. This view consists of two sections, the CRF Summary Section and the Audit Summary Section.

CRF Summary Section

The CRF Summary section provides details about the currently selected CRF document.

Table 13–10 Fields and Descriptions of the CRF Summary Section

Field	Description
Patient	The patient number associated with the currently active CRF.
Visit	The visit number associated with the currently active CRF.
Page	The page number associated with the currently active CRF (note that this field is blank for unplanned pages).
CRF	The name of the currently active CRF.
Date	The visit date that was entered in the CRF Header during initial data entry.
Document#	The number that was assigned to the CRF when it was created.
Status	The current entry status of the CRF.
Protection (present if applicable)	The current mode of the CRF (frozen or locked). This field is displayed if the CRF has been locked or if the patient position has been frozen.

Audit Summary Section

The Audit Summary section gives you details about the information that is collected in the Audit Trail of the CRF. It includes the following fields:

Table 13–11 Fields and Descriptions of the Audit Summary Section

Field	Description
Created on	The date and time that the CRF was assigned an entry status of "Created."
By	The user name of the person who created the CRF.
Last modified on	The date and time that the data in the CRF and/or its status changed.

Table 13–11   (Cont.) Fields and Descriptions of the Audit Summary Section

Field	Description
Last Transaction on	The date and time that the data in the CRF and/or its status changed, which is identical to "Last modified on". However, if the CRF is locked or frozen, than that date and time is recorded in this field.
By	The user name responsible for the "Last transaction".

Site Summary View

The Site view of the Summary task tab provides information about a given site. The information it provides includes contact information for the PI, patient enrollment figures, and an accounting of current CRF statuses.

Access

This view of the Summary task tab is accessible when the Activity List Window is open and a Site node is selected. When the system opens the Activity List window, it situates it in the RDC Classic Workspace in such a manner that the Summary task tab is viewable.

Prerequisites

In order to view the Site view of the Summary task tab:

1. your RDC Classic session must be configured to use the Activity List window

2. a Site node in the Navigation pane must be in focus.

Components

The Site summary view consists of two sections, which describe different information about the site that is in focus in the Activity List window:

1. Site Information Section

2. Site CRF Information Section

Site Information Section The Site Information section of the Site Summary view provides basic information about the site and an overview of the number of patients currently associated with the site, according to status.

Table 13–12   Fields and Descriptions of the Site Information Section

Field	Description
Name	The name that is assigned to the selected site.
Investigator	The name of the primary investigator who is assigned to the selected site.
Address	The mailing address of the currently selected site.
# Pts Created	The number of patient positions assigned to the selected site that are currently created.
# Pts Enrolled	The number of patient positions assigned to the selected site that are currently enrolled.
# Pts With Data	The number of patient positions assigned to the selected site for which data has been entered. This implies that for each patient counted, at least one CRF is at an entry status of Entry Started or Pass 1 Started.

Site CRF Information Section The Site CRF Information section of the Site Summary Task tab view provides detailed information about the CRFs that are associated with the patients at the currently selected site.

Table 13–13   Fields and Descriptions of the Site CRF Information Section

Field	Description
Planned	The number of planned CRFs currently associated with the selected site.
Unplanned	The number of unplanned CRFs currently associated with selected site.
Total	The total number of CRFs currently associated with the selected site, this should be the sum of the "Planned" and "Unplanned" fields.
With active discreps	The number of CRFs associated with the selected site that have at least one discrepancy with a status of "Active"
With other discreps	The number of CRFs associated with the selected site that have at least one discrepancy with a status of "Other"
Clean	The number of CRFs associated with the site that have either closed or obsolete discrepancies.
Not verified	The number of CRFs associated with the selected site that have never been verified.
Awaiting re-verification	The number of CRFs associated with the selected site that have previously been verified, have subsequently been modified, and so are awaiting re-verification.
Verified	The number of CRFs associated with the selected site that are currently verified.
Not approved	The number of CRFs associated with the selected site that have never been approved.
Awaiting re-approval	The number of CRFs associated with the selected site that have previously been approved, have subsequently been modified, and so are awaiting re-approval.
Approved	The number of CRFs associated with the selected site that are currently approved.

Study Summary View

The Study view of the Summary task tab provides information about the current study. The information it provides includes the number of sites in the study, patient enrollment figures, and an accounting of current CRF statuses.

Access

This view of the Summary task tab is accessible when the Activity List Window is open and a Study node is selected. When the system opens the Activity List window, it situates it in the RDC Classic Workspace in such a manner that the Summary task tab is viewable.

Prerequisites

In order to view the Study view of the Summary task tab:

1. your RDC Classic session must be configured to use the Activity List window

2. a Study node in the Navigation pane must be in focus.

Components

The Study summary view consists of two sections, which describe different information about the site that is in focus in the Activity List window:

1. Study Information Section

2. Study CRF Information Section

Study Information Section The Study Information section of the Study Summary view provides basic information about the site and an overview of the number of patients currently associated with the site, according to status.

Table 13–14   Fields and Descriptions of the Study information Section

Field	Description
Name	The name that is assigned to the protocol.
# Sites	The number of sites assigned to the selected study.
# Pts Created	The number of patient positions assigned to the selected study that are currently created.
# Pts Enrolled	The number of patient positions assigned to the selected study that are currently enrolled.
# Pts With Data	The number of patient positions assigned to the selected study for which data has been entered. This implies that for each patient counted, at least one CRF is at an entry status of Entry Started or Pass 1 Started.

Study CRF Information Section The Study CRF Information section provides detailed information about the CRFs that are associated with the patients in the study.

Table 13–15   Fields and Descriptions of the Study CRF Information Section

Field	Description
Planned	The number of planned CRFs currently associated with the study.
Unplanned	The number of unplanned CRFs currently associated with study.
Total	The total number of CRFs currently associated with the study, this should be the sum of the "Planned" and "Unplanned" fields.
With active discreps	The number of CRFs associated with the study that have at least one discrepancy with a status of "Active"
With other discreps	The number of CRFs associated with the study that have at least one discrepancy with a status of "Other"
Clean	The number of CRFs associated with the study that have either closed or obsolete discrepancies.
Not verified	The number of CRFs associated with the study that have never been verified.
Awaiting re-verification	The number of CRFs associated with the study that have previously been verified, have subsequently been modified, and so are awaiting re-verification.
Verified	The number of CRFs associated with the study that are currently verified.
Not approved	The number of CRFs associated with the study that have never been approved.

Table 13–15   (Cont.) Fields and Descriptions of the Study CRF Information Section

Field	Description
Awaiting re-approval	The number of CRFs associated with the study that have previously been approved, have subsequently been modified, and so are awaiting re-approval.
Approved	The number of CRFs associated with the study that are currently approved.

Spreadsheet Summary View

When focus in the Spreadsheet is on a Page Grouping tab (Study, Phase, or Visit), the Summary task tab displays two main sections: a Summary of CRFs Retrieved Section and a Summary of CRFs in Current Tab Section. These sections contain identical sets of fields. Because there are three Page Grouping Tabs (Study, Phase, and Visit, this kind of summary uses the same set of fields to display different sets of information depending on which Event Tab is active. The current Page Grouping changes the scope of the "Summary of CRFs in current tab" section.

In addition to the two main sections, there is also a section, Number of Patients, that reports the number of patients that are included in the currently active study.

The twelve fields in each of the two main sections are grouped into four categories. Table 13–16 lists the categories and fields that are present in each of the sections and describes each field.

Table 13–16   Categories and Fields for Section Spreadsheet View Summary Task Tab

Category	Field	Description
Visit	Planned	The number of planned visits
	Unplanned	The number of unplanned visits
	Total	The number of total visits (planned + unplanned)
Verification	Not verified	The number of CRFs that have never been verified
	Awaiting re-verification	The number of CRFs that have previously been verified, have subsequently been modified, and must be re-verified.
	Verified	The number of CRF that are currently verified
Discrepancy	With active discrepancies	The number of CRFs that contain at least one discrepancy that can be addressed by you or another user with your role
	With other discrepancies	The number of CRFs that contain discrepancies that must be addressed by a user in another role
	Clean	The number of CRFs in the current Spreadsheet view that have either closed or obsolete discrepancies.

Table 13–16 (Cont.) Categories and Fields for Section Spreadsheet View Summary Task

Category	Field	Description
Approval	Not approved	The number of CRFs that have never been approved
	Awaiting re-approval	The number of CRFs that have previously been approved, have subsequently been modified, and must be re-approved.
	Approved	The number of CRFs that are currently approved

Summary of CRFs Retrieved Section

The first section of the Summary tab provides information about the CRFs that are retrieved. This set of data is designated by and directly related to the criteria you selected in the Search window.

Because the summary information included in this section represents that sum of all data in the subset specified by the Search window criteria, the values in all of the fields are identical no matter which of the three Spreadsheet view tabs is active.

Summary of CRFs in Current Tab Section

The second section of the Summary tab provides information about the data that is part of the currently selected Event tab in the RDC Classic Spreadsheet.

- If the Study Event tab is currently active, the data in the "Summary of CRFs in current tab" section should equal the data in the "Summary of CRFs retrieved" section.

- If either the Phase or Visit Event tab is active, the data in the "Summary of CRFs in current tab" section does not equal the data in the "Summary of CRFs retrieved" section (assuming the study consists of more than one phase or visit).

Number of Patients

This area of the Summary tab displays the total number of patients that are present in the currently retrieved data set. This information is displayed in all Event tab summaries.

Usage

Selecting a Summary View from the RDC Classic Workspace

The view that is displayed in the Summary task tab reflects either the Spreadsheet component that is currently in **focus** or the currently selected Summary View. There are two methods to set or change the focus in the Spreadsheet and so change the view that is displayed in the Summary task tab:

1. Click the relevant Spreadsheet component, i.e., click a specific CRF page icon, patient, page column heading, or event tab.

2. Use the Summary View drop-down list.

Figure 13–2   An Open "Summary For" Task Tab Selection Drop-down List Box
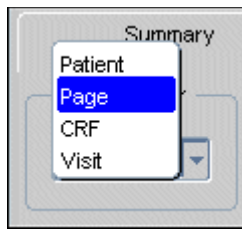
If you use the Summary View drop-down list box to select a view that is not currently in focus in the Spreadsheet, there are several possible results, which each depend on the view that you select and the current Spreadsheet focus.

- If you use the Summary View drop-down list to change the information displayed in the tab to either Patient or Page and the view does not match the current Spreadsheet focus, the information that is displayed will, by default, be the first item in the Spreadsheet.

- If you select CRF Summary view and a CRF cell is not currently in focus, a Message window is displayed which alerts you that a CRF is not currently selected (refer to Figure 13–3, "The "No CRF is currently selected" Message Window"). When you click the OK button in the message window, the drop-down list box reverts to the previously active summary view. If you then click a CRF cell, the Summary View changes to CRF.

Figure 13–3   The "No CRF is currently selected" Message Window

Selecting a Summary view from the Activity List Window

When the Activity List Window opens during initiation of the RDC Classic session, the study node is automatically in focus. This causes the system to display the Study Summary View. When you select a different level node, that is, a site or patient node, the system displays the appropriate Summary task tab view, either the Site Summary View or the Patient Summary View.

When you open the Activity List window during an RDC Classic session, the node associated with the most recently selected activity is in focus and the relevant view of the Summary task tab is displayed.

Discrepancy Task Tab

The Discrepancy task tab is the central location for your discrepancy management tasks. It allows you to work with one CRF at a time and gives you direct navigational access to discrepant datapoints.

This topic is divided into the following subsections:

- Discussion on page 13-15

- Discrepancy Actions on page 13-16

- List of Discrepancies Tab on page 13-16

- Individual Discrepancy Tab on page 13-18

- Usage on page 13-19

Discussion

The Discrepancy task tab provides real-time feedback on discrepant datapoints in the currently active CRF. The contents of the Discrepancy task tab are entirely dependent on the presence of discrepancies associated with the CRF.

The Discrepancy task tab provides you with an overview of all discrepancies in the CRF. It also allows you to navigate directly to the relevant response field for univariate, multivariate, and manual discrepancies.

You can work with all types of discrepancies except multivariate in the List of Discrepancies Tab. With the exception of editing the Comments field, you must use the Individual Discrepancy Tab to work with multivariate discrepancies.

You can edit the Error Message associated with manual and section discrepancies in either the List or the Individual discrepancy tab, as well as the discrepancy window. You must use the discrepancy window to modify the Error Message of a univariate discrepancy. The Error Message for multivariates cannot be modified.

Access the Discrepancy Task Tab

Like the other task tabs, when you select the Discrepancy task tab, it is displayed "on top" of the others, which allows you to view its contents. Click the task tab label, "Discrepancies" to access the Discrepancy task tab.

When the active CRF page has at least one discrepancy associated with it, the Discrepancy tab is composed of:

- a main "sub-tab", named "List" (refer to "List of Discrepancies Tab" on page 13-16)

- additional sub-tabs that represent individual discrepancies (refer to "Individual Discrepancy Tab" on page 13-18).

Contents Depend on Focus and Status

The information that is displayed in the Discrepancy task tab depends on the Spreadsheet component that is in focus.

Focus on a Spreadsheet Component Other Than a CRF Cell If focus is on a Spreadsheet component other than a CRF page, a message is displayed in the Discrepancy task tab:

Please select a CRF by clicking on a cell to view discrepancy information.

Focus on a CRF without a discrepancy If focus is on a CRF page that does not contain at least one discrepancy, this message is displayed in the Discrepancy task tab:

No discrepancies

Visual Cues

The Discrepancy task tab uses visual cues to help you quickly ascertain and assess the status of discrepancies associated with a CRF.

Discrepancy Status The color scheme that is used for CRF Icons to designate discrepancy status is also used in the Discrepancy task bar. Unlike the Spreadsheet, however, in which only one color can be used to represent the discrepancy status of the CRF, each individual discrepancy is displayed in the color that represents its current status.

Although discrepancies with a status of "Closed" are not represented with a color, in the Discrepancy task tab all closed discrepancy listings are displayed with a dark grey background in each field.

Highlighted Discrepancy In the List of Discrepancies Tab, a blue marker is placed adjacent to the Seq field as an indicator that the discrepancy listing is currently selected.

Highlighted Fields When you select a field, its text is highlighted by a dark blue background as an indication that it is selected. If it is an editable field, you can begin typing to insert text directly in the field.

Discrepancy Actions

There are certain methods that you can use to resolve discrepancies. These methods are called actions and are defined by the System Administrator.

RDC Classic is installed with a pre-defined set of actions, which are discussed here because they are general enough to illustrate how you use the Discrepancy task tab to manage and resolve discrepancies.

Default Actions

There are six default actions that are included as part of the RDC Classic installation. They are:

1. Send to site
2. Send for classification
3. Close - resolved
4. Closed - no resolution
5. Re-open
6. Go to data field

> **Note:**   You cannot take an action on discrepancies that have been closed by the system.

List of Discrepancies Tab

The List of discrepancies tab is the central location for working with the discrepancies associated with one CRF. It provides various features:

- Provides you with an overview of discrepancy information about that CRF
- Allows you to initiate an action on a discrepancy

- Allows you to enter informative text about a discrepancy

- Allows you to generate a new discrepancy, either for:

  - the entire CRF, or

  - a single datapoint

- View the history associated with a discrepancy.

While the order in which discrepancies are listed changes as the status of each is updated, once a discrepancy is lodged against a CRF it is always accessible through the Discrepancy task tab.

Access

By default, the List of Discrepancies tab is displayed whenever you click the Discrepancies task tab. If focus is elsewhere within the Discrepancy task tab, you can access the List of discrepancies by selecting its tab.

Components

The List of Discrepancies tab provides a substantial amount of information about each discrepancy associated with a CRF. Table 13–17, " Components of the List of Discrepancies Tab" lists and describes each item on the tab.

Table 13–17   Components of the List of Discrepancies Tab

Label	Type	Description
Seq	Field	Sequence number – a number that is assigned to each discrepancy that is based on its current status, its **timestamp**, and the CRF datapoint with which it is associated.
Text	Field	An editable field that describes the discrepancy. You can double-click the field to display the Field Editor Window, if you wish to draft text in it; otherwise, you can simply type the description directly in the field.
Status	Field	A descriptive field that displays the current status of the discrepancy.
Comments	Field	An editable text box that displays the current comment text associated with a given discrepancy. You can double-click the field to display the Field Editor Window, if you wish to draft text in it; otherwise, you can simply type the description directly in the field.
Action	Drop-down list	A drop-down list that gives you access to the set of Discrepancy Actions available.
Resolution	Field	An informative field that displays the action that was taken for a discrepancy that resulted in its resolution.
Resolution Comment	Field	An editable field that contains text that describes the resolution of the discrepancy. You can double-click the field to display the Field Editor Window, if you wish to draft text in it; otherwise, you can simply type the description directly in the field.
New	Button	Initiates the process of creating a new discrepancy.
History	Button	Opens the Discrepancy History window, which lists the changes to the currently selected discrepancy.

Ordering of Discrepancies in the List

A set of criteria determines the sequence number of each discrepancy in the List of Discrepancies tab. It is based on the current discrepancy status and the location of the datapoint with which each discrepancy associated. As the status of a discrepancy changes, as well as the status of other discrepancies, and other discrepancies are added to the CRF, the sequence number associated with a discrepancy changes.

Select a Discrepancy List Item

In order to work with a discrepancy from the List of discrepancies tab, you must first select it. To select a discrepancy, click any field in its listing.

When a discrepancy is selected, a blue indicator is displayed to the left of its Seq number. Figure 13–4 provides an example of a discrepancy list item that is currently selected. In the example graphic, Discrepancy "2" is selected.

Figure 13–4   Example of a Selected Discrepancy List Item
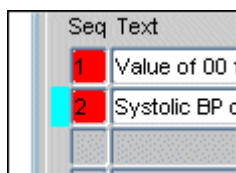
Individual Discrepancy Tab

For each discrepancy listed in the List of Discrepancies Tab, there is a corresponding individual tab, which displays the complete set of information related to a single discrepancy.

Access

To access an individual discrepancy tab, click the appropriate tab. When you do this, the tab you select is displayed "on top," and you can view or work with that discrepancy.

Components of an Individual Discrepancy Tab

The components of an individual discrepancy tab are identical for all statuses. Table 13–18, " Components of an Individual Discrepancy Tab" lists and describes each of the components that are present on each tab.

Table 13–18   Components of an Individual Discrepancy Tab

Label	Type	Description
Tab Title	Info Text	The label that is displayed on the tab, it includes the current sequence number and the discrepancy status.
Text	Info Text	The error message that describes the discrepancy.
Status	Info Text	A descriptive field that displays the current status of the discrepancy.
Id	Info Text	An internal identification number that is assigned to the discrepancy by Oracle Clinical.
Action	Drop-down list	A drop-down list that gives you access to the set of Discrepancy Actions that are designated for the study.

Table 13–18   (Cont.) Components of an Individual Discrepancy Tab

Label	Type	Description
History	Button	Opens the Discrepancy History window, which lists the changes in status that have occurred to the current discrepancy.
Resolution Comments and Reason	Info Text and Text Field	The Resolution Reason text field displays the reason that was selected when the discrepancy was resolved. The Resolution Comments text box displays the comment that was included when the discrepancy was resolved.
Comments	Text Field	An editable text box that displays the current discrepancy comment. You can type directly in the field or double-click in the text box to open the Field Editor Window.
Resolution Comments	Info Text	A field that displays the comment that was included with the resolution reason.
Variable	Data field	A field that displays one variable that is associated with the discrepancy. (Multivariate discrepancies only)
Value	Data field	A field that displays the current value of the corresponding variable. (Multivariate discrepancies only)

Usage

This section describes basic usage procedures for the List of Discrepancies tab and Individual Discrepancy tabs.

Work with the List of Discrepancies Tab

The List of Discrepancies Tab allows you to view summary information about all of the discrepancies associated with the CRF currently in focus.

Select a Discrepancy To select a discrepancy that is listed in the List of Discrepancies tab, click any of the fields in its row. A blue marker is displayed at the far left-side of the active discrepancy row.

Add a New or Update an Existing Internal Comment You can use the List of Discrepancies tab to add or update the internal comment associated with a discrepancy. To do this, you can work directly in the Comment field in the appropriate row or you can open the Internal Comments window. If the text of the comment is limited, working in the field may be more efficient. If the text of the comment exceeds the viewable portion of the field, the Internal Comment window allows you to view the entire comment at once.

Note: You can overwrite or edit existing comments: each comment is saved in the audit trail.

To add or edit an internal comment in the List of Discrepancies task tab:

1.   Select the discrepancy to which you want to add a new comment or edit an existing comment.

2.   You can either type the comment text directly in the Comments field or use an editor to compose the comment:

   ■   To type the comment directly in the field, single-click in the Comments field.

   ■   To use the Internal Comments for Discrepancy window, double-click in the Comments field.

You can paste content from the Microsoft Windows Clipboard into the Comments field and the Internal Comments window.

3. When you have composed or edited the comment text, you must save it:

■ For comments entered directly in the Comments field, either press F10 or select **File**, then **Save** from the option list.

■ For comments in the Internal Comments for Discrepancy window, click the **Save** button to close the window and save the comment.

Take an Action on a Discrepancy There are several methods you can use to take an action on a discrepancy. To accomplish this task using the List of Discrepancies tab:

1. Select the discrepancy on which you want to take an action.

2. Click the Action drop-down list arrow in the row that contains the discrepancy.

3. Select an appropriate action. Depending on the action you select, you may be presented with related windows, which require follow-up information.

Initiate a Discrepancy As an alternative to the Insert menu commands, you can use the New button on the List of Discrepancies tab to initiate a new discrepancy for the CRF that is currently open. When you click the New button, the system displays a window that prompts you to choose the type of manual discrepancy you want to initiate, either section or response field.

Figure 13–5 Select New Discrepancy Type
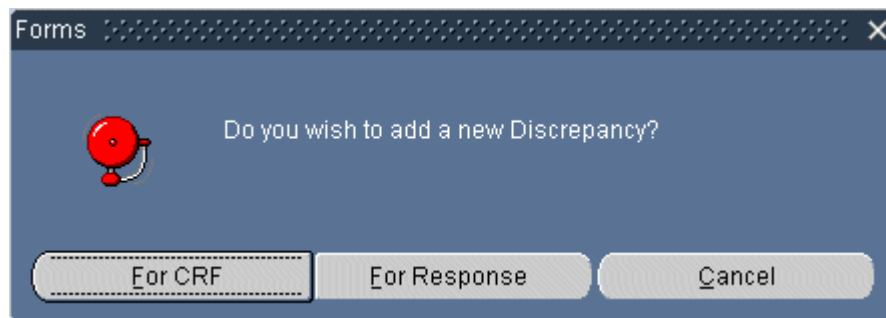
Work with Individual Discrepancy Tabs

An individual discrepancy tab is located in the Discrepancy task tab for each discrepancy that is associated with the CRF currently in focus. Note that each discrepancy is also listed in the List of Discrepancies tab.

Select an Individual Discrepancy Tab When you put focus in the Discrepancy task tab, the List of Discrepancies Tab is displayed by default. If you want to view an Individual Discrepancy Tab, click its tab label.

Add an Internal Comment to a Discrepancy There are several methods you can use to add a new comment to a discrepancy or edit an existing comment.

Note: You can overwrite or edit existing comments: each comment is saved in the audit trail.

To accomplish this task using an Individual discrepancy tab:

1. Select the Individual discrepancy tab for discrepancy to which you want to add a new comment or edit an existing comment.

2. You can either type the comment text directly in the Comments field or use an editor to compose the comment:

   - To type the comment directly in the field, single-click in the Comment field.

   - To use the Internal Comments for Discrepancy window, double-click the Comment field.

   You can paste content from the Microsoft Windows Clipboard into the Comment field and the Internal Comments window.

3. When you have composed or edited the comment text, you must save it:

   - For comments entered directly in the Comment field, either press F10 or select **File**, then **Save** from the option list.

   - For comments in the Internal Comments for Discrepancy window, click the Save button to close the window and save the comment.

Go to a Data Field Associated with a Multivariate Discrepancy To view the data field of a variable in a multivariate discrepancy:

1. Open the CRF that contains the multivariate discrepancy.

2. In the Discrepancy task tab, click the Individual Discrepancy tab of the multivariate discrepancy.

3. In the Individual discrepancy tab, select the Value field in the row of the variable of interest.

4. Use the Action drop-down list to select the "Go to data field" action.

   - If the data field is in the currently open CRF, the system displays and highlights the response field.

   - If the data field in a different CRF, the system opens that CRF in the Data Entry window in Discrepancy Review mode.

Verification Task Tab

This section describes the components of the task tab and provides general information on verification functionality.

This section consists of the following subsections:

- Discussion

- Verification Statuses

- Components of the Verification Task Tab

Discussion

The Verification task tab provides information about the verification status of the currently selected CRF. If you have the appropriate user privilege, the tab also allows you to verify, undo an existing verification, or re-verify the CRF that is currently in focus.

Access the Verification Task Tab

Like the other task tabs, when you select the Verification task tab it is displayed "on top" of the others, which allows you to view its contents. If it is not on top, use the mouse to click the task tab label to select it.

Contents Depend on Focus, Status, and Privilege

The information that is displayed in the Verification task tab is dependant on three factors:

1. the Spreadsheet component that is in focus

2. the verification status of the CRF page, and

3. the privileges assigned to your user name

Focus If the Spreadsheet focus is not on a CRF, the message, "Please select a CRF by clicking on a cell to view verification information" is displayed in the text area of the tab.

Status If a CRF page is selected, its verification information is displayed in the task tab.

- If the page has never been verified, a single line in the task tab states that, for the select patient, page number, and CRF description: "Current status is 'Not verified'"

- If the page has ever been verified (no matter what its current verification status is), the task tab provides an extensive set of historical data that allows you to track all changes made to the verification status of the CRF page.

User Privilege The privileges that are assigned to your user name directly affect what functions you are able to perform in RDC Classic. If you do not have "Verify" privileges for the current Study or Site, you are not able to directly change the verification status of a CRF. Consequently, certain components, such as the Verify button, are not present in the Verification task tab.

Verification Statuses

There are four verification statuses that can be assigned to a CRF page:

1. **not verified**

2. **verified**

3. **verification undone**

4. **awaiting re-verification**

The Verification task tab allows you to change the verification status of a CRF from one state to another. In addition, the system may automatically change the verification status of a CRF. When the value of a datapoint in a verified CRF changes, the system resets the verification status to awaiting re-verification. Note that in this case, the components of the task tab do not change. Once a CRF is verified, the verification history section is displayed even if the status of the CRF is awaiting re-verification or verification undone.

Components of the Verification Task Tab

The components that are present in the Verification task tab depend on the verification status of the CRF. The Verification task tab that is displayed for a CRF that has never been verified has a limited set of components (refer to ""Not verified" Task Tab

Components" on page 13-23). In contrast, the task tab for CRFs that have been verified consists of a larger set of components (refer to "Task Tab Components for CRFs Currently or Previously Verified" on page 13-23).

"Not verified" Task Tab Components

The Verification task tab that is displayed for CRFs that have never been verified has several components, which are listed and described in Table 13–19, " Components of the Verification Task Tab for CRFs w/ Status Not Verified".

Table 13–19   Components of the Verification Task Tab for CRFs w/ Status Not Verified

Label	Type	Description
Active CRF page information	Info Text	A text listing that includes the patient number, Page number, CRF description, and the current verification status
Comment	Field	The comment text that is included when a user verifies the CRF.
Keep comment between verifications	Check box	If selected, the same comment is added each time the CRF is re-verified.
Verify	Button	Sets the status of the active CRF to "Verified."

Task Tab Components for CRFs Currently or Previously Verified

The Verification task tab for CRF pages that have been verified at least once (regardless of current verification status) are described in Table 13–20, " Components of the Verification Task Tab for CRFs w/ Verification History".

Figure 13–6   Verification Task Tab for a Verified CRF

In general, the task tab for CRFs of this type displays significantly more information about the CRF, because it provides a history of the changes to the verification status.

Table 13–20   Components of the Verification Task Tab for CRFs w/ Verification History

Label	Type	Description
Active CRF page information	Info Text	Includes the patient Number, Page number, CRF description, and the current verification status
Date	Field	Date and timestamp of the entry in the Verification history table.
Operation	Field	The operation that caused a change in verification status.

Table 13–20   (Cont.) Components of the Verification Task Tab for CRFs w/ Verification

Label	Type	Description
By	Field	The user name of the study participant who invoked the change in verification status.
Comment	Field	The comment text included by the user who invoked the change in verification status.
Show changes	Button	Invokes the Audit Trail task tab with date criteria that is specified by the row that is currently in focus and listed in the "Since" date field. Note that this button is only enabled if changes have occurred since the CRF was verified.
Since	Date Field	The date of the entry that is currently selected in the Change of Status table.
Comment	Text Field	The comment text that is included when a user verifies the CRF.
Keep comment between verifications	Check box	If selected, the same comment is added each time the CRF is verified. This is useful if you are performing multiple verification tasks.
Verify	Button	Set the status of the active CRF to "Verified."
Undo Verification	Button	Set the status of the active, verified CRF to "Not verified" This button is active only if the CRF status is "Verified."
Re-verify	Button	Set the status of the active CRF from "Requires re-verification" to "Verified".

Approval Task Tab

This section describes the components and the use of the Approval task tab, which is a component of the RDC Classic Workspace.

This section covers the following topics:

- Discussion

- Access

- Components

Discussion

The Approval task tab displays the approval status of the currently selected CRF and provides the mechanism to change its approval status if you have the appropriate user privilege.

Contents Depend on Focus, Status, and Privilege

The information that is displayed in the Approval task tab is dependant on three factors:

1. the Spreadsheet component that is in focus

2. the approval status of the CRF page, and

3. the privileges assigned to your user name

Focus If the Spreadsheet focus is not on a CRF, the message, "Please select a CRF by clicking on a cell to view approval information" is displayed in the text area of the tab.

CRF Status If a CRF page is selected, its approval information is displayed in the task tab.

- If the page has never been approved, a single line in the task tab states that, for the select patient, page number, and CRF description: "Current status is 'Not approved'"

- If the page has ever been approved (no matter what its current approval status is), the task tab provides an extensive set of historical data that allows you to track all changes made to the approval status of the CRF page.

User Privilege The privileges that are assigned to your user name directly affect what functions you are able to perform in RDC Classic. If you do not have "Approval" privilege for the current site, you are not able to directly change the approval status of a CRF. Consequently, the components and functionality necessary to approved a CRF are not present in the Approval task tab.

Approval privilege is granted on a site-by-site basis. If you have access to more than one site and approval privilege to a limited number of those sites, then the components that are displayed in the Approval task tab will vary as you view CRFs for patients associated with sites to which your privileges vary.

Approval Status

The approval status of the currently active CRF is displayed in a line of text at the top of the task tab.

There are four approval statuses that can be assigned to a CRF:

1. **not approved**

2. **approved**

3. **awaiting re-approval**

4. **approval undone**

The Approval task tab provides you with the means to change the approval status of a CRF from one state to another. In addition, the system may automatically change the approval status of a CRF. When the value of a datapoint in an approved CRF changes, the system resets the approval status to "Awaiting Re-approval."

Access

Like the all of the task tabs, when you select the Approval task tab it is displayed "on top" of the others, which allows you to view its contents and perform the functions that it provides.

If you want to work with the Approval task tab and it is not currently in focus, use the mouse to click its task tab label.

Components

The components that are present in the Approval task tab depend on the approval status of the CRF and the approval privileges assigned to your user name.

"Not Approved" Task Tab Components

The Approval task tab that is displayed for CRFs that have never been approved has several components, which are listed and described in Table 13–21, " Components of the Approval Task Tab for CRFs w/ Status Not Approved".

Figure 13–7   Approval Task Tab for User with Approval Privileges

Note that the components that are displayed in Figure 13–7, "Approval Task Tab for User with Approval Privileges" are only visible for users who are granted the "Approve" privilege.

Table 13–21   Components of the Approval Task Tab for CRFs w/ Status Not Approved

Label	Type	Description
Active CRF page information	Info Text	A text listing that includes the patient Number, Page number, CRF description, and the current approval status
Comment	Field	The comment text that is included when a user approves the CRF.
Keep comment between approvals	Check box	If selected, the same comment is added each time subsequent CRFs are approved.
Password	Text box	The location to type the password associated with your user name, which initiates the electronic signature process for the currently active CRF.

Task Tab Components for CRFs Currently or Previously Approved

The Approval task tab that is displayed for CRFs that are currently or previously have been approved contains components that allow you to view changes, undo approval, or re-approve the CRF. Table 13–22, " Components of the Approval Task Tab for CRFs with Approval Histories" lists and describes components.

Figure 13–8   Approval Task Tab for an Approved CRF

The type of Approval task tab for CRFs that have been approved at least once contains substantially more components than that displayed for CRFs that have never been

approved. Table 13–22, " Components of the Approval Task Tab for CRFs with Approval Histories" lists and describes each component.

Table 13–22   Components of the Approval Task Tab for CRFs with Approval Histories

Label	Type	Description
Active CRF page information	Info Text	Includes the patient Number, Page number, CRF description, and the current approval status
Date	Field	Date and timestamp of the entry in the Approval history table
Operation	Field	The operation that caused a change in approval status.
By	Field	The user name of the study worker who invoked the change in approval status.
Comment	Field	The comment text included by the user who invoked the change in approval status.
Show changes	Button	Invokes the Audit Trail Task Tab with date criteria that is specified by the Approval history table row that is currently in focus and listed in the "Since" date field.
Since	Date Field	The date of the entry that is currently selected in the Approval history table
Comment	Text Field	Free text comment field for the next approval operation.
Keep comment between verifications	Check box	If selected, the same comment is added each time a CRF is approved.
Password	Text box	A fixture that allows you to type the password associated with your user name and open the "Approval" Password Confirmation window. This initiates the approval or the re-approval process. This text box is displayed in the task tab for CRFs that are of the status, "Not approved," "Approval undone," or "Awaiting re-approval."
Undo Approval	Button	Set the status of the active, approved CRF to "Approval undone" This button is active only if the CRF status is "Approved," or "Awaiting re-approval."

Audit Trail Task Tab

This section describes the components of the Audit Trail task tab. You use this tab to track changes that have occurred to datapoints in the CRF that is in focus.

This section consists of the following topics:

- Discussion

- Access

- Components

Discussion

The Audit Trail tab is a valuable component of the RDC Classic interface that provides extensive information when you want to find out the history of datapoints that have changed in a given CRF. It displays a list that is based on a significant date, such as the date the CRF was created or when data was changed.

Figure 13–9   Audit Trail Task Tab

Multi-section CRF

The Audit Trail task tab that is displayed for multi-section CRFs uses same the method as the Data Entry window to individually represent each CRF section. As you navigate from section to section in the Data Entry window, the Audit Task trail tracks the changes in focus, so that the audit trail tab for the currently active CRF section is constantly displayed.

Audited changes to the CRF header fields are displayed on the first CRF section tab.

Figure 13–10   Multi-section Audit Trail Task Tab

Access

To access the Audit Trail task tab, click its label. In order to view the audit history for a CRF, either the CRF cell must be in focus in the RDC Classic Spreadsheet, or the CRF must be open in Data Entry window.

If there is not an audit trail associated with the CRF in focus, a message is displayed in the task tab area, "No changes found." If there is an audit trail associated with one or more responses in the CRF, the task tab displays the audit trail change history table.

Components

The data that is displayed in the Audit Trail task tab is arranged in rows, which list each datapoint that has changed since the date selected in Changes since field(s) and columns that describe where, when, and what data has changed. Table 13–23, " Components of Audit Trail Tab" lists and describes the components.

Table 13–23   Components of Audit Trail Tab

Component	Type	Description
Changes since	Drop-down list box	Displays either a date in the history of the CRF or a user-defined date.
Field	Field	The name of the response field where data changed.
Row	Field	A designation that is related to the layout of the CRF design.
Original value	Field	The value of the datapoint before it changed to the "Current value."
Current value	Field	The current value of the datapoint.
Changed on	Field	The date and timestamp when the datapoint was changed to the Current value.
By	Field	The user name of the person who changed the value of the datapoint.
Reason	Field	The Audit Reason that was given at the time the datapoint value was changed.
Intervening Changes	Field	The number of changes that have occurred to the datapoint between the Original value and the Current value.
Show button	Button	A button that displays to the Audit History window for that response value.

"Changes since" Drop-Down List Box

The Changes since drop-down list offers two options:

- you can choose to view changes that have occurred during a period of time that is determined by system-generated date in the change history of the datapoint, or

- you can choose to specify a date.

To use a system-generated date, select a date from the drop-down list. If you want to specify a date, select the "User defined" option in the drop-down list. When you select the latter option, a second text box is displayed, which allows you to type a date that you want to use to define the time frame of the task tab.

Note that:

- the format for the date is "dd-Mon-yyyy hh24:mi:ss" (e.g., 01-Jan-2001 13:00:00)

- the time component of the date format is optional.

Figure 13–11   User Defined Option for "Changes since" Component

Links Task Tab

This section describes the Links task tab and provide guidance on how each type of link differs from the others.

The topics covered in this section are:

- Discussion
- Access
- Components

Discussion

The Links task tab allows you to access Web sites and applications directly from the RDC Classic Main Application window. The links may either be to external Web sites (e.g., www.Google.com) or they may be to internal "applications" that are defined by your System Administrator.

This capability, which is new in RDC Classic 4.5, allows the study sponsor to provide lists of links that branch from RDC Classic to Web sites or applications. The links can be direct or they may use your user name and role and/or the current RDC Classic focus (i.e., Study, Site, Patient, Visit, and CRF) to customize the content of the Web page or application.

> **Note:** If your Administrator has not defined any links for your user name or role an informational message stated that is displayed in the Links task tab.

The Links task tab is divided into three sections, each a column of up to eight links. The categories are:

1. General Links
2. Study/Site Links
3. Patient/Page Links

Figure 13–12   Links Task Tab
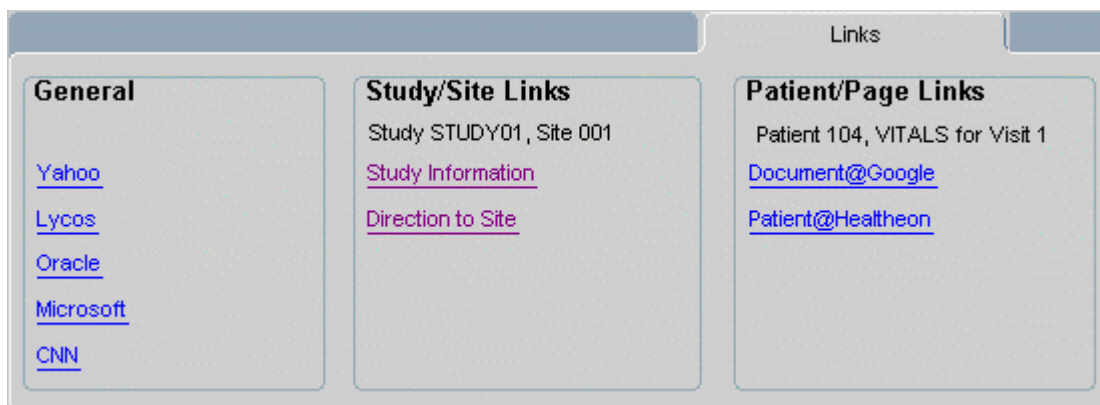
Context

The links that are presented in the Links task tab can use different kinds of information to generate Web pages or custom "applications." These "contextual" links use such information as your user name and role, the current study, site, patient, book, and CRF.

The links that are listed in the General column can use your user name and the role to which you are assigned to generate customized Web content.

The links that are listed in the Study/Site Links column can, in addition to the information used by the General links, use the study and site context to generate Web content.

The links that are listed in the Patient/Page Links column can, in addition to the information used by the General and Study/Site links, use the patient, book, and CRF to generate content.

If a link requires information that is not specified, the Internet browser is directed to an error page, which informs you why the link you clicked cannot be generated. This may happen if:

- "ALL" sites criterion is selected and the link requires a specific site.

- Spreadsheet focus is such that a patient is not selected and the link requires that a patient be in focus.

- Spreadsheet focus is such that a CRF is not selected and the link requires that a CRF be in focus.

Example 13–2   View a Web Page with Site-specific Information

Using the address information stored in the database for a site, your Administrator can configure a link that uses the site address to go directly to a Web page with a map of the site location.

When you click the link, "Directions to Site," the system uses the address information for Site 001 to open your Internet browser and generate a Web page with a map and directions.

Navigation

Each item in the Links task tab is hyperlinked to a Web site or application that is defined for it. When you click an item, an instance of your default Internet browser starts and opens to the site or application that is defined for the link.

If the focus of the cursor in RDC Classic is such that there is not sufficient context for the link to successfully generate a Web page, an error page is displayed in the browser that provides instructions on how to properly set the context before you click the link.

Access

To view the contents of Links task tab, click on the tab label. Note that the links in the task tab may change as you change the focus of the RDC Classic Spreadsheet.

Components

This Link task tab is divided into three section, which categorize the types of links that are present.

Status Line

The Study/Site and Patient/Page columns display the current context that is relevant to each in a status line immediately below the column heading:

- Study/Site lists the current study and site(s)

- Patient/Page lists the current patient, visit, and CRF name, as it is available

Figure 13–13   Context Displayed in Status Line for Dynamic Links
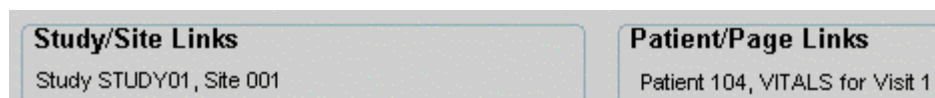
While you work in the Spreadsheet, the context information remains consistent for the Study/Site column because there is always a study and a site chosen. To change this context, you must either change the study (by selecting **File**, then **Change study menu**) or the site (using the Site criteria in the Search window). However, the context information for the Patient/Page column changes as you change focus within the Spreadsheet.

General Links

Items that connect you to non-study related Web sites are listed in the first column of the Links task tab. This may include links that are dependent on your user name and/or role, or they may be links to generic Web sites. Examples of General links are:

- Your study sponsor's home page

- Oracle's home page

- Google.com

- Yahoo.com

Study/Site Links

Items in this column link can you to sites or pages that are dependent on the current study and/or site that is selected. Examples of Study/Site links are:

- A link to documents that are specific to the current study

- A link that uses the current site's address to input into MapQuest and generate a Web page with directions to the site

Patient/Page Links

Items in this column can link you to sites or pages that are dependent on the current RDC Classic focus.

14

General RDC Classic Windows

There are several types of windows that you use in RDC Classic. With the exception of the Main Application Window, RDC Classic windows are displayed as pop-up windows that are displayed on top of the Main Application window. This section lists and describes the window that are common to all RDC Classic sessions.

Note that the Search window is described in the Chapter 15, "Search Window." The Main Application window is described in the section "Main Application Window" on page 11-3.

This section is comprised of the following subsections:

- Windows Associated with Starting Your RDC Classic Session on page 14-1
- Activity List Window on page 14-10
- Saved Search Windows on page 14-16
- Preferences Window on page 14-24
- Windows Associated with Running Reports on page 14-30
- Windows Associated with CRF Lock and CRF Unlock Functions on page 14-44
- Group Activities Windows on page 14-49
- Windows Associated with Common Spreadsheet Tasks on page 14-56
- Help Windows on page 14-58

Windows Associated with Starting Your RDC Classic Session

The windows that are displayed as you start your RDC Classic session include the:

- RDC Classic Launch Page
- Logon Window
- Change Password Window
- Change Study Window
- News Window
- Field Editor Window
- Search and Replace Window

RDC Classic Launch Page

You use the Launch page to initiate your RDC Classic session. It allows you access the Logon Window, where you enter the information that is required to log you in to RDC Classic.

Access

The Launch page is a Web page that is displayed in your Internet browser window. You access it by navigating your browser to your sponsor's installation of RDC Classic. Usually, you do this by typing a URL into the browser. Refer to the topics available in Chapter 5, "Getting Started" for more information on accessing and using the RDC Classic Launch page.

Components of the Launch Page

The Launch page consists of components that are hyperlinks to other locations. There are three types of hyperlinks present on the Launch page: text, images, and buttons. All provide access to a relevant URL.

Table 14–1   Components of the Launch Page

Label	Type of hyperlink	Description
Login	Button	Initiates the process of starting your RDC Classic session by opening the Logon Window.
Change Password	Hyperlink	Accesses the Change Password Window.
Login Help	Hyperlink	Accesses the Start Your RDC Classic Session topic in RDC Classic Help.
Documentation	Image link	Accesses the RDC Classic Online Help system.
Downloads	Hyperlink	Accesses the Downloads page.
Health Sciences	Hyperlink	Accesses the Oracle Health Sciences Web site.
OHSUG	Hyperlink	Accesses the Oracle Health Sciences User Group Web site.
Oracle	Hyperlink	Access the Oracle Corporation Web site.

Usage

The primary purpose of the RDC Classic Launch page is to facilitate the initiation of your RDC Classic session (which is described in "Start Your RDC Classic Session" on page 5-1). You click the Login button to do this.

In addition to initiating an RDC Classic session, you can accomplish the following tasks from the RDC Classic Launch page:

- Access login help
- Change your password
- View RDC Classic online help system
- Access the Downloads page
- Access the Oracle Health Sciences Web page
- Access the Home page for the Oracle Health Sciences Users Group (OHSUG)

Logon Window

You use the logon window, which is shown in the graphic in Figure 14–1, to type the information that is required to start an RDC Classic session. It is displayed after you click the Login button on the RDC Classic Launch page.

Figure 14–1   RDC Classic Logon Window — Blank
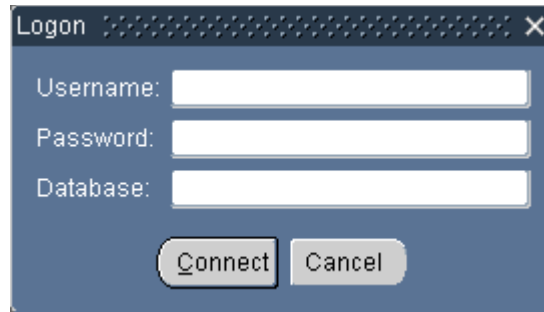
Access

You access the Logon window by clicking the Login button on the RDC Classic Launch Page each time you initiate a new RDC Classic session.

Components of the Logon Window

The Logon window consists of three text boxes and two buttons, which are listed and described in following table.
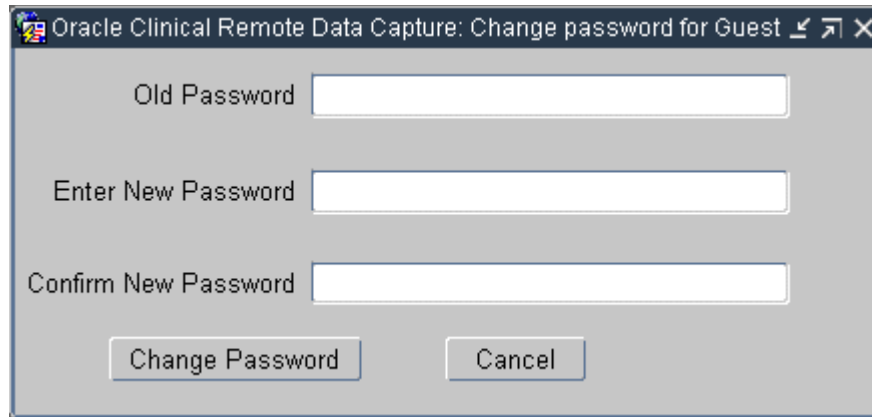
Table 14–2   Components of the Logon Window

Label	Type	Description
Username	Text box	Location where you type your user name, including the OPS$ prefix, if necessary. This field is not case-sensitive.
Password	Text box	Location where you type the password that is associated with your user name. Each character is represented by an asterisk. This field is case-sensitive.
Database	Text box	Location where you type the name of the database you want to access. This field is not case-sensitive.
Connect	Button	Initiates the RDC Classic session by checking the contents of the three text fields in the window.
Cancel	Button	Closes the window and does not initiate the RDC Classic session.

Change Password Window

The Change Password window allows you to change your current password. The graphic depicted in Figure 14–2 is an example of the window.

Figure 14–2   Change Password Window

Access

The Change Password window is displayed when you click the Change Password hyperlink on the RDC Classic Launch Page. When you click the hyperlink, a separate Oracle window is displayed that contains a blank Logon Window.

Components

The Change Password window consists of five components, which are listed and described in Figure 14–2. Note that all text fields in the Change Password window are case-sensitive.

Table 14–3   Components of the Change Password Window

Label	Type	Description
Old Password	Field	Location where you type your current password.
Enter New Password	Field	Location where you type your new password.
Confirm New Password	Field	Location where you re-type your new password, as a confirmation of what you typed in the Enter New Password text box.
Change Password	Button	Changes your password from its current value to what you typed in the Enter and Confirm New Password text boxes.
Cancel	Button	Closes the window and does not change your password.

Usage

Refer to "Change Your Login Password" on page 5-4 for information on using this window.

Change Study Window

You use the Change Study window to either specify or change a study during session startup or change to the study during a session. The window is only displayed if you have access to more than one study. The graphic in Figure 14–3 depicts a typical example of the Change Study window.

Figure 14–3   Change Study Window
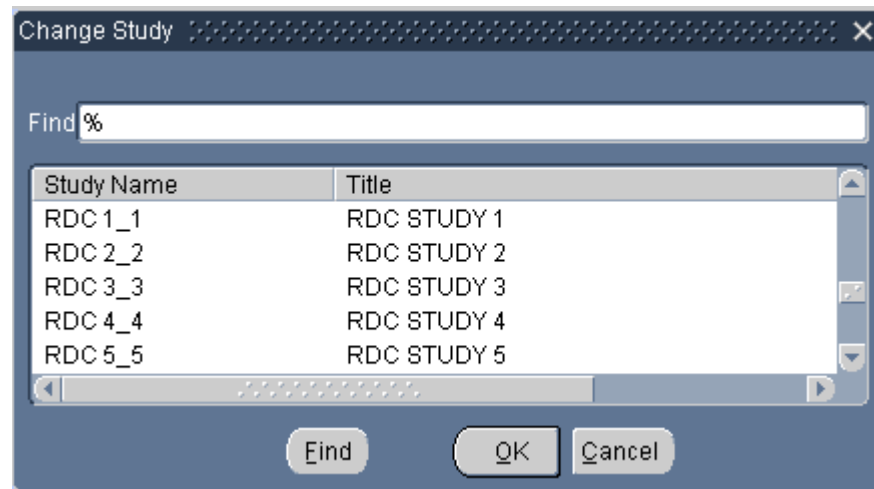
Access

You can only use the Change Study window if you have access to more than one study. If you do have multi-study access, the window is displayed by the system or as the result of actions that you take.

Automatic Access RDC Classic automatically displays the window during the session startup process if a default study is not defined for your user name. Usually, the default study is the one that you were using when you closed the previous RDC Classic session.

Manual Access During Session Startup If the Change Study window is not displayed automatically during session startup, and you want to use a study other than the default, you can access it by clicking the **Change Study** button in either the Search or the Activity List window.

Manual Access During a Session You can change the study during a session by opening the Change Study window. You access the window during a session through:

1. The **Change Study** command in the File menu

2. The **Change Study** button in the Search or the Activity List window

> **Note:**   If you have access to only one study:
>
> ■   the **File**, **Change Study** menu option is inaccessible, and
>
> ■   the Change Study button is not present in the Activity List window.

Components

The components of the Change Study window are listed and described in Table 14–4.

Table 14–4   Components of the Select Study Window

Label	Type	Description
Find	Text box	Location where you type a search string to locate a particular study.
Accessible Studies	List box	A scrollable box that displays the set of studies to which you have access.
Find	Button	Executes a query on the list of accessible studies, using the search string in the Find text box.
OK	Button	Submits your choice of study to the system.
Cancel	Button	Closes the window without specifying a study: ■ during initial login, the session is shut down ■ during a Change Study task, the session reverts to the study in which you were working

The Find text box automatically places the percent sign "wildcard" at the start of the search string. It is an optional component, so you can delete it from the entry. You can also use additional instances of the wildcard between characters to broaden the search.

Usage

To use the Change Study window:

1. Either:

    a. select a study from the list, or

    b. Type a search string in the Find text box, using the percent ("%") wildcard, as necessary, and click the **Find** button.

2. When the correct study is displayed in the Find text box, click the **OK** button.

    When you select a study, the system displays either the Activity List Window or the Search Window, depending on how your session is configured. (Refer to "Using the Search Window to Select Worksets" on page 6-2 for further information).

News Window

The News window is a method for sponsors to communicate information to study workers. It is displayed after you complete the Change Study Window. This section describes the News window, its purpose, how to access it, and how to use it.

Discussion

The News window is a convenient place to read and review important information that sponsors want study workers to know.

The types of news items and the content each contains are sponsor-specific. The information that is displayed, or "broadcast," in the news window can be customized according to the current:

■   Study

■   Site

- Role

- User name

- Date

The content of the News window can consist of one or two news item**s**. Each news item can also include a button that links to a URL, which provides additional information. When you click this button, the information is displayed in your Internet browser.

Figure 14–4, "News Window", is an example of a News window with information that is addressed to an Investigator.

Figure 14–4   News Window
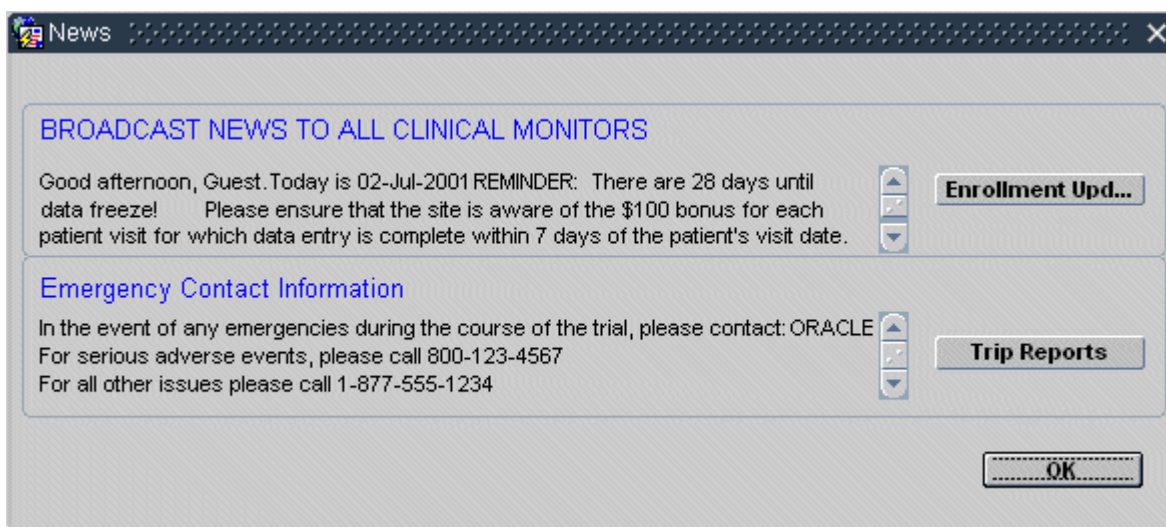
Access

The News Window may be displayed during the start of your RDC Classic session and at any other time during the session. RDC Classic displays the window automatically at the start of a session unless:

1. the system administrator has not configured the news, or

2. you have viewed the current news item(s) in a previous RDC Classic session.

Automatic Access If your study administrator configures the News window to display when you access a study, it is presented after you progress through the Change Study Window and before you access the Search Window or the Activity List Window. Therefore, the system displays the window when you launch RDC Classic and select a study and when you change to another study within a session.

Manual Access You can also access the News window at any time by using the **News** command on the File menu (refer to "File Menu" on page 11-5 for further information).

If you use the News menu command to open the News window when it is not configured, the system displays an alert window that notifying you that the News is not setup for the current study.

Usage

The News window can be a source of information that helps you complete your work and stay current with notices from the study sponsor. Your RDC Classic administrator can provide you with informational listings or with listings that provide active hyperlinks to additional data that are related to the goals of the study.

Field Editor Window

The Field Editor window, which is depicted in Figure 14–5, allows you to use common text editor tools to construct a new text message and view or edit an existing text message. It is particularly useful in situations where the text string extends beyond the visible portion of the relevant field. The editor allows you to view the text in its entirety.

Figure 14–5   Field Editor Window
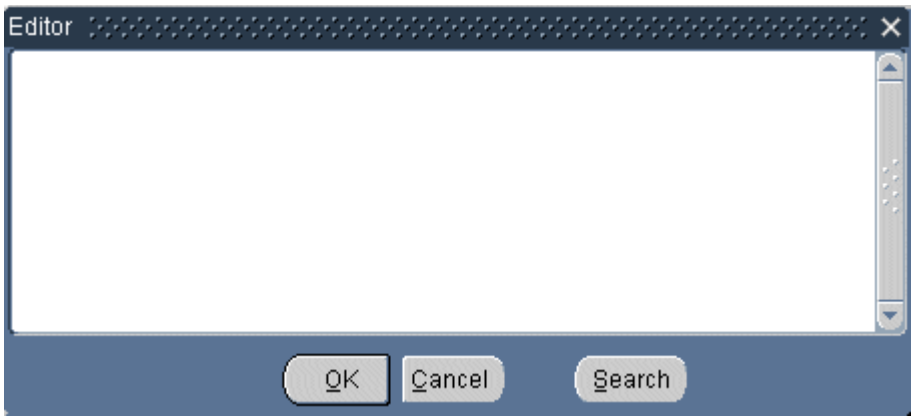
In addition to viewing the text string, the Field Editor provides common text editor functionality, such as copy, paste, and search.

Access

You access the Field Editor from the Edit menu. Use either the:

- **Edit**, **Field Editor** menu option, or
- **Alt+e**, e key combination.

The menu command is only accessible when focus is in field. When you open the Field Editor, it is specific to the field that is in focus. You must complete your work in the Field Editor window, that is, close it, before you can move focus to another field.

Components

The Editor window consists of a text-composition field, which allows you to use standard text editing features, and several buttons.

Table 14–5   Components of the Editor Window

Label	Type	Description
Editor	Text field	A text editing field that allows you to compose and edit text, using common text editor functionality.

Table 14–5   (Cont.) Components of the Editor Window

Label	Type	Description
OK	Button	Inserts the contents of the text field into the field that is in focus.
		Saves the text in the Editor to the database.
Cancel	Button	Dismisses the Editor window without changing the field in focus.
Search	Button	Opens the Search and Replace Window.

Usage

The Field Editor provides basic text editor functionality for the field that is currently in focus.

Cut, Copy, Paste The cut, copy, and paste functions are available through quick key combinations only. Note that these functions are also available in the data field itself.

Function	Shortcut Key
Cut	Ctrl+x
Copy	Ctrl+c
Paste	Ctrl+v

Edit Existing Text When you open the Field Editor window for a field that contains pre-existing text, you can edit the text manually or you can search for a specific text string and replace it.

To edit the text manually, either place the cursor in an appropriate location and type new text, or select the text that you want to replace and type the new content. To use the search and replace functionality, click the Search button. (Refer to "Search and Replace Window" on page 14-9 for further information.)

Commit Changes When you click the OK button, the system inserts the contents of the text field to the field in focus and closes the Field Editor window.

Search and Replace Window

The Search and Replace window allows you to quickly find or find and replace existing text in an editor window. It is useful when you want to edit a lengthy comment by finding and changing a certain word or phrase.

Access

You access it by clicking the Search button in the following windows:

- Field Editor Window
- Error Message Editor
- Internal Comment window

Figure 14–6   Search and Replace Window
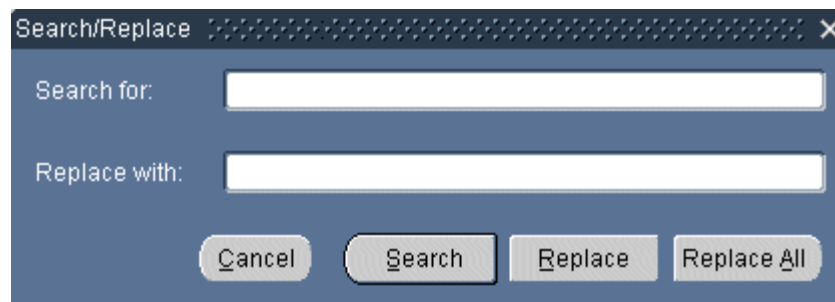
Components

The Search and Replace window consists of components that you use to type two text strings: one that the system searches for; one that it inserts as a replacement when it locates the first. All of the components are listed and described in Components of the Search and Replace window

Table 14–6   Components of the Search and Replace Window

Label	Type	Description
Search for	Text box	Location for you to type the search string you want to locate in the editor window.
Replace with	Text box	Location for you to type the text you want the system to use to replace the search string when it finds it.
Cancel	Button	Dismisses the window without searching or replacing any text in the editor window.
Search	Button	Initiates the search in the editor window for the contents of the Search for: text box.
Replace	Button	Replaces the highlighted text in the editor window with the contents of the Replace with: text box.
Replace All	Button	Replaces all occurrences of the search string in the editor window with the contents of the Replace with: text box.

Usage

The Search and Replace window can be used to either:

- search for certain text in the editor window, or

- search for certain text in the editor window and replace any or all occurrences of it.

Activity List Window

The Activity List window allows you to select the task, termed an *activity*, that you want to complete during an RDC Classic session. Your choice prompts the system to load a workset that includes the CRFs necessary to complete that task.

For example, if your task is to review active discrepancies for a patient, you would select an activity such as, "Review 12 active discrepancies for Patient 101." The system would load a workset in the RDC Classic Spreadsheet that consisted of all CRFs for Patient 101 that contain at least one active discrepancy.

Figure 14–7   Activity List Window
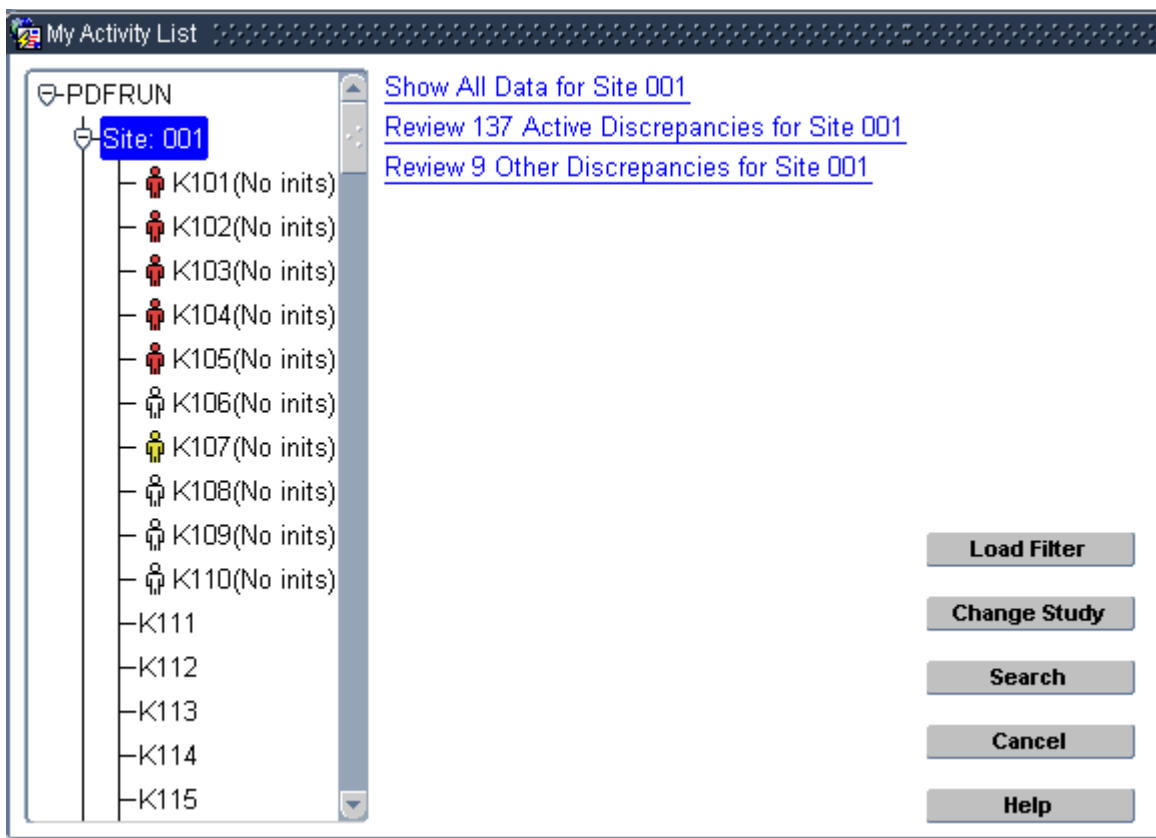
Access

When it is configured for your session, RDC Classic displays the Activity List window:

1. upon initial entry into your RDC Classic session

2. when you click the Activity List button that is adjacent to the Spreadsheet.

> **Note:** Refer to "Using the Activity List Window" on page 6-6 for additional information.

RDC Classic Session Startup

The Activity List window is displayed after you start an RDC Classic session. (Refer to "Start Your RDC Classic Session" on page 5-1 for complete information about this process.) After you successfully log in to RDC Classic, you must use either the Activity List window or the Search Window to select a workset that the system displays in the RDC Classic Spreadsheet. The difference between these two methods is:

■ the Activity List allows you to choose the task that you want to complete in RDC Classic – the search criteria is defined indirectly based on that task

■ the Search window allows you to directly define a custom set of search criteria.

During an RDC Classic Session

To use the Search window when the Activity List window is configured for your session, click the Search button, which is adjacent to the RDC Classic Spreadsheet.

Components

The Activity List window consists of two panes, or frames, that are arranged side-by-side. The components are referred to as:

- Title Bar

- Navigation Pane

- Task Pane

- Navigation Buttons

For each component in the Navigation pane, there is a corresponding set of activities that are displayed in the Task pane. As you select a different Navigation pane component, which is called a node, the list of activities displayed in the Task pane changes.

Title Bar

By default, the title bar simply displays the name of the window — "Activity List Window". However, when a saved search is designated as an Activity List window filter, the name of the search is displayed in title bar. This alerts you that the scope displayed in the Navigation and/or the activities listed in the Task pane may be altered.

Navigation Pane

The Navigation pane displays the site(s) and patient(s) to which you have access for the active study. Its tree-like structure, which is similar to the hierarchical folder arrangement used in Microsoft Windows Explorer, displays only the components to which you have access. Each component in the hierarchy is referred to as a node. Each node is associated with one of three levels. As you select different nodes, you navigate from the study to its constituent site(s), and then, within a site, to the patients assigned to that site.

The three levels that may be displayed in the Navigation pane are:

1. **Study** - the highest level in the hierarchy, there can be only one study-level node present in the Navigation pane. While it contains at least one site-level node as a sub-level, the number of site-level nodes that are displayed beneath the study-level node is the same as the number of sites to which you have access.

2. **Site** - the intermediate level in the hierarchy, there can be one or more Site nodes present in the Navigation pane, depending on:

   - the number of sites in the study, and

   - the number of sites to which you have access.

   Each Site node may contain one or more Patient nodes as sub-levels.

3. **Patient** - the lowest level in the hierarchy, there can be any number of Patient nodes present under each Site node, depending on:

   - the number of patients assigned to the site, and

   - the number of patients to which you have access.

> **Note:** Refer to "Interaction with the Summary Task Tab" on page 6-7 for information about how selection of different nodes in the Navigation pane affects the information that is displayed in the Summary Task Tab.

Expand/Collapse Nodes A node in the Navigation pane may be in one of three states:

1. empty - it does not contain sub-nodes

2. collapsed - it contains sub-nodes, but they are not displayed

3. expanded - it contains sub-nodes, which are displayed below the node, indented slightly.

There is a symbol adjacent to each node that provides information about its state.

Study Node The Study node is the top-level in the hierarchy displayed in the Navigation pane. It represents the currently active study. Therefore, the Navigation pane displays only one Study node at a time (because only one study can be active at a time).

When the Study node is selected, the tasks that are associated with it are displayed in the Task Pane.

When the Activity List window is displayed during initial login, the Navigation pane displays the study node expanded, which lists the constituent sites to which you have access.

Example 14–1   Typical Tasks at the Study Level

The following list of tasks is representative of the type of tasks you can perform at the Study node:

- **Review *<number>* open discrepancies for Study 01.**

  This task, where *<number>* is a variable that is replaced by the actual number of open discrepancies associated with site patients to which you have access, displays in the Spreadsheet all patients with at least one open discrepancy. This allows you to perform discrepancy management.

- **Show all data for Study 01.**

  This task displays in the Spreadsheet all patients assigned to Study 01 to which you have access and all CRFs that have an entry status of at least Created.

Site Node

Each site node that is displayed in the Navigation pane is a constituent of the active study to which you have access. If you have access to one site, then only one Site node will be displayed beneath the Study node, no matter how many sites are actually associated with the study.

As you select each Site node, the tasks that are configured for it are displayed in the Task pane. These tasks are of a scope that allows you to work with data across all of the patients to which you have access that are assigned to the site.

Example 14–2   Typical Tasks at the Site Level

The following list of tasks is representative of the type of tasks you can perform at the Site node:

■ **Review *<number>* open discrepancies for Site 001.**

This task, where *<number>* is a variable that is replaced by the actual number of open discrepancies associated with site patients to which you have access, displays in the Spreadsheet all patients with at least one open discrepancy. This allows you to perform discrepancy management.

■ **Show all data for Site 001.**

This task displays in the Spreadsheet all patients assigned to Site 001 to which you have access and all CRFs that have an entry status of at least Created.

Patient Node Each patient node that is displayed in the Navigation pane is associated with specific Site node. This is represented graphically by placing the patient nodes directly below and slightly indented in relation to the associated site node.

Because it is the lowest level in the hierarchy, a patient node cannot be expanded or collapsed. However, the icon that is adjacent to each patient node does provide you with discrepancy information about the data associated with the patient.

Table 14–7   Patient Node Icons

Icon	Description
👤	There are no CRFs associated with the patient that contain either an Active or Other discrepancy.
👤	At least one CRF associated with the patient has a discrepancy status of Other. However, there are no CRFs with a discrepancy status of Active.
👤	At least one CRF associated with the patient has a discrepancy status of Active. There may also be CRFs with a discrepancy status of Other.

Task Pane

The Task pane displays the list of tasks that are associated with the currently selected node in the Navigation pane. As you select different nodes, at different levels in the Navigation pane, the set of tasks changes and the tasks associated with the newly selected node are displayed.

In order to enable, or activate, a task, click its entry in the task list. This action closes the Activity List window, populates the Spreadsheet with the relevant data, and prepares RDC Classic so that you can immediately start working on the task.

Scope The tasks that are associated with a particular type of node act on a subset of data that is related to the level of the node. This relationship between a task and the set of data it refers to is called scope. When the Study node is selected in the Navigation pane, any task that you select queries all of the data in the study to which you have access. In comparison, when a patient node is selected, any task you choose queries only the data that is associated with that one patient.

Because tasks are sorted and displayed based on your user role and on the currently selected scope, the same tasks are displayed when you select different patients, only the data that is loaded in the RDC Classic Spreadsheet differs. Similarly, the set of tasks for different Site nodes is identical, only the patient data that are loaded in the RDC Classic Spreadsheet differs.

Navigation Buttons

There are three navigation buttons on the Activity List window that provide additional functionality. The buttons are:

- Load Filter Button
- Change Study Button
- Search Button
- Cancel Button
- Help Button

Load Filter Button This button opens the List of Saved Searches Window, which allows you to select a saved search to use as a filter on the activities in the Activity List window.

Change Study Button This button opens the Change Study Window, which allows you to switch another study.

Search Button The Search button opens the Search Window. It provides the same functionality as **Modify Search** in the **File** menu.

Cancel Button The functionality of the Cancel button is dependent on where you are in the login process.

- If the Activity List window is displayed as part of the session startup process, when you click the Cancel button RDC Classic displays a window that offers you three options:

  1. Change Study — This option displays the Change Study Window, which allows you to change the study.

  2. Exit RDC Classic — This option closes the application.

  3. Return to Activity List — This option puts focus on the Activity List window and allows you to continue the session login process.

- If you navigate to the Activity List window via the Activity List button adjacent to the RDC Classic Spreadsheet, when you click the Cancel button:

  1. The system closes the Activity List window.

  2. Focus returns to the RDC Classic Workspace.

  3. The search criteria is unchanged.

Help Button The Help button launches the RDC Classic Online Help and displays the Activity List window topic.

Usage

To use the Activity List window effectively, you need only identify the scope (Study, Site, or Patient) and the task that you want to complete. When you select a task, RDC Classic retrieves the necessary data and displays the workset in the RDC Classic Spreadsheet.

Refer to "Using the Activity List Window" on page 6-6 additional information.

Saved Search Windows

RDC Classic 4.5.1 permits users to save searches for use in the RDC Classic Search window, the Activity List window, and to directly specify a workset. The windows that you use to create, manage, and use saved searches are:

- Save Current Search Window

- List of Saved Searches Window

- Maintain Saved Search Window

- Copy Search Window

- SQL Query Window

Save Current Search Window

The Save Current Search window allows you to save the search criteria that were used to load the current workset. This makes the search available in the List of Saved Searches Window and the Maintain Saved Search Window.

Figure 14–8   Save Current Search Window
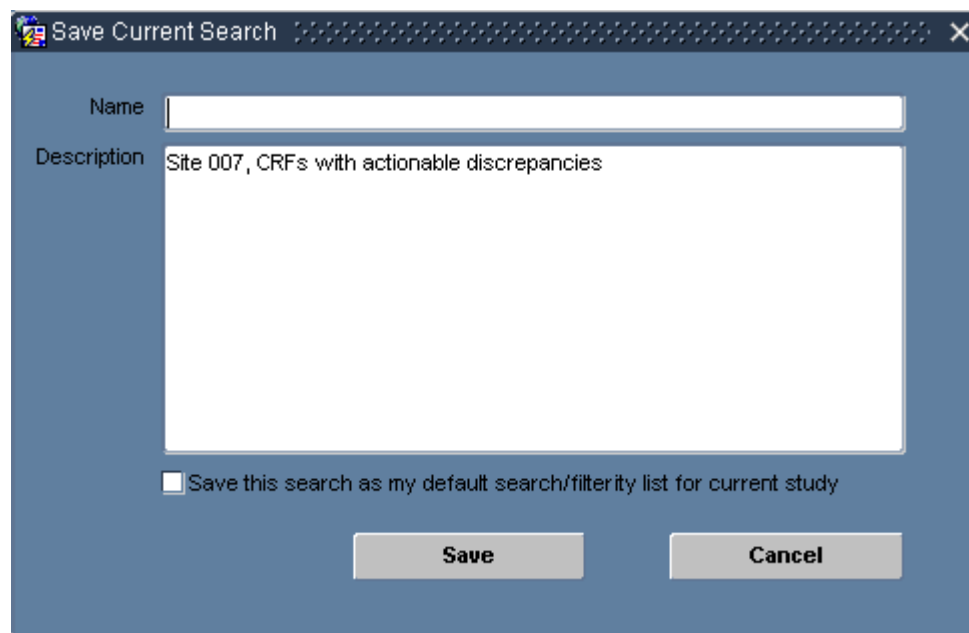
Access

You access the Save Current Search window from the Save Search command in the File Menu.

Components

The components of the Save Current Search window are listed and described in Table 14–8.

Table 14–8   Components of the Save Current Search Window

Label	Type	Description
Name	Field	A text box in which you type a descriptive name for the search you want to save. You must supply a name here; the system will not save the search until there is a unique name associated with it. The field has a 100 byte maximum.
Description	Field	A text box that describes the search criteria upon which the saved search is based. Initially, the system inserts the search criteria description that is displayed in the RDC Classic Spreadsheet Status Line. You can modify this description, as necessary. The field has a 2000 byte maximum.
Save as my default...	Check box	If selected, specifies that the search is designated as your default search.
Save	Button	Saves the search with the designated name, description, and default search setting.
Cancel	Button	Discontinues the save search action, closes the window, and returns focus to the RDC Classic Workspace.

Usage

When you save a search, via the Save Search command in the File menu, the system displays the Save Current Search window. Use this window to create a unique name for the search and to modify the description, if necessary. If you want to set the search to be the default for your sessions, select the **Save as my default search/filter for the current study** check box.

List of Saved Searches Window

The List of Saved Searches window displays a list of searches that you can use in your session. The set of searches that are available to you are those that meet the settings for your user name, the associated user role, and the current study. The window also includes the capability to quickly locate a particular saved search.

> **Note:**   Although users with administrative privileges are able to use the Maintain Saved Search Window to access and work with any saved search in the study database, the list that is available to is limited to the current scope for user, study, and role.

In addition to selecting a saved search to load, you use this window when a saved search is already loaded and you want to remove its settings. This action is analogous to setting all of the criteria in the Search window to default values.

Figure 14–9   List of Saved Searches Window
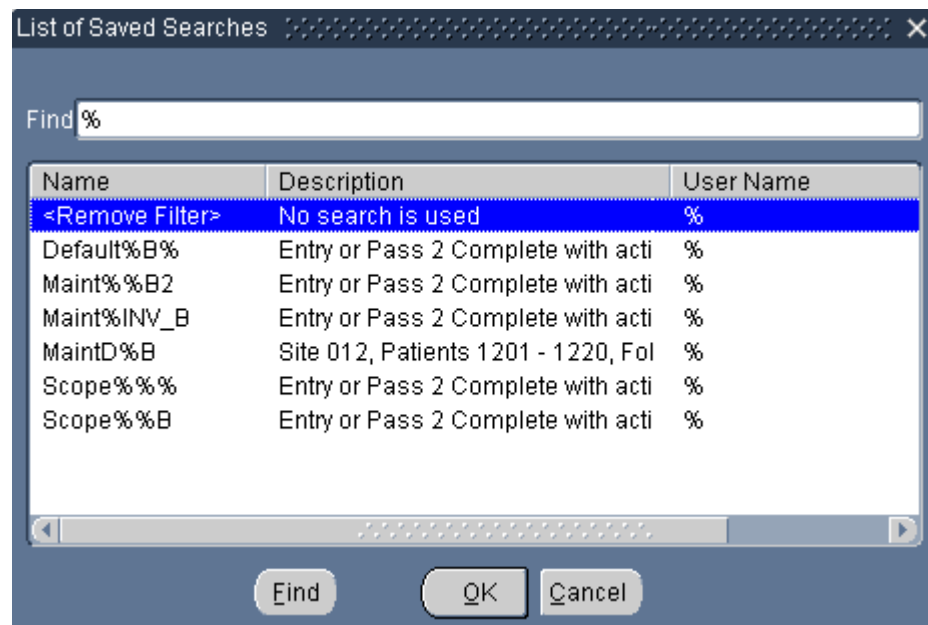
Components

The components of the List of Saved Searches are listed and described in Table 14–9.

Table 14–9   Components of the List of Saved Searches Window

Label	Type	Description
Find	Text box	A tool that uses a text string to search the list of saved search
Name	Column	The name associated with each saved search
Description	Column	The description associated with each saved search
User Name	Column	The user name associated with each saved search

Usage

To use the window to load a search or filter, highlight the row that corresponds to the saved search you want and click the **OK** button.

If the list of saved searches is extensive, you can search for the one you want. To use the Find tool:

1. Type a text string that is present in any of the columns, using the wildcard character ("%"), as necessary.

2. Click the **Find** button. The list of saved searches that match the search string is displayed.

To revert back to the full list of saved searches, do a search for the wildcard character ("%"), which returns all items in the list.

Access

You access the List of Saved Searches window from:

■   Load Filter button on the Activity List window

■   Load Search button on the Search window

■ Load Search command in the File menu

Maintain Saved Search Window

You use the Maintain Saved Search window to perform various tasks with existing saved searches. This includes making a copy, or deleting, changing the scope of a saved search. This allows you to make a saved search that you created available to other users and to do housekeeping of your set of saved searches.

There are two versions of the Maintain Saved Search window:

1. for users without administrator privileges, the window, which is depicted in Figure 14–10, "Maintain Search Window — Non-admin User", includes all searches to which the user has access; that is, those in which the user name and role components of the scope satisfy the current user and that user's assigned role.

2. for users with administrator privileges, the window, which is depicted in Figure 14–11, "Maintain Saved Search Window — Administrators", includes all saved searches that exist in the database; this gives the user the means to work with any search and re-implement it as necessary.

Figure 14–10   Maintain Search Window — Non-admin User

The primary differences between the two windows are:

- The window for non-admin users:
  - provides a list of saved searches that is limited to those that are available to the user, based on the scope values associated with each saved search
  - does not include the View Query button
- The window for RDC Classic administrators:
  - provides a list of all saved searches in the database, which the user can then modify, copy, or delete
  - provides access to the SQL Query Window via the **View Query** button

Components

The Maintain Saved Search window provides detailed information about each saved search it lists and allows you to manage the set of saved searches available to you. The upper portion of the window is a table consisting of a scrollable set of rows, with the scope information for each saved search displayed in fields across each row.

The first column displays the name of the saved search, which is initially specified in the Save Current Search Window. The remaining three columns display each of the scope values that are associated with a saved search. At the end of each row is a check box that allows you to identify a search as your default search.

Figure 14–11   Maintain Saved Search Window — Administrators

All of the components that comprise the Maintain Search windows are listed and described in Table 14–10.

Table 14–10   Components of the Maintain Search Window

Label	Type	Description
Search Name	Column	Displays the name associated with each saved search.
User	Column	Displays the User scope value for each saved search
Study	Column	Displays the Study scope value for each saved search
Role	Column	Displays the Role scope value for each saved search
Default	Check box	Specifies if a saved search is designated as your default for the current study. Color-coded to indicate if the saved search is available to you in the current study.
Description	Text box	The description associated with the currently selected saved search.
Search Conditions	Table	A listing of the conditions that comprise the search criteria associated with the currently selected saved search.
Show searches applicable...	Check box	Allows you to determine the set of saved searches that are listed in the window.
Delete	Button	Deletes the currently selected saved search.
View Query	Button	Opens the SQL Query Window; present only in the window displayed for RDC Classic administrators
Save	Button	Saves all pending changes in the window
Save As	Button	Opens the Copy Search Window, which initiates the process of creating a copy of an existing saved search.
Close	Button	Closes the window.

Show searches applicable...   This check box allows you to work either with the full set of searches that are currently available to you or a more limited set. The check box label and its functionality differs based on whether or not you are an RDC Classic administrator.

If you are not an RDC Classic administrator, the label is:

Show searches applicable to the current study

When the check box is selected, only those saved searches with a Study scope of the current study or default ("%") are listed in the table of saved searches. This allows you to view only those searches that you can use in the current study. This may be helpful if you want to select a default search, for example.

When the check box is clear, the list of saved searches includes all that are available to you, even those with a Study scope value other than the current study or default. You cannot use these saved searches in the current study, though you can modify the Study scope to make it available or create a copy of such a search.

If you are an RDC Classic Administrator, the check box label is:

Show searches applicable to the current study and user

This check box differs from the non-administrator version because, as an RDC Classic administrator, you are able to view and work with any saved search in the database. You use this setting to limit the list to those that are available for you your use in the current RDC Classic session and study.

When the check box is selected, only those saved searches with a Study scope of the current study or default ("%") are listed in the table of saved searches.

When the check box is clear, the list includes all saved searches in the database.

Note: The Default check box is color-coded to indicate whether a saved search is available for your use in the current study.

Access

All users access the Maintain Search window using the Maintain Search command on the Edit menu. The system opens the version of the window that is appropriate to the privileges associated with your user name.

Copy Search Window

You use the Copy Search window to create a copy of a saved search. The new saved search has the identical search criteria as the original, however, you have the option to modify the scope values, limiting or expanding the set of users who have accessed to it.

Figure 14–12   Copy Search Window

Components

The components of the Maintain Saved Search window are listed and described in Table 14–11.

Table 14–11   Components of the Copy Search Window

Label	Type	Description
Search Name	Text field	The name of the saved search. By default, this is, "Copy of *<original_saved_search_name>*". This value must be unique among the saved searches in the database.
User	LOV	The User scope value. For a non-admin user, the initial value is set to the current user's name. For an administrator, the initial value is set to the current user's name or, if the user scope in the source search is '%', then the '%' value is retained in the new search.

Table 14–11   (Cont.) Components of the Copy Search Window

Label	Type	Description
Study	LOV	The Study scope value. The initial value of this field matches the study scope of the source search.
Role	LOV	The Role scope value. For a non-admin user, the initial value is set to '%'. For an administrator, the initial value matches the role scope of the source search.
Description	Text field	A text box that describes the search criteria upon which the saved search is based. Initially, this field is identical to the Description field in the original saved search. You can modify the field, as necessary. The field has a 2000 byte maximum.

Usage

The Copy Search window allows you to create a copy of an existing search and to modify its scope and description at the same time.

Access

The system displays the Copy Search window when you click the Save As button in the Maintain Saved Search Window.

SQL Query Window

You use the SQL Query window to generate and view the SQL statement that a given saved search is based on. This allows you to perform debug and troubleshooting activities.

Figure 14–13   SQL Query Window
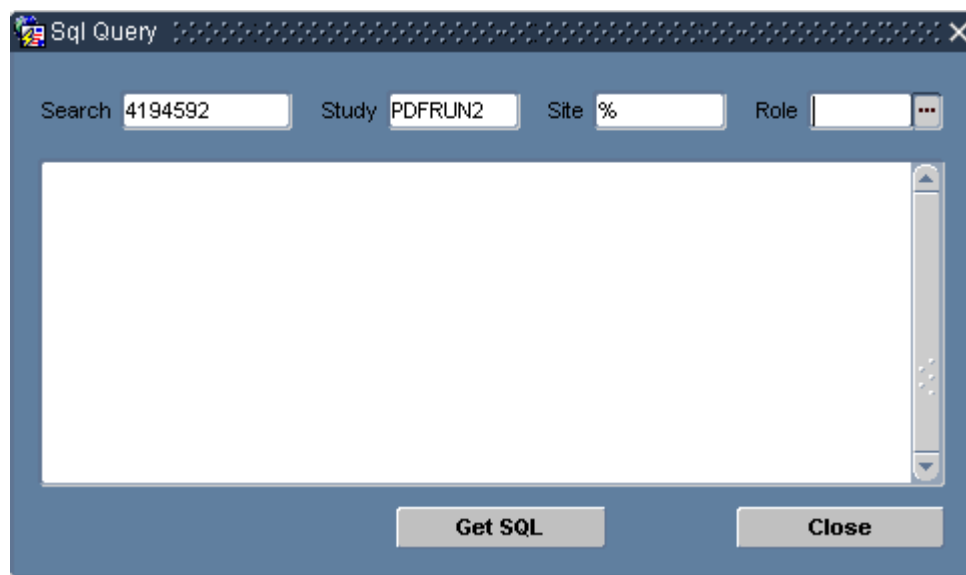
Components

The components of the SQL Query window are listed and described in Table 14–12.

Table 14–12   Components of the SQL Query Window

Label	Type	Description
Search	LOV	The saved search name that is used to generate the query. This field is required.
Study	LOV	The study name that is used to generate the SQL statement. This field is required.
Site	LOV	The name of a site that is part of the study specified in the Study field. The value in this field can be "%" ("ALL") or the name of a single site.
Role	LOV	The name of a user role that is used to generate the SQL statement. This field is required.
SQL	Text box	The SQL statement that defines the criteria specified by the saved search and the study, site, and role parameters.
Get SQL	Button	Causes the SQL statement to be retrieved and stored in the SQL: text box.
Close	Button	Dismisses the window.

Usage

To generate a SQL statement, you must supply specific values for three of the four parameters that are available in the window. The Search parameters provide the bulk of the search criteria used in the query.

The Study and Role parameters are required because each is used in every search to provide context. For example, the role of the user performing a search determines the discrepancy status of each CRF and may limit the results of the search.

The Site parameter is optional when you get the SQL statement. If you specify a site, the query adds it to the end of the query to further restrict the results.

If you do not specify a Study or a Role parameter, the system does not fetch the query. However, you have the option to change any of the parameters and re-fetch the query. In this way, you can evaluate how different values for the Role, for example, alter the query and/or the resultant workset.

To capture a query that is displayed in the window, click-drag from the upper left-hand corner of the text box to the lower right-hand position, just to the right of the last line of text. The system highlights in blue any text that you select. When the text is selected, use the Copy quick-key combination (Ctrl-c) to copy the text to the Windows clipboard. You can then use the Paste quick-key combination (Ctrl-v) to paste it into an editor or SQL*Plus.

Access

You access the SQL Query window by clicking the **View Query** button on the Maintain Saved Search Window that is available to RDC Classic administrators.

Preferences Window

The Preferences window allows you to manage various application settings for the current RDC Classic session. Two tabs separate the settings into general session settings:

■   General Tab

■   Data Entry Tab

Default Settings

A default set of preferences is defined for each study to which you have access. These are displayed when you open the Preferences window for the first time in a session. The RDC Classic administrator is responsible for the configuration of these settings.

> **Note:** Your system administrator establishes and maintains your default preferences settings through the RDC Classic Configuration Settings window. Management of these settings is described in Chapter 18, "RDC Classic Administration Tasks."

Changes to Default Settings

When you change default settings in the Preferences window, those changes are active until:

- You make further changes.

- You change the study.

- You close the RDC Classic session.

When you change the study or start a new session, the default settings are enabled.

Access

Access the Preferences window by selecting **Preferences** from the option list on the Edit menu. When you select the menu command, RDC Classic opens the Preferences window on top of the RDC Classic Workspace.

Note that the presence of **Preferences** on the option list of the **Edit** menu is controlled by configuration settings that your system administrator specifies. If the menu command is not accessible in the Edit menu and you wish to alter default Preferences window settings, contact your system administrator for assistance.

Session Configuration

Your system administrator can configure your RDC Classic session so that the Preferences menu command is not accessible from the Edit menu. When the Preferences menu command is not accessible, you cannot alter the components that are available in the Preferences window.

Components

The Preferences window is divided into two tabs. The components of the tabs are described in the following subsections:

- General Tab Components

- Data Entry Tab Components

General Tab Components

The General tab of the Preferences window contains settings that affect how RDC Classic functions during data entry. It consists of settings in the following categories:

- Date Format

- Debug Settings

- System Settings Section

■ Time Zone Section

Figure 14–14 Preferences Window — General Tab
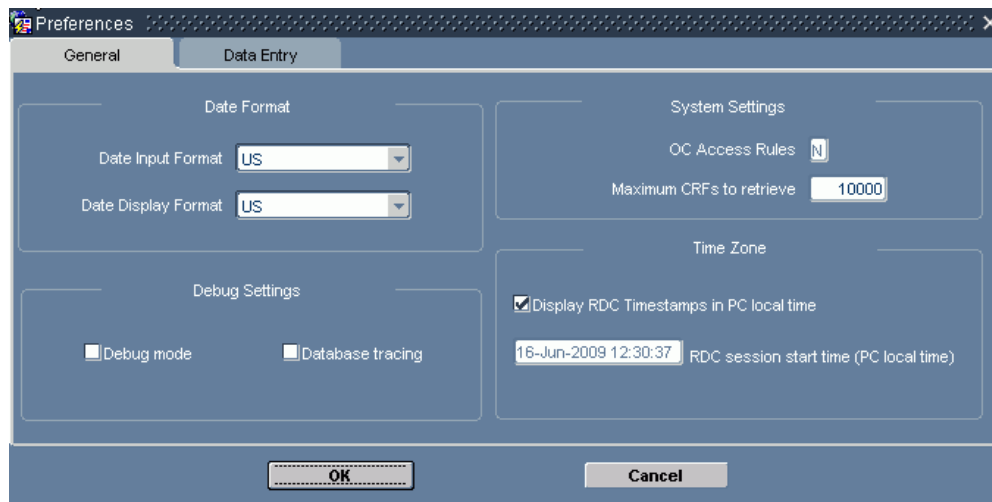
Date Format

This section consists of two date format settings, one affects the way you enter dates in a CRF, the other affects the way the system presents date data.

Date Input Format There are four date formats that RDC Classic recognizes; these are listed in Table 14–13.

Table 14–13 RDC Classic Date Formats

Format Title	Description	Example	Meaning
US	MM-DD-YYYY	12-01-2002	December 1, 2002
European	DD-MM-YYY	12-01-2002	January 12, 2002
Swedish	YYYY-MM-DD	2002-01-12	January 12, 2002
Standard	DD-Mon-YYYY	12-Jun-2002	June 12, 2002

The setting for the Date Input Format option defines the date format that you will use to input dates into RDC Classic. It is important that this information is correct because it ensures the system calculates the correct date.

When you click the drop-down arrow for this option, you are presented with three date formats:

1. US

2. European

3. Swedish

Date Display Format This setting defines the format that dates are displayed in Data Entry windows. Like the Date Input Format setting, it is a drop-down selection box. You set this to either of two choices:

1. Current selection in the Date Input Format drop-down box

2. Standard

The implication of these choices is that, at any given time, you are able to work with up to two date formats:

- You can input date data in one of three formats.

- You can display dates either in Standard format or the format that you choose for data input.

Debug Settings

These two check boxes enable diagnostic tools that are used by your System Administrator and Oracle Technical Support to analyze how RDC Classic is working. Do not select either of these check boxes unless you are explicitly instructed to do so by your System Administrator. While the tools that are activated by these options are useful, both severely affect the performance of RDC Classic.

System Settings Section

This section consists of a read-only setting that affects the way RDC Classic handles auditing and validation. It also includes a setting that affects the maximum number of CRFs that are retrieved in your workset.

Oracle Clinical Access Rules This component displays the current accessibility rule for your RDC Classic session. The setting itself is specified by the RDC Classic administrator, using the RDC Classic Configurator. You cannot change this setting in the Preferences window.

The setting affects the way that RDC Classic:

- handles response data auditing requirements

- processes validation procedures.

The setting can be either "N" (the default value) or "Y". When it is set to "N", RDC Classic functions normally. When it is set to "Y", RDC Classic uses the same accessibility rules that are used in Oracle Clinical.

Maximum CRFs to Retrieve This option specifies the maximum number of CRFs that RDC Classic can retrieve at any one time. Normally, you do not have to adjust the value in this text box. However, under certain circumstances, your system administrator may instruct you to change the default value.

Time Zone Section

This section allows you to adjust how timestamp data is displayed in RDC Classic and to gauge how long your RDC Classic session has been running.

Display RDC Classic Timestamps in PC's Local Time When this option is selected, all timestamps displayed in RDC Classic are converted from the server's time zone to your computer's time zone. Note that this setting does not affect the timestamp data that are saved to the database. The system simply uses the time zone adjustment value stored in your computer and applies it to timestamp values displayed in RDC Classic.

RDC Classic Session Start Time This is an information item that records the date and time you initiated the current RDC Classic session. The values reflect the date and time that is kept by your local computer.

Data Entry Tab Components

The Data Entry tab in the Preferences window allows you to configure various workspace features. This includes how the system navigates to other CRFs, whether clicking a CRF icon opens the Data Entry window, and how the system handles field-to-field navigation during data entry. The tab consists of three sections:

- CRF Progression
- Action When Clicking on a Cell
- Data Entry Settings

Figure 14–15   Preferences Window — Data Entry Tab
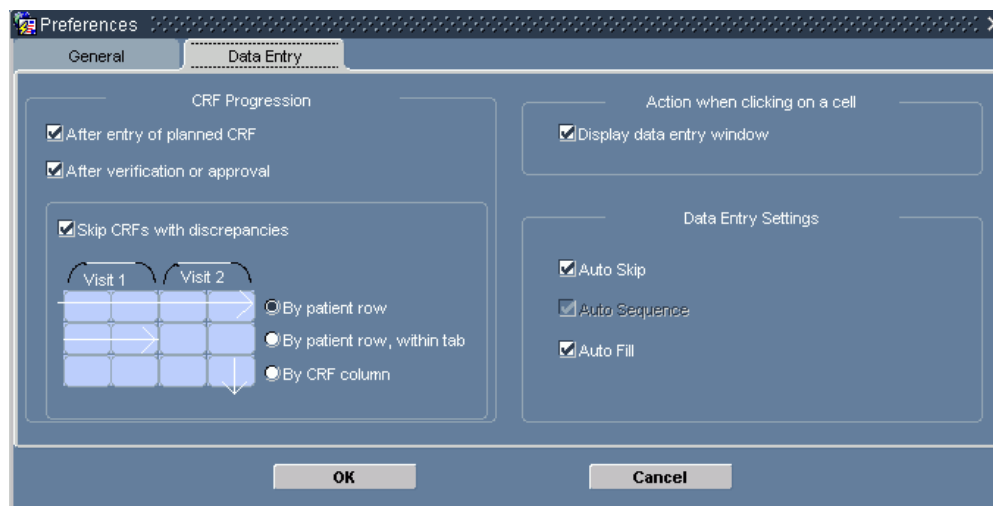
CRF Progression

In data entry, CRF progression refers to the way that focus shifts as you complete work on a given CRF. The options that are present in this section allow you to control how focus changes after you perform these tasks:

- initial data entry
- change the verification status
- change the approval status

You should note the following about these settings:

1. The progression sequence does not include unplanned CRFs. You must overtly select the icon for an unplanned CRF in order to open it in the Data Entry window.

2. If you want to disable CRF progression for data entry, clear the **After entry of planned CRF** check box.

3. If you want to disable CRF progression for approval and verification tasks, clear the **After verification or approval** check box.

4. If you disable CRF progression for both data entry and verification/approval, the settings of the sequence direction and discrepant CRFs parameters do not apply to those tasks, but do affect the functionality of the **Next** and **Previous** buttons, as well as the associated menu commands. Refer to "RDC Classic Toolbar" on page 11-13 and "CRF Menu" on page 11-10 for additional information.

After Entry of Planned CRF Use this setting to enable progression after initial data entry in a planned CRF. When this setting is selected, after you collect data for the last question in the CRF, as part of initial data entry, the system opens the next planned CRF that is not created.

After Verification or Approval Use this setting to enable progression after you approve or verify a CRF. It affects how you work with the Verification Task Tab and the Approval Task Tab. When this option is selected, focus changes to the next CRF in the sequence after you approve or verify a CRF. When it is not selected, focus remains in the current CRF after you modify the verification or approval status.

Skip CRFs with Discrepancies This setting causes the system to not include CRFs with actionable discrepancies (that is, those at either the active or other discrepancy status) in the progression sequence. This setting is useful when you are performing approval or verification tasks and do not want to include discrepant CRFs.

Progression Direction This option affects the direction of the CRF progression sequence. You use the radio buttons to control where the system looks for the CRFs that are in the progression sequence. The graphic adjacent to the radio buttons serves as an aid that describes each type of automatic progression sequence.

The options for this setting and the effect of each option on data entry and verification/approval are described in the following list:

- **For patient row** – sets the progression sequence for the current patient row, across all Spreadsheet views. This means that when you conclude work on a CRF for a given patient, focus moves to the next planned CRF, i.e., the CRF with the next higher page number. If there are not any such CRFs in the current visit, the system searches subsequent visits in order until a CRF page that meets the criteria for the current operation is found. If a CRF is not found, focus remains on the last accessed CRF.

  - **Data Entry** - When the current (planned) CRF is completed, the system changes focus to the next CRF for the current patient that is not created, even if it is part of a subsequent Spreadsheet view.

  - **Approval or Verification** - When you approve or verify the current CRF, the system changes focus to the next CRF for the current patient that is not approved or verified (based on the previous action), even if it is part of subsequent Spreadsheet view.

- **For patient row, within tab** – sets the progression sequence for the current patient, within the current Spreadsheet view tab (that is, either for the visit, phase, or study). This means that when you conclude work on a CRF for a given patient, focus moves to the CRF associated with the next CRF that meets the criteria for the current workset, but only within the current tab. If there are no CRFs in the current tab that satisfy the criteria for the current operation, focus remains on the current CRF.

  - **Data Entry** - When the current CRF is completed, the system changes focus to the next CRF for the current patient that is not created, if one exists within the current Spreadsheet tab.

  - **Approval or Verification** - When you approve or verify the current CRF, the system changes focus to the next CRF for the current patient that is not approved or verified (based on the previous action), if one exists within the current Spreadsheet tab.

- **By CRF column** – sets the progression sequence for the current CRF column, across patient rows. This means that when you conclude work on a CRF for a given patient, focus moves down the CRF Column to the next CRF that meets the criteria for the current operation. If there are no such CRFs in the current Page column, focus remains on the last accessed CRF.

  - **Data Entry** - When the current CRF is completed, the system changes focus to the next CRF in the CRF Column that is not created.

  - **Approval or Verification** - When you approve or verify the current CRF, the system changes focus to the next CRF in the CRF Column that is not approved or verified (based on the previous action).

In general, automatic progression proceeds, until no 'eligible' CRFs are available. At that point, automatic progression stops and the last accessed CRF remains in focus.

Action When Clicking on a Cell

When selected, the **Display data entry window** setting causes the Data Entry window to open when you click on a CRF Cell. If this setting is not selected, you **cannot** access the Data Entry window.

Data Entry Settings

The settings in this section affect field-to-field navigation during initial data entry.

Auto Skip When this option is selected, it causes focus in the Data Entry window to move to the next field in the response sequence when you type the number of characters that are defined for the current field.

Auto Sequence This option is associated with automatic progression in the Data Entry window. It is not user-configurable.

Auto Fill This option allows you to type in just enough characters in a Data Entry window data field for the system to ascertain what value you intend to enter. At that point, if you navigate to another data field, by pressing the Tab or Enter key, or using the mouse cursor, the first data entry field is filled with the complete value.

For example, if the list of values (LOV) for a data field includes the values, "Normal" and "Not Done", and you type "nor" and tab out of the data field, the system will fill the data field with the value, "Normal."

Windows Associated with Running Reports

This topic provides descriptions of the windows that the system displays when you run reports. It describes the components and functionality of each.

- Reports Window

- Report Submission Window

- Submission Details for Report Window

- Submitted Batch Jobs Window

- Schedule Jobs Window

- Report Previewer Window

- Output File Window

- Log File Window

■   Report Queue Manager Window

Reports Window

You use the Reports window to initiate the process of running a report. The window provides you with the capability to choose between the patient data report and the workbook report. It also allows you to select the page layout of the report.

> **Note:**   Refer to "Reports in RDC Classic" for information about the differences between the reports that are available in RDC Classic.

When you initiate the report process, the system communicates with other Oracle Clinical components, which collect and organize the data to include in the report, and then it displays other windows that you use to modify parameter, start the report process, and monitor the progress of the PDR.

Figure 14–16   Reports Window
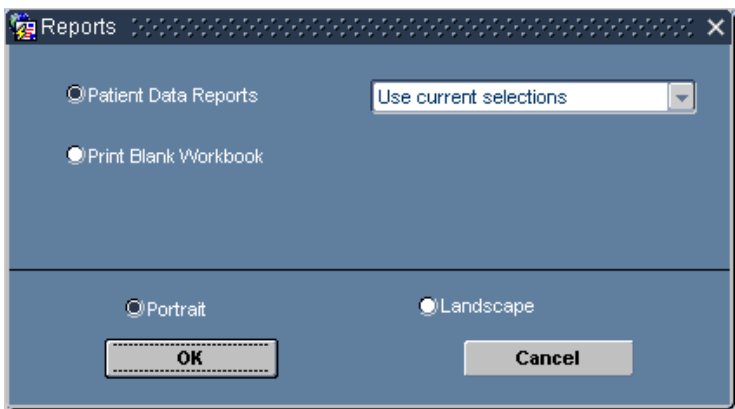
Access

You access the Reports window from the **Reports** command on the File menu. When you select this command, you are presented with the Reports window.

Components

The Reports window is comprised of:

■   a section that you use to specify the type of report you want to run

■   options for the page orientation

■   two buttons

When you access the Reports window to run a report, there are several options that can be set that define what kind of report you run.

> **Note:**   Selected options are saved for the current session only.

Table 14–14 describes the options in the Reports window.

Table 14–14   Reports Window Components

Label	Type	Description
Patient Data Reports	Radio button	Generates a report that includes CRFs with patient data and, optionally, other sections. This type of report gives you two options includes two radio buttons that allow you choose the method you wish to use for the report. 1. **Use Current Selections** - this option uses the criteria currently specified in the Search Window to generate the report. 2. **Specify report parameter**s - this option allows you to specify report criteria during the "Running Patient CRF Reports" process.
Print Blank Workbook	Radio button	Prints all CRFs in a workbook, however, no patient data or information is included.
Report format	Radio button	The Report format affects the reports. The non-CRF sections are formatted according to this setting. In the report, the CRFs are also formatted by this setting. This option allows you to specify the page format of the report. The two choices are: ■ Portrait ■ Landscape
OK	Button	Saves your current report window options, closes the window, and opens the Report Submission Window.
Cancel	Button	Closes the Reports window without saving your changes to the default report window options and reverts focus to the RDC Classic Workspace.

Report Submission Window

You use the Report Submissions window to specify parameters that affect the different aspects of the patient data report (PDR) that you are running. The number and type of parameters that are available are dependent on the type of PDR you choose to run.

Figure 14–17   Report Submission Window (Use Current Selections Option)

Access

The system displays the Report Submission window when you run a report from the Reports window.

Components

The Report Submission is comprised of a set of components that allow you to control how the report runs, when it runs, and that provide access to status windows.

Table 14–15   Report Submission Window Components

Label	Type	Description
Server/Queue	Data field	The name of the Report Server.
Printer	Data field	The name of the printer that is on the application server network.
Report parameters	List of data fields	A list of parameters; each consists of a Description field, which is the parameter name, and a Current Value field, which contains the value of the parameter.
Mandatory?	Check box	A read-only check box for each report parameter that indicates if a value is required in order to run the report.
LOV?	Check box	A read-only check box for each report parameter that indicates if a list of values exists for the parameter.
Pattern?	Check box	A read-only component for each report parameter that indicates if you can include the wildcard character ("%") in the Current Value field.
Exit	Button	Closes the window.
Submit Job	Button	Sends the report job to the scheduler.
Job Details	Button	Opens the Submission Details for Report window.
Job Status	Button	Opens the Submitted Batch Jobs window.
Schedule	Button	Opens the Schedule Jobs window.
Change Study	Change Study	Opens the Change Study window.

Use current selections When you run a patient data report and specify to use current selections, the system uses the current workset as the basis for the CRFs that are included in the report. However, you can specify a certain set of parameters that affect whether data is marked and if the Discrepancy and/or Report Response History sections are included. When you initiate a report using current selections, the Report Submission window lists five parameters that you can configure in the Report Parameters section.

Table 14–16 specifies which type of report includes each parameter and lists the default values for the applicable parameters.

Specify report parameters When you run a patient data report and choose to specify report parameters, the system provides an expanded set of parameters that allow you to modify the set of CRFs that are included in the report. Table 14–16 specifies the parameters that are included with each type of report and lists the default values for applicable parameters.

Report parameters

The Report Parameters list varies based on choices made in the Reports window.

Table 14–16 lists the complete set of parameters that are available when you run reports. The table also lists the default value for each parameter, if present. Use the "PDR Type" column to identify the type of PDR in which each parameter is used:

- S – "Specify report parameters"

- B – Both "Use current selections" and "Specify report parameters"

The system presents all of these parameters when you select the Specify Report Parameters radio button in the Reports window. A subset of these parameters is presented for other types of PDRs.

Table 14–16   List and Description of Report Parameters

Parameter	Default Value	PDR Type
Book Name for Report		S
Site to report on		S
Starting patient		S
Ending patient		S
Start on or after date		S
End on or before date		S
Type of date for starting and ending dates	Visit	S
Mark values changed since what date	None	B
Specific date for marking		B
Discrepancy status choice	All statuses	S
Approval Status Choice	All statuses	S
Verification Status Choice	All statuses	S
Include Discrepancy Detail Report?	Y	B
Include Audit History Report?	Y	B
Date Format in Patient Data Report		B

Book Name for Report When this parameter is present in the window, a value must be specified for it before you can modify any other parameters. Use the LOV to select a book that is part of the current study. CRFs associated with patients that are not assigned to the book you choose will be designated as unplanned.

Site to report on This parameter allows you specify a site to include in the PDR. It is required. Use the LOV to select from a list of sites that are part of the workset.

Starting patient This parameter designates a starting patient number. Use the LOV to select a valid patient number that is used as the starting number for a range of patient numbers. If you wish to include all patients, do not enter a value in this field or the Ending patient field

Ending patient This parameter designates an ending patient number. You use it either singly or in combination with the Starting patient parameter. Use the LOV to select a valid patient number that is used as the ending number for a range of patient numbers.

- If you wish to include all patients, do not enter a value in this field or in the Starting patient field.

- If you wish to include only one patient number, specify the number in the "Starting patient" field and leave this field blank.

- If you want to include all patients up to a certain number, leave the Starting patient field blank and set the ending patient number in this field.

Start on or after date This parameter designates the start of a date range that is in conjunction the "Type of date for starting and ending dates" parameter and may be used with the End on or before date parameter to define a date range. If you enter a value in this field then only data with a timestamp on or after that date will be included in the report.

End on or before date This parameter specifies the end of a date range that is used in conjunction with the Start on or after date parameter and the "Type of date for starting and ending dates" parameter. It is an inclusive value, that is, if you enter a value in this field then only data with a timestamp on or before that date will be included in the report

- If you want to include all dates prior to a specific date, type the date that is one day before the specific date and leave the Start on or after date field blank.

> **Note:** The format for the Start on or after date and the End on or before date parameters is DD-MON-YYYY.

Type of date for starting and ending dates this parameter determines how the system uses the date(s) specified in the Start on or after date and the End on or before date parameters. The options are:

- **Visit** (default) – only includes CRFs with a visit date that is included in the period specified by the Starting and Ending dates.

- **Creation** – only includes CRFs for which initial data entry occurred in the period specified by the Starting and Ending dates.

Mark values changed since what date The purpose of designating values to mark is that it enables readers to locate that data quickly. Data that is marked is displayed in italic font-style. This parameter has four possible values, which are accessible by clicking the LOV button.

If the parameter is set to a non-default value, only the data values that are marked are included in the Audit History section.

Value	Description
None (default)	Mark nothing; when this parameter is selected, no data is marked in the report. However, all audited data is included in the Audit History section.
Last approval	Mark data values that have changed since the date that the associated CRF was last approved. The only CRFs affected by this parameter are those that have an approval status of awaiting re-approval.
Last verify	Mark data values that have changed since the date that the associated CRF was last verified. The only CRFs affected by this parameter are those that have a verification status of awaiting re-verification.

Value	Description
Specific date	Mark data values that have changed since the date specified in the "Specific date for marking" parameter, which is on the line below this parameter. For CRFs that contain data that has been created or updated since the date specified, only data that has changed since that date are marked.
	If you select this parameter you must enter a valid date in the field associated with the "Specific date for marking" parameter.

Specific date for marking This parameter is only used if you select a value of "Specific date" for the "Mark values changed since what date" parameter, in which case, a value for this parameter is required.

It specifies a date after which any created or modified responses are marked with italic font. For example, if you want to quickly identify all responses that have changed since the beginning of 2001, enter a value of "01-JAN-2001" in this field.

Note that the format for the date is DD-MON-YYYY.

Discrepancy status choice This parameter allows you to narrow the criteria to include/exclude CRFs based on discrepancy status.

Value	Description
All statuses (default)	Does not exclude CRFs based discrepancy status.
Active	Includes CRFs that contain at least one active discrepancy.
Closed	Includes CRFs that contain at least one closed discrepancy.
Other	Includes CRFs that contain at least one discrepancy with an other status.
None	Includes CRFs that do not contain a discrepancy.

Approval Status Choice this parameter allows you to narrow the criteria to include/exclude CRFs based on approval status.

Value	Description
All statuses (default)	Include all CRFs
Approved	Includes only CRFs in the approved status
Not Approved	Include only CRFs in the not approved status
Awaiting Reapp	Includes only CRFs in the awaiting re-approval status
Undone	Includes only CRFs in the approval undone status

Verification Status Choice this parameter allows you to narrow the criteria to include/exclude CRFs based on verification status.

Table 14–17   Verification Status Choices Parameter

Value	Description
All statuses (default)	Include all CRFs
Verified	Includes only CRFs in the verified status
Not Verified	Include only CRFs in the not verified status

Table 14–17   (Cont.) Verification Status Choices Parameter

Value	Description
Awaiting Rever	Includes only CRFs in the awaiting re-verification status
Undone	Includes only CRFs in the verification undone status

Include Discrepancy Detail Report? This parameter determines if the report will include the "Discrepancy Detail Report" section.

There are two options for this parameter:

- **Y** – includes the discrepancy report
- **N** – omits the discrepancy report

Include Audit History Report? This parameter determines if the report will include the "Audit History Report" section

There are two possible values for this parameter:

- **Y** – includes the Audit History section
- **N** – omits the Audit History section.

If you do not include this section, the Deleted CRFs section is also omitted from the PDR.

Date Format in Patient Data Report This parameter determines the format the system uses to print all dates in the PDR.

Format	Description/Example
US	MM-DD-YYYY
EUROPEAN	DD-MM-YYYY
SWEDISH	YYYY-MM-DD
STANDARD	DD-MON-YYYY
DYNAMIC	Same as used in the CRF header information.

Usage

The following subsections describe the general usage of the Report Submission window for different PDRs.

Print a blank workbook When you choose to print a blank workbook, the system displays the Report Submission window with a single parameter, Book Name. Use the LOV button to specify the workbook that you want to run.

Submission Details for Report Window

You use the Submission Details window to ensure that the system settings necessary to run the report are configured correctly and to submit the report job to the report server. In addition, you can access the Schedule Jobs window.

Figure 14–18   Submission Details for Report Window

Access

You access the Submission Details window by clicking the Job Details button in the Report Submission Window.

Components

The Submission Details window consists of data fields that allow you to configure where the PDR will run and what format it will be. It also contains buttons that allow you to submit the report job or schedule it for a later time.

Submitted Batch Jobs Window

The Submitted Batch Jobs window allows you to monitor the status of multiple reports jobs and to view reports and/or the associated log files. The window lists the jobs that have been submitted for you to the Report Server.

Figure 14–19   Submitted Batch Jobs Window
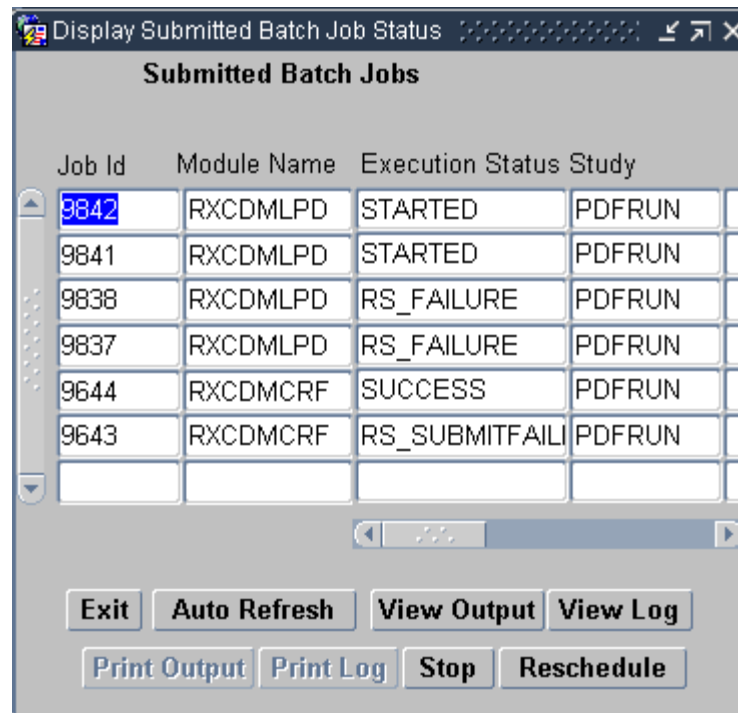
Access

The system displays the Submitted Batch Jobs window when you click the Job Status button on the Report Submission Window.

Components

The Submitted Batch Jobs window consists of a large number of columns, which extend across the window, and a number of buttons, which you use to access reports and view information about reports. The components are listed and described in Table 14–18.

Table 14–18   Submitted Batch Jobs window Components

Label	Type	Description
Job ID	Data field	The identifier that is assigned to each submitted job.
Module Name	Data field	A system designation that describes the type of PDR.
Execution Status	Data field	The current status of the PDR job.
Study	Data field	The name of the study that the report is using to run.
Parameter Set Name	Data field	N/A
Output File Name	Text box	The file name and its location on the application server where the report is saved, if you chose the "FILE" value in the Job Details window.
Failure Text	Text box	System-generated explanation that accompanies report jobs that do not succeed.
Log File Name	Text box	The file name and location on the application server where the log file for the report job is saved.

Table 14–18   (Cont.) Submitted Batch Jobs window Components

Label	Type	Description
Mode of Execution	Data field	The value of the "Mode of Execution" parameter that is configured in the Job Details window.
Module Type	Data field	A system-generated value that describes the type of job.
Server Queue	Data field	The name of the Reports Server queue.
Print Queue	Data field	The name of the Print Queue, used when the report is set to PRINTER output type.
Job Request Time	Data field	The timestamp of the job request to the Reports Server queue.
Job Submission Time	Data field	The timestamp of the job submittal to the Report Server.
Scheduled Time	Data field	The timestamp of when the job is scheduled to be submitted to the Report Server.
Job Start Time	Data field	The timestamp of when the Reports Server initiated the report job.
Job Completion Time	Data field	The timestamp of when the Report Server completed the report job.
Format	Data field	The format of the report, which is specified in the Output Format field in the Submission Details window.
Report ID/Process	Data field	A system designation.
Job Name	Data field	The system-generated name assigned to the report job.
RS Scheduler	Data field	The name of the Report Server scheduler.
Schedule String	Data field	When the RS Scheduler is used, this field lists the timestamp of when the report is scheduled to run.
Command Line	Data field	Displays the contents of the command that allows administrators to run reports from the command line. This is not applicable to RDC Classic users.
Exit	Button	Closes the window.
Auto Refresh	Button	Instructs the system to constantly update the status of each open job. When the system is in refresh mode, this button changes to Cancel Refresh.
Cancel Refresh	Button	Instructs the system to stop updating the status of each open job. When you click this button, the system changes it to the Auto Refresh button.
View Output	Button	Opens the Output File Window for the selected report job.
View Log	Button	Opens the Log File Window for the selected report job.
Print Output	Button	Not available.
Print Log	Button	Not available.
Stop	Button	Stops the batch process for the selected row.
Reschedule	Button	Opens the Schedule Jobs Window for the selected row.

Usage

In order to work with a specific report, you must select it. You do this by clicking any field in its row. When a row is highlighted, all of the buttons that are available take action on the report listed in that row.

Track the Progress of a Submitted Report After you submit a report and the report server starts to process it, you can monitor its progress using the Auto Refresh feature. When you activate Auto Refresh, other features of the Submitted Batch Jobs window are unavailable. When Auto Refresh is active, the button changes to Cancel. To stop the Auto Refresh process, click the Cancel button.

View a Report To view a report that has completed:

1. Select its associated row.

2. Click the View Output button. The system opens the Output File Window.

3. In the Output file window, ensure that the filename in the text box references the report number you want to view.

4. Click the OK button. The system opens the PDF report, using the Adobe Reader plug-in within an instance of Microsoft Explorer. At that point, you have the option to print the report or save it to a directory on your local computer.

View a Report Log File To view the log file of a report that has completed:

1. Select its associated row.

2. Click the View Log button. The system opens the Log File Window.

3. In the Log file window, ensure that the filename in the text box references the report number of the log file you want to view.

4. Click the OK button. The system opens the Microsoft Windows File Download window. You can choose to open the immediately or save it to a directory on your local computer.

Schedule Jobs Window

The Schedule Jobs window allows you to setup a report job to run in the future. It provides the capability to run the report once or multiple times, at designated intervals.

Access

You can access the Scheduler through the following Reports windows:

■   **Reschedule** button on the Submitted Batch Jobs window

■   **Schedule** button on the Submission of Module window

Components

The Report Scheduler consists of components that provide feedback on the Report Server name and the current schedule for the submission of the relevant report. There are three sections in the window: one to specify the reports server, one to specify a start time for the report job, and one to setup repeating the report run at stated intervals.

Usage

The following sections describe common tasks that use the Schedule Jobs window.

Run the Report Immediately To run a report job immediately:

1. Ensure the name of the reports server is correct.

2. Select the Immediately radio button in the Start section.

3. Select the "Do not Repeat" radio button in the Repeat section.

4. Click the OK button. The system submits the job to the report queue.

Run the Report at a Specific Time To run the report at a specific date and time:

1. Ensure the name of the reports server is correct.

2. Select the "At" radio button in the Start section.

3. In the field to the right of the "At" radio button, type the time at which you want the report to run. Use the 24-hour time format. For example, to set the time to 8:25 pm, use the notation: "20:25".

4. Type the date you want the report to run in the "On" field. Use the DD-MON-YYYY date format.

5. Click the OK button. The system submits the job to the report queue to be run at the date and time you specified.

Run the Report at Specific Intervals To run report at specific intervals:

1. Ensure the name of the reports server is correct.

2. Use either the "Run the Report Immediately" or the "Run the Report at a Specific Time" to setup the initial run of the report.

3. In the Repeat section, select one of the radio buttons, other than "Do not repeat", based on the interval period during which you want the system to run the report.

   - Use the first radio button labeled "Every" to run the report at a stated interval that you determine. Use the first drop-down list to select a number. Use the second drop-down list to select minutes, hours, days, weeks, or months.

   - Use the second radio button labeled "Every" to run the report once a month on a given day of the week.

   - Use the third radio button, which is labeled "Last", to run the report on a given day. Use the first drop-down list to specify the name of the day. Use the second drop-down list to specify the last date during the month that you want to run the report.

4. Click the OK button. The system submits the job to the report queue to be run at the date and time you specified.

Report Previewer Window

The system displays the Report Previewer window when you submit a report job from the Submission Details for Report Window. It provides feedback on the progress of the job. It also gives you access to the Submitted Batch Jobs Window.

Figure 14–20   Report Previewer Window
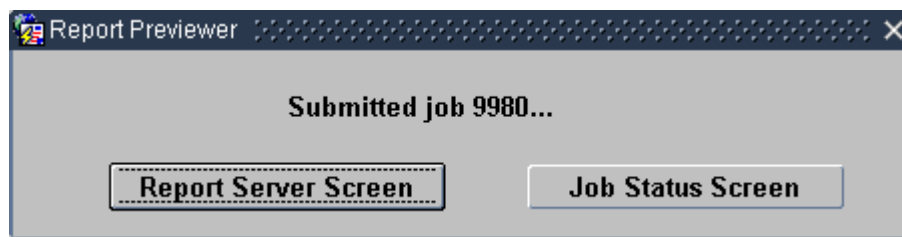
Access

The system displays this window automatically when you submit a report job.

Components

The window consists of two buttons:

1. Report Server Screen – opens the Report Queue Manager Window

2. Job Status Screen – opens the Submitted Batch Jobs Window

Output File Window

You use the Output File Details window to open a report for viewing and printing on your computer. While it is displayed on your computer, you also have the option to save a copy of the PDF file locally.

Figure 14–21   Output File Details Window
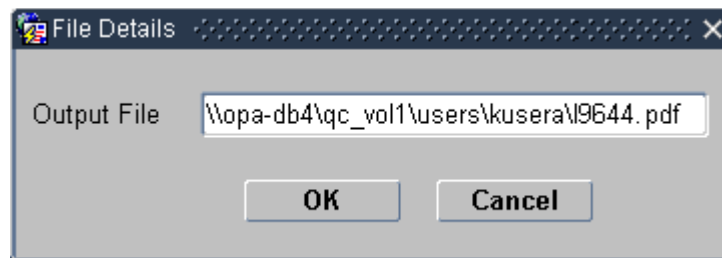
Access

You access the window by clicking the View Output button on the Submitted Batch Jobs Window.

Components

The Output File Details window consists of a text field and two buttons. The text field displays the location of the output report file that is highlighted in the Submitted Batch Jobs window.

The OK button opens the report file in Adobe Reader on your computer. The Cancel button closes the window and reverts focus to the Submitted Batch Jobs window.

Log File Window

You use the Log File Details window to view the location of the log file and to open it for viewing. In general, it is not necessary to access the log files, however, you may be instructed to do so in order to troubleshoot reports.

Figure 14–22   Log File Details Window
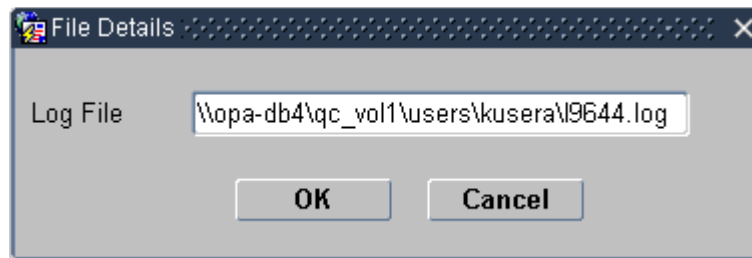
Access

You access the window by clicking the View Log button on the Submitted Batch Jobs Window.

Components

The Log File Details window consists of a text field and two buttons. The text field displays the location of the log file associated with the report that is highlighted in the Submitted Batch Jobs window.

The OK button opens the log file in a text editor on your computer. The Cancel button closes the window and reverts focus to the Submitted Batch Jobs window.

Report Queue Manager Window

The Report Queue Manger window allows you to access the Report Server Screen, which is a Web page that is generated by the report server to monitor and control report jobs. In general, the tasks that are required for RDC Classic report jobs can be adequately managed from the Submitted Batch Jobs Window.

Figure 14–23   Report Queue Manager Window
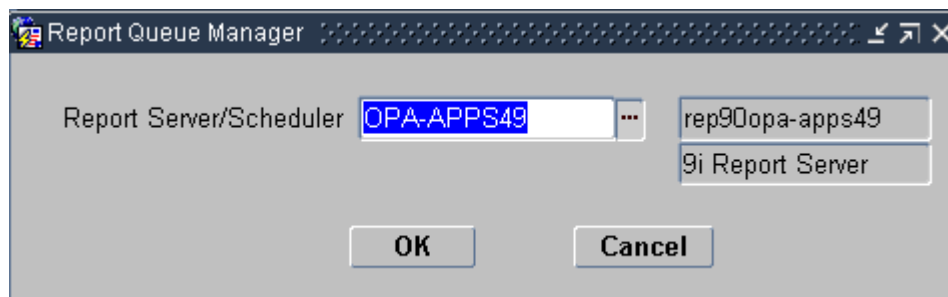
Access

You access the Report Queue Manager window:

- Clicking the Report Server Screen button on the Report Previewer Window
- Selecting **Action**, then **Report Queue Manager** from the option list

Windows Associated with CRF Lock and CRF Unlock Functions

This section describes the windows that the system uses to process locking and unlocking tasks. It consists of the these topics:

- Current CRF Lock Process Window

- Users Who Can Update Window
- Valid User Names Window

Current CRF Lock Process Window

The system displays this window as part of the process of locking a single CRF. It allows you to modify settings that determine how the system processes a CRF for locking. It also provides the mechanism to initiate the lock procedure.

Figure 14–24   Lock CRF Window
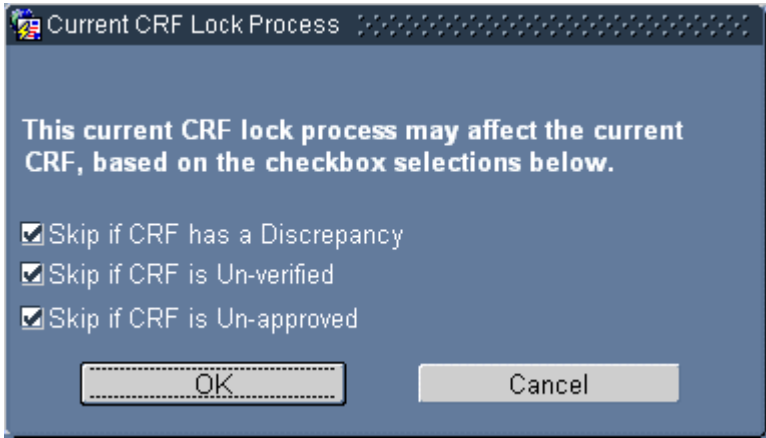
Access

The system displays this window when you select **CRF**, then **Lock CRF** from the option list to initiate the lock CRF procedure. The menu command is only accessible when your user name is assigned the lock privilege.

Components

The Current CRF Lock Process window consists of several check boxes and action buttons. The check boxes allow you to determine how the system processes the CRF.

Table 14–19   Components of the Current CRF Lock Process Window

Label	Type	Description
Skip if CRF has a discrepancy	Check box	If selected, the CRF is not locked if an open discrepancy is associated with it.
Skip if CRF is un-verified	Check box	If selected, the CRF is not locked if it is not in the verified verification status.
Skip if CRF is un-approved	Check box	If selected, the CRF is not locked if it is not in the approved approval status.
OK	Button	Submits the CRF to the system for processing, based on the check box selections.
Cancel	Button	Closes the window without changing the lock status of the CRF.

Usage

Usage of the window is straightforward, you ensure that the appropriate check boxes are selected and click the OK button, which causes the system to process the CRF. If the CRF meets all of the criteria defined by selected check boxes, the system sets its

status to locked. If the CRF does not meet the criteria, the system does not alter its status. In either case, it displays a message window that informs you of the results.

If you click the Cancel button, the system closes the window without processing the CRF and returns focus to the RDC Classic Spreadsheet.

Task Reference

This window is used in "Lock an Individual CRF" on page 5-15.

Users Who Can Update Window

The system displays this window as part of the process of unlocking a CRF. You use the window to specify the users you want to assign the required privilege to update a locked CRF.

Figure 14–25   Users with Update for Current CRF Window
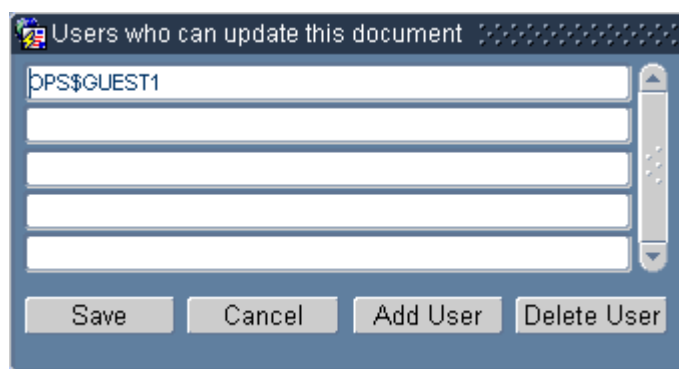
The graphic in Figure 14–25 depicts a typical instance of the window.

Access

The system displays this window when you select **CRF**, then Unlock CRF from the option list to initiate the unlock CRF procedure. The menu command is only accessible when your user name is assigned the unlock privilege.

Components

The window consists of a set of fields, which can list the user names who are allowed to update the locked CRF, and four buttons that provide you with the capability to work with the list of user names and to cancel the unlock action. The components are listed and described in Table 14–20, " Components of the Users with Privileged Update Window".

Table 14–20   Components of the Users with Privileged Update Window

Label	Type	Description
List of Users	Text boxes	A listing that displays the set of user names that are currently assigned the capability to update the CRF. There is one field for each user name.
LOV	LOV button	The system displays this button when focus in an empty List of Users text box. When activated, the system opens the Valid User Names Window. (Same functionality as the Add User button.)

Table 14–20   (Cont.) Components of the Users with Privileged Update Window

Label	Type	Description
Save	Button	Assigns to each user name currently listed the capability to update the CRF and closes the window.
Cancel	Button	Discontinues the unlock CRF task, reverts the list of users to its state before the window opened, and closes the window.
Add User	Button	Opens the Valid User Names Window. (Same functionality as the List of Users LOV button.)
Delete User	Button	Removes the currently selected user name from the list of users.

Usage

To open the Valid User Names window so you can add a user to the list:

1. Place focus in the first empty List of Users text box.

2. Click either the LOV button or the Add User button. The system opens the Valid User Names window.

To delete a user name from the list:

1. Place focus in the row of the user name you want to remove from the list.

2. Click the Delete User button.

Task Reference

This window is used in "Unlock a CRF" on page 5-16.

Valid User Names Window

This window allows you to select a user name to add to the list of users who are able to update a locked CRF.

Access

You access this window from the Users Who Can Update Window when you click either the:

- **List of Users** LOV button, or
- **Add Users** button.

Figure 14–26   Valid User Names Window
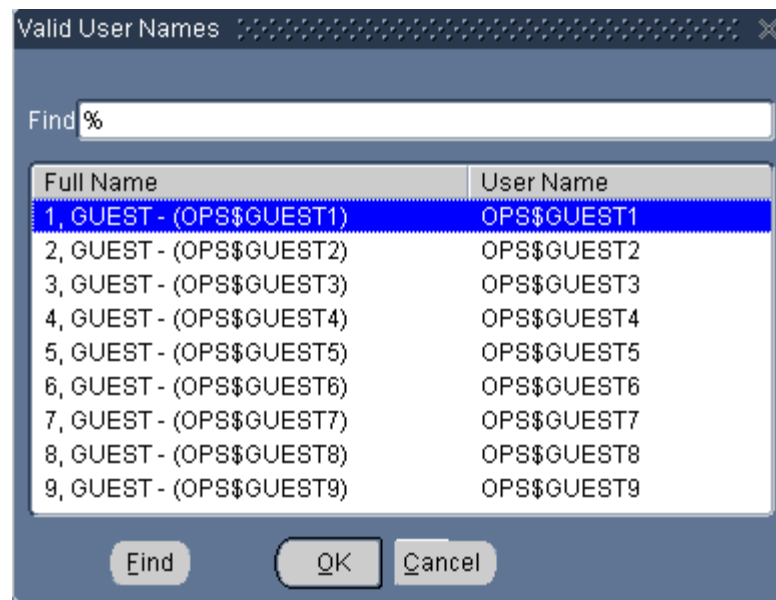
Components

The Valid User Names window consists of a table and components that allow you to search the list. The list consists of users who have access to the study. The set of components that comprise the Valid User Names window are listed and described in Table 14–21.

Table 14–21   Components of the Valid User Names Window

Label	Type	Description
Find	Text box	Allows you to enter a search string to locate a user name displayed in the list of users. You can include wild cards in the search string.
List of Users	Table	The list of users who are have access to the current.
Find	Button	Uses the contents of the Find text box to search the list of users.
OK	Button	Inserts either the user name in the Find text box or the current selection in the List of Users into the Users Who Can Update Window.
Cancel	Button	Discontinues the task of selecting a user name, closes the window, and reverts focus to the Users Who Can Update Window.

Usage

When the system displays this window, you can select a user name in one of three ways:

1. Type the user name (including the OPS$ prefix) directly in the Find text box and click the OK button

2. Select a user name from the List of Users list box and click the OK button

3. Type a search string in the Find text box and click the Find button; when the system returns one or more user names, select the appropriate listing and click the OK button.

When you select a listing and click the OK button, the system adds the user name to the Users Who Can Update Window.

Task Reference

This window is used in "Unlock a CRF" on page 5-16.

Group Activities Windows

This section describes those windows that are presented when you perform batch operations in RDC Classic. There are three general tasks that you can perform in batch mode:

1. Change the verification status of CRFs – the windows that are used for these tasks are in "Verification Group Activity Windows" on page 14-49.

2. Change the approval status of CRFs – the windows that are used for these tasks are in the "Approval Group Activity Windows" on page 14-51.

3. Change the lock status of CRFs – the window that facilitates this task is in the "Group Lock Window" on page 14-55.

> **Note:** All Group activities can only be performed for one site at a time. Therefore, you must select a site in the Search window or in the Activity List in order to enable the Group Activities menu options.

Verification Group Activity Windows

The system displays a group verification window when you initiate one of the two commands in the Group Activities menu that affect the verification status of CRFs. There are two types of window: one to verify CRFs in the workset, one to undo the verification of CRFs.

Figure 14–27   Group Undo Verification Processing
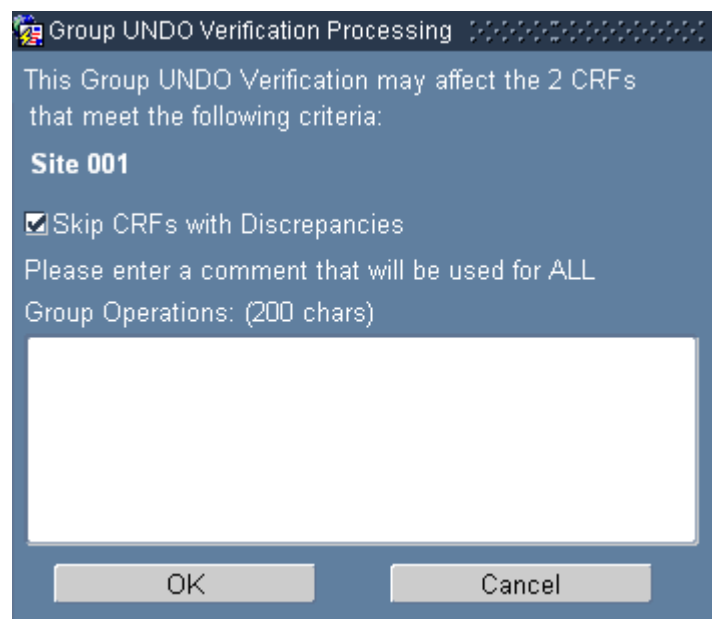
The group verification windows allow you to:

- review the number of CRFs that may be affected by the pending group activity

- review the search criteria

- choose to skip or include discrepant CRFs in the group activity

- type a comment that is included with each CRF affected by the action

- initiate or cancel the action.

Access

You access the two group verification windows through menu commands:

- Select **Group Activities**, then **Verify CRFs** from the option list to open the Group Verification Processing window

- Select **Group Activities**, then **UNDO Verified CRFs** from the option list to open the Group UNDO Verification Processing window.

Figure 14–28   Group Verification Processing Window
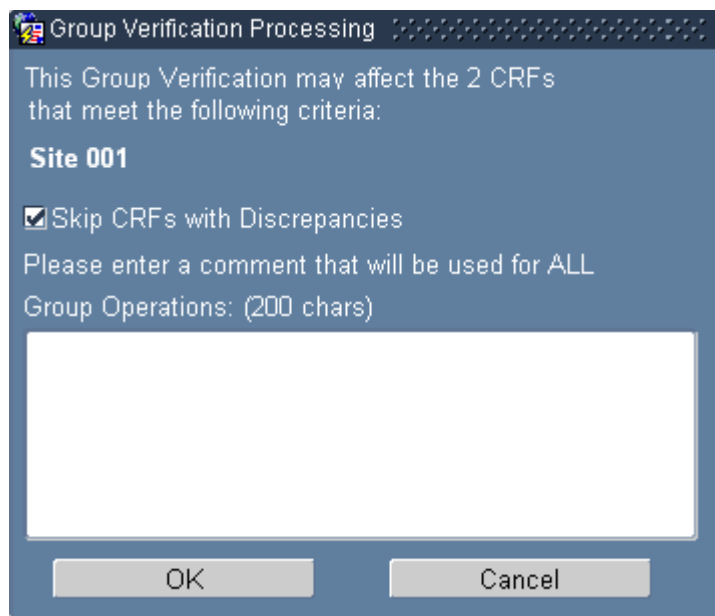
Components

The components that comprise the group verification windows are listed and described in Table 14–22, " Components of the Group Verification Windows". Because the group verification actions are complements of each other, the two windows are identical except for labeling.

Table 14–22   Components of the Group Verification Windows

Label	Type	Description
CRFs affected	Info text	An informative text message that states what action (either verification or undo verified) is pending and the number of CRFs that may be altered.
Search criteria	Info text	A listing of the current search criteria.

Table 14–22   (Cont.) Components of the Group Verification Windows

Label	Type	Description
Skip CRFs with Discrepancies	Check box	Specifies if the action should include discrepant CRFs or not. The default setting is selected.
		Present in the Group Verification Processing window only.
Comment	Text box	Location to type a text message that is included with each CRF that is altered.
OK	Button	Initiates the action and closes the window.
Cancel	Button	Discontinues the action and closes the window.

Usage

When the system displays a group verification window, do these steps:

1. Review the "CRFs affected" statement and the search criteria information to ensure the correct CRFs are displayed in the Spreadsheet.

2. Examine the "Skip CRFs with Discrepancies" check box and ensure it is set correctly.

3. If necessary, type a comment in the Comment text box.

4. Click one of the action buttons:

    a. Click the OK button to initiate the action.

    b. Click the Cancel button to discontinue the action.

If you click the OK button, the system displays a Group Procedure Status Windows that informs you of the number of CRFs that were affected by the action.

Task Reference

The following tasks use one of the group verification windows:

■ Verify a Group of CRFs on page 7-7

■ Undo Verification for a Group of CRFs on page 7-8

Approval Group Activity Windows

This section describes the windows that the system uses to support the group activities that affect the approval status of CRFs in the workset. There are two types of window: one to approve CRFs in the workset, one to undo the approval of CRFs.

The graphic in Figure 14–30, "Group Undo Approval Processing Window" depicts a typical example of the window the system displays for group approvals. The graphic in Figure 14–31, "Password Confirmation Window for Group Approval" depicts a typical example of the window the system displays for group undo approval actions.

Figure 14–29   Group Approval Processing Window
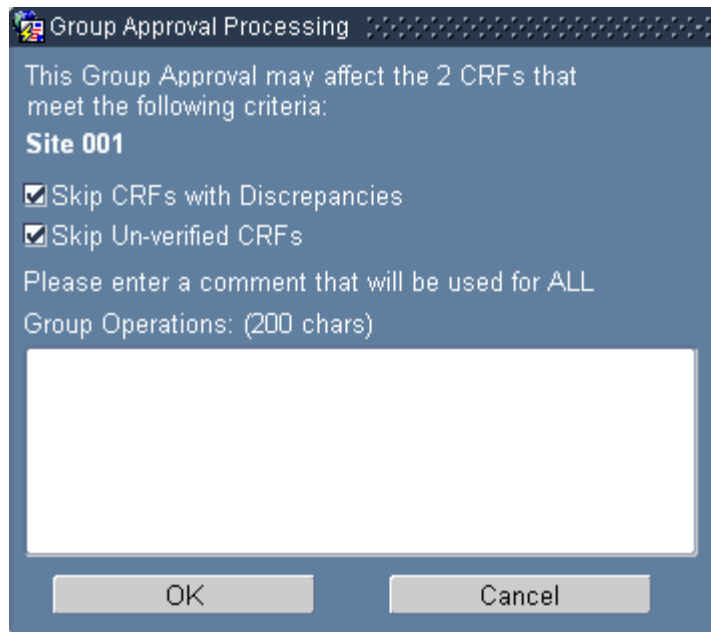
You use the group approval windows to:

■   review the number of CRFs that may be affected by the pending group activity

■   review the search criteria

■   choose to skip or include discrepant CRFs in the group activity

■   choose to skip or include CRFs that are not verified

■   type a comment that is included with each CRF affected by the action

■   initiate or cancel the action.

Access

The system displays the group approval windows when you successfully complete one of the Password Confirmation Windows.

■   Select **Group Activities**, then **Approve CRFs** from the option list to initiate the process which accesses the Group Approval Processing window

■   Select **Group Activities**, then **UNDO Approved CRFs** from the option list to initiate the password confirmation process which accesses the Group UNDO Approval Processing window.

Components

The components that comprise the group approval windows are listed and described in Table 14–23, " Components of the Group Approval Windows". Because the group approval actions are the complement of each other, the two windows are identical except for labeling.

Table 14–23   Components of the Group Approval Windows

Label	Type	Description
CRFs affected	Info text	An informative text message that states what action (either approve or undo approval) is pending and the number of CRFs that may be altered.
Search criteria	Info text	A listing of the current search criteria.
Skip CRFs with Discrepancies	Check box	Specifies if the approval action should include discrepant CRFs or not. The default setting is selected. Present in the Group Approval Processing window only.
Skip Un-verified CRFs	Check box	Specifies if the approval action should include CRFs that are not verified. The default setting is to skip CRFs that are not verified. Present in the Group Approval Processing window only.
Comment	Text box	Location to type a text message that is included with each CRF that is altered.
OK	Button	Initiates the action and closes the window.
Cancel	Button	Discontinues the action and closes the window.

Figure 14–30   Group Undo Approval Processing Window
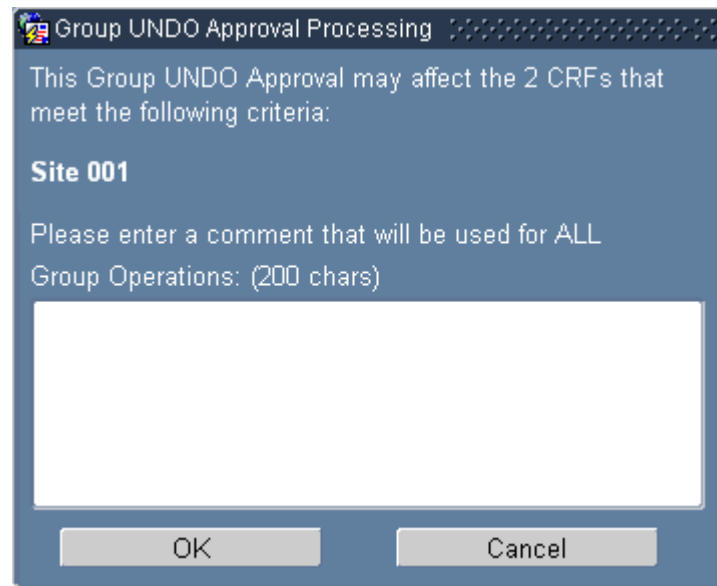
Usage

When you successfully complete the Password Confirmation Window and the system displays a group approval window, do these steps:

1. Review the "CRFs affected" statement and the search criteria information to ensure the correct CRFs are displayed in the Spreadsheet.

2. For group approval:

   a. Examine the "Skip CRFs with Discrepancies" check box and ensure it is set correctly.

   b. Examine the "Skip Un-verified CRFs" check box and ensure it is set correctly.

3. If necessary, type a comment in the Comment text box.

4. Click one of the action buttons:

a. Click the OK button to initiate the action.

b. Click the Cancel button to discontinue the action.

If you click the OK button, the system displays a Group Procedure Status Windows that informs you of the number of CRFs that were affected by the action.

Task Reference

The following tasks use one of the group approval processing windows:

- Approve a Group of CRFs on page 7-10

- Undo Approval for a Group of CRFs on page 7-11

Password Confirmation Windows

The system uses the password confirmation windows as a verification mechanism to ensure that the appropriate user is initiating a group approval action. When you successfully complete the window, the system displays one of the group approval windows.

The graphic in Figure 14–32, "Group Undo Verify Status Window" depicts a typical example of the window the system displays for group approvals. The window the system displays for group undo approval actions is similar.

Access

You access the password confirmation windows by selecting:

- **Group Activities**, then **Approve CRFs** from the option list, or

- **Group Activities**, then **UNDO Approved CRFs** from the option list.

In either case, the system displays a password confirmation window that you must complete before the group approval action can proceed.

Figure 14–31   Password Confirmation Window for Group Approval
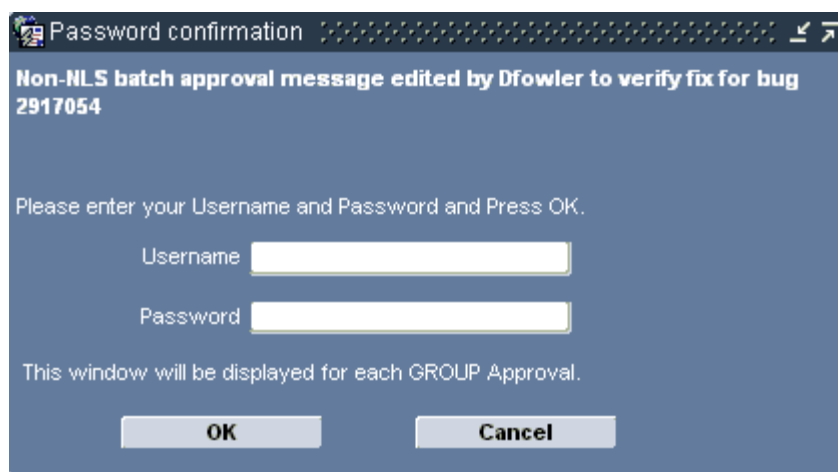
Components

The components that comprise the password confirmation windows are listed and described in Table 14–24, "Components Password Confirmation Window". The only difference between the two windows is the information text.

Table 14–24   Components Password Confirmation Window

Label	Type	Description
Electronic signature implications	Info text	An informative text message that states the implications of completing the current window. This may either be a default statement or it may be sponsor-defined.
Username	Text box	Location to type the user name that you used to log into the session.
OK	Button	Closes the window and displays the appropriate group approval window.
Cancel	Button	Discontinues the action and closes the window.

Usage

When you select a group approval action and the system displays a password confirmation window, use these instructions to complete the window and proceed to a Approval Group Activity Window.

Task Reference

The following tasks use one of the password confirmation windows:

- Approve a Group of CRFs on page 7-10
- Undo Approval for a Group of CRFs on page 7-11

Group Lock Window

You use the Group Lock window to lock more than one CRF in a single operation.

Access

Access the Group Lock window by selecting **Group Activities**, then **Lock CRFs** from the option list. The system displays this window when you select **CRF**, then **Lock CRF** from the option list to initiate the lock CRF procedure. The menu command is only accessible when your user name is assigned the lock privilege.

Components

The Current CRF Lock Process window consists of several check boxes and action buttons. The check boxes allow you to determine how the system processes the CRF.

Table 14–25   Components Group Lock Processing Window

Label	Type	Description
Skip CRFs with discrepancies	Check box	If selected, the process does not include discrepant CRFs
Skip Un-verified CRFs	Check box	If selected, the process does not include CRFs that are not verified.
Skip Un-approved CRFs	Check box	If selected, the process does not include CRFs that are not approved

Table 14–25   (Cont.) Components Group Lock Processing Window

Label	Type	Description
OK	Button	Initiates Group Locking process
Cancel	Button	Closes the window without initiating the Group Locking process

Usage

Usage of the window is straightforward, you ensure that the appropriate check boxes are selected and click the OK button, which causes the system to process the CRF. The system includes all applicable CRFs in the process, which changes the lock status of each. When the process completes, the system displays a message window that informs you of the results.

If you click the Cancel button, the system closes the window without processing the CRF and returns focus to the RDC Classic Spreadsheet.

Group Procedure Status Windows

The group procedure status windows give you the results of a complete group activity. This allows you to review the number of CRFs affected by the action and assess if you want to redo the action. For example, based on the results the system displays in a status window, you may want to alter the search criteria or change the settings in the group activity window.

Figure 14–32   Group Undo Verify Status Window
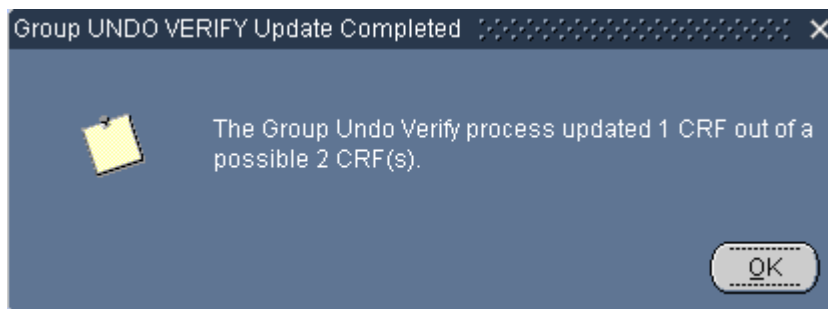
Access

The system displays a status window at the conclusion of each group activity.

Components

Each window consists of a status message and an OK button.

Windows Associated with Common Spreadsheet Tasks

This section describes those windows that are displayed when you perform function in the Spreadsheet.

This section includes descriptions of the following windows:

- Insert New Patient Window
- Add Unplanned CRF Window

Insert New Patient Window

The Insert new patient window allows you to associate a patient with a specific patient number.

Figure 14–33   Insert New Patient Window
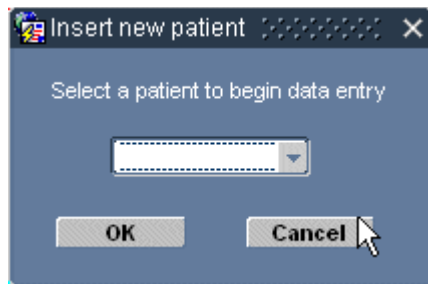
Access

You access the Insert new patient window when you initiate the task of adding a new patient by selecting **Insert**, then **Patient** from the option list or clicking an empty patient cell.

Components

The components that are present in the "Insert new patient" window are list and described in Table 14–26.

Table 14–26   Components of the Insert New Patient Window

Label	Type	Description
Patient number	Drop-down list	Displays the list of available patient numbers
OK	Button	Inserts the number selected in the drop-down list
Cancel	Button	Closes the window and does not insert a new patient

Usage

To use the Insert new patient window, click the drop-down list arrow to view the available patient numbers. Select an appropriate number and click the OK button. The system inserts the new patient number in the first available Patient Number cell.

Task Reference

The "Insert a New Patient" task uses the Add Unplanned CRF window.

Add Unplanned CRF Window

You use the Add Unplanned CRF window to add a CRF to an existing visit. This task is commonly used to add an Adverse Events and/or a Concomitant Drugs CRF to a visit. The system allows you to add a CRF to a visit the current patient, with the following restrictions:

■   the CRF is not already part of the visit, and

■   the CRF is particularly designated as one that can be used in an unplanned manner (this is specified in the Oracle Clinical DCI Book Constraints setting).

Figure 14–34   Add Unplanned CRF Window

Access

You access the "Add Unplanned CRF" window by selecting **Insert**, then **CRF** from the option list. This initiates the procedure of adding a CRF to the visit that is currently in focus.

Components

The components that are present in the Add Unplanned CRF window are listed and described in Table 14–27.

Table 14–27   Components of the Add Unplanned CRF Window

Label	Type	Description
Status	Info text	A description of the current patient and visit.
CRF	Drop-down list	Displays the list of pages that are available, i.e., those that are not part of the visit that is currently in focus. When you select an entry, it is immediately inserted in the visit.
Cancel	Button	Closes the window and does not insert a new page.

Usage

To use the Insert Unplanned CRF window, click the drop-down list arrow to view the set of CRFs that can be added to the current visit. The list includes those CRFs that are not part of the current visit, either as planned or unplanned CRFs, and are permitted to be collected more than once during the study.

When you select a CRF, the system immediately inserts the new CRF in the first available column to the right of the last planned CRF in the visit. It then opens the Data Entry window with that CRF, for the patient that is in focus.

Task reference

The "Add an Unplanned CRF" task uses the Add Unplanned CRF window.

Help Windows

The Help windows give you access to the documentation that describes RDC Classic. There are two types of help: general and context-sensitive. The initial text that general help presents is consistent no matter where you are in the application when you activate help. When you invoke context-sensitive help, you are presented with initial text that is relevant to that part of the application currently in focus.

In addition to the general and context-sensitive help, which is displayed in an Internet browser window, you can use the CRF Icon Legend window to quickly view a key, or legend, of the icons that are used to describe the different CRF statuses.

This section includes the following topics:

- Access
- RDC Classic Online Help Window
- Response Field Help Window
- Context-Sensitive Help Window
- CRF Icon Legend Window
- About Window

Access

There are several methods you may use to access the Help window. Which method you choose determines the type of help that is displayed.

From the Help Menu

There are several choices you can make from among the commands in the Help menu. Which one you choose determines the type of help that is displayed.

From the Toolbar

The Help button that is on the standard toolbar provides context-sensitive help that is relevant to the window that is currently active or in-focus.

RDC Classic Online Help Window

The Help window provides access to all existing RDC Classic documentation. It resides in your Internet browser window and consists of:

- Navigation frame (on the left)
- Content frame (on the right)

Main help consists of the full RDC Classic Online Help Window, which provides a Navigation pane, with access to the Table of Contents, Index, and full-text Search, and a Content pane, which initially displays the main help page.

In addition to the navigation features of the RDC Classic Help interface, you can also use the components of the Internet browser to navigate.

> **Note:** Refer to "System Requirements" on page 1-3 for more information about Internet browser settings.

Access

There are two different modes of access to the RDC Classic Help:

- General
- Context-sensitive

General help General help starts the Help system "at the top," with the RDC Classic Help Home page displayed in the navigation frame. It allows you to navigate

throughout the help contents, but does not start with a specific topic. You access the RDC Classic Help by selecting **Help**, then **Help** from the option list.

Context-sensitive help Context-sensitive help, in contrast, uses the current RDC Classic focus and displays the relevant topic in the navigation frame. You access the RDC Classic Help in context-sensitive mode by pressing the F1 key or by clicking the Help toolbar button, which is displayed in the following graphic.

Components

The RDC Classic Help system offers components that allow you to efficiently find where information you need is located and then navigate directly to those topics.

Navigation frame As described above, the RDC Classic Help window is divided into two frames. The navigation frame, on the left-hand side of the window, provides the following components that let you locate the information you require:

- Contents - a table of contents for the help system that allows you to "drill-down" into the contents, from general topics to more specific. An icon is adjacent to each topic. The significance of each icon is described below.

    A "closed book" icon indicates that the topic contains sub-topics, which you can access by clicking the icon.

    An "open book" icon indicates that the sub-topics associated with the topic are displayed. Note that the sub-topics may be represented by "closed book" icons, an indication that they contain sub-topics.

    A "document" icon indicates that the topic does not contain sub-topics.

- Index - a hyperlinked listing of index terms.

- Search - a full-text search engine for the help system that returns a hypertext set of topic headings that you can click to immediately navigate to the topic.

- 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.

Content frame The content frame is where you read the help system topics. You change the topic that is displayed in the frame either by using the navigation frame, the toolbar buttons that are at the top of the content frame, or by clicking hypertext links in the displayed topic.
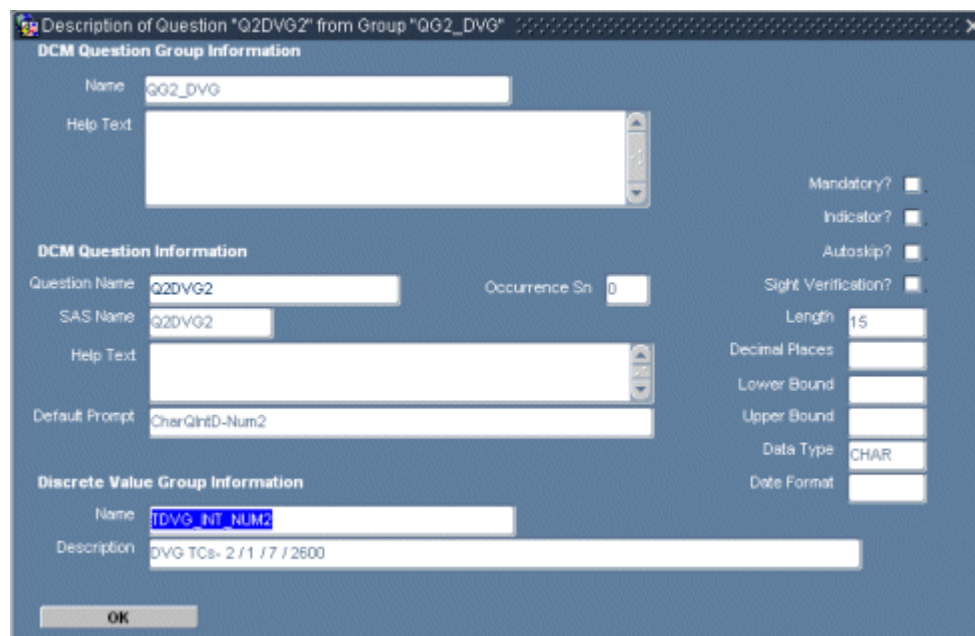
The toolbar that is displayed at the top of the content frame provides navigation to adjacent topics, which are generally related to the current topic, the capability to print the topics, and an "auto-sync" feature. Table 14–28 describes the toolbar buttons.

Table 14–28   Components of the Content Frame Toolbar

Button	Name	Description
	Auto-sync	Synchronizes the topic displayed in the Help window with its location in the table of contents.
	Navigation Frame	Opens the Navigation pane on the left side of the Help window.
	Previous	Displays the previous topic.
	Next	Displays the next topic.
	Print	Prints the current topic

Response Field Help Window

The Response Field Help window that the system displays from the Data Entry window provides the basic information that describes the question that is in focus.

Figure 14–35   Response Field Help Window

Access

You access the Response Field Help window by pressing the F1 key while a response field is in focus.

Context-Sensitive Help Window

When you call context-sensitive help from RDC Classic, the help system launches in a browser window. Rather than the two-frame configuration that is depicted in Figure 14–36, "RDC Topics Window Displaying Explanation of the CRF Icons", in context-sensitive mode, the help system loads the topic that describes the GUI feature that is active and displays it in the Content frame. The Navigation frame is not displayed. However, you can use the Nav Frame button to open the Navigation frame.

CRF Icon Legend Window

The RDC Topics window gives you rapid access to a legend that explains all of the CRF icon statuses. It also allows you to access the RDC Classic Help system and display a list of frequently performed tasks and the instructions to perform each one.

Access

You use the **RDC Help Topics** command in the Help menu to access the RDC Topics window.

Figure 14–36   RDC Topics Window Displaying Explanation of the CRF Icons
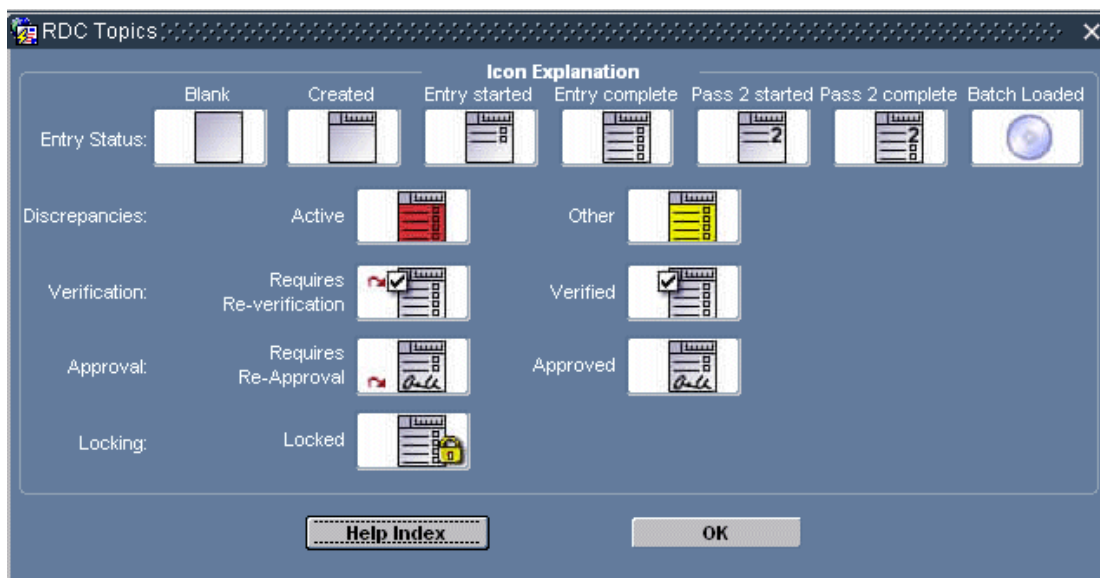
Components

The Help topics window consists of a key, or legend of the CRF icons that are used to describe each of the CRF statuses for each cell in the Spreadsheet that is associated with a CRF. In addition, the Help Index button opens the RDC Classic Help system, which provides access to common RDC Classic tasks.

About Window

The About window is displayed by selecting **Help**, then **About** from the option list. It lists the version history of your Oracle products on the host computer.

15

Search Window

The Search window is one of two tools you use to specify a **workset** in the RDC Classic Spreadsheet (the other is the Activity List Window). In contrast to the Activity List window, which allows you to indirectly query the study database by choosing an activity, the Search window gives you direct access to define search criteria that results in a workset with a specific set of patient data. You can use the Search window to define search criteria that return a workset as broad – all the patient data you to which you have access – or as narrow – a single CRF – as your task requires.

This section describes the terminology, structure, and components of the Search window. The topics that are covered in this section are:

- Discussion on page 15-1

- Access the Search Window on page 15-3

- Search Window Components on page 15-4

- Search Window Usage on page 15-8

- Subsearch Windows on page 15-10

Refer to "Using the Search Window to Select Worksets" on page 6-2 for information about how to define search criteria that allow you to complete common RDC Classic tasks.

Discussion

This section provides a description of how the Search window is organized, how to access it, the terms that are used to describe it, and the methods you can use to navigate to the various Search window components.

The Search window is central to using RDC Classic effectively because it allows you to specify which data that comprise the workset. By changing Search window criteria, you change the patients and/or CRFs that are available for your tasks. The functionality of the Search window allows you to select a subset of data that is as wide or as narrow as you require.

The Search window allows you to view the current set of search criteria in a single view. It also provides the entry point to change each criterion.

> **Note:**   Refer to "Strategies to Best Use the Search Window" on page 6-3 for a discussion of how setting different Search window criteria can limit the CRFs that are available for other criteria and affect the overall set of CRFs retrieved in the workset.

Figure 15–1   RDC Classic Search Window
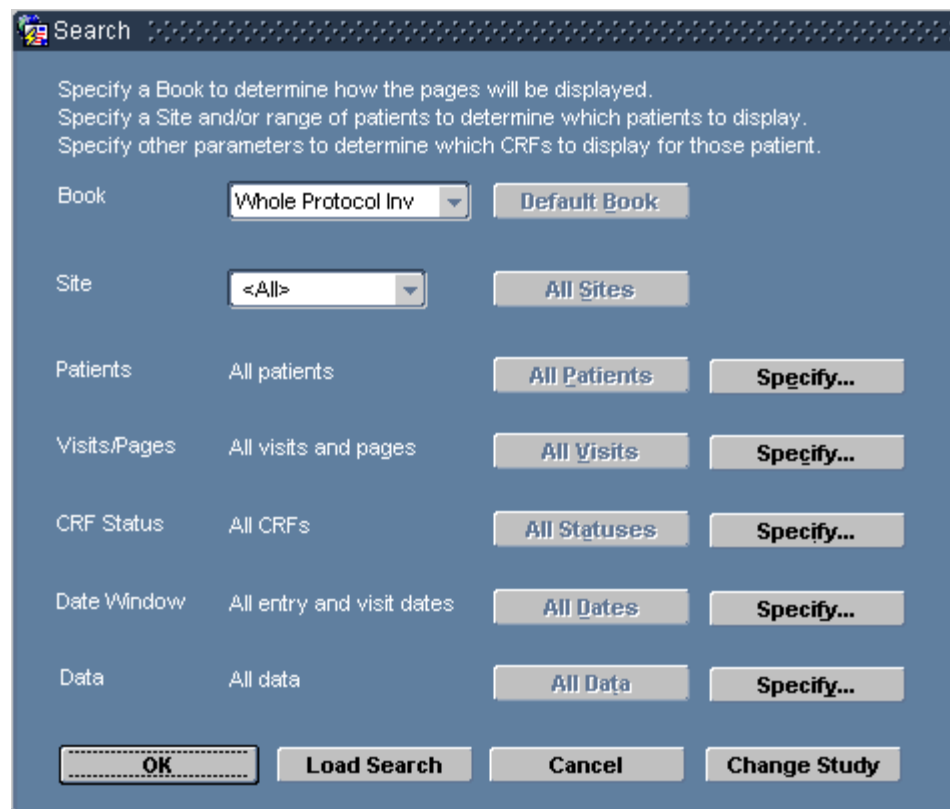
Retrieving Data with the Search Window

The data that comprise a clinical study can be extensive. When you use the default settings in the Search window, the resulting workset consists of all of the CRFs to which you have access. The primary purpose of the Search window is limit the workset so you can work with a manageable set of data that is directly applicable to your task.

For example, if your task is to approve CRFs, it is generally unnecessary to include CRFs that are already approved in the workset. You can use the Search window to limit the workset so that it consists of only those CRFs that are eligible for approval. You use the Search window to define the current workset during an RDC Classic session.

It is important to recognize when the workset consists of all of the data available to you and when it consists of a portion of that data. This information is continuously displayed in the Title Bar of the Main Application Window, the Data Entry window status bar, and the RDC Classic Spreadsheet status line. In addition, the current value of each criterion is displayed in a status line in the Search window. This status line is located just to the right of each criterion label and allows you to quickly know if the it is at its default value.

Terminology

This section discusses certain terms that are used to describe the components of the RDC Classic Search window. Refer to the Glossary for complete definitions of RDC Classic-specific terms.

The terms that are used to describe the Search window are:

- **criterion**
- **parameter**
- **search criteria**
- **setting**
- **search phrase**

Access the Search Window

The method you use to access the Search window is, to a certain extent, dependent on the configuration of your RDC Classic session. Specifically, it depends on the tool that is your default method to display a workset in the Spreadsheet. This section consists of the following topics:

- Session Startup
- Change Current Study
- During a Session
- From the Activity List Window

Session Startup

If the Activity List window is not configured for your session, the system displays the Search window as part of the session initiation process. It is displayed after you are logged in to the database and a study is selected. Refer to "Start Your RDC Classic Session" on page 5-1 for information about session startup, study selection, and other windows that may display before the Search window displays.

Change Current Study

When you change the current study, the system displays the search window to allow you specify the workset for new study (if the Activity List window is not configured for your session). Refer to "Change the Study During an RDC Classic Session" on page 5-12 for information on this procedure.

During a Session

The Search window is displayed as part of the RDC Classic startup process and when you change studies. If you want to modify your search criteria at any other point in your RDC Classic session, you have two options:

1. **Default values** - Select **File**, then **New Search** from the option list to open the Search window with all criteria set to default values.

2. **Current values** - Select either **File**, then **Modify Search** from the option list or the **Search** button in the Spreadsheet to open the Search window with all of the criteria set to current values. The **Search** button is available when the Activity List window is not configured for your session.

New Search Window

The New Search command opens the Search window with the default values set for all parameters and criteria. This command is helpful when you want to "start over" and define a new set of search criteria. Use this option if:

- you want to use the default settings, that is, you want to retrieve all of the data that you have permission to access

- there are many criteria currently set and you want to "start over" with the default criteria settings and modify criteria from that point.

To open the Search window in this mode, select **File**, then **New Search** from the option list.

Modify the Search Window

The Modify Search command opens the Search window with the parameters and criteria set to the values used to specify the current workset. This command is helpful when several criteria are not set to default values and you want to make minor changes to a few parameters.

To open the Search window you can either:

- click the **Search** button (if the Activity List window in not configured for your session), or

- select **File**, then **Modify Search** from the option list.

From the Activity List Window

When the system displays the Activity List window, you can use the Search button in the lower right-hand corner of the window to access the Search window. You can also use the New Search and Modify Search commands, which are components of the File menu, during the session.

The New Search menu command opens the Search window with criteria set to default values. However, the Modify Search commands opens the Search window with criteria set to the values defined by the last task you selected in the Activity List window (assuming you have not used the Search window to modify search criteria prior to this instance).

Search Window Components

The Search window (refer to Figure 15–1, "RDC Classic Search Window") encompasses the components and functionality that allow you to choose subsets of the study data. It provides the necessary navigation buttons, drop-down lists, text messages, and basic window functionality that enables you to efficiently and accurately select the appropriate criteria for the task at hand.

The Search window criteria transition from general to more specific as you move down in the window. You use the first two criteria, Book and Site, to establish the general set of data with which you want to work. The remaining five criteria allow you to "drill-down" into parameters that allow you to define narrower worksets.

The general components that comprise the Search window are listed and described in Table 15–1, " Components of the Search Window".

Table 15–1   Components of the Search Window

Component	Type	Description
Book criterion	Drop-down list	Allows you to change the setting for the Book criterion. This component cannot be altered if only one book is associated with the current study.

Table 15–1   (Cont.) Components of the Search Window

Component	Type	Description
Site Criterion	Drop-down list	Allows you to change the setting for the Site criterion. This component cannot be altered if you have access to one site.
All...	Button	Allows you to set a criterion to its default by resetting each of its parameters. The button is only active when the criterion is set to a non-default setting.
Specify...	Button	Opens the criterion-specific subsearch window, identified by the adjacent label. The subsearch windows allow you to modify the default criteria values.
OK	Button	Closes the Search window, places focus in the first patient row and first CRF column in the Spreadsheet, and loads the workset that satisfies the current **search criteria**.
Load Search	Button	Opens the List of Saved Searches Window, which allows you to load a saved search in the Search window.
Cancel	Button	During a session, reverts to the current workset without altering the search criteria.
		At session startup or during the process of changing the study, opens a window that allows you to:
		■ exit RDC Classic
		■ open the Change Study Window
		■ return to the Search window.
Change Study	Button	Opens the Change Study Window. If you have access to one study, the button is inaccessible.

There is one **All...** and one **Specify...** button for each of the following criteria:

■   Patients Subsearch Window

■   Visit/Page Range Subsearch Window

■   CRF Status Subsearch Window

■   CRF/Visit Dates Subsearch Window

■   Data Subsearch Window

Book Criterion

The Book criterion allows you to specify the Book that you wish to work in. It includes a drop-down list, which allows you to select any book in the current study. When you choose a book other than the default, the Default Book button becomes active. This allows you to quickly switch back to the default book.

> **A Note about books in RDC Classic:**   A book in RDC Classic is the electronic equivalent a hard-copy casebook. It consists of a collection of CRFs.

Access

When you access the Search window upon login or when you initiate a new search, the name of the Default Book is automatically selected in the drop-down list. When you open the drop-down list, you can view all of the books that are defined for the current study.

Components

The Book criterion section of the Search window consists of a:

1. drop-down list of books that are available in the current study

2. Default Book button.

Usage

There is always a default book assigned to each study. When you launch RDC Classic, change to a new study, or select **File**, then **New Search** from the option list, the default book is automatically selected for the Book criterion. If you select **File**, then **Modify Search** or the **Search** button on the Spreadsheet, the book that you selected previously in the session is the active book.

The Default Book button remains inactive until you select a non-default book. If you click the Default Book button when it is active, the Book criterion reverts to its default value.

Whatever value is selected for the Book criterion, it does not limit the data that is displayed in the Spreadsheet. All patients with data that meet the rest of the Search window criteria are displayed in the Spreadsheet. CRFs for patients that are not assigned to the active book are displayed as unplanned pages in the Spreadsheet.

Use the Book criterion drop-down list box to change to another book.

> **Note:** If there is only one book defined for the current study, the drop-down list box is inactive.

Change the Book To change from the default book to a non-default book or from a non-default book to any other non-default book:

1. Click the Book criterion drop-down list arrow.

2. Locate the name of the book you wish to activate and select it. If necessary, use the scroll bar to view all choices.

3. Either:

   a. Click the OK button to close the Search window, or

   b. Select any other criteria that are necessary to your task.

Change to the Default Book To change from a non-default book to the default book:

1. Open the Search window.

2. Click the Default Book button.

Default Book

3. Either:

    a. Click the OK button to close the Search window, or

    b. Select any other criteria that are necessary to your task.

Note: The Default Book button is only active when a non-default book is selected.

Site Criterion

The Site criterion allows you to specify either one site or all of the sites that you have permission to access within the currently active Study. Note that the list of sites that are presented is not dependent on the Book criterion.

Access

You access the Site criterion by opening the Search window. Refer to "Access the Search Window" on page 15-3 for information on how to open the Search window throughout an RDC Classic session.

Components

The Site criterion section of the Search window consists of a:

1. drop-down list of sites that are available in the current study

2. All Sites button.

Usage

When you access the Search window upon login or when you initiate a new search, the value of the Sites criterion is either the name of the Site to which you are assigned or, if you have access to more than one site, "ALL" sites. If you have access to more than one site, when you open the drop-down list you can view all of the sites to which you have access and you can select any one of them.

If you have access to more than one site, the All Sites button remains inactive until you select a particular site.

If you have access to only one site, the drop-down list and the All Sites button remain inactive.

Change to a single site When you navigate to the Search window from the Select Study window or if you open the Search window by selecting **File**, then **New Search**, the Sites criterion is set to "<ALL>". To change to a single site:

1. Click the drop-down list arrow to view all of the sites to which you have access

2. Use the scroll bar, if necessary, to locate a site.

3. Click the site name to select it.

Change to ALL Sites When the Site criterion is set to a non-default value, that is, when you have selected a single site, the All Sites button is active.

To change the Site criterion from a single site to all sites, click the **All Sites** button.

Multi-Parameter Criteria

After Book and Site, the remaining criteria are managed in individual subsearch windows because each is comprised of multiple parameters. You use the subsearch window to modify these parameters. The components and usage of each of these windows is described in "Subsearch Windows" on page 15-10.

Access

You access the criteria by opening the Search window, which may be presented at session startup and is accessible during your session. (Refer to "Access the Search Window" on page 15-3 for information on how to open the Search window throughout an RDC Classic session.)

You access an individual criterion by clicking its associated "Specify..." button. When you click it, the system opens the subsearch window for that criterion.

Components

The Search window components for each criteria consists of a default button and a "Specify..." button.

Usage

The default button for each criteria is active or inactive based on the current value of the criterion.

- If the criterion is set to its default value, the button is inactive.

- If the criterion is set to a non-default value, the button is active.

When the default button is active, it allows you to quickly reset all of the parameters to default values, which, in turn, sets the criterion to its default value.

The Specify... button is always active. When you click it, the system opens the subsearch window for that criterion. The current setting of each parameter that comprises the criterion is displayed in the window.

Search Window Usage

This section describes general Search window functionality. It consists of the following topics:

- Using the Book and Site Drop-Down List Boxes

- Using the Default Buttons

- Using the Specify... Buttons

- Using the Cancel Button

- Using the Change Study Button

Refer to "Select a Workset" on page 6-1 for topics that describe using the Search window to accomplish specific tasks.

Using the Book and Site Drop-Down List Boxes

You use drop-down list boxes to set the Book and Site criteria. By default, these criteria are set to the following settings:

- The book is set to the default book for the study.

- Site is set to:

  - <ALL> if you have privileges at more than one site

  - an individual site if you have privileges at one site.

You use the drop-down list to view and select other settings that are available. If more than one book is defined for the study, use the drop-down list to select one. If you have access to more than one site, use the Site drop-down list to make a selection.

If the CRFs to which you have access are defined in only one book or only one book is defined for the study, the drop-down list is not accessible. Similarly, if you have access to only one site, the Site drop-down list no accessible.

Using the Default Buttons

There is a default button adjacent to each criteria. It remains inactive until you change one or more parameters that alter the criteria setting to something other than default. When you click an active default button the system reverts the relevant criteria to its default status.

Using the Specify... Buttons

The Specify... button is adjacent to all of the criteria, except Book and Site. It gives you access to the Subsearch window associated with the criteria that is specified in its associated criterion.

Figure 15–2   Specify Button
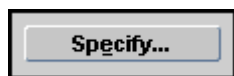
The Subsearch window enables you to change the parameters that comprise a given criteria. As illustrated in Figure 15–4, "Patients Subsearch Window", a subsearch window consists of drop-down lists and buttons that you use to choose the parameters.

Within a subsearch window, use the OK button to save the changes you make to parameters and the Cancel button to revert to the previously saved parameters.

Using the Cancel Button

The functionality of the Search window Cancel button depends on the task on which you are working.

Session Startup

If you click the Cancel button during session startup, the system displays an action window that allows you to choose to:

1. Change the study – opens the Change Study window

2. Exit RDC Classic – closes the application

3. Return to Search

Figure 15–3   Message Window from Cancel on Search Window
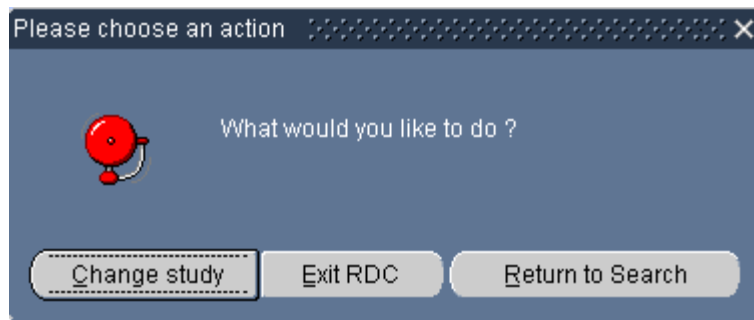
During a Session

If you click the Search window Cancel button during a session, the system discards any changes you have made to any criteria, reverts to the current search criteria, and closes the Search window.

Using the Change Study Button

If the Search window is open and you want to change the current study, you generally have to close the Search window, by clicking either the OK or Cancel buttons, and select **File**, then **Change Study** from the option list to open the Select Study window.

However, if a study is not already open, you can navigate directly from the Search window to the Select Study window and change the study. To do this:

1. In the Search window, click the Cancel button.

    > **Note:**   If a study is already open when you click the Cancel button, the Search window simply closes and previously selected criteria remain active.

2. An action window is displayed (refer to Figure 15–3), which allows you to:

    - Change studies, which opens the Select Study window

    - Exit the form, which closes RDC Classic

    - Return to Search, which closes the current window and moves focus back to the Search window.

3. Click the "Change study" button.

4. The Select Study window is displayed.

5. Use the Select Study window as you normally would.

Subsearch Windows

This section describes the Search window criteria that are managed with a subsearch window. All search criteria, with the exception of the Book and Site criteria, consists of multiple parameters that combine to give each criterion its value. You use the subsearch windows to modify the parameters.

This section consists of the following topics:

- Patients Subsearch Window on page 15-11

Patients Subsearch Window

The Patients criterion allows you to display CRFs based on the following parameters:

- Patient
- Freeze Status
- Missing Pages
- Overdue Visits

Access

When you click the appropriate Specify... button on the Search window, the Patient Subsearch window is displayed, which gives you access to the parameters that define the Patients criterion.

Figure 15–4   Patients Subsearch Window
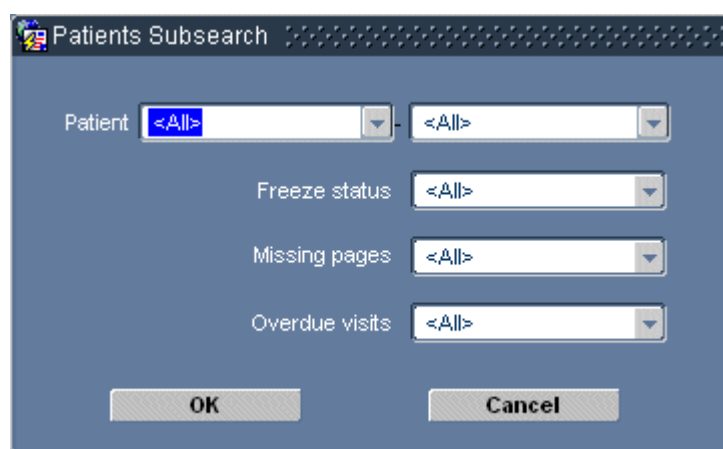
Components

The components that comprise the Patients Subsearch window are listed and described in Table 15–2, " Patients Subsearch Window Components". The scope and usage of each parameter are described in subsequent sections.

Table 15–2   Patients Subsearch Window Components

Parameter	Type	Description
Patient	Drop-down list boxes or LOV	Allows you to specify either a single or a range of patient numbers.
Freeze Status	Drop-down list box	Allows you specify the freeze status of patients.
Missing Pages	Drop-down list box	Allows you specify if the workset should include missing pages.

Table 15–2   (Cont.) Patients Subsearch Window Components

Parameter	Type	Description
Overdue Visits	Drop-down list box	Allows you to specify if there are overdue visits associated with the patients.

In addition to the parameter-specific components, the window also contains an OK and a Cancel button.

Default Parameters The default criterion is for all patients to be selected, therefore each parameter is set to "ALL" by default. This causes the search process to consider all patients that are associated with the currently selected Site criterion. The resulting workset will include all patients with at least one CRF that satisfies the search criteria.

Patient Parameter The Patient parameter consists of two related fields that, when taken together, define an inclusive range of patient numbers. The default setting is "All", which retrieves all of the patients that your user name has access to under the currently defined Study and Site.

The list of patient numbers is dynamic: when you select the starting patient number, the patient numbers that are available in the second drop-down list start at the first value after the value in the first field.

> **Note:** For system performance reasons, the Patient From and To fields use drop-down lists when the number of patients to display is less than 501. If the number of patients to display is greater than 500, the system displays the set in an LOV window.

Using this parameter, you can retrieve data for:

- all patient numbers – This is the default setting for the Patient number range parameter. It causes the search to include all patients to which you have access in the study database for which at least one CRF is created.

- a single patient number – This setting is unique, in that it is not necessary for a CRF that satisfies the search criteria to exist. If all subsequent criteria, that is, Visit/Pages, CRF Status, etc., are set to default values, the patient number is displayed, even if a CRF has not yet been created for the patient. This allows you to use the parameter to initiate data entry for a specific patient number.

- a contiguous range of patient numbers – This setting allows you to limit the search criteria to specific set of contiguous patient numbers. You use both drop-down list boxes: in the first, select the starting, or lower value; in the second, select the ending, or upper value.

Freeze Status Parameter This parameter restricts the retrieved data based on whether the patient is frozen or not. This allows you to choose to work only with unfrozen patients (e.g., for a data entry session), or to work only with frozen patients (e.g., for data review sessions).

There are three possible settings for this parameter:

1. All pages - does not limit the search based the freeze status of the patient

2. Frozen - only frozen patients

3. Not frozen - selects only those patients that are not frozen.

Missing Pages Parameter This Patients Subsearch parameter allows you to restrict the data that is retrieved for a session based on whether there are missing pages for a patient.

The system considers a CRF to contain a missing page if it contains a section that should have been collected (according to the protocol) for the current patient.

There are three options for this parameter:

1. All (default) - does not limit the search based on the presence or absence of missing CRFs

2. With - only patients that include CRFs with missing pages

3. Without - only patients that do not include CRFs with missing pages.

Overdue Visits Parameter This Patients Subsearch parameter allows you to restrict the data that is retrieved for a session based on the absence or presence of overdue visits.

> **Tip:** Use this parameter to quickly display all patients that are currently overdue for a study visit.

There are three options for this parameter:

1. All (default) - does not limit the search based on the presence or absence of overdue visits.

2. With - only patients that have overdue visits

3. Without - only patients that do not have overdue visits.

Usage

This criterion is useful if you have a certain set of patients with which you want to work. For example, to enter data for patient numbers 1 through 10, you can simply use the Patient Range parameter to display only those patients in the Spreadsheet.

Select a Single Patient Number If you wish to display a single patient number in the Spreadsheet, you may choose a patient number that either contains or does not contain data.

> **Tip:** You can use this procedure to initiate data entry for a patient that does not contain data.

To select a single patient number:

1. In the Patients Subsearch window, use the first Patient parameter drop-down list box to select the patient number.

2. Click the OK button. The system closes the Patient Subsearch window and returns focus to the Search window.

Include a Range of Patient Numbers To define a range of patient numbers:

1. In the Patients Subsearch window, use the first Patient drop-down list box to select a starting patient number.

2. Use the second Patient drop-down list box to select an ending patient number.

3. Click the OK button. The system closes the Patient Subsearch window and returns focus to the Search window.

> **Note:** If you select a range of patients and none of the patients in the set contain data, only the first patient in the range is displayed in the Spreadsheet.

Include Patients Based on Freeze Status To change the Freeze Status parameter:

1. In the Patients Subsearch window, use the Freeze Status drop-down list box to select a freeze status.

2. Click the OK button. The system closes the Patients Subsearch window and returns focus to the Search window.

> **Note:** You can use this procedure as a template to alter the "Missing pages" and "Overdue Visits" parameters.

Visit/Page Range Subsearch Window

You use the Visit/Page Range subsearch window to change the Visits/Pages criterion. The parameters that comprise this criterion allow you to define a data set that is based on the following parameters:

1. Phase

2. Visit

3. Page

4. Page status

5. Show all unplanned pages?

The parameters are arranged in order, with the parameter with the largest scope, Phase, at the top of the window. When you change a parameter from its default value, it generally limits the scope of subsidiary parameters. For example, if you set the Phase parameter to "Phase 1", the visits that are available in the Visits parameter are limited to those that are part of Phase 1.

Access

When you click the appropriate Specify... button on the Search window, the system displays the Visit/Page Range Subsearch window, which gives you access to the parameters that define the Visit/Page Range criterion.

Figure 15–5 Visits/Page Range Subsearch Window

Components

The components that comprise the Visit/Page Range Subsearch window are listed and described in Table 15–3. The scope and usage of each parameter are described in subsequent sections.

Table 15–3 Visit/Page Range Subsearch Window Components

Parameter	Type	Description
Phase	Drop-down list box	Allows you to specify a single phase.
Visit	Drop-down list boxes	Allows you to specify either a single visit or a range of sequential visits.
Page	Drop-down list boxes	Allows you to specify either the name of a single page number or a range of sequential page numbers.
Page status	Drop-down list box	Performs the action you initiated on the Approval task tab and closes the window.
Show all unplanned pages?	Check box	Specifies the initial setting of the Hide/Show Unplanned pages toggle button.

In addition to the parameter-specific components, the window also contains an OK and a Cancel button.

Default criterion The default criterion is for all visits and pages to be selected, therefore each parameter controlled by drop-down list boxes is set to "ALL". This causes the search process to consider all visits that are associated with the currently selected Site criterion.

Phase parameter The Phase parameter allows you to choose either all of the phases in the book, which is the default setting, or a single phase.

Visit parameter The Visit parameter consists of two related fields that, when taken together, define an inclusive range of visits. The default settings is "ALL," which allows the search to consider all visits.

The list of visits is dynamic:

- when you select a single phase (using the Phase parameter), the visits that are available in the first drop-down list box are limited to those that are associated with the selected phase

- when you select the starting visit number in the first drop-down list box, the visits that are available in the second start at the first visit after the value in the first field.

Using this parameter, you can retrieve data for:

- all visits – This is the default setting for the Visit parameter. When the parameter is set to this value, the search will include all of the visits that are available.

- a single visit – When you select a value in the first, but not the second, drop-down list box, the search is limited to that single visit.

- a range of visits – This setting allows you to limit the search to specific set of sequential visits. You use both drop-down list boxes: in the first, select the starting, or earlier, visit; in the second, select the ending visit.

Page parameter The Page parameter consists of two related fields that, when taken together, define an inclusive range of CRF page numbers. The default settings is "ALL," which allows the search to consider all CRF pages.

The list of pages is dynamic:

- when you select a single visit (using the Visit parameter), the CRFs that are available in the first drop-down list box are limited to those that are associated with the selected visit

- when you select the starting CRF page number in the first drop-down list box, the pages that are available in the second start at the first page number after the value in the first field.

Using this parameter, you can retrieve data for:

- all CRF pages – This is the default value for the Page parameter. When it is set to the default, the search includes all available CRF pages.

- a single CRF page – When you select a value in the first drop-down list box, but not the second, the search is limited to a single CRF page number.

- a range of CRF page numbers – This setting allows you to limit the search to a specific set of sequential CRF page numbers. You use both drop-down boxes: in the first, select the starting, or lower, CRF page number; in the second, select the ending number.

Page status parameter The Page status parameter consists of a single drop-down list box in which you can specify that the search be limited to either planned or unplanned CRFs.

The default setting is to retrieve all pages. When the default is selected, the CRFs for all planned pages are displayed in the Spreadsheet and the "Show Unplanned Pages" button is displayed in the first column header after the last planned paged column.

Using this parameter, you can retrieve data for:

- all CRF page – This is the default value. When the parameter is set to this value, the search includes both planned and unplanned CRFs.

- planned pages only – When you select this value, by selecting "Planned" in the drop-down list box, the search includes only those CRFs that are planned for the current book. In addition, the system forces the Show all unplanned pages?

parameter check box to clear and does not permit it to be selected; in the RDC Classic Spreadsheet, the "Hide/Show Planned Pages" toggle button is unavailable.

- unplanned pages only – When you select this value, by selecting "Unplanned" in the drop-down list box, the search only includes those CRFs that are not planned for the current book. In addition, the system automatically selects the Show all unplanned pages? parameter check box; in the RDC Classic Spreadsheet, the "Show/Hide Unplanned Pages" toggle button is not available because only unplanned pages are displayed in the Spreadsheet.

> **Note:** When you choose "Unplanned" in the Page Status drop-down list, the "Show all unplanned pages? parameter" check box is automatically selected.

Show all unplanned pages? parameter This parameter consists of a check box that causes the system to automatically display unplanned pages without use of the "Show/Hide Unplanned Pages" toggle button.

The default setting is for this parameter to be not active. This setting causes the "Show Unplanned Pages" button to be displayed in the first empty column after the planned pages for each visit.

If you select this parameter the check box to select this parameter, unplanned pages are displayed in the Spreadsheet and the "Hide Unplanned Pages" button is displayed in the first empty column after the unplanned pages for each visit.

This parameter has a direct dependency on the Page status parameter:

- If the Page Status is set to "Planned Pages," the system sets this parameter to its default setting, that is, the check box is clear. It also prevents you from selecting it.

- If the Page Status is set to "Unplanned Pages," the system sets this parameter to its non-default setting, that is, the check box is selected.

Usage

The Visit/Pages Range Subsearch window allows you define a data set that is based on:

- the study phase

- a visit or a range of visits

- a page or range of pages

- the planned/unplanned status of pages

In addition, you can specify whether or not you want unplanned pages to be displayed automatically.

Select all visits in a phase You use the Phase drop-down list box to view all phases in the current book. To limit the search criteria to a single phase, select an item in the list.

Select a specific visit You use the first Visit drop-down list box to select a specific visit. The list includes all of the visits in the current book and possibly limited by the Phase parameter.

> **Note:** Use these instructions as the basis to set the Page parameter to a single of CRF page numbers.

Select a range of visits To select a range of visits:

1. In the Visit/Page Range Subsearch window, use the first Visit parameter drop-down list box to select the starting visit.

2. Use the second drop-down list box to select the last visit you want to include in the parameter.

3. Click the OK button. The system closes the subsearch window and returns focus to the Search window.

> **Note:**   Use these instructions as the basis to set the Page parameter to a range of CRF page numbers.

Revert to the Default Values of a Range Parameter When you have previously changed a range parameter from its default and you want to revert to its default, which typically is "ALL", there are two methods you can use:

1. Use the All Visits button on the Search window - this reverts all parameters in the Visit/Page Range Subsearch window to default values.

2. In the relevant parameter, select "ALL" in the starting (i.e., the left-hand) drop-down list box.

Exclude Planned or Unplanned CRFs To set the Page Status parameter:

1. In the Visit/Page Range Subsearch window, use the Page status parameter drop-down list arrow to select either value.

2. Click the OK button. The system closes the subsearch window and returns focus to the Search window.

CRF Status Subsearch Window

The CRF Status Subsearch window allows you to modify the CRF Status criterion. It allows you to set the following parameters:

1. CRF Status

2. Discrepancy Status

3. Verification Status

4. Approval Status

5. Lock Status

Access

When you click the appropriate Specify... button on the Search window, the system displays the CRF Status Subsearch, with each parameter set to its current value.

Figure 15–6   CRF Status Subsearch Window
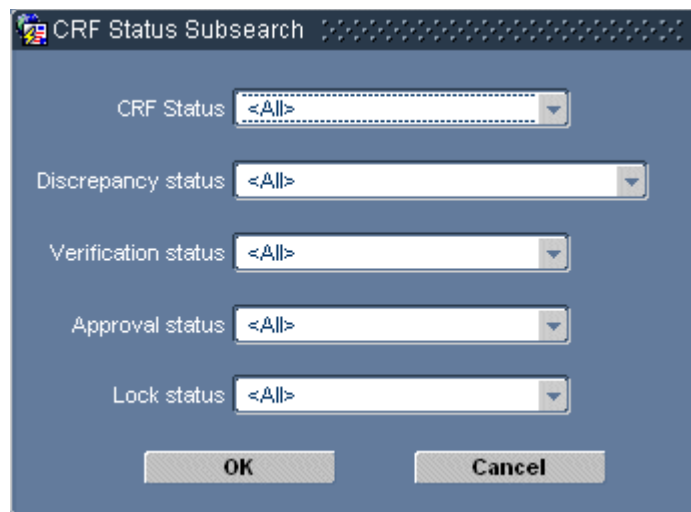
Components

The CRF Status Subsearch window consists of five drop-down list boxes, which you use to change the value of each parameter, and two buttons.

Table 15–4   CRF Status Subsearch Window Components

Component	Type	Description
CRF Status	Drop-down list box	Allows you to specify the **data entry status** of CRFs.
Discrepancy Status	Drop-down list box	Allows you to specify the **discrepancy status** of CRFs.
Verification Status	Drop-down list box	Allows you to specify the **verification status** of CRFs.
Approval Status	Drop-down list box	Allows you to specify the **approval status** of the CRFs.
Lock Status	Drop-down list box	Allows you to specify the **lock status** of the CRFs.

In addition to the parameter-specific components, the window also contains an OK and a Cancel button.

Default Parameters The default criterion is for all CRFs to be selected, therefore, each parameter is set to "ALL" by default. This causes the search process to consider all available CRFs without regard to the different CRF statuses.

CRF Status Parameter The CRF Status parameter allows you select data based on the entry status of CRFs. The values that are available for this parameter are listed in Table 15–5, " CRF Status Parameter Settings".

Table 15–5   CRF Status Parameter Settings

Setting	Includes
All (Default)	All CRFs, regardless of the data entry status
Blank	CRFs that are marked as blank

Table 15–5   (Cont.) CRF Status Parameter Settings

Setting	Includes
Created	CRFs with an entry status of **created**
Entry started	CRFs with an entry status of **entry started**
Entry complete	CRFs with an entry status of **entry complete**
Pass 2 Started	CRFs with an entry status of **pass 2 started**
Pass 2 Complete	CRFs with an entry status of **pass 2 complete**
Batch Loaded	CRFs that have been **batch loaded**

You can use these parameter settings to retrieve CRFs that are all at a certain juncture in the data entry and validation process.

Discrepancy Status Parameter The Discrepancy Status parameter allows you to retrieve CRFs based on the absence or presence of discrepancies and, if present, the status or designation of the discrepancies in the CRF.

Table 15–6   Discrepancy Status Parameter Settings

Setting	Description
All (Default)	Includes all CRFs, regardless of the presence of discrepancies or discrepancy status
Without discrepancies	CRFs that do not contain a **open** discrepancy
With actionable discrepancies	CRFs that contain at least one **active** discrepancy that can be acted upon by the current user
With other discrepancies	CRFs that contain at least one **other** discrepancy that can be acted upon by another user
With actionable or other discrepancies	CRFs that contain at least one **open** discrepancy
With closed discrepancies	CRFs that contain at least one **closed** discrepancy

As Table 15–6 indicates, a CRF with several different types of discrepancies can be retrieved using several parameter settings. For example, if a CRF contains both actionable and closed discrepancies, it will be retrieved with the following parameter settings:

- All

- With actionable discrepancies

- With actionable or other discrepancies

- With closed discrepancies

Verification Status Parameter The verification status parameter allows you to retrieve a set of CRFs that are at the same point in the verification process. Table 15–7 describes the five settings available for this parameter.

The default value for the verification status parameter is retrieve all CRFs, of all verification statuses. In order to limit the CRFs retrieved to a set with a certain verification status, use the other settings.

Table 15–7   Verification Status Parameter Settings

Setting	Description
All (Default)	Includes all CRFs, regardless of the **verification status**
Not verified	CRFs that are not assigned a verification status of **verified**
Verified	CRFs with a verification status of **verified**
Awaiting re-verification	CRFs with a verification status of **awaiting re-verification**
Verification undone	CRFs with a verification status of **verification undone**

Approval Status Parameter The approval status parameter allows you to retrieve a set of CRFs that are at the same point in the approval process. Table 15–8 describes the five settings available for this parameter.

Table 15–8   Approval Status Parameter Settings

Setting	Description
All (Default)	Includes all CRFs, regardless of the **approval status**
Not approved	CRFs that are not assigned a approval status of **approved**
Approved	CRFs with a approval status of **approved**
Awaiting re-approval	CRFs with a approval status of **awaiting re-approval**
Approval undone	CRFs with a approval status of **approval undone**

Lock Status Parameter The lock status parameter allows you to retrieve a set of CRFs that are either locked or unlocked. Table 15–9 describes the three settings available for this parameter.

Table 15–9   Lock Status Parameter Settings

Setting	Description
All (Default)	Includes all CRFs, regardless of the **lock status**
Locked	CRFs that are not assigned a lock status of **locked**
Unlocked	CRFs with a lock status of **unlocked**

Usage

You can define the CRF status criterion using any combination of the following parameters:

- Data entry status
- Discrepancy status
- Verification status
- Approval status
- Lock status

Include All CRFs of a Given Status The procedures for modifying a parameter settings are similar for all parameters in the CRF Status Subsearch window. Use the following instructions to change each parameter:

To change a parameter setting:

1. In the CRF Status Subsearch window, use the appropriate drop-down list box to select a value for the parameter of interest.

2. Click the OK button. The system closes the subsearch window and returns focus to the Search window.

3. Click the OK button to close the Search window and cause the system to display the new workset.

For example, you can use this criterion to display in the Spreadsheet only those CRF that are at the "Entry Complete" status, or only those CRFs that contain "Closed" discrepancies.

Use Multiple Parameters to Define the CRF Status Criterion You can use other parameters in the CRF Status subsearch window to further limit the data set. For example, by combining the "Entry Complete" setting for the CRF Status parameter and "Not verified" setting for the Verification status parameter, you can include in the workset those entry complete CRFs that are not verified.

CRF/Visit Dates Subsearch Window

The CRF/Visit Dates criterion allows you to retrieve a set of CRFs that is based on when either CRFs and/or discrepancies are created and/or modified. Unlike most other subsearch windows, the CRF/Visit Dates Subsearch window is not divided into discrete parameter-based components.

You use the CRF/Visit Subsearch window, which the graphic in Figure 15–7, "CRF/Visit Dates Subsearch Window" depicts, to define a series of parameters that, when taken together, form a phrase that RDC Classic uses to search the data and retrieve a set of CRFs that satisfy the search phrase.

Essentially, you construct a search phrase that answers the questions, "What happened?" and, "When did it happen?" In addition, you can use the "Visit dates from" parameter to further constrain the search.

Access

When you click the appropriate Specify... button on the Search window, the system displays the CRF/Visit Dates Subsearch window, with each parameter set to its current value.

Figure 15–7   CRF/Visit Dates Subsearch Window
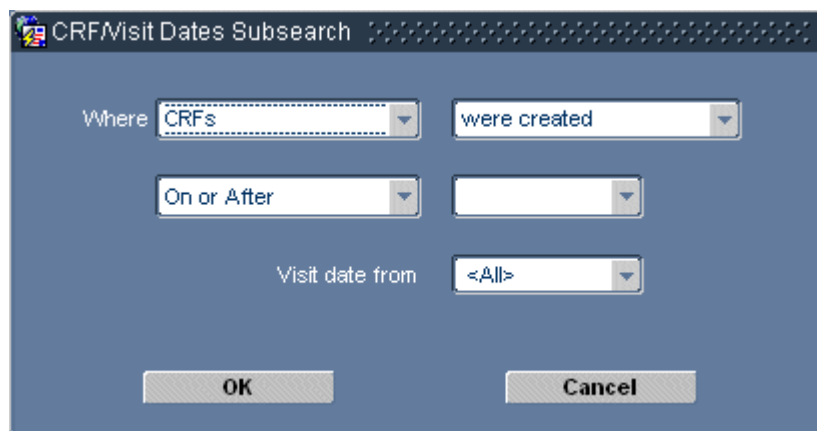
Components

The CRF/Visit Date Subsearch window consists of five drop-down list boxes. You coordinate four of them to construct a search phrase. The fifth, "Visit data from," is optional, but, if used, further limits the search phrase. Each parameter is listed and described in Table 15–10, " CRF /Visit Dates Subsearch Window Components".

Table 15–10   CRF /Visit Dates Subsearch Window Components

Component	Type	Description
CRFs/Discrepancies	Drop-down list box	Allows you to specify the subject of the search phrase
Created/Modified	Drop-down list box	Allows you to specify the action of the search phrase
Time Frame	Drop-down list box	Allows you to specify a time frame for the search phrase
Timestamp	Combination list box(es)	Allows you to specify a timestamp, or a time period, that defines the time frame, by either selecting a system-provided date or typing a date in the field
Visit Date	Drop-down list boxes	Allows you to limit the search phrase based on a visit date range
OK	Button	Saves the settings in the window, closes it, and reverts focus to the Search window
Cancel	Button	Discards changes to the settings in the window, closes it, and reverts focus to the Search window

Default Criterion The default setting for this criterion is for all CRFs to be selected, which means that none of the parameters on the CRF/Visit Dates Subsearch window are set.

CRFs/Discrepancies Parameter This parameter consists of the first of two drop-down list box fields adjacent to the "Where" label. You use the two fields in combination to form part of search phrase. Table 15–11 describes the three settings for the CRFs/Discrepancies parameter.

Table 15–11   CRFs/Discrepancies Parameter Settings

Setting	Description
CRFs	The search phrase will pertain to CRFs only
Discrepancies	The search phrase will pertain to discrepancies only
CRFs or Discrepancies	The search phrase will pertain to either CRFs or discrepancies

Created/Modified Parameter This parameter consists of the second of two drop-down list box fields adjacent to the "Where" label. You use this field to complete the first part of the search phrase. Table 15–12 describes the three settings for the Created/Modified parameter.

Table 15–12   Created/Modified Parameter Settings

Setting	Description
were Created	The search phrase only pertains to created timestamps
were Modified	The search phrase only pertains to modified timestamps

Table 15–12   (Cont.) Created/Modified Parameter Settings

Setting	Description
were Created or Modified	The search phrase pertains to both created and modified timestamps

Time Frame Parameter This parameter consists of a drop-down list box that allows you to specify a time frame during which the event defined by the first two parameters occurred. Table 15–13 describes the four settings for the Time Frame parameter.

Table 15–13   Time Frame Parameter Settings

Setting	Description
Before	The search is limited to dates that occurred before the Timestamp parameter
On	The search is limited to the date specified by the value of the Timestamp parameter.
On or After	The search is limited to date that occurred on and after the value of the Timestamp parameter.
Between	The search is limited to the period between the two timestamps. You must select a value for each timestamp field.

When you select the "Between" value, the system changes the Timestamp parameter so that two timestamps can be set, which define a time period.

Timestamp Parameter This parameter consists of one or two fields. You use combination list boxes to set the value of each. The number of fields you use depends on the value of the Timestamp parameter. If its value is "Between", the system displays a second field that allows you to select a second timestamp as the ending point of the period.

The values that are available for this parameter are simply a list of dates in the previous year. You also have the option of typing a date directly in either of these fields that is not in the LOV. Use the same date format that you would for a data entry date field.

The date that you enter in the second timestamp field must be greater, that is, it must come after, the date you entered in the first field. When you use a second timestamp field, its list of values is restricted to those dates that are after the value you entered in the first timestamp field.

Visit Date Parameter This parameter consists of drop-down list of all of the visit dates in the currently selected book, although the list may be further constrained by other criteria, such as a visit range specified in the Visit/Page and, as stated above, a default value of "ALL", which includes all of the visit dates in the book in the subsearch.

The "Visit date from" parameter allows you to limit the criterion to a time period that is described by a set of visit dates. In contrast to the other parameters in the window, this parameter is not required in order to construct search phrase. However, you can use this parameter either in conjunction with a search phrase. Alternatively, you can not set the search phrase parameters and use only the Visit Date parameter.

When you select any value other than the default, the system displays a second field, which also consists of a drop-down list box, which allows you to specify a range of dates. The range extends from the visit date you select in the first drop-down list forward in time to the date you select in the second drop-down list.

Usage

The two basic uses of the CRF/Visit Subsearch window are to construct a search phrase and specify a range of visit dates.

Construct a Search Phrase Use the CRF/Visit Subsearch window to define a series of parameters that, when processed together, form a phrase that RDC Classic uses to search the data and retrieve a set of CRFs that satisfy the search phrase.

1. In the CRF/Visit Dates Subsearch window, use the CRFs/Discrepancies drop-down list box to select a subject.

2. Use the Created/Modified drop-down list box to select the action.

3. Use the Timeframe drop-down list to select a timeframe for the search. The value you select determines if there is one or two fields in the Timestamp parameter. The "Between" value causes the system to display a second field, which is for the ending timestamp.

4. Use the drop-down list box(es) to select the value of the Timestamp parameter.

   You can use the "Specify Visit Dates" line to further narrow your search by specifying that the CRFs retrieved by the parameters in the first two lines are restricted by the visit date.

5. Click the OK button. The system closes the subsearch window and returns focus to the Search window.

Specify Visit Dates To specify a visit date range in which to search:

1. Use the first field of the "Visit date from" parameter to select the earliest visit date that you want to define the time period. When you make a selection, that is, when you change the default, the system displays a second field.

2. Use the drop-down list box in the second field to set the endpoint of the time period:

   a. if you use the default, which is "All," the visit date range that is defined includes all visits dates between the date you set in the first drop-down list and the current calendar date

   b. if you select a date, the visit date range that is defined includes all visits in the time period, inclusive.

3. Close the subsearch window.

4. Close the Search window.

Data Subsearch Window

The Data Subsearch window allows you to define a set of parameters that is based on specific data contained in existing CRFs. Use this criterion if you wish to retrieve existing CRFs so that you can review, update, verify, and or approve the data that each contain.

Access

When you click the Specify... button adjacent to the Data label on the Search window, the system opens the Data Subsearch window with each parameter set to its current value.

Figure 15–8   Data Subsearch Window

Components

The Data Subsearch window consists of seven parameters, several of which use multiple fields. The components are listed and described in Table 15–14, " Data Subsearch Window Components". Fuller descriptions of each parameter can be found in subsequent sections.

Table 15–14   Data Subsearch Window Components

Component	Type	Description
CRF	Drop-down list box	Allows you to specify the name of a CRF.
Section	Drop-down list box	Allows you to specify the name of a CRF section.
Question Name	Drop-down list box(es)	Allows you to specify a question name as the first part of a Question/Response search phrase.
Relational Operator	Drop-down list box(es)	Allows you to select an operator that joins the Question Name and the Response Value settings.
Response Value	Drop-down list box(es) or text box	Allows you to specify a response value as the second part of a Question/Response search phrase. Each instance of this parameter is active when its corresponding Question Name parameter is set.
		If the Relational Operator is set to "=", "Like", or "Not Like", this field is text box that accepts a text search string.
		If the Relational Operator is set to "Null" or "Not Null", this parameter is not present.

Table 15–14   (Cont.) Data Subsearch Window Components

Component	Type	Description
Boolean Operator	Drop-down list box	Allows you to select an operator that relates the first and the second Question/Response search phrases. This active when the first Response Value parameter is set.
Document Number	Drop-down list box	Allows you to select a document number.
Lab With/Without Subset	Drop-down list box	Allows you to specify the name of a laboratory that supplied data. This is active when the CRF/Section includes laboratory-supplied data.
Qualifying Value	Drop-down list box	Allows you to specify a value to a qualifying question. This is active when the CRF and/or Section contains a qualifying question group.
Comment Type	Drop-down list box	Allows you to specify a type of comment to search.
Comment Text	Text field	Allows you to specify a search string that the system uses to search comments of the type specified in the Comment type parameter. This is active when a Comment type is selected.

Default Setting The default for the Data criterion is to retrieve all data, without regard to the contents of the CRFs. Consequently, all parameters are either set to "ALL" or are set to NULL, which means that the parameter is not set.

CRF and Section Parameters The first line of the Data Subsearch window consists of two parameters, labeled "CRF" and "Section". The parameters are related to one another – for example, the value of the CRF parameter may affect the set of values available in the Section parameter. Several of the choices that are available in other subsequent parameters are dependent on the selections you make in these two parameters.

The default setting for both parameters is "ALL", which selects all CRFs and all Sections, respectively.

- When the Section parameter is "ALL", the CRF parameter may be set to any CRF name in the current book, subject to other, higher-level criteria selections that may restrict the data. When you select a CRF name, the set of values in the Section parameter is limited to the section names that exist in the selected CRF.

- When the CRF parameter is "ALL", the Section parameter may be set to any section name in the current book, subject to other criteria restricting the data. When you select a value for the Section parameter, the CRF parameter must be set to either "ALL" or a CRF name that contains the section specified in the Section parameter.

- If you select a section that contains a qualifying value question, the system makes Qualifying Value parameter active.

Question Name There are two Question name parameters: one for each search phrase that can be constructed in the subsearch window. There is no default value for either parameter. The values that are available in the drop-down lists are dependent on the settings of the CRF and Section parameters. When a CRF, or CRF and CRF section combination are selected, the system populates the first Question Name parameter with all questions in the relevant CRF or section.

The system does not populate the second Question Name parameter with questions until all three parameters in the first Question Name search phrase are set.

There are no default values for the either the Question or the Answer values in either search phrase. However, each of these values remain inactive until a parameter or value that is its antecedent is selected.

Relational Operator This parameter consists of a drop-down list box that you use to select an operator. Each Question Name search phrase is constructed with a relational operator, which links the Question Name and Response Value parameters. Table 15–15 describes the ten operators that you can use to construct the search phrase.

The equal sign ("=") is the default value for the relational operator, however, it is not displayed until it is required.

When the search is run, if you have not used a wildcard in your search string, the system "wraps" the Response Value in wildcards. The effect of this is the search will match any value that contains the search string.

Also, when you select either the "Null" or the "Not Null" operator, the system removes the Response Value parameter from the search phrase, since it is not required to complete the search.

Table 15–15   Values for the Relational Operators in the Data Subsearch Window

Operator	Description
=	Only includes data that matches the response value; can be used with either numeric or alphabetic data.
<>	Only includes data that does not match the response value. Use for numerical data only.
>	Only includes data that is greater than the response value. Use for numerical data only.
>=	Only include data that is greater than or equal to the response value. Use for numerical data only.
<	Only includes data that is less than the response value. Use for numerical data only.
<=	Only includes data that is less than or equal to the response value. Use for numerical data only.
Like	Includes the search string that is set as the value of the Response Value parameter.
Not Like	Excludes the search string that is set as the value of the Response Value parameter.
Null	Includes all responses that do not contain a value.
Not Null	Includes all responses that contain a value.

Response Value This parameter can be a drop-down list box that provides a list of the current set of values entered for the Question Name you've specified. However, any value can be specified, with the numeric restriction noted above (below) and keeping in mind the datatype of the question.

The form that the parameter takes is dependent on the value of the Relational Operator parameter. If it is set to equal to, less than, or greater than, the Response Value parameter is a drop-down list box. When the Relational Operator parameter is set to the equal sign, you can set the Response Value to any value, that is, either alphabetic characters, alphanumerical, or numerical.

For the Relational Operators below, only numeric values should be specified. Non-numeric values are not properly evaluated with respect to these operators.

Refer to Table 15–15, " Values for the Relational Operators in the Data Subsearch Window" for the list of operators that should only be used with numeric data.

When the Relational Operator parameter is set to "Like" or "Not Like", type a search string in the Response Value text box. The system returns any responses that contain the search string.

> **Note:** Note that the search string is case-sensitive and you can use the "%" wildcard in the string.

When the Relational Operator parameter is set to "Null" or "Not Null", the value of the response is not considered. The only factor that the system considers is whether a given response field contains data or not. If it does, it is not null. If it does not contain data, it is null. Therefore the Response Value parameter is not required.

Boolean Operator This parameter links the first and the second search phrases. It is only active when the first search phrase is complete. There are two values that is can be set to:

- AND – requires that both the first and the second search phrases are met in order for the system to return the CRF

- OR – requires that either the first or the second search phrase is met in order for the system to return the CRF.

The AND value is the default for the Boolean operator, however, it is not displayed until it is required.

Document Number The Document number parameter is a drop-down list that allows you to specify and retrieve a document based on its assigned number.

The default value for the Document number parameter is "ALL", which retrieves every existing CRF document from the set that is defined by any previous criteria or parameter choices.

If you wish to select a value other than the default, use the drop-down list box controls to view the scrollable list of values and click the appropriate entry.

Lab With/Without Subset The "Lab with/without subset" parameter allows you to select the laboratory that is responsible for the data in a CRF. Even with the CRF parameter at its default value ("ALL"), the Lab... parameter is only active if the data in at least one of the CRFs has been collected from a laboratory. Similarly, if the CRF parameter is at its default value and you choose a section parameter that does not contain laboratory data, the Lab... parameter is inactive.

When the parameter is active, its default value is "ALL".

The values in the Lab... parameter are displayed in a drop-down list. The list includes all of the laboratories that supply data that was collected for the CRF and/or section settings that are defined in those parameters.

Qualifying Value This parameter is inactive until you select a CRF section, using the Section parameter, that contains a qualifying question. When the Section parameter is set to a section name that contains qualifying value question, the system presents the following entries in the drop-down box for the parameter:

- <ALL> – this is the default value, it searches for every occurrence of the section

- "Value" – searches for one of the response values that are defined in the qualifying question definition; there is a separate setting for each response value. There is a separate item for each acceptable response value in the question definition.

When you set this parameter, you can choose to search for all occurrences of the response values for the qualifying question, or you can choose to search for an individual response value.

For example, a multi-section CRF contains four identical "Vitals" sections, which collect vital statistics at different times post dose, and differentiates between the sections via a qualifying question with the values: "0," "1," "2," and "3" hours post dose. If you selected "Vitals" for the Section parameter, the Qualifying Question parameter would allow you to choose from five entries: <ALL>, "0," "1," "2," and "3."

Comment Type The Comment type parameter allows you to specify a particular the type of comment that you want to search. You use this parameter in conjunction with the Comment Text, which you use to specify a text string.

The default value for the Comment type parameter is "ALL," which indicates that all comment text is included in the query. That is, CRFs are not selected based the comment.

There are seven comment types from which you can choose. If you change this parameter from its default value, the system requires that you also type a search string in the Comment Text.

Table 15–16   Descriptions of the Comment Type Parameter Options

Comment type	Description
CRF comment	The Comment field of a CRF headers
Discrepancy text	The text that is displayed in the Text field of the Discrepancy task tab and the Error Message field of discrepancy windows
Discrepancy comment	The text that is displayed in the Comment field of the Discrepancy task tab and the Optional or Internal Comment field of discrepancy windows
Investigator comment	The text of an investigator comment that is associated with a data response field
Verification comment	The comment text that is included with a verification action.
Approval comment	The comment text that is included with an approval action.
Audit comment	The comment text that is included with an audit change reason.

Comment Text The comment text parameter allows you to type a search string that is used to retrieve CRFs that contain text that matches the search string in a comment of the type that you select in the Comment Type. When you do select a Comment type parameter, the system requires that you also include a search string in the Comment text parameter.

The default setting for Comment text is "inactive." The field remains inactive until you select a Comment Type.

When you type a search string in the text box, RDC Classic automatically inserts the percent character ("%") before the first search string character and after the last. RDC Classic uses this value as the basis for searching the CRFs that are selected by your previous Selection window criteria choices for a matching comment type that includes your search string.

The percent character has a special meaning when used in database applications: it acts as a "wildcard" for any string of characters. The implication of this is that the search string that you enter can be a part of a larger word or it can stand on its own.

Usage

The Data criterion allows you to define a data set that is based on response data contained in the CRFs.

Note that setting the "Qualifying value" parameter must be done in conjunction with other parameters in the Data Subsearch window that specify a CRF that contains a qualifying value. Unless such parameters are set, the Qualifying value parameter remains inactive.

The tasks that are described in this topic are:

- Specify CRF and Section Parameters on page 15-31

- Construct a CRF Question Search Phrase on page 15-31

- Sequence of Value List Generation on page 15-32

- Constructing Search Phrases on page 15-32

- Specify a Document Number on page 15-32

- Specify a Lab on page 15-32

- Specify a Comment Type and Content on page 15-33

Specify CRF and Section Parameters To specify the CRF and/or the Section parameters:

1. You can choose to select either or both of these parameters.

   a. To specify the CRF parameter, click its drop-down list and select a CRF. Your choice determines the values that are displayed in the Section drop-down list. Proceed to Step 2.

   b. To specify the Section parameter only, do not change the CRF parameter from its default value. Click the Section drop-down list and chose a section. Proceed to Step 3.

2. If you want to specify a Section parameter, in addition to the CRF parameter, click the Section drop-down list and choose a section.

3. Close the subsearch window.

4. Close the Search window.

Construct a CRF Question Search Phrase The CRF question search phrase consists of three fields, which, when taken together, form a search phrase that specifies a question name and a set of acceptable response values:

- a question value

- a relational operator value, and

- an answer value.

When you select a value for the Question Name parameter, the system populates the drop-down list associated with the Response Value parameter with all existing responses to the selected question name.

Sequence of Value List Generation After the CRF/Section parameter is specified, the Question value drop-down list is populated with all of the questions that comprise the CRF or section that you chose.

The second search phrase remains inactive until you completely define the first search phrase by specifying an Answer value. When you select a value for the first search phrase answer:

1. the default Boolean operator, is displayed in its drop-down list, and

2. the Question value drop-down list in the second search phrase is populated with all of the questions that comprise the CRF or section that you chose.

When you select a value for the Question value in the second search phrase:

1. the default relational operator, is displayed in its drop-down list

2. the Answer value for the second search phrase is populated.

Figure 15–9   Top Portion of the Data Subsearch Window

Constructing Search Phrases The first search phrase drop-down list contains the set of question names that exist for the CRFs and/or sections that you selected above. When you make a selection for this parameter, the Value drop-down list is populated with all of the answers that have been collected for that question.

The second drop-down list contains a set of relational operators that allow you define a range of allowable values or limit the search to a specific value.

You must make a selection in each of the three drop-down lists in order to construct a viable search phrase.

Specify a Document Number To specify a document number:

1. In the Data Subsearch window, click the Document number drop-down list arrow.

2. Select a document number.

3. Click the OK button to close the Data Subsearch window.

4. Click the OK button to close the Search window.

Specify a Lab To specify a lab:

1. In the Data Subsearch window, click the "Lab with/without subset" drop-down list arrow.

2. Select a the name of a lab.

3. Click the OK button to close the Data Subsearch window.

4. Click the OK button to close the Search window.

Specify a Comment Type and Content To specify the type of comment and the content of the comment:

1. In the Data Subsearch window, click the Comment Type drop-down list arrow. The set of possible types of comments are displayed.

2. Select a comment type. The "Comment text" field becomes active.

3. In the Comment text field, type the text that is included in the comments of the type you want to retrieve.

   ■   you can search for partial text strings using the "%" character

   ■   the text field must contain at least the "%" character (no quote marks), which will retrieve CRFs that contain comments of the type you specified in Step 2.

4. Click the OK button to close the Data Subsearch window.

5. Click the OK button to close the Search window.

16

RDC Classic Windows

This section describes the windows that are present when you are entering the data in the RDC Classic application. It consists of the following topics:

Data Entry Window

This section describes the Data Entry window components and provides an overview of its functionality. It also includes topics that describe the windows that are related to functionality associated with the Data Entry window.

This section covers the following topics:

- Discussion
- Access
- Components
- Sizing Window
- Usage

Discussion

The Data Entry window is the primary tool that you use to record, review, and modify response data. For each CRF in the study, the application displays an electronic representation of the CRF header, which contains information that identifies and describes the CRF; CRF section header(s), which, if present, contain information that identifies and describes each CRF section; and the questions and response fields, which are used to collect the response values.

Access

In general, you access the Data Entry window by clicking on a CRF cell.

Several other factors can affect whether the system opens the Data Entry window:

- If you click a CRF cell that represents a CRF that is not part of the workset, the system displays a message window and does not open the Data Entry window.

- If the CRF is not part of the current book, the system displays a window that allows you to change the book. If you choose to not change the book, the system does not open the Data Entry window.

Components

Table 16–1 describes the three main components of the Data Entry window.

Table 16–1   Major Components of the Data Entry Window

Label	Description
Title Bar	Provides relevant information about the current CRF displayed in the Data Entry window.
CRF Header	Provides a location to collect information about the CRF, such as the date, time, and comment.
CRF Section	The location where CRF questions are listed and you record the response data for each applicable question. It is also where you review and update data.

Title Bar

The Data Entry window Title bar serves three purposes:

1. It displays pertinent information about the current CRF and the data point in focus.

2. It provides access to the Sizing Window (refer to "Re-size the Data Entry Window" on page 16-7).

3. It provides a means to close the Data Entry window (refer to "Close the Data Entry Window" on page 16-9).

The information that can be displayed in the title bar of the Data Entry window includes:

- Patient number
- Page number
- CRF name
- Event number
- CRF page number
- Response field information

CRF Header

The Data Entry window header is present at the top of every CRF. It is used to capture information about the CRF. It includes three standard items:

1. Visit date text box

2. Blank check box (the "blank flag")

3. Comment text box

Comment Text Box

The CRF Header allows you to attach a text comment to a CRF by using the Comment text box. Place the cursor in the text box and type the comment you wish to include.

Note that comments that are entered here are associated with the entire CRF, not with a particular datapoint.

CRF Section

The bulk of the Data Entry window is comprised of the CRF Section area, which is where you work with patient data. In RDC Classic, a section is a grouping of like questions in a CRF.

Multi-section CRF Data Entry Windows

When the Data Entry window displays a multi-section CRF, several features that may not be displayed in single-section CRFs are present.

Figure 16–2   Example of a Multi-section CRF Data Entry Window

When performing data entry for a multi-section CRF, process each section in the sequence in which it is presented. This means, for each CRF section, you should:

1. Complete any required values in the section header.

2. Complete the questions in the question area.

3. Proceed to the next CRF section.

If you must work with only one CRF section and it is not the first section in the CRF, mark each section prior to it as blank, by selecting the blank flag in the section header, and navigate to the next section until you reach the section on which you want to work.

Sizing Window

You can use the Sizing window lets you move and/or re-size the Data Entry Window. The system applies the changes that you make to the Sizing window, that is, the way that you re-size and re-locate it, directly to the Data Entry window. These changes persist for the current **session**. This section describes the purpose and functionality of the Sizing window.

Access

You access the Sizing window by clicking the Data Entry window title bar. It allows you to modify size and position of the Data Entry window.

Oracle recommends that you resize the Data Entry window, if necessary, so that the Spreadsheet view tabs, the current patient list, and the task tabs remain visible.

Figure 16–3   Sizing Window
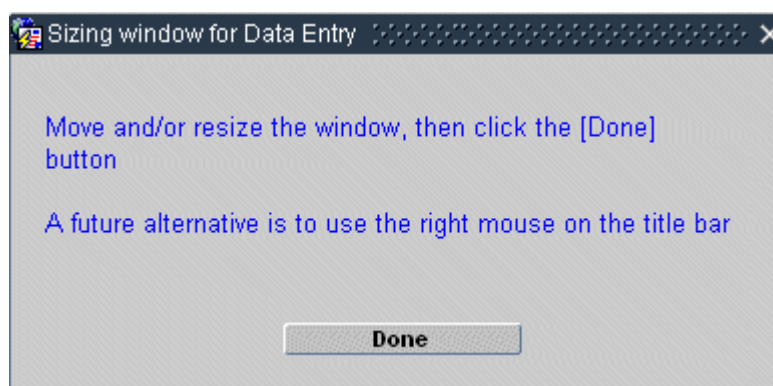
Components

The Sizing window is a window that the system allows you to re-size and/or re-position. It consists of instructional text and two components to close the window when it is the correct size and in the appropriate position. These components are:

1. Done button

2. "X" button

Usage

Refer to "Re-size the Data Entry Window" on page 16-7.

Usage

This section describes how to use Data Entry window components to complete the following tasks:

- Complete the CRF Header

- Process the Blank Flag in a CRF or CRF Section Header

- Re-size the Data Entry Window

- Close the Data Entry Window

Complete the CRF Header

The CRF header is located at the top of the Data Entry window. When you open a CRF, RDC Classic places focus in the first required field in the CRF header. You must complete all required fields in the CRF header before RDC Classic assigns the entry status "Created" to the CRF.

The CRF header collects and stores information about the CRF, such as the patient name, visit number, visit date, etc. RDC Classic automatically collects a portion of this information based on the CRF cell you click to open the CRF. However, you may be required to provide certain other information that RDC Classic cannot automatically discern, for example, the date that the visit took place.

The CRF header area of the Data Entry window contains fields that collect required information about the CRF. It may also contain fields that collect optional information, for example, a Comment field.

All required fields in the CRF header must be complete before you can begin to enter response field data in the CRF question area.

Use the instructions in the following sections to complete the CRF header fields in a CRF.

Visit date field The Visit Date field may or may not be present in a CRF header and, if present, can either be required or optional. When you create a CRF by clicking an empty CRF cell, if the date is required, you must enter a valid date before you can proceed to other parts of the Data Entry window. However, the functionality is identical in the required and optional cases. When focus is in the Visit Date field, there are several methods you can use to record a date.

Method	Description
Type value	Use the current date input format to type the correct visit date in the field. (Refer to "Date Format" on page 14-26 for information about this Preferences Window setting.)
Shortcut key	Type: ■ "T" for today's date ■ "Y" for yesterday's date ■ "L" for the last entered value
LOV	Open the List of Values window, which displays: ■ all previously entered visit dates ■ Today (the current date) ■ Yesterday (the previous day's date) ■ Last Entered (the most recently entered date in the current session)

When focus is in the Visit Date text box, a List of Values (LOV) button is displayed, If you click the button (or type F9) the Visit Date window opens. The graphic in Figure 16–4, "Visit Date Window" depicts a typical example of this window, which allows you to select from a variety of dates, such as the current date (Today), the previous day's date (Yesterday), the date you last entered, and a the dates that you have entered for the current visit for the current patient.

Figure 16–4 Visit Date Window
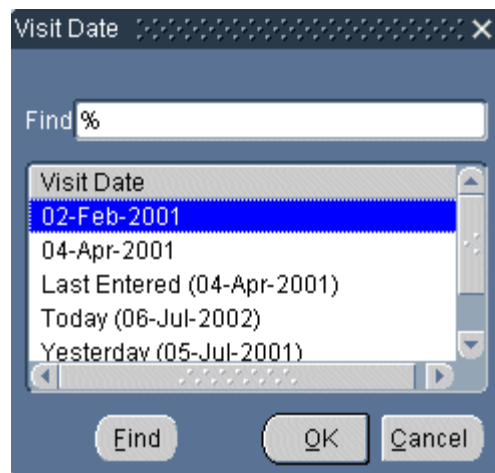
After the correct date is displayed in the field, use either the Tab or Enter key to navigate to the next field, which is:

- the next required CRF header field, if present, or

- the first response field in the Question area of the first CRF section.

Alternatively, you can use the mouse to navigate to another CRF header field. This is necessary if you want to complete an optional CRF header field because RDC Classic does not automatically navigate to such fields.

Comment field A comment field is included in the document header of a CRF to provide a means for you to associate a text message to the entire CRF.

To insert the comment, put focus in the Comment text field and type the message you want to include. The maximum length available for the comment is 200 characters.

You can also use the RDC Classic Field Editor to type the comment. This is particularly useful if the text of the comment exceeds the viewable portion of the field.

Select **Edit**, then **Field Editor** from the option list (or the **Alt+e, e** quick key combination) to open the Field Editor Window.

Process the Blank Flag in a CRF or CRF Section Header

The Blank check box is used to mark the current CRF as "blank." When you select the check box, you are presented with a confirmation window that prompts you to confirm that you want to mark the CRF as blank and then save it (refer to Figure 16–5, "Blank CRF Confirmation Window").

- If you click the OK button, the CRF is saved and the next CRF in sequence is opened in the Data Entry window (depending on Automatic Progression settings).

- If you click the Cancel button, the confirmation window closes and the Blank check box is cleared.

Figure 16–5   Blank CRF Confirmation Window
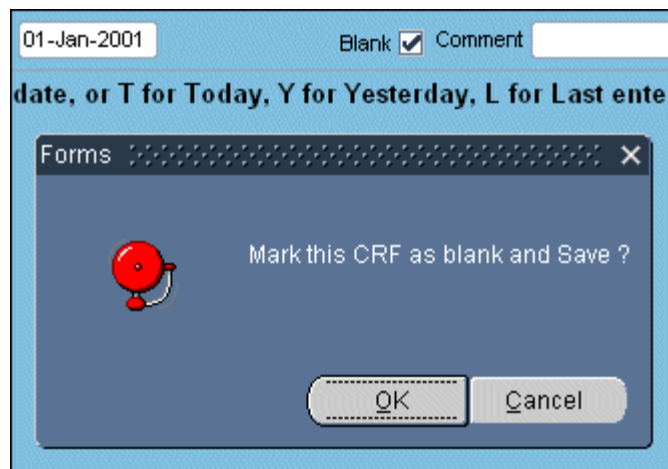
> **Note:**   If you mark as blank a CRF that has already been created and for which data has already been entered, the data is deleted from the CRF. However, the delete action is captured in the Audit Trail for each individual datapoint.

Re-size the Data Entry Window

Changes to the size and position of the Data Entry window allow you set up your work environment for maximum efficiency. When you change the Data Entry window, your choices are persistent throughout your work session.

There are two methods that allow you to change the size and/or position of the Data Entry window. Both are invoked by clicking on the Data Entry window title bar:

■   Step-wise, or discrete re-sizing and/or re-positioning, using the right-click menu

■   Free-form changes in size and/or position, using the Sizing window

Before you can move and/or resize the Data Entry window, you must open the Sizing Window. You use this window to change the size of the Data Entry window. You also use it to move the Data Entry window to a new position. Any changes, in size and/or position, that you make to the Sizing window are made to the Data Entry window after you close the Sizing window.

■   To access the Sizing window; single-click on the Data Entry window title bar

■   To close the Sizing window after moving and/or resizing; click the Done button.

To change the size or position of the Data Entry window:

1. Single-click on the Data Entry window title bar. The Sizing window is displayed. It is the same size and in the same position as the Data Entry window.

2. Depending on which action you wish to perform, do these steps:

   a. To move the window:

      –   Click-drag the Sizing window title bar.

      –   Move the window to its desired position.

      –   Release the mouse button.

b. To resize the window:

- Move the mouse pointer over the border you wish to change.

- When the pointer changes to a double-headed arrow, click-drag the border to resize the window to the desired position.

- Release the mouse button.

3. Repeat Steps 2a and 2b until the window is the size and in the position you choose.

4. Click the Done button.

You can also change the size of the window through menu commands. Using this method allows you to change the size and position of the Data Entry window in one direction at a time. There are two choices for each change:

■ a relatively small change, or

■ the maximum or minimum change that the system allows.

You access this method by right-clicking on the Data Entry window title bar, which displays a menu of options. Table 16–2 describes the function of each command in the Sizing window.

Table 16–2   Functionality of Menu Commands in the Sizing Window

Menu Command	Description of Window Change
Left	Move the window one unit to the left
Right	Move the window one unit to the right
Up	Move one unit up
Down	Move one unit down
Max Left	Move as far left as permitted
Max Right	Move as far right as permitted
Max Up	Move as far up as permitted
Max Down	Move as far down as permitted
Increase Height	Increase the vertical size one unit
Increase Width	Increase the horizontal size one unit
Decrease Height	Decrease the vertical size one unit
Decrease Width	Decrease the horizontal size one unit
Max Height	Increases the vertical size as much as permitted
Max Width	Increases the horizontal size as much as permitted
Max Size	Increase the horizontal and vertical size as much as permitted
Min Height	Decreases the vertical size as much as permitted
Min Width	Decreases the horizontal size as much as permitted
Close	Closes the Data Entry window

Close the Data Entry Window

Use the "X" button that is in the far right-hand side of the Title bar to close the Data Entry window.

- If there are no changes pending, the Data Entry window closed immediately.

- If there are pending changes, you are prompted to do one of three choices (refer to Figure 16–6, "Confirm Close with Pending Changes" for a graphic of the confirmation window):

  1. Yes - save the pending changes and close

  2. No - close the Data Entry window without saving the pending changes

  3. Cancel - go back to the Data Entry window without closing or saving pending changes.

Figure 16–6   Confirm Close with Pending Changes
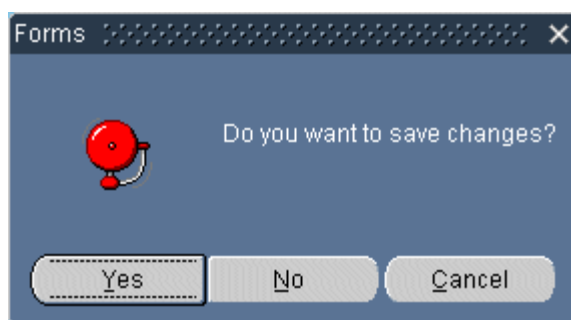
Task Reference

The following tasks use the Data Entry window:

- Mark the CRF Blank During Initial Data Entry on page 8-5

- Mark a CRF Section Blank During Initial Data Entry on page 8-5

- Insert a Repeating Question Groups Row on page 8-6

- Initiate an Investigator Comment on page 8-3

- Update an Existing Investigator Comment on page 9-5

Windows Associated with Data Entry Tasks

This section provides descriptions of the windows that RDC Classic presents when you are completing data entry tasks.

- Investigator Comment Window

- Audit Information Window

- Audit Change Reason Type Codes Window

- Audit History Window

Investigator Comment Window

The Investigator Comment window allows you to associate an investigator comment with the response field that is in focus in the Data Entry Window. You also use the window to review or update an existing investigator comment.

Access

Because each investigator comment must be associated with a particular datapoint, you must have the Data Entry Window open and focus must be in a data field in order to insert a comment.

Figure 16–7   Investigator Comment Window
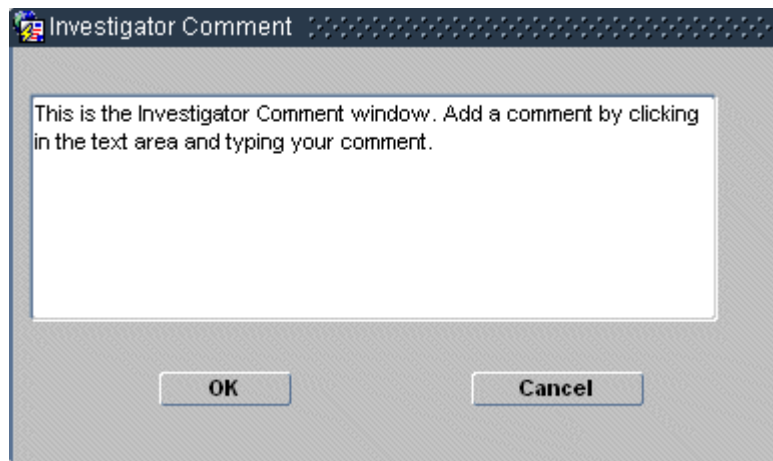
There are two ways to open an Investigator Comment window so you can initiate an comment:

■   The Investigator Comment menu command on the Insert Menu

■   The Investigator Comment button on the RDC Classic Toolbar

Components

The Investigator Comment window is a simple feature, comprised of three main components:

1. a text area

2. an OK button

3. a Cancel button

Use the text area to compose the comment. The comment may be up to 2000 characters (including spaces) in length.

When you complete the comment and want to save it, click the OK button. If at any point before you click the OK button you decide not to add a comment to this datapoint, click the Cancel button.

Usage

You can use standard Microsoft Windows keyboard functionality as you compose or edit the investigator comment. This includes copy, cut, and paste shortcut key combinations.

Task Reference

The following tasks use the Investigator Comment window:

■   Initiate an Investigator Comment on page 8-3

■   Update an Existing Investigator Comment on page 9-5

Audit Information Window

This section describes the different types of Audit Information window, describes the situations under which the system displays each, and provides usage information.

The following four windows are covered in this section. Each is a different version that is displayed in specific circumstances. Three of the windows consist of identical sets of components, while the fourth is slightly different due to variations in processing CRF header and CRF section header updates.

1. Audit Information for Data Change

2. Audit Information for Investigator Comment Change

3. Audit Information for CRF Deletion

4. Audit Information for CRF Change.

Discussion

The Audit Information window allows you to select a change reason and include comment text when you update a CRF that is at the **entry complete** data entry status.

RDC Classic audits every change that a CRF undergoes and includes a system-generated reason for each change. However, when the CRF reaches entry complete status, such that changes to response data are considered data updates, RDC Classic prompts you for a user-specified change reason each time you update a datapoint. You choose the change reason from among a set of choices that your system administrator defines. In addition, you are provided the opportunity to augment the change reason with an optional text message.

When it is displayed, a change reason is pre-selected, based on your user role and the study design. You can, however choose another reason from an LOV.
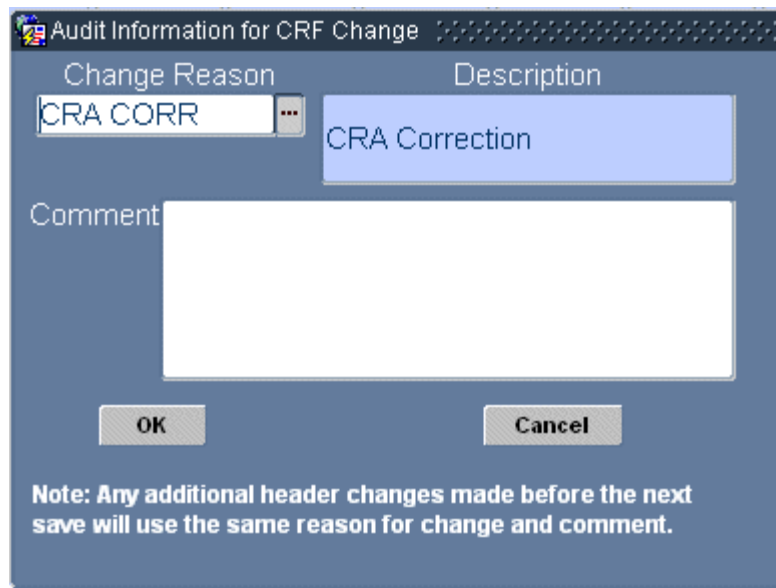
Access

The Audit Information window is displayed automatically when you initiate a change in a CRF that must be audited with a user-supplied change reason.

An Audit Information window It is displayed in the following circumstances: whenever you update a datapoint in a CRF that has an entry status of "Entry Complete."

Table 16–3   Display Conditions for Audit Information Windows

Window	Conditions for Display
Data Change	When you change the contents of a response field and attempt to navigate away from the field.
Investigator Comment	When you click the OK button in the Investigator Comment window.
CRF Deletion	When you click the OK button in the Delete CRF window.
CRF Change	Change CRF or CRF section header information, including the Blank flag. The window is displayed for the first change and the system automatically uses the change reason selected for all subsequent CRF changes until the CRF is saved.

Figure 16–8 Audit Information for CRF Change Window

Response Data Change The system displays the Audit Information for Data Change window when you change the value of a response field in a CRF that is at the **entry complete** status.

If there is a pending change to the investigator comment associated with the current response field when you update the response, this window displays the change reason you specified for the investigator comment update. You can then use this window to alter the change reason, the optional comment, or both. Any changes you make to the Audit Information window are then applied both to the response field and the investigator comment.

If you want to use a different change reason for the investigator comment, save pending changes after you update the comment and before you modify the response field.

Investigator Comment The system displays the Audit Information for Investigator Comment window when you initiate a new or update an existing investigator comment in a response field that is part of an **entry complete**. However, if there is an update pending to the associated response field, that is, if you changed the response value and have not saved the change, the system does not display this window when you update the investigator comment. Rather, it uses the change reason that you specified for the update to the response.

If you want to use a different change reason for the investigator comment, save pending changes prior to updating the investigator comment.

Refer to "Update an Existing Investigator Comment" on page 9-5 for a complete description of this task.

CRF Change The system displays the Audit Information for CRF Change window when you change the value of any field in a CRF header or CRF section header for an entry complete CRF.

Only one change reason can be associated with changes to the header information for a given save action. When you change one header field and select a change reason, the system uses that change reason and comment (if supplied) for subsequent changes to header fields until the CRF is saved.

If you want to change more than one header field and provide different change reasons for each field, save pending changes after each update.

CRF Deletion The system displays the Audit Information for CRF Deletion window when you delete an entry complete CRF.

Components

The Audit Information windows are comprised of the components that are listed and described in Table 16–4.

Table 16–4   Audit Information History Window Components

Label	Type	Description
Change Reason	Text Field w/LOV	A short description of the change reason; you can use the LOV to choose another reason from the Audit Change Reason Type Codes Window.
Description	Info Text	A read-only, long description of the currently selected Change Reason.
Comment	Text box	A text box that allows you to type an explanatory comment that is associated with the change. The comment is displayed in the Comments field of the Audit History Window.
Save	Button	Initiates an explicit save, which commits the data update, the Change Reason, and the Comment (if present) to the study database.
		This button is present in all windows except the Audit Information for CRF Change window.
OK	Button	Sets the CRF header and/or CRF Section header update(s) and the change reason as pending changes which are saved the next time the CRF is saved.
		This button is only present in the Audit Information for CRF Change window.
Cancel	Button	Closes the window and puts the data field in focus, which allows you to revert back to the original value of the response.
		Note that this button is unavailable in the CRF Delete and Investigator Comment Change versions of the window.
Note	Explanatory text	Specifies how RDC Classic processes pending changes in the CRF header and CRF section header.
		This component is only present in the Audit Information for CRF Change window.

Change Reason The Change Reason component displays the default selection from the sponsor-defined Change Reason Type Code List. The list includes a default change reason that is associated with your user role, which the system selects by default. When you select a change reason other than the default, that choice becomes the new default change reason.

There are two sets of change reasons. Each set is defined by the sponsor, however, one set is specific to CRF changes, that is, changes to CRF and CRF section header information. The system accesses the second set for all other actions that use an Audit Information window.

Usage

When the system displays the Audit Information window, a default value is displayed in the Change Reason text field. You have the option to use the default or to select an alternative from the sponsor-defined list of change reasons. To view the list, click the LOV button adjacent to the Change Reason component, which causes the Audit Change Reason Type Codes Window to open.

To include a comment with the change reason, place the insertion point in the Comment text box and type the comment. You can also paste the contents of the Windows Clipboard in the text box. Use the Ctrl-c key combination to copy text to the Clipboard and then use the Ctrl-p key combination to paste the text into the text box at the insertion point location.

Task Reference

The following tasks use the Audit Information window:

- Clear the Blank Flag and Proceed with Data Entry on page 9-7
- Complete the Audit Information Window on page 9-4
- Update CRF and/or CRF Section Header Data on page 9-4
- Update Response Data for a CRF on page 9-5
- Update an Existing Investigator Comment on page 9-5
- Initiate an Investigator Comment on page 8-3
- Mark a CRF or CRF Section Blank on page 9-6
- Review the Approval or Verification History of a CRF on page 9-3

Audit Change Reason Type Codes Window

This window provides a list of change reasons for the current task you are performing on an entry complete CRF.

Access

You access the Audit Change Reason Type Code window by accessing the Change Reason LOV in an Audit Information window.

Figure 16–9 Audit Change Reason Type Code Window
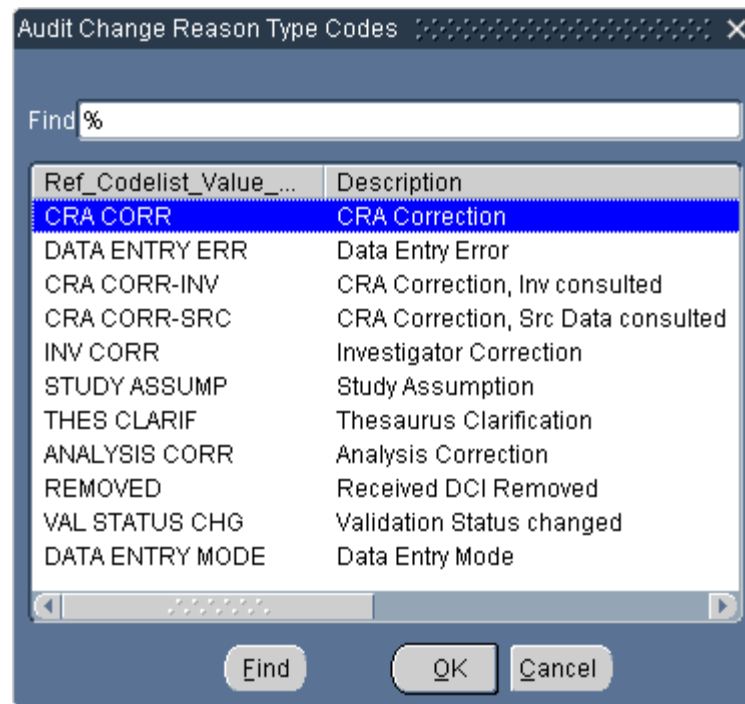
Components

The Audit Change Reason Type Codes window consists of a text box, labeled "Find," that allows you to search the list of change reasons, which are displayed in a tabular field below the text box. There are three buttons that allow you to initiate a search, select a change reason, and cancel the action by closing the window.

Audit History Window

The Audit History window (refer to) allows you to view the intervening changes that have occurred to a response value between its "Current value," and its "Original value," as it is displayed in the Audit Trail Task Tab. It provides a row for each change to the datapoint that describes:

■   when the change was made

■   what the new value is

■   who made the change

■   why the change was made.

The window displays a row of data for changes that correlate to columns in the Audit Trail task tab:

■   one row for the Original value

■   one row for the Current value

■   one row for each intervening change.

The number of rows for intervening changes equals the number displayed in the Intervening Changes column in the task tab.

Figure 16–10   Audit History Window
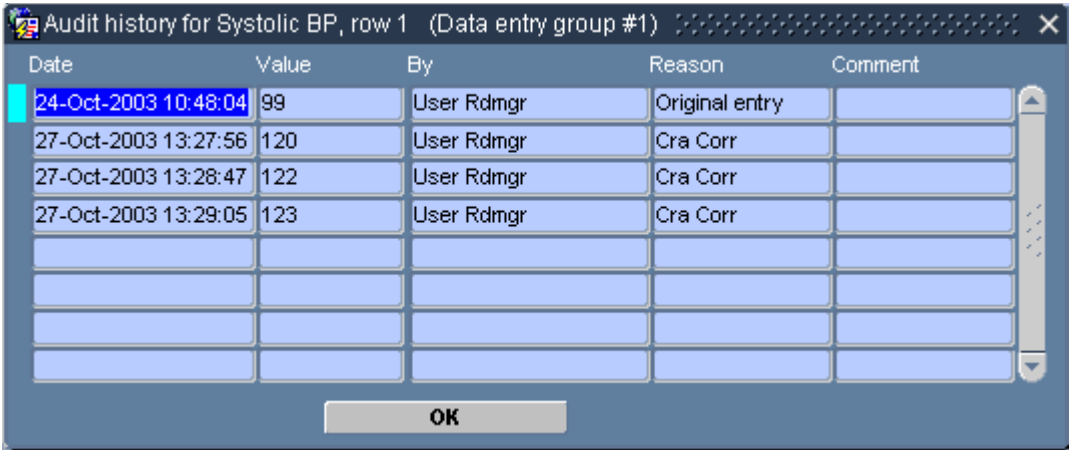
Access

You access the Audit History window by clicking the Show button on the Audit Trail Task Tab for a given response field.

Components

The information in the Audit History window is organized into columns and rows. Each field is described by its column header. The fields in the window are read-only, that is, you cannot edit any of the information that is displayed. Table 16–5, " Listing and Descriptions of Components in the Audit History Window", lists and describes the components in the window.

Table 16–5   Listing and Descriptions of Components in the Audit History Window

Label	Type	Description
Descriptive title	Title bar	The window title and descriptive information about datapoint.
Date	Field	The date and timestamp of the change to the datapoint.
Value	Field	The value that the datapoint was changed to.
By	Field	The user name of the person who changed the value of the datapoint.
Reason	Field	The change reason that was given at the time the datapoint value was changed.
Comment	Field	The optional comment that was included with the Audit Information Window.
OK	Button	Closes the window.

Windows Associated with CRF Approval

The Password confirmation windows allow you to approve or rescind approval for a CRF with the equivalent of an electronic signature.

This section consists of the following topics:

- Approval Password Confirmation Windows

- Undo Approval Password Confirmation Window

Approval Password Confirmation Windows

The Password Confirmation window is displayed whenever you approve a CRF. The following actions will cause it to be displayed:

- initial approval

- re-approval.

When you approve a CRF, you type your user name in the Password text box of the Approval Task Tab and press the Enter key. This action displays a version of the Password confirmation window that is specified for approving CRFs.

Discussion

There are two Password confirmation windows that are associated with the Approval Task Tab and the approval process. While the components of each are similar, each is displayed at a different point in the approval process. The first is the "Approval" Password Confirmation window, which is displayed whenever you approve a CRF (refer to Figure 16–11, ""Approval" Password Confirmation Window"). The second is the "Undo Approval" Password Confirmation window, which is displayed whenever you undo the approval of a CRF (refer to Figure 16–12, "Password Confirmation Window for Undo Approval").

Refer to "Approve a CRF" on page 9-10 for further information about the procedure to approve a CRF.

Figure 16–11   "Approval" Password Confirmation Window
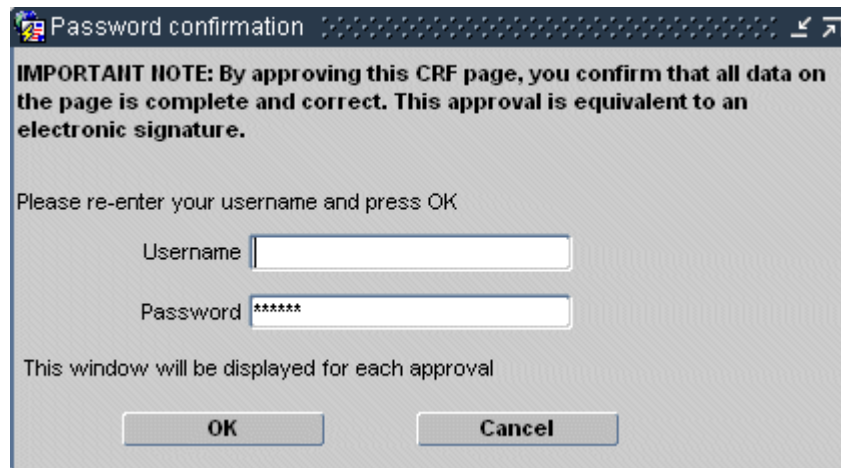
Components

There are five components of the Password Confirmation window. Four of the components are identical for the "Approve" and the "Undo Approval" windows. The only component that is different is the explanatory text, which describes the action that is occurring, i.e., you are either performing an approval or undo approval operation.

Table 16–6 lists and describes the components of that are present in the Password Confirmation windows.

Table 16–6   Password Confirmation Window Components

Label	Type	Description
Explanatory Text	Info Text	A description of the action you are taking. There is a different message for approval and undo approval. Each is configurable by your sponsor.
Username	Text box	Location where you type your user name, including the OPS$ prefix. This field is not case-sensitive.
Password	Text box	Location where you type the password that is associated with your user name. Each character is represented by an asterisk. This field is case-sensitive.
OK	Button	Performs the action you initiated on the Approval task tab and closes the window.
Cancel	Button	Dismisses the action you initiated on the Approval task tab and closes the window.

The explanatory text that is included in the window is dependent on which operation you are preforming.

When you perform initial approval of a CRF by typing your password in the text box that is in the Approval task tab and pressing the Enter key, the Password Confirmation window is displayed with your password pre-filled in the appropriate field, you are only required to type your user name (included the OPS$ prefix).

Undo Approval Password Confirmation Window

The system presents a password confirmation window when you initiate an undo approval action. It is similar to the window that is displayed during the approval action.

Figure 16–12   Password Confirmation Window for Undo Approval
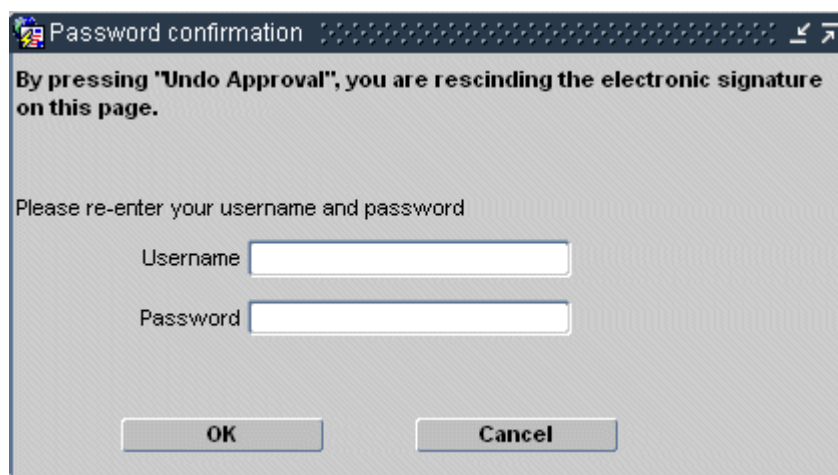
Access

The Password Confirmation window is displayed whenever you undo the approval of a CRF. When you undo an approval, you click the Undo Approval button on the Approval Task Tab. This action displays a version of the Password Confirmation window that is specified for undoing the approval of CRFs.

Refer to "Undo CRF Approval" on page 9-11 for further information about the procedure to undo approval for a CRF.

Components

There are five components of the Password Confirmation window. Four of the components are identical for the "Approve" and the "Undo Approval" windows. The only component that is different is the explanatory text, which describes the action that is occurring, i.e., you are either performing an approval or undo approval operation.

Table 16–7 lists and describes the components of that are present in the Password Confirmation windows.

Table 16–7   Password Confirmation Window Components

Label	Type	Description
Explanatory Text	Info Text	A description of the action you are taking. There is a different message for approval and undo approval. Each is configurable by your sponsor.
Username	Text box	Location where you type your user name, including the OPS$ prefix. This field is not case-sensitive.
Password	Text box	Location where you type the password that is associated with your user name. Each character is represented by an asterisk. This field is case-sensitive.
OK	Button	Performs the action you initiated on the Approval task tab and closes the window.
Cancel	Button	Dismisses the action you initiated on the Approval task tab and closes the window.

The explanatory text that is included in the window is dependent on which operation you are preforming.

When you perform initial approval of a CRF by typing your password in the text box that is in the Approval task tab and pressing the Enter key, the Password Confirmation window is displayed with your password pre-filled in the appropriate field, you are only required to type your user name (included the OPS$ prefix).

Windows Associated with Managing Discrepancies

This section describes the windows that you work with while managing discrepancies:

- Discrepancy Windows
- Discrepancy for CRF Section Window
- Comment for Question Window
- Validation Failure Window
- Internal Comments Windows
- Resolution Reason Window
- Discrepancy History Window

Discrepancy Windows

You can use the discrepancy windows to modify existing univariate, manual, and section discrepancies. This includes updating Error Messages, Comments, Comment Reason (for manual and section discrepancies), and taking action. You must use the Individual discrepancy tab to work with multivariate discrepancies.

The windows that are displayed for the following discrepancies are all comprised of similar components. Refer to these topics for a description of each window:

- Discrepancy for CRF Section Window
- Comment for Question Window
- Validation Failure Window

The following table (Table 16–8) lists the type of discrepancy that you use each of these windows to manage.

Table 16–8   List of Windows Used for Univariate and Manual Discrepancies

Discrepancy	Window name	Description
CRF Page (section discrepancy)	Discrepancy for CRF Section Window	Used to enter a manual header discrepancy, which is associated with a CRF page. Subsequent editing and actions for the discrepancy must be done through the Discrepancy Task Tab.
		Multiple manual header discrepancies can be initiated for a CRF by selecting **Insert**, then **Data Entry** from the option list.
Manual discrepancy	Comment for Question Window	Used to enter or edit a manual discrepancy, which is associated with a response datapoint. Subsequent editing and actions for the discrepancy can be done in this window or in the Discrepancy Task Tab.
		One manual discrepancy can be associated with a response datapoint.
Discrepancy	Validation Failure Window	Displayed as the result of an edit check of a value entered in a response datapoint. Used to alert the user to the occurrence of the discrepancy; to describe or add to the discrepancy Message or Comment; and to take action on the discrepancy. Subsequent editing and actions for the discrepancy can be done in this window or in the Discrepancy Task Tab.
		One discrepancy can be associated with a response datapoint.

Discrepancy for CRF Section Window

The Discrepancy for CRF Section window allows you to add a **section discrepancy** that is associated with a CRF. Figure 16–13 is a graphic that depicts a typical Discrepancy for CRF page window.

Access

The Discrepancy for CRF page window is displayed when you select either:

1. **Insert**, then **Section Discrepancy** from the option list, or

2. **Edit**, then **Section Discrepancy** from the option list when a section discrepancy is already associated with the CRF section

3. Click the New button on the Discrepancy task tab; when you do this, the system displays a window that allows you to choose which type of manual discrepancy, CRF section, or response field, that you want to add.

You can associate more than one section discrepancy with a CRF.

Figure 16–13 Discrepancy for CRF Page Window

Components of the CRF Section Discrepancy Window

The components of the Discrepancy for CRF page window are listed and described in Table 16–9.

Table 16–9   Components of the Discrepancy for CRF Page Window

Label	Type	Description
Operator Comment Reason	LOV	A pre-filled LOV that allows you to specify the reason that you are inserting the manual header discrepancy.
Message	Text box	An editable text box for comments that are displayed in the Text field on the Discrepancy task tab.
Message editor	Button	Provides access to a text editor you can use to compose the Message.
Comments	Text box	Location for a text comment that is displayed in the Comments field on the Discrepancy task tab.

Table 16–9   (Cont.) Components of the Discrepancy for CRF Page Window

Label	Type	Description
Internal Comment editor	Button	Provides access to the Internal Comment Window.
Internal Comment History	Button	Provides access to the Internal Comment History Window
Save	Button	Saves all pending changes and closes the window.
Cancel	Button	Discards all pending changes and closes the window.
Status	Info Text	Displays the current status of the discrepancy.
Action	Drop-down list	A drop-down list that gives you access to the set of Discrepancy Actions available.
Review Status	Info Text	Displays the current review status of the discrepancy.
Resolution Code	Info Text	Displays the Resolution Reason for discrepancies that are resolved.
Resolution Comment	Text box	Displays the reason that was given when the discrepancy was resolved.
Resolution Comment Editor	Button	Provides access to the Resolution Comment editor.

Comment for Question Window

You use the Comment for Question window to review, insert or update a **manual discrepancy** that is associated with the individual response field

The graphic in Figure 16–14 depicts a typical Comment for Question window. In this case, a manual discrepancy is about to be inserted for a question named "Systolic BP."

Each response field can have one **open** manual discrepancy associated with it.

Figure 16–14   Comment for Question Window

Access

If a manual discrepancy is not associated with a response field, you can use the Comment for Question window to initiate a discrepancy by selecting **Insert**, then **Discrepency (manual)** from the option list.

If a manual discrepancy is associated with a response field, you can use the Comment for Question window to review or update the discrepancy record by selecting **Edit**, then **Discrepency (manual)** from the option list.

Components of the Comment for Question Window

The components of the Comment for Question window are listed and described in Table 16–10.

Table 16–10   Components of the Comment for Question Window

Label	Type	Description
Question name	Title bar	Informative text that describes the currently active question.
Comment Reason	LOV	An LOV that allows you to select a reason from a set of sponsor-defined choices.
Message	Text box	An editable text box for typing the error message that you want to display in the Text field on the Discrepancy task tab.
Message editor	Button	Provides access to a text editor you can use to compose the error message.
Comments	Text box	A location to type an explanatory comment that augments the error message.
Internal Comment editor	Button	Provides access to the Internal Comment Window.
Internal Comment History	Button	Provides access to the Internal Comment History Window
Save	Button	Saves all pending changes and closes the window.
Cancel	Button	Discards all pending changes and closes the window.
Status	Info Text	Displays the current discrepancy status of the discrepancy.
Action	Drop-down list	A drop-down list that provides access to the set of **discrepancy actions**.
Review Status	Info Text	Displays the current review status of the discrepancy.
Resolution Code	Info Text	Displays the Resolution Reason for discrepancies that are resolved.
Resolution Comment	Text box	Displays the resolution reason that accompanied the resolution action.
Resolution Comment Editor	Button	Provides access to the Resolution Comment editor.

Task Reference

The following tasks use this window:
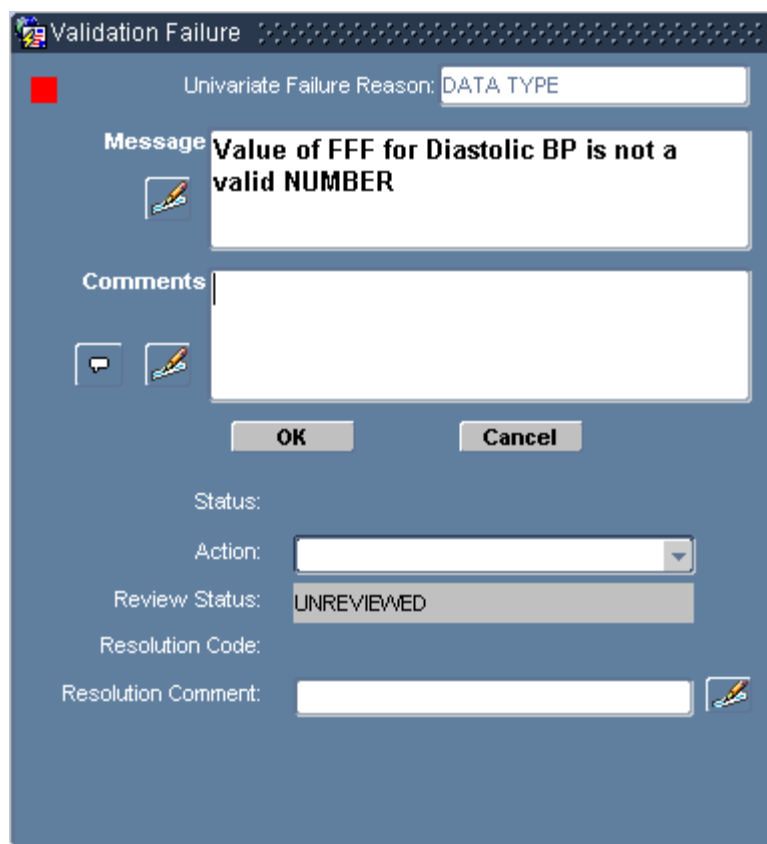
- Initiate a Discrepancy for a Response Field on page 8-6
- Update an Existing Discrepancy on page 9-8

Validation Failure Window

This window is displayed when you enter or update a datapoint with a value that violates the criteria established for that question in the study protocol. This causes a **univariate discrepancy** for that response datapoint.

The graphic in Figure 16–15 depicts a typical Validation Failure window. In this case, the letter "D" has been typed in a data response field for a question that collects values for gender. The study is designed such that the system expects either an "M" or an "F" to be entered in the response field. When a different value is entered and the user attempted to navigate out of the response field, the system generates a discrepancy and displays the window.

Figure 16–15   Validation Failure Window

Access

There are two conditions that will cause the system to display the Validation Failure window, either the system presents it automatically, or you select **Edit**, then **Discrepancy** from the option list to open it.

The system displays this window when you enter a value in a response datapoint that does not meet certain criteria. When you attempt to navigate to the next datapoint, the Validation Failure window is displayed. This allows you to:

- review the reason why the discrepancy was raised
- include a comment with the discrepancy
- take action, such as routing it for review or resolving it.

> **Note:** When the system presents the Validation Failure window in response to a discrepant datapoint, you can use the Cancel button to close the window, put focus back in the response field, and address the problem with the response, without generating a discrepancy. This gives you the opportunity to correct a mis-read or mis-typed value with the actual value. However, if you do not change the datapoint to a non-discrepant value and attempt to change focus, the window will be displayed again.

In order to view this window manually, the Data Entry Window must be open and focus must be in a response field for which a **univariate discrepancy** exists. When these conditions are met, select **Data Entry**, then **Discrepancy** from the option list to open the window. If you attempt to open this window when focus is in a response field that does not contain a discrepancy, a message window is displayed which states that there is no discrepancy associated with the response.

> **Tip:** When focus in the Data Entry Window is in a response field for which a discrepancy exists, the title bar of the Data Entry window includes the following, as an indicator: <Univ>

When you open the Validation Failure window for an existing discrepancy, you can do all of the tasks described above, and you can view, edit, and comment on any pre-existing comments that you or another user has entered for the discrepancy.

Components

The components of the Validation Failure window are listed and described in Table 16–11.

Table 16–11   Components of the Validation Failure Window

Label	Type	Description
Univariate Failure Reason	Info Text	A short description of the criterion that the response data failed to satisfy.
Message	Text box	A longer description of the reason for the discrepancy. When the discrepancy is initiated, this text box is pre-filled with a system-generated description of the cause for the discrepancy, which you can edit.
Message editor	Button	Provides access to a text editor you can use to edit the message.
Comments	Text box	Location for a text comment that is displayed in the Comments field on the Discrepancy task tab.
Comment editor	Button	Provides access to the Internal Comment Window.
Comment History	Button	Provides access to the Internal Comment History Window.
OK	Button	For system-generated display of the window: Acknowledges the discrepancy and saves it to the database.
		For manual display of the window (for existing discrepancy): Saves pending changes and closes the window.

Table 16–11   (Cont.) Components of the Validation Failure Window

Label	Type	Description
Cancel	Button	Closes the window without saving any changes made in the window and returns focus to the discrepant datapoint.
Status	Info Text	Displays the current status of the discrepancy. The status is not defined until the discrepancy is saved.
Action	Drop-down list	A drop-down list that gives you access to the set of Discrepancy Actions available.
Review Status	Info Text	Displays the current review status of the discrepancy.
Resolution Code	Info Text	Displays the Resolution Reason for discrepancies that are resolved.
Resolution Comment	Text box	Displays the reason that was given when the discrepancy was resolved.
Resolution Comment Editor	Button	Provides access to the Resolution Comment editor.

Usage

The primary purpose of the Validation Failure window is to allow you to acknowledge that the current value of the response field raised a discrepancy. However, you can also use the window to take immediate action on the discrepancy.

There are two types of discrepancy actions: routing and resolution. Routing actions assign the discrepancy to the members of another user role. For example, a routing action that could be available for the Investigator role is, "Send to Site," which assigns the discrepancy to the Site user group. The system permits you to include an optional comment that it saves with the discrepancy.

In contrast, resolution actions immediately close the discrepancy. However, you must provide a resolution reason and, optionally, a resolution comment when you select this action.

Internal Comments Windows

The windows that you use to work with internal comments for a discrepancy are:

- Internal Comment Window

- Internal Comment History Window

- Internal Comments for Discrepancy Window

There are several methods you can use to work with internal comments for a discrepancy. You can use the windows that are described in this section or you can use the components in the Discrepancy Task Tab to make the same kind of changes. The Comment windows provide an editor that allows you to work with lengthy comments more efficiently. However, whichever method you use, you access and work with only one set of data for each discrepancy. Each time you add new comment or make changes to an existing comment, the changes are saved as a new comment entry.

Using the windows that are described in this section, you can:

- view a chronological listing of previous comments

- add new comments

- edit existing comments

Although you can edit existing comments, it is important to note that this is equivalent to adding a new comment. When you make changes in a comment text field, whether you erase the existing comment and compose new text, or make a simple change to the existing comment, the new comment is saved in its entirety as a separate entry in the comment history for that discrepancy.

Table 16–12   Internal Comment Windows Functionality and Access

Window Name	Function	Access
Internal Comment Window	Text editor for composing and editing internal comments for discrepancies.	Comment button on the Discrepancy Windows.
Internal Comment History Window	A chronological listing of the comments that have been entered for a manual or discrepancy. Includes the user name of the person who changed the comment.	Comment History button on Discrepancy Windows.
Internal Comments for Discrepancy Window	A combination of the Internal Comment Window and the Internal Comment History Window.	Double-click the Comments field in either the Individual Discrepancy Tab or the List of Discrepancies Tab for the relevant discrepancy.

Internal Comment Window

The Internal Comment window is a text editor with access to search and replace functionality that you can use to compose and edit internal comments that are associated with a discrepancy.

Figure 16–16   Internal Comment Window

Access You access the Internal Comment window from the Discrepancy Windows, by clicking the button that is adjacent to the Comments text box. Three different windows, which are displayed for different types of discrepancies, provide access to the Internal Comment window. The windows are:

- Discrepancy for CRF Section Window

- Comment for Question Window

- Validation Failure Window

Figure 16–17   Internal Comment Window Button

Components The Internal Comment window consists of the components that are listed and described in Table 16–13.

Table 16–13   Components of the Internal Comments Window

Label	Type	Description
Editor	Text Editor	An editable field for changing the existing or inserting a new comment for the discrepancy.
OK	Button	Saves pending changes and closes the window.
Cancel	Button	Discards pending changes and closes the window.
Search	Button	Opens the Search and Replace window.

Internal Comment History Window

The Internal Comment History window provides a record of the comments that have been entered for a manual or discrepancy. It is not an editable window, such as the Internal Comments for Discrepancy Window, rather it provides a listing of all internal comments that have been recorded for a discrepancy.

Figure 16–18   Internal Comment History Window
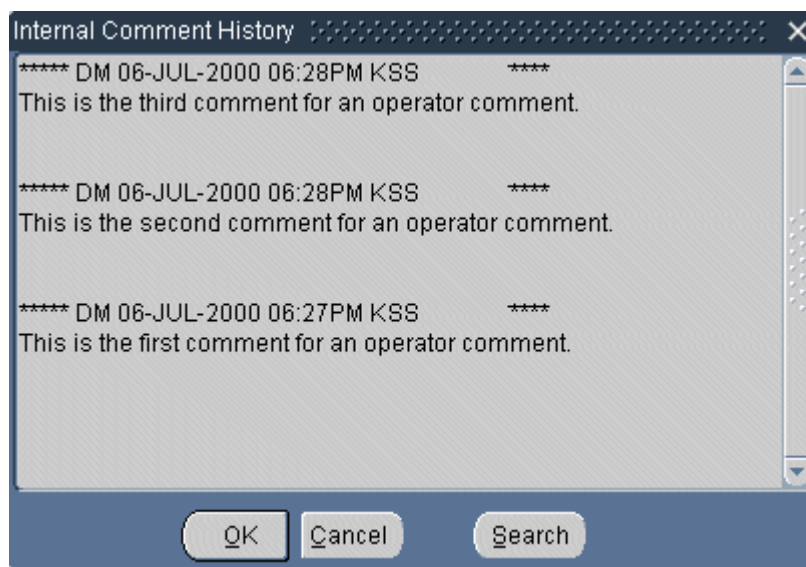
Access You access the Internal Comment History window by clicking its button on the following windows:

- Validation Failure Window

- Comment for Question Window

- Discrepancy for CRF Page Window

The button that you use to open the Internal Comment History window is the same on all of these windows. It located next to the Comments Editor button, adjacent to the Comments field. The graphic depicted in Figure 16–19 shows the button with a red square for identification.

Figure 16–19   Internal Comment History Button

Components The Internal Comment History window consists of four components, which are listed and described in Table 16–14.

Table 16–14   Components of the Internal Comment History Window

Label	Type	Description
Comment History	Info Text	A non-editable listing of each comment that has been saved for the discrepancy. The listing is in reverse chronological order and the save timestamp and user name of the author precedes each comment entry.
OK	Button	Closes the window.
Cancel	Button	Closes the window.
Search	Button	Opens the Search and Replace Window, however, because the listing cannot be edited, the Replace function is not enabled.

Internal Comments for Discrepancy Window

The Internal Comments for Discrepancy window serves two purposes. It is an editor for new and existing comments, and it tracks each comment that is saved and displays each version with a timestamp and the name of the user who saved the comment.

Figure 16–20   Internal Comments for Discrepancy Window
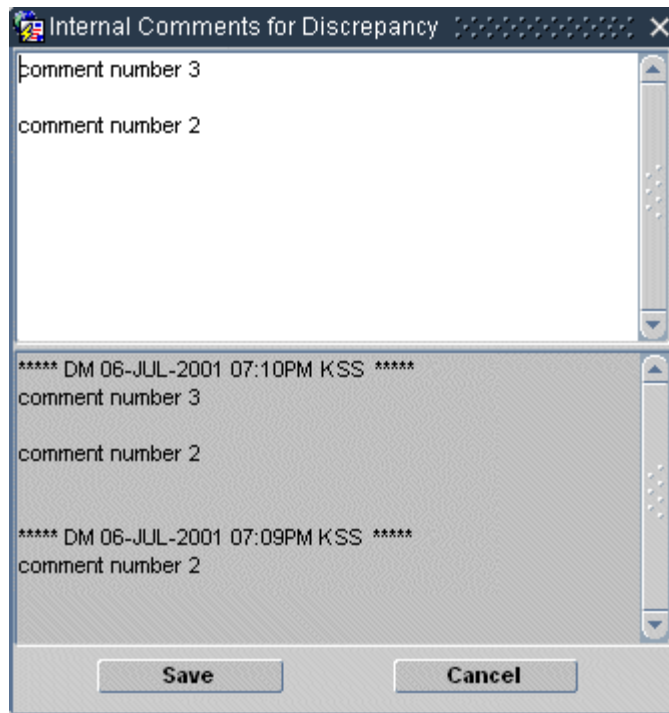
Access You access the Internal Comments for Discrepancy window by double-clicking the Comments field in either the Individual Discrepancy Tab or the List of Discrepancies Tab for the relevant discrepancy.

When you open the window, the current comment is displayed in the text edit field and all previous comments are displayed in the history field. You can use standard editor functionality, such as Cut, Copy, and Paste, to edit the existing comment or insert new comment text.

Note that only changed comments are saved as new entries in the history listing.

Components The components of the Internal Comments for Discrepancy window are listed and described in

Table 16–15   Components of the Internal Comments for Discrepancy Window

Label	Type	Description
Editor	Text Editor	An editable field for changing the existing or inserting a new comment for the discrepancy.
Comment History	Info Text	A non-editable listing of each comment that has been saved for the discrepancy. The listing is in reverse chronological order and the save timestamp and user name of the author precedes each comment entry.
Save	Button	Saves pending changes and closes the window.
Cancel	Button	Discards pending changes and closes the window.

Resolution Reason Window

This window is displayed when you attempt to manually close a discrepancy. It is associated with Discrepancy Actions that allow you to resolve, or close, a discrepancy.

The graphic in Figure 16–21 depicts the Resolution Reason window with a resolution reason of "Investigator Verification."

> **Note:** You can also resolve a discrepancy using the Validation Failure Window.

Figure 16–21   Resolution Reason Window
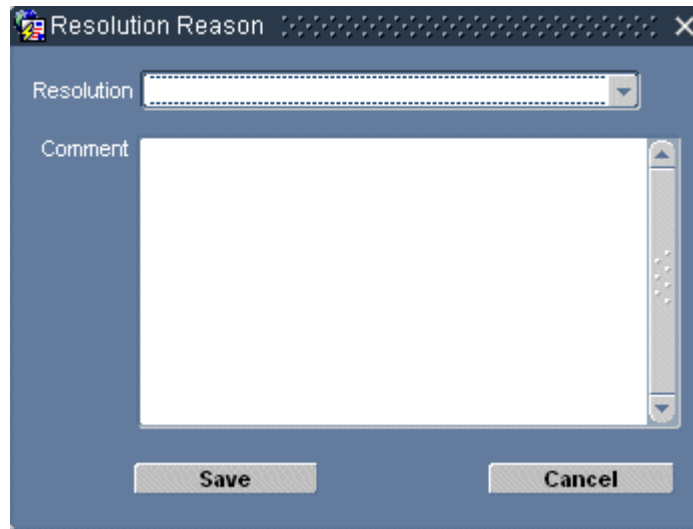
The window allows you to choose a reason from a list of study-specific options and it provides a free-text field that provides a method to add pertinent comments, which are saved and displayed in the Resolution Comment fields for the discrepancy in the Discrepancy Task Tab.

Access

You access the Resolution Reason window from one of several other components that are associated with Discrepancy Management. All of these components include a Discrepancy Action drop-down list that includes one or more actions that resolve, or close, a discrepancy. When you select such an action, the Resolution Reason window is displayed.

Examples of components that give you access to the resolution actions on the Action drop-down list include:

- List of Discrepancies Tab
- Individual Discrepancy Tab
- Validation Failure Window
- Internal Comment History Window

Components

There are four components in the Resolution Reason window, which are listed and described in Table 16–16.

Table 16–16   Components of the Resolution Reason Window

Label	Type	Description
Resolution	Drop-down box	A pre-filled list of possible resolution reasons. This is determined and set at the study sponsor level.
Comment	Text box	An editable field that you use to type comments about the current discrepancy resolution.
Save	Button	Resolves the discrepancy, using the resolution reason you selected and the (optional) comment text you typed. Note that you must select a resolution reason.
Cancel	Button	Closes the window without resolving the discrepancy or saving the comment text.

Discrepancy History Window

The Discrepancy History window provides a chronological listing of the changes that have been made to a discrepancy. It is similar to the Audit History Window.

Access

You access the Discrepancy History window by clicking the History button on either the List of Discrepancies Tab or an Individual Discrepancy Tab.

Figure 16–22   Discrepancy History Window
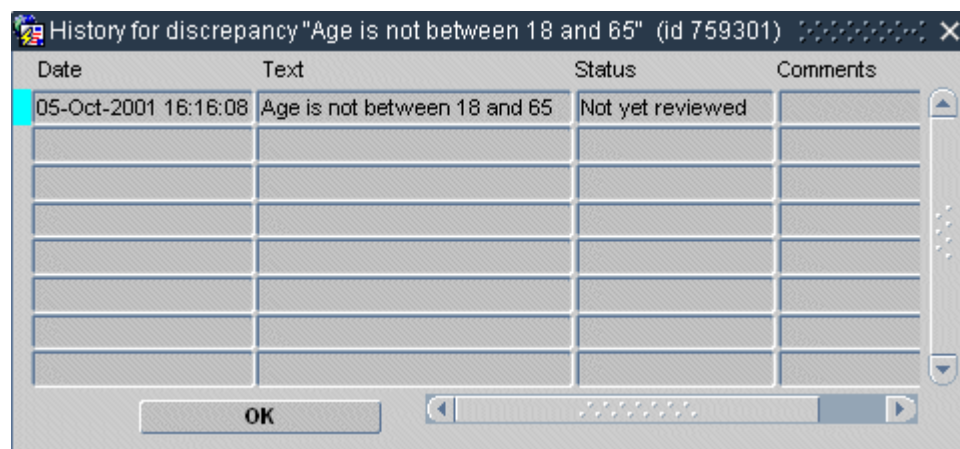
Components of the Discrepancy History Window

The components that comprise the Discrepancy History window are listed and described in Table 16–17, " Discrepancy History Window Components".

Table 16–17   Discrepancy History Window Components

Label	Type	Description
Date	Info	The timestamp that the discrepancy was saved to the study database.
Text	Info	A description of the discrepancy cause or the reason for the change in status; this is either user- or system-generated, depending on the type of discrepancy.

Table 16–17   (Cont.) Discrepancy History Window Components

Label	Type	Description
Status	Info	The discrepancy status at the time specified in the Date field.
Comments	Info	The comment that the user included with the discrepancy.
Resolution	Info	If the discrepancy is resolved, the reason that was selected in the Resolution Reason Window.
Resolution Comment	Info	If the discrepancy is resolved, the comment that the user included in the Resolution Reason Window.
By	Info	The user name of the person who resolved the discrepancy.
OK	Button	Closes the window.

Part IV

RDC Classic Administration Tasks

This section includes administration tasks that apply to the Oracle Clinical Remote Data Capture Classic (RDC Classic) application. For RDC Onsite, refer to the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

This part consists of the following sections:

- Administering RDC Classic in Oracle Clinical on page 17-1
- RDC Classic Administration Tasks on page 18-1
- Managing the Activity List on page 19-1

17

Administering RDC Classic in Oracle Clinical

System administration for RDC Classic requires that you perform certain tasks in Oracle Clinical and others in RDC Classic Administration. This section describes the tasks you perform in Oracle Clinical. Refer to "RDC Classic Administration Tasks" on page 18-1 for the those tasks that you complete in RDC Classic Administration.

RDC Classic requires certain new reference codelists, and a new form for setting security at remote sites. All codelists are type INSTALLATION, so that they have standard values across a replicated network.

This section covers the following topics:

- Enrolling RDC Classic Users on page 17-1
- Configuring the RDC Classic Discrepancy System on page 17-3
- Setting the Change Reason on page 17-5
- Limiting Unplanned CRFs in RDC Classic on page 17-5
- Maintaining Standard Message Texts on page 17-6
- Using the News System on page 17-7
- Working with the RDC_CLIENT Package on page 17-9

Enrolling RDC Classic Users

RDC Classic users require Oracle database accounts like other Oracle Clinical users. RDC Classic recognizes the following database roles in addition to the Oracle Clinical roles:

Database Role	Typical user profile
RXC_DMGR	Data Manager
RXC_SUPER	Data Manager
RXC_CRA	Clinical Research Associate.
RXC_SITE	Study Coordinator or other person at the remote site responsible for entering patient data.
RXC_INV	Investigator at the remote site who can approve CRFs.

All RDC Classic users must be granted the role that matches their job function (refer to the *Oracle Clinical Administrator's Guide* for a complete list and additional instructions). The USER GROUP ROLES reference codelist coordinates a database role with an RDC Classic user group.

Within RDC Classic, user groups control the appearance of discrepancies and the functions that users can perform. You configure the user groups in the User group roles reference codelist.

User Groups

An RDC Classic user group is a named set of system users who are assigned the same RDC Classic role. It is *not* the same as an Oracle group user account.

The USER GROUP ROLES reference codelist defines the number and names of the user groups for an installation. Refer to the *Oracle Clinical Administrator's Guide* for information on this codelist.

You cannot delete a user group's codelist entry, but you can deactivate it by clearing its Active? checkbox. You can add user groups by inserting records as usual. (Refer to "Set Up a New User Group" on page 17-2 for details on creating custom user groups.)

User Group Roles

The installation reference codelist USER GROUP ROLES maps Oracle database roles to the named RDC Classic user groups. That is, when users log into RDC Classic, the database role granted to their Oracle account is compared to the Short Values in the reference codelist and the first match, in order of priority, determines the user group to which the user is assigned. Refer to the *Oracle Clinical Administrator's Guide* for information on the USER GROUP ROLES codelist.

Set Up a New User Group

If you have the RXC_SUPER or RXC_ADMIN database roles you can create new user group definitions. First you assign a name to the user group, then you set its role.

Define the User Group

To define a new user group:

1. Navigate to **Admin**, then **Reference Codelists**, and **Installation Codelists** menu path. The system displays the Maintain Installation Codelists window.

2. Query for the codelist, "USER GROUPS".

3. Use the **Data**, then **Insert Record** menu command to insert a record in the Reference Codelist Values section. Type the new group name in the Short Value field.

4. Save pending changes.

5. Query for "USER GROUP ROLES".

6. Use the **Data**, then **Insert Record** menu command to insert a record in the Reference Codelist Values section.

    a. Type the group name in the **Long Value** field.

    b. Type the database role in the **Short Value** field.

7. Save pending changes.

8. Query for DATA CHANGE REASON TYPE CODE.

9. Use the **Data**, then **Insert Record** menu command to insert a record in the Reference Codelist Values section.

    a. Type the group name in the Long Value field.

    b. Type the default change reason in the Short Value field (refer to "Setting the Change Reason" on page 17-5 for details).

10. Save pending changes.

Create Discrepancy Reference Codelists

In order to use the new user role in RDC Classic, you must create a mechanism that allows discrepancies to be assigned a status for the role and a setup a group of actions that members of the role can take on a discrepancy. You do this by creating two new installation reference codelists:

1. `DISCREPANCY ACTIONS <user group name>`

2. `DISCREPANCY STATUS <user group name>`

Connect to the database as OPA and, in SQL*Plus:

1. If needed, create a new database role for the user group. (Refer to the *Oracle Clinical Administrator's Guide* for information on adding roles to Oracle Clinical.)

If you plan to use existing Oracle Clinical roles, such as RXC_DMGR, proceed to Step 2.

2. Create the installation reference codelists DISCREPANCY ACTIONS *<user_group>* and DISCREPANCY STATUS *<user_group>*.

To do this, you can copy, paste, and edit the appropriate sections of the SQL script that creates reference codelists. This script is RDCpopulatedata.sql in the install directory.

Configuring the RDC Classic Discrepancy System

In the RDC Classic Spreadsheet, a CRF icon represents each CRF in which data has been recorded. The system colors those CRFs with open discrepancies either red or yellow, depending on the discrepancy status for the current user. CRFs with at least one open discrepancy that is actionable by the current user's role are red. Those with at least one open discrepancy that is actionable by a different role are yellow. Active (red) discrepancies take precedence over other (yellow) discrepancies, so the system colors a CRF with both active and other discrepancies red.

You setup the discrepancy indicators and actions with two sets of installation reference codelists. You also set the default reason given for a data change per user group in a reference codelist.

- Setting Discrepancy Groups
- Setting Discrepancy Actions

Setting Discrepancy Groups

The coloring of CRF icons with regard to discrepancies in the RDC Classic Spreadsheet are shown in Table 17–1.

Table 17–1   RDC Classic Discrepancy Icons and Statuses

Icon	Status	Implication
	ACTIVE	The CRF contains at least one open discrepancy that requires attention by the user group to which the current user is assigned.

Table 17–1   (Cont.) RDC Classic Discrepancy Icons and Statuses

Icon	Status	Implication
	OTHER	The only open discrepancies in the CRF require the attention of a user group different than the one to which the current user is assigned.
	CLOSED	The CRF contains no open discrepancies – either it never contained discrepant data or any discrepancies have been resolved/closed.

When Oracle Clinical is installed, an installation reference codelist named DISCREPANCY STATUS *ROLE* is created for each of the default user groups: CRA, DM, INV, and SITE. (Refer to the *Oracle Clinical Administrator's Guide* for additional information about these codelists.) Each codelist maps the Oracle Clinical discrepancy review statuses to the RDC Classic discrepancy statuses appropriate to the user group. Table 17–2 shows the default discrepancy statuses for each user group.

Table 17–2   User Groups and Default RDC Classic Discrepancy Statuses

Short Value – Oracle Clinical Discrepancy Review Status	Long Value – RDC Discrepancy Status			
	CRA	**DM**	**INV**	**SITE**
UNREVIEWED	ACTIVE	ACTIVE	ACTIVE	ACTIVE
CRA REVIEW	ACTIVE	OTHER	ACTIVE	ACTIVE
INV REVIEW	ACTIVE	OTHER	ACTIVE	ACTIVE
DM REVIEW	OTHER	ACTIVE	OTHER	OTHER
TMS EVALUATION	OTHER	OTHER	OTHER	OTHER
TMS IN PROGRESS	OTHER	OTHER	OTHER	OTHER
RESOLVED	CLOSED	CLOSED	CLOSED	CLOSED
IRRESOLVABLE	CLOSED	CLOSED	CLOSED	CLOSED
CLOSED	CLOSED	CLOSED	CLOSED	CLOSED

For example, putting Table 17–1 and Table 17–2 together, a user in the DM group would see a discrepancy of review status DM REVIEW as having a red icon, while a user in the SITE group would see the same discrepancy as yellow.

Note that the discrepancy review status does not determine what functions a user can perform on the discrepancy or the patient data. Refer to the next section, and "Setting Study/Site Security Privileges" on page 18-1. Refer to the DISCREPANCY ACTIONS *ROLES* codelists in the *Oracle Clinical Administrator's Guide* to determine what routing and resolution actions each user role can take on a discrepancy.

Setting Discrepancy Actions

In RDC Classic, a user changes the review status of a discrepancy by choosing an item from a drop-down list box. The installation reference codelists DISCREPANCY ACTIONS ROLE Codelists define which items are available to each user group.

There is a codelist for each named user group, by default DM, CRA, SITE and INV. For example, Table 17–3 shows the entries for DISCREPANCY ACTIONS DM.

Table 17–3   Default Discrepancy Actions for User Group DM

Short Value (Oracle Clinical discrepancy review status)	Long Value (meaning)
INV REVIEW	Send to site
CRA REVIEW	Send to CRA
TMS EVALUATION	Send for classification
RESOLVED	Close - resolved
IRRESOLVABLE	Close - no resolution

Setting the Change Reason

When an RDC Classic user updates a CRF that is in the entry complete data entry status, the system displays an Audit Information window, which prompts the user for a change reason. The user must select the change reason from a list of values. The list of values is defined in a reference codelist that you maintain. By altering the values in the codelist, you can choose which is the default reason and you can modify existing or add new entries that suit your business requirements.

The change reason list of values is populated by the entries in the installation reference codelist. Refer to the DATA CHANGE REASON TYPE CODE codelist in the *Oracle Clinical Administrator's Guide* for more information. You can modify this codelist to alter the choices that the system presents to the user who modifies an accessible CRF.

To set the default data change reason for a user group, put the group name in the Long Value field of that reason code (Short Value column). Table 17–4 lists several example entries. You can also put a comma-separated list of roles in a single field.

Note that changing the Long Value of a DATA CHANGE REASON TYPE CODE entry has no effect on data entry through the standard Oracle Clinical forms. This feature is available in RDC Classic only.

Table 17–4   Sample DATA CHANGE REASON TYPE CODE Updates

Seq	Reason code (Short Value)	User group role (Long Value)
1	DATA ENTRY ERR	SITE
5	CRA CORR	CRA
8	INV CORR	INV
11	ANALYSIS CORR	DM

Limiting Unplanned CRFs in RDC Classic

RDC Classic users can add unplanned CRFs and visits using commands in the RDC Workspace. Refer to the SINGLE DCI TYPES codelist in the *Oracle Clinical Administrator's Guide* for the CRFs that an end user cannot add.

When an RDC Classic user adds an unplanned visit, by choosing **Visit** in the **Insert** menu, the system creates a visit with all the DCIs from the previous scheduled visit, except for any DCI whose DCI type, as entered in the DCI definition screen, has an entry in SINGLE DCI TYPES. Similarly, when an RDC Classic user adds an unplanned CRF, by choosing **CRF** in the **Insert** menu, the system presents the user with a LOV comprised of all DCIs not yet included in the current visit, except for those listed in the codelist.

Maintaining Standard Message Texts

This section describes how to maintain and create standard messages that are displayed to the user during data entry and discrepancy management.

The system displays customized text to RDC Classic users when the system generates a univariate discrepancy as the result of a validation error.

Table 17–5   Customizable Univariate Discrepancy Messages

Discrepancy Type (Short Value)	Default Text (Description)
DATA TYPE	Value of \VALUE_TEXT\ for \SAS_LABEL\ is not a valid \DATA_TYPE\
DVG	Value of \VALUE_TEXT\ for \SAS_LABEL\ not found in \DISCRETE_VALUES\
DVG SUBSET	Value of \VALUE_TEXT\ for \SAS_LABEL\ not found in \DISCRETE_VALUES\
LENGTH	Value of \VALUE_TEXT\ for \SAS_LABEL\ exceeds expected length of \LENGTH\
LOWERBOUND	Value of \VALUE_TEXT\ for \SAS_LABEL\ below minimum value of \LOWER_BOUND\
MANDATORY	Value for \SAS_LABEL\ has not been supplied
MISSING_PT	Value of \VALUE_TEXT\ for \SAS_LABEL\ is awaiting classification
MISSING_SCT	Value of \VALUE_TEXT\ for \SAS_LABEL\ is awaiting classification
PARTIAL DATE	Value of \VALUE_TEXT\ for \SAS_LABEL\ is an incomplete date or time
PRECISION	Value of \VALUE_TEXT\ for \SAS_LABEL\ exceeds \DECIMAL_PLACES\ decimal places
THESAURUS	Value of \VALUE_TEXT\ for \SAS_LABEL\ is not in the lookup thesaurus
UPPERBOUND	Value of \VALUE_TEXT\ for \SAS_LABEL\ above maximum value of \UPPER_BOUND\

The discrepancy type codes are defined in a System reference codelist and cannot be modified. Table 17–6 describes the substitution variables.

Table 17–6   Substitution Variables for Univariate Discrepancy Messages

Name	Description
\ASSOC_ID\	ID number of the associated discrepancy.
\CRF_PAGE_NO\	Page number of the question in the Case Report Form.
\DATA_TYPE\	Data type of the question.
\DATE_TIME_FMT\	Date time format (for example, DD-Mon-YYYY)
\DCM_NAME\	DCM Name
\DCM_PROMPT\	Question prompt
\DCM_SUBSET\	DCM Subset number
\DECIMAL_PLACES\	Number of decimal places
\DESCRIPTOR1\	Descriptor for a repeating question group
\DVG_NAME\	DVG name
\LENGTH\	Length of question
\LOWER_BOUND\	Lower limit of a range of allowable values.
\REPEAT_SN\	Sequence number of the question in a repeating question group.
\SAS_LABEL\	SAS label

Table 17–6   (Cont.) Substitution Variables for Univariate Discrepancy Messages

Name	Description
\SAS_NAME\	SAS name
\UPPER_BOUND\	Upper limit of a range of allowable values.
\VALUE_TEXT\	Value of the response
\DEFAULT_PROMPT\	Default prompt for the question.
\DISCRETE_VALUES\	Allowable values as a comma-delimited list.

Using the News System

The News system provides a bulletin board method of communication with RDC Classic users.

For the Customizer

You can customize the content that RDC Classic users see in the News window. You can also add custom code to the PL/SQL functions that display that content.

Note that Oracle does not officially support this feature.

Figure 17–1   News Window
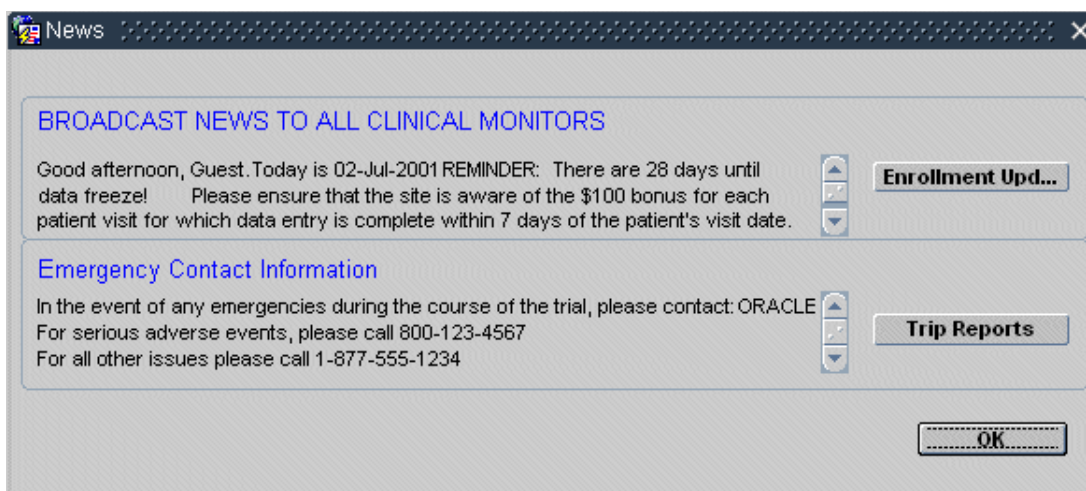
Maintaining the News Definitions

To customize the content of the News window, select the **Maintain News** node from the RDC Classic Administrator menu tree. The system displays the **News definition for RDC** window, which is depicted in Figure 17–2.

You can define one or two news items for the user to read on starting RDC Classic. The items can vary according to:

- The study

- A site within the study

- A user account id (for example, OPS$JSMITH)

- A user group role (for example, CRA)

- A time frame

- A priority (1 is highest, 5 lowest)

- Position on the screen (1 is upper, 2 lower)

Note that if you target a news item to one particular site, the only users who see it are those who access to only that site. The News window appears before users choose their site, if they have access to more than one.

For both news items, you can specify:

- A headline (shown in blue, refer to Figure 17–1) and body content

- A label for the command button

- The URL to access on clicking the button

Figure 17–2   News Definition Window

You can use the following substitution parameters within the News field:

Substitution Parameter	Description
\TIME OF DAY\	According to the Application Server clock
\SYSDATE\	System date of Application Server
\DAYS TO dd-Mon-yyyy\	Calendar days, not inclusive
\FIRST NAME\	User's given name, from Oracle Accounts form
\LAST NAME\	User's surname, from Oracle Accounts form
\NAME\	First name Last name, with initial caps

Working with the RDC_CLIENT Package

This package contains PL*SQL procedures that you can modify to customize various aspects of the RDC Classic system's behavior. Oracle requires that you modify only the code in the package body (file RDCpb_client.sql). Do not modify the package specification (file RDCps_client.sql).

Table 17–7 describes the contents of the RDC_CLIENT package.

Table 17–7   Contents of Package RDC_CLIENT

Name	Description
News	Configures the display of the RDC Classic News window
RdciAccess	Determines which RDCIs are displayed in the RDC Classic Spreadsheet
DeriveDocumentNumber	Derives an identification number from the key fields of the document. It can be used to differentiate between RDC Classic- and Oracle Clinical-created RDCIs based on document number
timeout_mins	Sets the timeout period for the display of password confirmation windows during the CRF approval process
get_approval_header	Populates the explanatory text that is displayed in the Approval Password confirmation windows that is presented during the CRF approval process
get_undo_header	Populates the explanatory text that is displayed in the Undo Approval Password confirmation window that is presented during the CRF undo approval process
lParse_news	Performs string substitution on text supplied in the News Definition form
getConfigurationModule Function	Retrieves the appropriate configuration name for the current user, based on the assignment parameters
get_batch_approval_header	Populates the explanatory text that is displayed in the Group Approval Password confirmation window, which is presented during the Approve CRFs process
get_batch_approval_undo_header	Populates the explanatory text that is displayed in the Group Undo Approval Password confirmation window, which is presented during the Undo Approved CRFs process

News Procedure

Purpose

This procedure populates the News window page of the RDC Classic main window.

Parameters

pStudy (in varchar2) — Name of the study to receive the news.

pSite (in varchar2) — Name of a site within the study.

pRole (in varchar2) — Name of a user group role (for example, DM, CRA).

pUser (in varchar2) — Userid of a person at the site.

pTitle1 (out varchar2) — Headline for first (upper) news item.

pNews1 (out varchar2) — Content of first news item.

pLabel1 (out varchar2) — Label for more information button for first news item.

pURL1 (out varchar2) — URL linked to by first button. If null, button is disabled.

pTitle2 (out varchar2) — Headline for second (lower) news item.

pNews2 (out varchar2) — Content of second news item.

pLabel2 (out varchar2) — Label for more information button for second news item

pURL2 (out varchar2) — URL linked to by second button. If null, button is disabled.

Return Value
Not applicable.

Comments
If you write your own code for this procedure, remember to check the parsing rules in local function lParse_news.

Related Functions
lParse_news Function

Logic as Shipped
Find records entered in the News definition form.

For each item,

If it's empty, set all outputs to null

else return title, label, and URL unchanged, and the parsed news content.

RdciAccess Function

Purpose
Sets batch loaded data hidden based on study site.

Parameters
pSite (in) — Name of the site name.

pMode (in) — Kind of environment: T for Test or P for Production.

pRdciId (in) — Identification number of the Received DCI.

pRdciStatus (in) — Status code of the Received DCI

pUpdateSitelist (in) — Comma-separated list of sites with "Update batch"

pBrowseSitelist (in) — Comma-separated list of sites with "Browse batch"

Return Value
U if current user has update access, B if browse access, N if no access.

Comments

In the RDC Classic main window, the users with update access see a disk icon on a white background. Double-clicking the icon opens the Data Entry window in update mode.

Users with browse access see a disk icon on a gray background. Double-clicking the icon opens the Data Entry window read-only.

Users with no access to batch loaded data also see the icon on a gray background, but double-clicking opens only the CRF header pane, not the whole Data Entry window.

Logic as Shipped

If RDCI status is BATCH LOADED and site is in UpdateSitelist

return U /* user may update data*/

else

if RDCI status is BATCH LOADED and site is in BrowseSitelist

return B /* user may browse data*/

else

return N /* user can not see data*/

DeriveDocumentNumber Function

Purpose

This function allows you to derive an identification number from the key fields of the document. Modify the code according to your business rules. For example, you could make the site number part of the document number.

Parameters

`study` (in varchar2) — The name of the study.

`clinical_study_id` (in number) — The ID number of the study.

`patient` (in varchar2) — The external identifier (code name) of the patient.

`patient_position_id` (in number) — The patient's position number.

`investigator` (in varchar2) — The code name of the investigator.

`investigator_id` (in number) — The ID number of the investigator.

`site` (in varchar2) — The code name of the site.

`site_id` (in number) — The ID number of the site.

`DCI` (in varchar2) — The name of the Data Collection Instrument.

`dci_id` (in number) — The ID number of the DCI.

`event` (in varchar2) — The name of the clinical planned event.

`clin_plan_eve_id` (in number) — The ID number of the clinical planned event.

`subevent` (in number) — The ID number of a subtype of the planned event.

`rxc_env_type` (in varchar2) — Environment type: T for Test or P for Production.

Return Value

The ID number as a varchar2. The default is a system-generated sequence number.

Comments

Serves the same purpose as the function of the same name in the Oracle Clinical package ocl_client. If you have customized code in that package, you can copy and paste it into rdc_client.

Logic as Shipped

Return "R" concatenated to the next value from sequence Received_dci_seq2.

timeout_mins Function

Purpose

Sets the limit on idle time between prompts for password confirmation for electronic signatures and source data verifications.

Parameter

`nStudy_id` (in) — Clinical study ID

Return Value

Integer number of minutes before password must be re-entered.

Comments

"Idle time" means no activity in the Approve or Verify tab, respectively. Activity in other tabs or in the main window does not reset the timer.

Logic as Shipped

Return 10.

get_approval_header Function

Purpose

This function populates the explanatory text that is displayed in the Approval Password Confirmation window, which is presented during when the user approves a CRF.

Parameter

`nStudy_id` (in) — Clinical study ID

Return Value

The text message that is displayed in the Password confirmation window.

Related Functions

get_undo_header Function, timeout_mins Function

Logic as Shipped

```
'IMPORTANT NOTE: By approving this CRF page, you confirm that
all data on the page is complete' || 'and correct. This approval
is equivalent to an electronic signature.'
```

get_undo_header Function

Purpose

This function populates the explanatory text that is displayed in the Undo Approval Password Confirmation window, which is presented when the user undoes approval of a CRF.

Parameter

`nStudy_id` (in) — Clinical study ID

Return Value

The text message that is displayed in the Password confirmation window.

Related Functions

get_approval_header Function, timeout_mins Function

Logic as Shipped

'"By pressing "Undo Approval", you are rescinding the electronic signature on this page.'"

lParse_news Function

This is a local function that is only found in the package body.

Purpose

Called by procedure News; performs string substitution on text supplied in the News Definition form (refer to Figure 17–2 on page 17-8).

Parameter

`pText` (in varchar2) — Content of a news item including substitution variables.

Return Value

News item with substitution variables replaced by substrings.

```
varchar2 is
vOut varchar2(500); nPos pls_integer; dEnd date; vName varchar2(70);
```

Comments

You can modify the business rules for each substitution variable (refer to the list on page 17-8). You can also create your own variables, if you create the business logic for them.

Related Functions

News Procedure

Logic as Shipped

Search input for each variable in turn.

If found, replace that substring according to business rules.

getConfigurationModule Function

Purpose

This function processes the assignment parameters in the RDC Classic Configurations settings to determine the configuration module of the current user.

Parameters

`Uname` (in varchar2)

`Study` (in varchar2)

`Userrole` (in varchar2)

Return Value

The configuration name for the current user.

Logic as Shipped

Four configurations are shipped as part of the installation: three use role-based assignment parameters and the one is the default for all other users. If the user's role is INV, CRA, or SITE, the corresponding configuration name is returned. If the user's role is not one of those, the Default configuration is returned.

get_batch_approval_header Function

Purpose

This function populates the explanatory text that is displayed in the Approval Password Confirmation window, which is presented when the user selects the **Group Activities**, then **Approve CRFs** menu command.

Parameter

`nStudy_id` (in) — Clinical study ID

Return Value

The text message that is displayed in the Password confirmation window for group approval actions.

Related Functions

get_batch_approval_undo_header function

Logic as shipped

"'IMPORTANT NOTE: By approving this group of CRFs, you confirm that all data are complete and correct. Each approval is equivalent to an electronic signature."

get_batch_approval_undo_header function

Purpose

This function populates the explanatory text that is displayed in the Password Confirmation window, which is presented when the user selects the **Group Activities**, then **UNDO Approved CRFs**.

Parameter

nStudy_id (in) — Clinical study ID

Return value

The text message that is displayed in the Password confirmation window for group undo approval actions.

Related Functions

get_batch_approval_header Function

Logic as Shipped

'IMPORTANT NOTE: By undoing the approval on this group of CRFs, you are rescinding the electronic signature on each CRF.'

18

RDC Classic Administration Tasks

The topics covered in this section are:

- Setting Study/Site Security Privileges on page 18-3
- Study Security Tasks on page 18-3
- RDC Classic Site Security Tasks on page 18-7
- Work with the RDC Classic Configurations Settings on page 18-9

Setting Study/Site Security Privileges

At the highest level, your organization's database administrators regulate access to data by granting program, project, study, and group membership privileges to people's database and Oracle Clinical accounts. Refer to the *Oracle Clinical Administrator's Guide* for information about enrolling users. If your Oracle Clinical account has study design (RXC_DES or RXC_DMGR) roles, and you have been granted Admin privileges to RDC Classic studies or sites, you can also regulate users' access to studies and sites.You can give a user full access to a program, project, or study in the Oracle Accounts form. Select **Admin**, then **Users**, and **Oracle Accounts**.

You use the Maintain Study Security and Maintain Site Security windows to setup and administer user privileges at the study and site level, respectively, in RDC Classic. You can access these windows either through Oracle Clinical or RDC Classic Administrator.

You must have RXC_ADMIN, RXC_SUPER, or RXC_SUPER_NOGL privileges to use the Study Security and Site Security options. Users' access to the Query Study/ Site Security and News options is determined by the study-level access set on their Oracle accounts.

> **Note:** All users who require access to RDC Classic must be granted the RDC_ACCESS and RXC_RDC roles.

Privileges in RDC Classic

The privilege levels in RDC Classic are slightly different from previous versions of Oracle Clinical, as shown in Table 18–1.

Table 18–1   Functional Privileges for RDC Classic

Name	Privilege Granted and Method of Use
APPROVE	Allows the user to electronically sign CRF pages. This privilege is required before the system enables the various GUI components that control the approval status of CRFs. This includes the buttons on the Approval task tab and the relevant commands in the Group Activities menu. **Note:** This privilege is granted at the site level only.
BROWSE	Read-only access to manually-entered patient data. Allows the user to view all data related to a CRF, including response data, discrepancy information and change histories, but does not allow the user to enter or update any data.
BRW_BATCH	Read-only access to batch-loaded data in the Data Entry window.
LOCK	Lock an individual or group of CRFs to prevent updates to its data.
UNLOCK	Select one or more users who are then given access to a single locked CRF. **Note:** This privilege is granted at the site level only.
UPDATE	Enter and update patient data. Allows initial entry and updates to manually-entered patient data and to update discrepancy records.
UPD_BATCH	Update batch loaded data in the Data Entry window.
UPD_DISCREP	Update entries in the discrepancy database. Allows user to create, change, and close discrepancies, in the Discrepancies tabs.
UPD_LOCK_OC	Assigns privileged update to the user. This privilege is specific to working in Oracle Clinical.
VERIFY	Electronically confirm that Source Data Verification has been performed. Enables the command button on the Verify tab.

Notes:

1. UPDATE includes UPD_DISCREP, but not UPD_BATCH or BRW_BATCH.
2. UPD_BATCH includes BRW_BATCH.
3. All other privileges imply at the BROWSE privilege. That is, it is only necessary to grant the Browse privilege to users who will have no other privilege. Also, note that BROWSE does not include BRW_BATCH.

Table 18–2 lists the sets of privileges typically granted to different roles. Note that certain privileges are granted at the Study level, while others are granted on a site-by-site basis.

Table 18–2   Sample Privilege Assignments

Job	Study Level	Site Level
Investigator	BROWSE	APPROVE
Site entry person	---	UPDATE, BRW_BATCH
CRA	BROWSE, BRW_BATCH	UPD_DISCREP, VERIFY
Data manager	BROWSE, BRW_BATCH, UPD_DISCREP	

Levels of Access in RDC Classic

Within RDC Classic, privileges at the site level take precedence over those granted at the study to which the site belongs. This gives you the flexibility to grant a user more extensive privileges at one site and still allow that user to access data at other sites within the same study.

For example, you could grant an investigator BROWSE access to a study and APPROVE access to a single site. The investigator would then be able to view the results from other sites, but approve only on patient data from the assigned site. Assuming, of course, that their Oracle Account has study access and all the sites are in that same study.

Public Access in RDC Classic

You can use the reserved word PUBLIC as a user name in the RDC Classic Study/Site Security forms, to indicate all users. However, be careful of using PUBLIC at the site level. If a user has one type of access at the study level and PUBLIC has different access at the site level, the site level access is used.

Admin Privilege

You can grant the Admin privilege for studies or sites to users with study design roles (RXC_DES and RXC_DMGR), after which they are able to use the Study/Site Security options for their assigned studies or sites only. This allows you to delegate some of the security tasks to someone else.

To grant the Admin privilege, check the Admin? box in either the Maintain access to studies or the Maintain access to sites within study form. The Admin privilege does not imply any access to patient data; you must also grant at least BROWSE access.

You may not grant the Admin privilege to the PUBLIC user name.

Study Security Tasks

This section describes the tasks that you can accomplish through the Maintain study security and Query study security buttons in the Administration menu for RDC window.

The topics in this section are:

- View Information for All Studies in a Database
- View the Studies and Privileges Assigned to a User
- Add a User to a Study
- Modify Study Privileges for an Existing User
- Determine the Sites in a Study
- Access Site Security from Study Security

View Information for All Studies in a Database

To view site, user, and privilege information for all studies in a database:

1. Use the RDC Administration Launch page to login to the Administration menu for RDC window.

2. In the RDC Administrator's window, click the Maintain Study Security button, which opens the Select Study window.

3. In the Select Study window, type the name of the study in which you want to work. Use the LOV, if necessary, to view a list of all studies in the database.

4. Click the OK button to select the study, which opens the Maintain Access to Studies window.

5. The Study drop-down list should display the name of the study you chose in Step 3. Click the drop-down list arrow to display all choices.

6. Scroll to the last entry in the list, which is blank, and select it. All of the studies are listed in the window.

View the Studies and Privileges Assigned to a User

To view the studies and privileges assigned to a user:

1. Use the RDC Administration Launch page to login to the Administration menu for RDC window.

2. In the RDC Administrator's window, click the Query Study Security button, which opens the "Query access to studies" window.

3. In the Select Study window, type the name of the study in which you want to work. Use the LOV, if necessary, to view a list of all studies in the database.

4. Click the OK button to select the study, which opens the Maintain Access to Studies window.

5. The Study drop-down list should display the name of the study you chose in Step 3. Click the drop-down list arrow to display all choices.

6. Scroll to the last entry in the list, which is blank, and select it. All of the studies are listed in the window.

7. In the User drop-down list, select the user name in which you are interested.

Add a User to a Study

To add a user to a study:

1. Use the RDC Administration Launch page to login to the Administration menu for RDC window.

2. In the RDC Administrator's window, click the Maintain Study Security button, which opens the Select Study window.

3. In the Select Study window, type the name of the study in which you want to work. Use the LOV, if necessary, to view a list of all studies in the database.

4. Click **OK** to select the study, which opens the Maintain Access to Studies window.

5. In the Maintain Access to Studies window, use the **User** drop-down list, located at the top of the window, to select the user name that you want to add to the study. This causes a single row to be displayed in the window.

6. Click the **Privileges** cell to open the "Privileges for *<newuser>*..." window.

7. Use these actions to select the privilege or privileges that you want to assign to the new user:

   ■ Click a privilege to highlight and select just that privilege

   ■ Ctrl-click in the same row to toggle a selection between "highlighted" and "not highlighted"

- Shift-click to select more than one row

> **Note:** You must assign at least **one** privilege to a user.

8. Click **OK** to save the privileges you chose for the new user.

9. Select the **Admin?** checkbox to give the new user Administrator privileges.

10. Click **Save** to create the new user. Focus moves to the first row in the window.

Modify Study Privileges for an Existing User

To change study privileges for an existing user:

1. Use the RDC Administration Launch page to login to the Administration menu for RDC window.

2. In the RDC Administrator's window, click the Maintain Study Security button, which opens the Select Study window.

3. In the Select Study window, type the name of the study in which you want to work. Use the LOV, if necessary, to view a list of all studies in the database.

4. Click **OK** to select the study, which opens the Maintain Access to Studies window.

5. Locate the user name for which you want to modify privileges.

6. In the Privileges column for the relevant user-row, click the **Privileges** cell. This action opens the "Privileges for *<newuser>*..." window.

7. Use these actions to change the set of privileges that are assigned to the user:

   - Click a privilege to highlight and select just that privilege

   - Ctrl-click in the same row to toggle a selection between "highlighted" and "not highlighted"

   - Shift-click to select more than one row

8. When the set of privileges is correct, click **OK** to save the changes and close the "Privileges for *<newuser>*..." window.

> **Note:** You must assign at least **one** privilege to a user.

9. In the Maintain Access to Studies window, click **Save** to save the changes to the database.

10. Click **Exit** to close the Maintain Access to Studies window.

Determine the Sites in a Study

To determine the names of the sites that are part of a study:

1. Use the RDC Administration Launch page to login to the Administration menu for RDC window.

2. In the RDC Administrator's window, click the Query Study Security button, which opens the Select Study window.

3. In the Select Study window, type the name of the study in which you want to work. Use the LOV, if necessary, to view a list of all studies in the database.

4. Click the OK button to select the study, which opens the Query Access to Studies window.

5. Click the Sites button, which opens a window that has three drop-down lists at the top, named: Study, Site, and User, respectively. The data rows list the names of the sites and the users who have access to each.

6. Use the Site drop-down list to select a site. This will then display all of the users for that site only in the data rows.

You can also use the "Study" drop-down list to change the study and review site and user information for the new study.

Access Site Security from Study Security

To access the site security features from the study security window:

1. In the Select Study window, type the name of the study in which you want to work. Use the LOV, if necessary, to view a list of all studies in the database.

2. Click the OK button to select the study, which opens the Maintain Access to Studies window.

3. Click the Sites button, which is adjacent to the Save and Exit buttons, to open a window that allows you to manage site security.

Setting Study Security for RDC Classic Users

The Maintain Access to Studies window provides administrators and superusers the capability to assign RDC Classic study privileges to a user, including assigning administrative privileges. Users with administrator privileges can in turn assign further users and grant them privileges for that study.

To assign study-level privileges, from the Admin menu, select Users, then select Study Security. If you have not yet selected a study, Oracle Clinical prompts you to do so now. Enter the study, or select one from the LOV, then click OK. The Maintain Access to Studies window opens.

Adding User Privileges for a Study

For each user for whom you want to specify study privileges, add a record in the Maintain Access to Studies window by clicking to the left of the next empty row. To specify the privileges for a user:

1. In the Study field, select the study for which you want to define a user's access. The Maintain Access to Studies window defaults this field to the currently selected study.

2. In the User field, select the user whose privileges you want to define.

3. Click in the Privileges field. The Privileges window opens, listing the privileges and their descriptions.

4. Select the privileges you want to add for this user by clicking in a single row to select a single privilege, or use Ctrl-click or Shift-click to select multiple privileges.

5. Click OK to close the Privileges window. Your choices populate the Privileges field of the selected row.

6. If you want to assign this user administrator privileges for this study, click Admin, then select the box. You cannot grant administrator privileges for the user PUBLIC.

7. Click Save.

RDC Classic Site Security Tasks

This section describes the tasks that you can accomplish using the Maintain site security and Query site security buttons on the Administration menu for RDC window. It includes the following topics:

- Add a User to a Site
- Modify Site Privileges for a User

Add a User to a Site

To add a user to a site:

1. Use the RDC Administration Launch page to login to the Administration menu for RDC window.

2. In the RDC Administrator's window, click the Maintain Site Security button, which opens the Select Study window.

3. In the Select Study window, type the name of the study in which you want to work. Use the LOV, if necessary, to view a list of all studies in the database.

4. Click the OK button to select the study, which opens the Maintain access to sites within study window.

5. In the "Maintain Access to Sites within study" window, use the Site drop-down list to select the site to which you want to add the user. When you select the site, the data rows display all users currently assigned to the site.

6. In the User drop-down list, select the user you want to add to the site. When you select the user, it is displayed in the User column of the first available data row.

7. In the new data row, click the Privileges field, which opens the Privileges window.

8. Use these actions to change the set of privileges that are assigned to the user:

- Click a privilege to highlight and select just that privilege
- Ctrl-click in the same row to toggle a selection between "highlighted" and "not highlighted"
- Shift-click to select more than one row

9. When the set of privileges is correct, click the OK button to save the changes and close the "Privileges for *<newuser>*..." window.

> **Note:** You must assign at least **one** privilege to a user.

10. In the "Maintain Access to Sites within study" window click the Save button to save the changes to the database.

Modify Site Privileges for a User

To change the privileges that are assigned to a user at a site:

1. In the RDC Administrator's window, click the Maintain Site Security button. The system displays the Select Study window.

2. In the Select Study window, use the LOV, to select the study in which you want to work.

3. Click the OK button. The system opens the Maintain Access to Sites withint Study window.

4. In the "Maintain Access to Sites within study" window, use the Site drop-down list to select the site to which you want to modify the privileges of the user. When you select the site, the data rows display all users currently assigned to the site.

5. In the User drop-down list, select the user name of the user whose privileges you want to modify. When you select the user, the system inserts it in the User column of the first available data row.

6. In the new data row, click the Privileges field. The system displays the Site Privileges window.

7. Use these actions to change the set of privileges that are assigned to the user:

   ■ Click a privilege to highlight and select just that privilege

   ■ Ctrl-click in the same row to toggle a selection between "highlighted" and "not highlighted"

   ■ Shift-click to select more than one row

   Note: You must assign at least **one** privilege to a user.

8. When the set of privileges is correct, click the OK button to save the changes and close the "Privileges for <*newuser*>..." window.

9. In the Maintain Access to Sites within Study window, click the Save button to save the changes to the database.

Setting Site Security

You can assign privileges to users at specific sites within a study. From the Admin menu, select Users, and then select Site Security. If you have not yet selected a study, the system prompts you to do so now. Enter the study, or select one from the LOV, and click OK. The Maintain Access to Sites Within Study window opens.

Adding User Privileges for a Site Within a Study

From the Maintain Access to Sites Within Study window, to specify site privileges for a user:

1. The currently selected study appears in the Study window, in the upper left part of the window. If you want to define the privileges for a site in a different study, select a new study from the selections in this field.

2. Select a site in either of the following ways:

   ■ Activate a new record row by clicking in any of the fields of the row. A blue rectangle appears. Select the site from the Site field in that row.

   ■ Click to the left of the row you want to modify, and select the site from the Site field in the upper part of the window.

3. In the User field, select the user whose privileges you want to define.

4. Click in the Privileges field. The Privileges window opens, listing the privileges and their descriptions.

5. Select the privileges you want to add for this user.

   ■ Click a single row to select a single privilege.

   ■ Ctrl-click individual rows.

   ■ To select a group of privileges that are contiguous in the list:

   a. Click to select a privilege at either end of the group.

   b. Shift-click the privilege at the other end of the group.

6. Click OK to close the Privileges window. Your choices populate the Privileges field of the selected row.

7. If you want to assign a user administrator privileges for this site, click the Admin box. (You cannot grant administrator privileges for the user PUBLIC.)

8. Click Save.

Remove all Site-level Privileges for a User

Because site-level privileges have precedence over study-level, it may be necessary to remove all site-level privileges for a user who requires access to many, or all, sites in a study. In this case, you have the alternative to apply the same set of privileges to all sites the user must access or to remove access at the site-level and ensure the study privileges are set appropriately, which may be more expedient.

This is particularly applicable when the user does not require approve or unlock privilege, since these are only administered at the site-level.

When a user is assigned privileges for a particular site, the system does not permit you to simply clear all of the rows in the Site Privileges window. Rather, you must use the Record menu to remove the row. To do this:

1. In the Maintain Access to Sites within Study window, select the row that corresponds to the site and the user with which you want to work.

2. Select the **Record**, then **Delete** menu command. The system removes the row from the window.

Work with the RDC Classic Configurations Settings

The RDC Administration Menu window provides a tool that allows you to manage RDC Workspace for all users in a given database. You use the RDC Configurations settings to setup configurations, which determine how an RDC session starts for a set of users. The settings that comprise each configuration allow you to change GUI components, such as altering the labels on task tabs; and remove components, such as the Spreadsheet view drop-down list. In addition, you use the Configurator to define the initial Preferences window settings, such as whether or not users can access the Preferences window during an RDC session.

The RDC Configurations settings allows you to access, modify, copy, and generate new configurations. Each configuration consists of twenty-five settings that you can change. In addition, it provides three parameters to discretely specify the set of users to which each configuration is applicable. Using the applicability parameters in conjunction with the settings that are available allows you provide granular control over the configurations that are available to RDC Classic users in various user groups and studies.

Discussion

An RDC configuration consists of three primary components:

- A configuration name
- A set of assignment parameters
- A set of configuration settings

These components are inter-related, such that:

- There may be more than one set of assignment parameters associated with a given configuration name, however:

  - For each set of assignment parameters, a distinct listing for that configuration name must be present in the list

  - When there are multiple instances of a configuration name in the list, each must have associated with it a unique set of assignment parameters.

  - When you alter the configuration settings for a configuration name, the settings for all other like-named configurations also change

On installation, Oracle Clinical/RDC Classic provides a set of four configurations:

- RDC CONFIGURATION — the default settings that apply to all users
- RDC CONFIGURATION CRA — settings that apply to the CRA role
- RDC CONFIGURATION INV — settings that apply to the INV role
- RDC CONFIGURATION SITE — settings that apply to the SITE role

You can use these configurations as-is, you can modify them, or you can use them as the basis to generate new configurations.

Configuration Name

Each configuration is defined by a set of twenty-five configuration settings and a unique configuration name. A configuration name can be listed more than once in the set of configurations, as long as each instance of the name is associated with an assignment parameters that is unique among the like-named configurations.

For example, it is permissible to have five configurations that are named RDC CONFIGURATION CRA, as long as the assignment parameters for each are different. For example, if the assignment parameters were as follows:

Config #	User	Study	Role
1	%	%	CRA
2	%	STUDY03	%
3	%	STUDY11	%
4	OPS$JSMITH	%	%
5	OPS$JDOE	%	%

The system would assign the RDC CONFIGURATION CRA under the following circumstances:

- All users assigned the CRA role
- All users, regardless of role, who access STUDY03 or STUDY11

■ Users jsmith and jdoe, regardless of assigned role or the study that is accessed.

Assignment Parameters

There are three assignment parameters that the system uses to apply the correct configuration when a user logs into RDC Classic.

■ User Name

■ Study Name

■ User Role

These are listed in order of decreasing precedence; that is, study takes precedence over role and user takes precedence over study and role. When a user initiates an RDC Classic session, the system parses the assignment parameters for all configuration names, first by User Name, then Study Name, and finally by User Role, until it matches one of the parameters to the user.

For example, if one configuration, RDC CONFIGURATION STUDY03, is set for all users who access Study03, and another configuration, RDC CONFIGURATION JDOE, is set for the user, jdoe, when jdoe accesses Study3, the JDOE configuration takes precedence because it corresponds at the user name level, and the system loads that configuration. If any other user starts a session and accesses study3, the system loads RDC CONFIGURATION STUDY03.

In a similar manner, the four configurations that are installed with Oracle Clinical are invoked based on the role associated with each user. If the user is part of the CRA, INV, or SITE user groups, the associated configuration is used. If the user is not associated with one of these groups, the system uses the default, RDC CONFIGURATION.

The default value for each assignment parameter is the percent sign (the wildcard), which includes "ALL". For example, the percent sign in the User Role for the default RDC CONFIGURATION includes all user groups. When you place focus in a given assignment parameter field, the system activates an LOV button, which gives you access to the set of values that are valid for that field.

Configuration Management Tasks

This section includes instructions to complete the following tasks:

■ Create a New Configuration

■ Modify the Assignment Parameters for a Configuration

■ Create a Copy of an Existing Configuration

■ Modify Configuration Settings

■ Delete a Configuration

Create a New Configuration

When you create a new configuration, you base it on an existing configuration. However, you give it a unique configuration name and, once it is created, you can modify the assignment parameters and the configuration settings as necessary. The new configuration is independent of the configuration upon which it is based.

To create a new configuration through the RDC Configurations settings:

1. In the RDC Administration tree, choose **Maintain**, then **Configurations**. The system opens the RDC Configurations window.

2. Click the Create button. The system opens the Create New Configuration window.
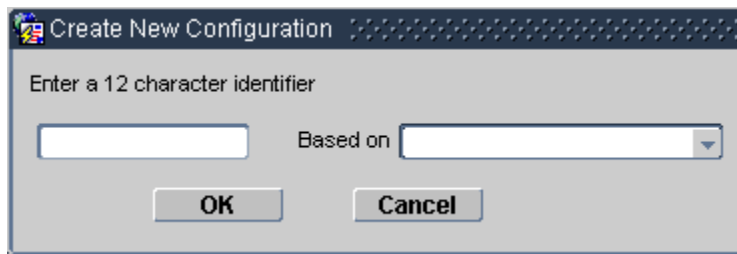
3. In the Create New Configuration window:

    a. Type a unique text string to identify the configuration; use up to 12 characters.

    b. Use the "Based on" drop-down list to select an existing configuration upon which you want to base the new configuration (leave blank for the default configuration).

4. Click the OK button. The system displays a confirmation window.

5. Click the Yes button to confirm creation of the new configuration. The system inserts the new configuration in the Configuration Name list.

This procedure creates a new reference codelist that is named "RDC CONFIGURATION *<identifier>*", where *<identifier>* is the unique text string you typed in Step 3a.

Refer to "Modify Configuration Settings" on page 18-13 for the procedure to change the settings for the new configuration.

Modify the Assignment Parameters for a Configuration

When you create a new configuration, the values for all the settings are the same as the configuration on which it is based, however, all of the assignment parameters are set to default values, that is the percent sign, or "ALL".

To change the assignment parameters:

1. In the RDC Administration tree, choose **Maintain**, then **Configurations**. The system opens the RDC Configurations window.

2. Place focus in the row of the configuration name with which you want to work.

3. Select the Assignment Parameter field that you want to modify. The system activates the LOV button for the field.

4. Click the LOV button or press the F9 key. The system opens the relevant List of Values window.

5. Select an appropriate parameter.

6. Click the OK button. The system inserts the selected value in the parameter field.

7. Save pending changes.

Create a Copy of an Existing Configuration

To create a copy of an existing configuration, at least one of the assignment parameters associated with the existing configuration must be set to a non-default value.

To create a copy of an existing configuration:

1. In the RDC Administration tree, choose **Maintain**, then **Configurations**. The system opens the RDC Configurations window.

2. Click **New**. The system opens the New Assignment Parameters window.

3. In the New Assignment Parameters window, select the existing configuration for which you want to create a copy.

4. Click **OK**. The system displays a confirmation window.

5. Click **Yes** to confirm creation of the configuration. The system inserts the new configuration in the Configuration Name list with the same name as the original configuration and all assignment parameters set to default values.

6. Save pending changes.

Refer to "Modify the Assignment Parameters for a Configuration" on page 18-12.

Modify Configuration Settings

To change the configuration settings:

1. In the RDC Administration tree, choose **Maintain**, then **Configurations**. The system opens the RDC Configurations window.

2. Place focus in the row that contains the configuration you want to change.

3. In the Configuration Settings, locate each setting you want to change and modify it to a new value.

4. When the set of configurations is acceptable, save pending changes.

When you change the settings of a configuration, the change affects all users that fall under all of the parameter assignments that exist for that configuration.

Delete a Configuration

To delete a configuration:

1. In the RDC Administration tree, choose **Maintain**, then **Configurations**. The system opens the RDC Configurations window.

2. Place focus in the row that contains the configuration you want to delete.

3. Click **Delete**. The system displays a confirmation window.

4. Click **Yes**. The system automatically saves pending changes.

RDC Classic Configurations Settings

This section describes the following settings that define RDC Classic configurations:

- Hide Task Tabs
- Task Tab Header Text
- Hide the Preferences Menu Choice Y/N
- Hide Group Activities Menu Choice Y/N
- Hide Surround Type Drop-down
- CRF Progression Settings
- Default Search Option
- Oracle Clinical Accessibility Rules

Hide Task Tabs

These settings control five of the task tabs that are available in RDC Classic:

- Hide the Discrepancy Tab from the user Y/N

- Hide the Approval Tab from the user Y/N

- Hide the Verify Tab from the user Y/N

- Hide the Audit Tab from the user Y/N

- Hide the Links Tab from the user Y/N

The default value for each parameter is "N", which means that the task tab is not hidden. Set the parameter to "Y" if you do not want the system to display the task tab.

Task Tab Header Text

These settings determine the label that the system uses for each task tab. When the value for a parameter is null, the system-defined value is used. If the value is not null, it is used to replace the default label. These settings are:

- Label for the Summary Tab - Default to Summary

- Label for the Discrepancies Tab - Default to Discrepancies

- Label for the Verify Tab - Default to Verify

- Label for the Approval Tab - Default to Approval

- Label for the Audit Trail Tab - Default to Audit Trail

- Label for the Links Tab - Default to Links

Hide the Preferences Menu Choice Y/N

This setting determines if the Preferences menu command is present in the Edit menu in the RDC Classic menu bar. The default value is "N", which means that the menu command is present in the Edit menu.

If you set the value to "Y", the user cannot access the Preferences window and so cannot modify any settings it controls.

Hide Group Activities Menu Choice Y/N

This setting determines if the Group Activities menu item is displayed on the RDC Classic menu bar. The default value is "N", which means that the menu is displayed in the Workspace and its menu commands are accessible to the user, subject to the requisite privileges.

If you set the value to "Y", the user cannot access any Group Activity menu command.

Hide Surround Type Drop-down

This setting determines if the Spreadsheet View drop-down list box is present in the RDC Spreadsheet. The default value is "Y", which means that the drop-down list box is not present in the Spreadsheet and the user cannot change the default Spreadsheet view, which is the Visit view.

If you set the value to "N", the user can access the component and can change the Spreadsheet view to its other value, which are Study and Phase.

CRF Progression Settings

These settings control how RDC Classic automates CRF-to-CRF navigation. Four settings are linked to the Data Entry tab settings in the RDC Preferences window:

- CRF progression: After planned CRF

- CRF progression: After verification or approval

- CRF progression: Skip CRFs with discrepancies

- CRF progression CRF direction

Three of the parameters, which correspond to check boxes in the Preferences window, accept either a "Y," for yes, or a "N," for no. The "Y" causes the system to select the check box, while a "N" causes the system to clear the check box.

The fourth parameter, "CRF direction," has three valid choices, which each correspond to a radio button in the top portion of the CRF Progression section. The acceptable values are:

- By Patient

- Within Tab

- By Page

Default Search Option

This setting controls the default data selection tool that is available in a session. The choices are either:

- SEARCH – the system uses the Search window as the default; the Activity List window is not available.

- ACTIVITY – the system uses the Activity List window as the default, however the Search window is also available

This parameter should only be set to "ACTIVITY" if you ensure the Activity List is suitably configured for use.

Oracle Clinical Accessibility Rules

This setting controls the rules that RDC Classic uses to process CRFs with regard to auditing. The default value, which is "N", is to use RDC Classic accessibility rules.

Default Settings

The RDC Classic installation includes four configurations. The values of settings for each configuration are listed codelists. Refer to the following topics in the *Oracle Clinical Administrator's Guide*:

- RDC CONFIGURATION – the default settings that apply to all users

- RDC CONFIGURATION CRA – settings that apply to the CRA role

- RDC CONFIGURATION INV – settings that apply to the INV role

- RDC CONFIGURATION SITE – settings that apply to the SITE role

Work with the RDC Classic Configurations Settings

19

Managing the Activity List

The Activity List window is a standard RDC Classic feature that allows users to load a workset in the RDC Spreadsheet based on the selection of a task, rather than search criteria defined in the Search window. When it is present in a session, the Activity List serves as a more intuitive alternative to the Search window that allows users to begin working on tasks immediately.

Discussion

Administration of the Activity List includes configuring activities and enabling RDC Classic sessions to use the Activity List window.

Configure the Activity List for Use in RDC Classic Sessions

You use the "Default Search Option" setting in the RDC Classic Configurations Settings to specify that the Activity List window is present when a user starts an RDC Classic session.

- When Default Search Option is set to ACTIVITY, all sessions associated with the configuration use the Activity List window as the default tool to specify worksets. Users have the option to access the Search window, either from the Activity List window or the File menu.

- When the parameter is set to SEARCH, all sessions associated with the configuration use the Search window to specify worksets and the Activity List window is not accessible.

Interaction with the Summary Task Tab

When the Activity List window is open, it is positioned just above the Summary task tab in the RDC Workspace. This allows the user to view information that is displayed in the task tab.

The Summary task tab displays information that tracks with the scope of the node that is currently selected in the Navigation pane of the Activity List window. Three summary views are available, one for each scope:

- Study

- Site

- Patient

Refer to "Summary Task Tab" on page 13-2 for details.

Default Activities

When you install RDC Classic, there are a set of activities that are automatically available for use in the Activity List window. In most cases, you will use these as the basis to develop a custom list of activities.

■ Study

1. **Review All <xx> Active discrepancies** – if there is at least one CRF in the study with an active discrepancy for the current user

2. **Review All <xx> Other discrepancies** – if there is at least one CRF in the study with an other discrepancy (and no active discrepancies) for the current user

3. **Show all data for Study <study_name>** – if there is at least one CRF entered for a patient in the study

■ Site

1. **Review All <xx> Active discrepancies for Site <site_name>** – if there is at least one CRF in the site with an active discrepancy for the current user

2. **Review All <xx> Other discrepancies <site_name>** – if there is at least one CRF in the site with an other discrepancy (and no active discrepancies) for the current user

3. **Show all data for Site <site_name>** – if there is at least one CRF entered for a patient in the site

■ Patient

1. **Show all Data for Patient <patient_id>** - if there is at least one CRF entered for the patient

2. **Begin new Data Entry for Patient <patient_id>** - if no CRFs have been entered for the patient.

Activity List Structure

This section consists of the following topics:

Background Structure of the Activity List Window

The Activity List consists of two major modules, one for the Navigation pane and one for the Task pane. This section consists of the following topics:

■ Navigation Pane

■ Task Pane

■ Link Type

■ Activity Conditions

■ Activity Evaluation

Figure 19–1 Example of the Activity List Window
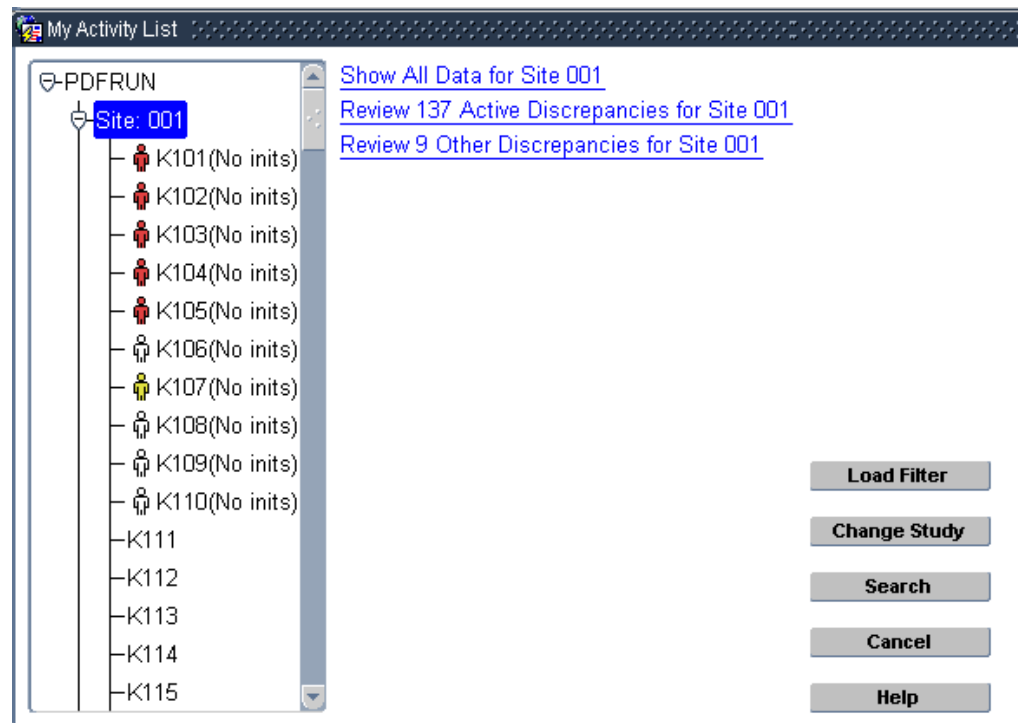
Navigation Pane

The Navigation pane uses a hierarchical tree structure with three levels of organization. Each level corresponds to a scope. Each instance of a level that is displayed in the Navigation pane is referred to as a node.

Table 19–1   Scope, Number of Nodes, and Explanation

Scope	Number of Nodes	Explanation
Study	One	Only one study can be accessed at a time.
Site	1 to ?	Based on the security settings specified for the user. This must be at least one, but is only limited by the number sites defined in the study.
Patient	1 to ?	Based on the number of patient numbers that are assigned to the site.

Task Pane

The Task pane lists the activities that are available to the user for the currently selected node. When a user clicks an activity, the system alters the search criteria appropriately, queries the database for the search criteria and loads the result into the RDC Spreadsheet as the workset.

Initially, the Study node is active and the Task pane lists the activities associated with that scope and user role. As the user selects nodes in other scopes, the list of activities in the Task pane changes to display the set of activities that are associated with the scope, the specific node, and the role of the user.

When the Activity List window opens as part of session initiation, the scope is set to Study and all of the activities that are available to the user's role at that scope are listed

in the Task pane. As the user changes the scope by selecting other nodes, the list of activities in the Task pane changes accordingly.

Link Type

Each activity is a pre-defined short cut that is displayed as a hyperlink in the Task pane. There are two types of links:

- P (Procedure) — Queries all patients/CRFs within the current node that meet the criteria set out in the activity.

- U (URL) — Launches a browser instance and navigates to the URL associated with the activity.

Activity Conditions

Each activity can have certain conditions placed on it. These conditions can define when the system displays the activity in the Task pane, even when its associated scope is active. If a condition is defined for an activity, the condition must evaluate to "TRUE" in order for the activity to be included in the displayed set of activities. If there are no conditions defined for an activity, the activity is always displayed for its specific scope and user roles.

Activity Evaluation

When the user selects a node, the system evaluates each activity and displays those that are appropriate.

System Processing

The RDC_ACTIVITY_LIST View uses the values in the RDC_ACTIVITIES Table to create a URL object (object type of RDC_ACTIVITY_T) that contains the text of the hyperlink and the code that is executed when the user selects the activity. The text in this object is previously parsed and includes the values for any TAGS included in the activity text.

The primary code that processes this object resides in a function called, RDC_USER_ACTIVITY_TAGS.getActivities. This function does the following:

- Creates the activity text by parsing the TEXT value to find, evaluate, and substitute appropriate strings for tags that occur within the text; for example, "%OPEN_DISCREPS% may evaluate to "23", which this function inserts in the activity text

- Determines if, based on the result of the display expression (the DISPLAY_EXPR column), the activity should be included in the Task pane; if the field evaluates to FALSE, the activity is not included

- If the value of ACTIVITY_TYPE is "U" (for URL), then parse the ACTIVITY_EXEC field in case the URL contains a TAG; for example, the URL may contain "%CURR_STUDY%", which returns the name of the current study and inserts it in the URL

Based on the above processing, if the activity can be included in the list of activities, it is added to the object table RDC_ACTIVITY_LIST_T. The object view, RDC_ACTIVITY_LIST, is based on this object table.

When all activities are parsed and placed into the object table RDC_ACTIVITY_LIST_T, the RDC_USER_ACTIVITY_LIST View presents all applicable activities in the Task pane.

Example of Activity List Processing

An example is presented here to illustrate the system processing entailed in a single activity.

Assumptions The following conditions are assumed for this example:

- The user is part of the CRA user group.

- The user has access to the HANDSON study and sites 001 and 002.

- The scope of the activity is set to XSITE, that is, across sites.

- The scope in the Navigation pane is STUDY, which simulates initial login and session initiation.

- There are active discrepancies associated with CRFs in site 001, but not in site 002.

Note that because the scope is XSITE, the system will process each activity for every accessible site.

RDC_ACTIVITIES Table Record Table 19–2 describes the record in the RDC_ACTIVITIES table for this example.

Table 19–2   Columns and Field Values for Example Activity

Column	Value
ACTIVITY_ID	2000
USER_ROLE	CRA
TEXT	Review %OPEN_DISCREPS% active discrepancies for site %P_SITE%
ACTIVITY_SCOPE	XSITE
ACTIVITY_TYPE	P
ACTIVITY_EXEC	rdc_activity_std.process_open_discreps
DISPLAY_EXPR	%OPEN_DISCREPS%>0

Processing The system processes the relevant record in the RDC_ACTIVITIES table in the following manner:

1. The system populates the RDC_ACTIVITY_LIST object view. The bulk of the processing occurs through the RDC_USER_ACTIVITY_TAGS.getActivities function.

2. For each activity listed in the RDC_ACTIVITIES table, the function getActivities(ID, SCOPE, TEXT, TYPE, EXEC, DISPL_EXPR) is processed. The record that is listed in Table 19–2, " Columns and Field Values for Example Activity" is processed:

   getActivities(2000, ''XSITE', 'Review %OPEN_DISCREPS% active discrepancies for site %P_SITE%', 'P', 'rdc_activity_std.process_open_discreps', '%OPEN_DISCREPS%>0');

3. The getActivities function calls a local procedure called lSetLink for each site to which the user has access. This occurs because the value of Activity_Scope is 'XSITE'.

   The conditions of the example generate two lSetLink calls:

```
lSetLink('Review %OPEN_DISCREPS% active discrepancies for
site %P_SITE%', 'rdc_activity_std.process_open_discreps',
'001','P', '%OPEN_DISCREPS%>0', 1, myList);
```
and
```
lSetLink('Review %OPEN_DISCREPS% active discrepancies for
site %P_SITE%', 'rdc_activity_std.process_open_discreps',
'002','P', '%OPEN_DISCREPS%>0', 2, myList);
```

where '1' in the first call and '2' in the second are unique index numbers for the object table and 'myList' is an RDC_ACTIVITY_LIST_T object table used to hold the URL_INFO information that is used in the RDC_ACTIVITY_LIST view.

4. The lSetLink procedure calls a function called 'parseActivity', which evaluates the text "Review %OPEN_DISCREPS% active discrepancies for site %P_SITE%".

Also, if the ACTIVITY_TYPE is 'U', the function evaluates the ACTIVITY_EXEC value, because the URL is allowed to contain one or TAGS. However, in the example, ACTIVITY_TYPE is 'P', so the parseActivity function evaluates TEXT value.

The two calls to parseActivity are:

parseActivity('Review %OPEN_DISCREPS% active discrepancies for site %P_SITE%', '%OPEN_DISCREPS%>0', '001');
and
parseActivity('Review %OPEN_DISCREPS% active discrepancies for site %P_SITE%', '%OPEN_DISCREPS%>0', '002');

Processing the parseActivity function The parseActivity function evaluates the first call, which is displayed in Step 4, above, in the following manner:

1. Locates and evaluates TAGS, using the RDC_ACTIVITY_TAGS table to identify what should be executed or substituted for the tag:

   a. %OPEN_DISCREPS% – this tag executes RDC_ACTIVITY_STD.OPEN_DISCREPS; the TAG Type is 'F' (function). The function is executed and evaluates to '3'.

   %OPEN_DISCREPS% = 3

   b. %P_SITE% – this tag substitutes for SITE; the TAG Type is 'P' (parameter substitution). The parameter evaluates to '001'

   %P_SITES% = 001

2. Transforms the TEXT value with the TAG substitution so that it is:

   'Review 3 active discrepancies for site 001.'

3. Decides if the activity should be displayed in the Task pane. If the DISPLAY_EXPR is null or evaluates to TRUE, then the activity is displayed.

   The value of DISPLAY_EXPR is ('%OPEN_DISCREPS%>0'). Because it is not null, it must be evaluated.

   The value of %OPEN_DISCREPS% was found to be '3'. So the expression in DISPLAY_EXPR is '3 > 0'.

4. Because the DISPLAY_EXPR evaluates to TRUE, the process adds the item to the object table.

The second call is evaluated in a similar manner, however, in the case of site 002, the RDC_ACTIVITY_STD.OPEN_DISCREPS evaluates to '0' (that is, there are no active discrepancies for site 002), which causes the DISPLAY_EXPR to become '0 > 0', which is FALSE. Therefore, the site 002 activity is not added to the object table.

URL_INFO table status Based on the processing of the parseActivity function, one activity has been added to the object view. The URL_INFO is:

- Text = Review 3 active discrepancies for site 001

- Activity_Exec = RDC_ACTIVITY_STD.PROCESS_OPEN_DISCREPS

- Site = 001

RDC_USER_ACTIVITY_VIEW status A query of the RDC_USER_ACTIVITY_LIST view returns the following.

Table 19–3   RDC_USER_ACTIVITY_VIEW Query

Column	Value
ACTIVITY_ID	2000
USER_ROLE	CRA
ACTIVITY_TYPE	P
ACTIVITY_SCOPE	XSITE
TEXT	Review 3 active discrepancies for site 001
ACTIVITY_EXEC	rdc_activity_std.process_open_discreps
SITE	001

Processing Activities

When the user selects an activity that is displayed in the Task pane, the initial system response is based on the ACTIVITY_TYPE.

URL Activities

If the ACTIVITY_TYPE is 'U', which indicates the activity is a URL, the system does the following:

```
Web.show_document( {value in Activity_Exec column} )
```

For example:

```
Web.show_document(1014)
```

where **1014** is the study ID.

This causes the client computer to start the default Internet browser and navigate to the specified URL.

Procedure Activities

If the ACTIVITY_TYPE is 'P', which indicates the activity is a procedure, the system response is more involved, as outlined in the following steps:

1. `RDC_USER_ACTIVITY_PROCESS.CLEAR_STACK` – this clears the memory stack that the system uses to populate with the activity query.

2. `SET_LIST.RESET_ALL` – this is an RDC Classic Form Program unit that resets all of the values in the SEL block, which comprises all of the Search window fields.

    a. RDC_ACTIVITY_STD.PROCESS_OPEN_DISCREPS

        – add_to_stack('SITE','001'); – adds SITE to the memory stack

        – add_to_stack('DISCREP_STATUS','ACTIVE'); – adds DISCREP_STATUS to the memory stack

    b. UTILS.PROCESS_WIZARD_SEARCH – retrieves the search parameters from the stack, sets each parameter in the Search window and executes the search, which is analogous to clicking the OK button in the Search window:

        – sets SITE = 001

        – sets DISCREP_STATUS=ACTIVE

    This loads the Search window with the appropriate parameters and executes UTILS.PROCESS_SEL_OK. This is the same processing that executes when a user manually changes Search window parameters.

The result of this processing is that the workset that contains the CRFs with active discrepancies from site 001 is displayed in the RDC Spreadsheet.

Tables Associated with the Activity List Window

This section describes the tables that are associated with the Activity List window.

RDC_ACTIVITIES Table

Table 19–4 lists the column names and descriptions of values for the RDC_ACTIVITIES table. This table contains the setup information for all the activities that are defined in the system.

Table 19–4   Columns in the RDC_ACTIVITIES Table

Column Name	Description of Value
ACTIVITY_ID	A unique key for the activity.
USER_ROLE	Role names for which the Activity will be displayed. Each user logging into RDC Classic has one role associated with them. For example, when a Data Manager (role DM) logs into the system, activities with the column USER_ROLE = '%' or the column USER_ROLE contains the DM role will be displayed. The Activity may still not display if it does not PASS a criteria setup in the DISPLAY_EXPR column. Please read the notes on that column to understand how this criterion is used.
	This column can be one of three different role values (example value follow each in parentheses):
	1. single role (DM)
	2. multiple roles (DM, CRA, SITE)
	3. all roles (%)
TEXT	This value consists of the text wording of the activity in the English version of RDC Classic. It may contain TAGS that provide substitution variables. This value is always in English.

Table 19–4   (Cont.) Columns in the RDC_ACTIVITIES Table

Column Name	Description of Value
ACTIVITY_SCOPE	The scope in which the activity is eligible for display in the Task pane. There are for possible values: 1. STUDY 2. XSITE 3. SITE 4. PATIENT
ACTIVITY_TYPE	This value is either: ■ "P", for procedure, or ■ "U", for URL.
ACTIVITY_EXEC	This value is either the procedure name, for ACTIVITY_TYPE "P", or the actual URL, for ACTIVITY_TYPE "U".
DISPLAY_EXPR	This value can either be null or it may be the display expression associated with the activity. If the value is not null, the expression must evaluate to TRUE in order for the system to include the activity in the Task pane.

TEXT The value in each TEXT column record is the actual wording that is presented to the user as an activity and any TAGs that allow for variable substitution, for example, Site Number, number of Active Discreps for a site, etc. TAGs are denoted with % signs, for example; %OPEN_DISCREPS%. When a TAG is found in the TEXT, the process locates the TAG in the RDC_ACTIVITY_TAGS Table and runs the code named in the FUNCTION_NAME of this table to produce the variable substitution for the TAG. A complete example may be as follows:

TEXT column field = Review %OPEN_DISCREPS% active discrepancies for site %P_SITE%

Activity shown - "Review 3 active discrepancies for site 001"

ACTIVITY_SCOPE Currently, there are four SCOPE levels:

1. STUDY is the highest level and will reflect activities for all sites for which the user has access.

2. XSITE also displays activities at the STUDY scope level BUT will break up the activities for each SITE for which the user has access.

3. SITE reflects activities for the current SITE selected in the Navigation Pane.·

4. PATIENT reflects activities for the current PATIENT selected in the Navigation Tree.Scope levels are based on the users selection within the Navigation Tree.

Initially, the SCOPE is set to STUDY upon entering the Activity List.

ACTIVITY_TYPE There are two types of Activities:·

1. P for procedure, meaning the activity will start a procedure within the database named in the ACTIVITY_EXEC column of this table. For example; rdc_activity_std.process_open_discreps·

2. U for URL, indicates that the activity will initiate a new browser session and navigate to the URL found in the ACTIVITY_EXEC column of this table. ·

   For example; http://opa-apps26.us.oracle.com/v_rsdir/study%CURR_STUDY%.htm

Note: The code that can be executed for activity type U can also contain TAGS. The procedure substitutes a value for each TAG during the creation of the activity. For example, the URL above, for a study named 'HANDSON', would be processed as: http://opa-apps26.us.oracle.com/v_rsdir/studyHANDSON.htm

ACTIVITY_EXEC This column holds the Procedure name or URL, depending on value of the ACTIVITY_TYPE = 'P' or 'U', respectively. For example: P = rdc_activity_std.process_open_discreps; U = http://opaapp.us.ora.com/v_rsdir/study%CURR_STUDY%.htm

DISPLAY_EXPR This column contains the final display criteria for an activity. After making sure that the activity is at the correct scope level, user role matches the activity role, the DISPLAY_EXPR, possibly, will determine whether the activity is displayed or not.If a condition is present in this column then it must evaluate to TRUE to be displayed. It is mainly used to suppress activities that would yield a NO DATA FOUND error. For example, if we have an activity like: Review %OPEN_DISCREPS% active discrepancies for site %P_SITE% then a valid activity might look like: Review 0 active discrepancies for site 002. This will cause the search to retrieve NO CRFs. A valid criteria to place on this activity would be to display this activity only when the number of active discrepancies > 0, i.e. %OPEN_DISCREPS% > 0.

RDC_ACTIVITY_TAGS Table

This table contains the tags that are defined in the system and the execution module (function name) that evaluates the tag. Table 19–5 describes the column names and values for the RDC_ACTIVITY_TAGS table.

Table 19–5   Columns in the RDC_ACTIVITY_TAGS Table

Column Name	Description of Value
ACTIVITY_TAG	This value contains the TAG that can be found in the RDC_ACTIVITIES Table columns: TEXT, ACTIVITY_EXEC and DISPLAY_EXPR. When each of these columns is parsed, if a TAG is found, the process searches this column to find the TAG match so that it can identify the code or substitution variable to use to display in place of the TAG. If a match is found it processes the expression found in the FUNCTION_NAME column.
FUNCTION_TYPE	This value describes whether the tag is associated with a function or a parameter substitution.
FUNCTION_NAME	This value is either the name of the substitution variable or the name of the function in the system.

ACTIVITY_TAG Contains the TAG that can be found in the RDC_ACTIVITIES table columns: TEXT, ACTIVITY_EXEC and DISPLAY_EXPR.

The system parses each of these fields and if a TAG is identified, the process searches this field to locate the TAG match so the system can identify the code or substitution variable to use to display in place of the TAG. When a match is found, the system processes the expression found in the FUNCTION_NAME column.

FUNCTION_TYPE Currently, there are two values for the TAG Function Type:

1. F (function) – executes the function located in the FUNCTION_NAME field

2. P (parameter) – sets the TAG to the name of a particular SITE

FUNCTION_NAME Depending on the FUNCTION_TYPE value, this value in this field can be one of several types.

If the FUNCTION_TYPE = F then this column holds a database function, for example: rdc_activity_std.open_discreps.If the FUNCTION_TYPE is P then this column holds the keyword SITE. The TAG gets the value of the current SITE being processed.

RDC_ACTIVITY_COLUMN table

Table 19–6 describes the column names and values for the RDC_ACTIVITY_COLUMN table. This table lists all the columns that are currently defined for the Search window.

Table 19–6   Columns in the RDC_ACTIVITY_COLUMN Table

Column name	Description of value
ACTIVITY_COLUMN_ID	This value contains unique key.
COLUMN_NAME	This value contains the name of a column that is defined for the Search window.

COLUMN_NAME This column holds a list of all the COLUMN names that can be filled in to perform a search. Behind the scenes, the Activity List places values into the different search columns in the Advanced Search screen. There needs to be a valid column name in this table to perform a proper search. If the column is not found, then a search is not performed.

Views Associated with the Activity List Window

This section describes the views that are used to display the different activities to the RDC Classic application.

RDC_ACTIVITY_LIST View

This view contains a list of activities, including multiple rows for SITE scope if the user has access to multiple clinical sites. This view is used to create the TEXT of the activities that are displayed in the Task pane. It uses the function RDC_USER_ ACTIVITY_TAGS.getActivities to produce the TEXT, including all relevant TAG substitutions. An activity is only present in this view if it has been processed completely and the DISPLAY_EXPR evaluates to TRUE.

```
CREATE OR REPLACE FORCE VIEW RXC.RDC_ACTIVITY_LIST
OF "RDC_ACTIVITIES_T"
WITH OBJECT IDENTIFIER (activity_id)
AS
select a.activity_id,
CAST(rdc_user_activity_tags.getActivities(
a.activity_id, a.activity_scope,
a.activity_type, a.activity_exec, a.display_expr)
AS rdc_activity_list_t) FROM rdc_activities a
where
( instr(','||a.user_role||',',','||rdc_user_activity_
tags.getCurrRole||',') > 0
or
a.user_role = '%' )
and
instr(rdc_user_activity_tags.getCurrScope,','||a.activity_
scope||',') > 0
order by
```

```
decode(a.activity_
scope,'STUDY',1,'XSITE',2,'SITE',3,'PATIENT',4,5),
a.activity_id;
```

RDC_USER_ACTIVITY_LIST View

This view is queried within RDC Classic to produce the final list of activities that are displayed to the user. It joins the RDC_ACTIVITIES Table with the RDC_ACTIVITY_LIST View.

```
create or replace view rdc_user_activity_list
AS select a.activity_id, a.user_role, a.activity_type,
a.activity_scope, t.text, t.activity_exec, t.site
from   rdc_activities a, table(select url_info from rdc_
activity_list
where activity_id = a.activity_id) t;
```

Defining an Activity for the Activity List

This section describes how to define an activity. To illustrate the process, the topics in this section describe the steps to produce the following activity:

"You have %NUM_UNAPP% CRFs to Approve"

For this example activity, the function and the procedure are already coded, however, a new TAG must be constructed.

> **Note:** The instructions to define a new activity assume the reader has a firm understanding of the structure of Oracle Clinical databases and the SQL language.

This section includes the following topics:

- Copy the Demo Packages on page 19-12
- Edit rdc_activity_client_ps.sql on page 19-13
- Edit rdc_activity_client_pb.sql on page 19-15
- Create a new TAG for NUM_UNAPP on page 19-16
- Create the Activity on page 19-17
- Install the New Code and Insert the New TAG and Activity on page 19-18

Copy the Demo Packages

The first step in the process of creating a new activity is to copy the demo packages, which are shipped and installed as part of the Oracle Clinical/RDC Classic installation process.

The names you use for the copied files are irrelevant, as long as each is unique. In this section, the string, *client*, is inserted to make the filenames unique.

1. At a command prompt, type:

   ```
   opa_setup <database_name> <code_env>
   ```

2. Change directories to RXC_INSTALL:

```
cd $RXC_INSTALL
```

3. Copy `rdc_activity_dmo_ps.sql` to `rdc_activity_client_ps.sql`

4. Copy `rdc_activity_dmo_pb.sql` to `rdc_activity_client_pb.sql`

After you create these two package files, you can use them for all subsequent functions and procedures that are required to create new activities.

Edit rdc_activity_client_ps.sql

Edit the file `rdc_activity_client_ps.sql`, as follows:

1. Change the line:

   ```
   Create or replace package rdc_activity_dmo as
   ```

   to:

   ```
   Create or replace package rdc_activity_client as
   ```

2. Change the lines:

   ```
   end rdc_activity_dmo;
         /

   show errors
   grant execute on rdc_activity_dmo to rxclin_read;
   exec opa_ddl.createdroppublicsynonym('rdc_activity_dmo');
   ```

   to:

   ```
   end rdc_activity_client;
         /

   show errors
   grant execute on rdc_activity_client to rxclin_read;
   exec opa_ddl.createdroppublicsynonym('rdc_activity_client');
   ```

3. Change the line:

   ```
   function num_unapproved return varchar2;
   ```

   to:

   ```
   function num_unapp return varchar2;
   ```

4. Change the line:

   ```
   end num_unapproved;
   ```

   to:

   ```
   end num_unapp;
   ```

5. Change the line:

   ```
   procedure process_unapproved(pSite in varchar2:=null);
   ```

to:

```
procedure process_unapp(pSite in varchar2:=null);
```

6. Change the line:

```
end process_unapproved;
```

to:

```
end process_unapp;
```

As you construct other activities, leave the balance of the information in this package specification as-is, using it as a template for your work. Remove sections as you find them unnecessary for your activities.

When you complete the preceding steps, the rdc_activity_client_ps.sql file should resemble the following code.

```
Rem   Created by copying rdc_activity_dmo_ps.sql into this file name.
Rem
Create or replace package rdc_activity_client as

Rem - Standard variables setup for use in local procedures defined in the body
Rem - Do not erase or change
Rem
/* System wide variables */
vStudy     clinical_studies.study%type;
nStudyId   clinical_studies.clinical_study_id%type;
vSite      ocl_sites.site%type;
nSiteId    ocl_sites.site_id%type;
vBook      dci_books.name%type;
nBookId    dci_books.dci_book_id%type;
vPatient   patient_positions.patient%type;
nPatientId patient_positions.patient_position_id%type;
vRole      varchar2(50);
vMode      varchar2(1);

/* Patient variables */
 vSex          patient_positions.reported_sex%type;   /* Patient sex */
 dBirth        date;                                   /* Date of birth */
 vMissingPages varchar2(500);                          /* List of missing pages */
 vPatBook      dci_books.name%type;                    /* Default DCI book */
 nCRFs         pls_integer;                            /* Number of CRFs */
 nCRFActiveDisc pls_integer;                           /* Number of CRFs with active discrepancies
*/
 nCRFOtherDisc  pls_integer;                           /* Number of CRFs with other discrep's */
 nActiveDisc    pls_integer;                           /* Number of active discrepancies */
 nOtherDisc     pls_integer;                           /* Number of other discrepancies */
 nClosedDisc    pls_integer;                           /* Number of closed discrepancies */
 nCRFVerified   pls_integer;                           /* Number of verified CRFs */
 nCRFReverify   pls_integer;                           /* Num of CRFs awaiting re-verification */
 nCRFApproved   pls_integer;                           /* Number of approved CRFs */
 nCRFReapprove  pls_integer;                           /* Number of CRFs awaiting re-approval */
 vFirstVisit    varchar2(20);                          /* First visit */
 dFirstMin      date;                                  /* Earliest date of first visit */
 dFirstMax      date;                                  /* Latest date of first visit */
 vLastVisit     varchar2(20);                          /* Last visit */
 dLastMin       date;                                  /* Earliest date of last visit */
 dLastMax       date;                                  /* Latest date of last visit */
```

```
vNextVisit      varchar2(20);                               /* Next visit */
dNextMin        date;                                       /* Earliest date of next visit */
dNextMax        date;                                       /* Latest date of next visit */
dMinEntry       date;                                       /* Earliest data entry date */
dMaxEntry       date;                                       /* Latest data entry date */
dMaxMod         date;                                       /* Latest data modification date */

Rem - End of package variable setup
Rem
Rem - Clients new packages added under this comment
Rem
function num_unapp return varchar2;
procedure process_unapp(pSite in varchar2:=null);

end rdc_activity_client;
/


show errors
grant execute on rdc_activity_client to rxclin_read;
exec opa_ddl.createdroppublicsynonym('rdc_activity_client');
```

Edit rdc_activity_client_pb.sql

Edit the rdc_activity_client_pb.sql file as follows:

1. Change the line:

   ```
   Create or replace package body rdc_activity_dmo as
   ```

   to:

   ```
   Create or replace package body rdc_activity_client as
   ```

2. Change the line:

   ```
   end rdc_activity_dmo;
   ```

   to:

   ```
   end rdc_activity_client;
   ```

3. Change the line:

   ```
   function num_unapproved return varchar2 is
   ```

   to:

   ```
   function num_unapp return varchar2 is
   ```

4. Change the line:

   ```
   end num_unapproved;
   ```

   to:

   ```
   end num_unapp;
   ```

5. Change the line:

```
                    procedure process_unapproved(pSite in varchar2:=null) is

                    to:

                    procedure process_unapp(pSite in varchar2:=null) is
```

6. Change the line:

```
end process_unapproved;
```

to:

```
end process_unapp;
```

The changes you make to the file in Steps 3 and 4 should result in code immediately before the "end rdc_activity_client;" command line that resembles the following:

```
function num_unapp return varchar2 is
nOut pls_integer;
begin
  begin
  lGet_internal_ids;
  if vMode = 'P' then
      select count(*) into nOut from received_dcis rdci
      where  clinical_study_id=nStudyId
        and  (site_id = nSiteid or nSiteid is null)
        and  rdc.rdci_app_status(vMode,rdci.received_dci_id) in ('NOT APPROVED','UNDONE');
  else
      select count(*) into nOut from received_dcisT rdci
      where  clinical_study_id=nStudyId
        and  (site_id = nSiteid or nSiteid is null)
        and  rdc.rdci_app_status(vMode,rdci.received_dci_id) in ('NOT APPROVED','UNDONE');
  end if;
  exception
    when no_data_found then nOut := null;
  end;
  return to_char(nOut);
end num_unapp;

procedure process_unapp(pSite in varchar2:=null) is
begin
  if pSite is not null then
      rdc_user_activity_process.add_to_stack('SITE',pSite);
  end if;
  rdc_user_activity_process.add_to_stack('APPROVAL_STATUS','NOT APPROVED');
end process_unapp;
```

As you construct other activities, leave the balance of the information in this package build as-is, using it as a template for your work. Remove sections as you find them unnecessary for your activities.

Create a new TAG for NUM_UNAPP

You create a new tag using an insert statement for the RDC_ACTIVITY_TAGS Table.

The following table describes the columns that are referenced in the insert statement.

Column	Description
1st	TAG NAME
2nd	Created when
3rd	Created by
4th	Function type
5th	Function name
6h	Modification timestamp – insert as NULL
7th	Modified By – insert as NULL

The form of the insert statement is:

```
insert into rdc_activity_tags values ('NUM_UNAPP',sysdate,user,'F','rdc_activity_
client.num_unapp',to_date(NULL),NULL);
```

Create the Activity

You create the new activity using an insert statement for the RDC_ACTIVITIES Table.

The following table describes the columns that are referenced in the insert statement.

Column	Description
1st	Activity ID – must be unique, you should specify a large number; RDC Classic ships with IDs < 1000; search for max(activity_id) in the RDC_ACTIVITIES Table to ensure you use a unique ID
2nd	Created when
3rd	Created by
4th	User Role – set to CRA for this example; alternative values are '%' for all roles, or DM, CRA, INV (for multiple roles), or any non-default role defined in the database
5th	Text of Activity – uses the TAG created in the "Create a new TAG for NUM_UNAPP" section
6h	Activity Scope – set to SITE for this example; alternative values are: STUDY, XSITE, and PATIENT
7th	Activity Type – set to 'P' for example; alternative is 'U' for URL
8th	Display Expression – set for this example to an expression that only displays the activity if CRFs in the unapproved or requires re-approval statuses exist for the user (role)
9th	Modification timestamp – insert as NULL
10th	Modified By – insert as NULL
11th through 14th	Insert as NULL

The form of the insert statement is:

```
insert into rdc_activities values (1999000,sysdate,user,'CRA','You have %NUM_
UNAPP% CRFs to Approve','SITE','P','rdc_activity_client.process_unapp','%NUM_
UNAPP%>0',to_date(NULL),NULL,NULL,NULL,NULL,NULL);
```

Install the New Code and Insert the New TAG and Activity

To install the new code and insert the new TAG and activity:

1. At a command prompt, type:

    ```
    opa_setup <database_name> <code_env>
    ```

2. Change directories to RXC_INSTALL:

    ```
    cd $RXC_INSTALL
    ```

3. Log in to SQL*Plus as rxc.

4. At the SQL prompt, type the following commands:

    ```
    SQL> @ rdc_activity_client_ps.sql

    SQL> @ rdc_activity_client_pb.sql

    SQL> Insert into rdc_activity_tags values ('NUM_UNAPP',sysdate,user,'F','rdc_
    activity_client.num_unapp',to_date(NULL),NULL);

    SQL> insert into rdc_activities values (1999000,sysdate,user,'CRA','You have
    %NUM_UNAPP% CRFs to Approve','SITE','P','rdc_activity_client.process_
    unapp','%NUM_UNAPP%>0',to_date(NULL),NULL,NULL,NULL,NULL,NULL);

    SQL> commit;
    ```

The activity is ready to be tested.

Glossary

A

access

A property of a user name which denotes that certain privileges have been granted to that user. The term is used in RDC Classic documentation as a means to convey that a set of privileges have or have not been granted to a particular user. An example of typical usage is:

The Change Study button is displayed if you have access to more than one study.

access key

The keyboard key corresponds to the letter that is underlined in an item's on-screen title. The access key may be activated either singly or in combination with the ALT key.

See also: **shortcut key**

active

A **discrepancy status** that indicates the relevant discrepancy is actionable by members of your **user group**.

activity

An item in the Task Pane of the Activity List Window. Each activity is related to the node that is in focus in the Navigation Pane and functions as a link that creates a workset and loads the associated patients and CRFs in the RDC Classic Spreadsheet.

See also: **node**, **scope**, **workset**

AERS

An acronym for the Oracle Adverse Event Reporting application.

approval history

A record, or set of records, associated with a CRF that lists each change in **approval status** starting with the initial approval action.

approval status

A designation that describes the current state of approval for a CRF. In RDC Classic, there are four approval statuses:

1. **not approved**

2. **approved**

3. **approval undone**

4. awaiting re-approval

See also: **discrepancy status**, **entry status**, **verification status**

approval undone

An **approval status** that indicates a user with the approve privilege has removed the approved status of a CRF via the Undo Approval action.

approve

A **privilege** assigned to a user name that allows the user to alter the **approval status** of a CRF or a group of CRFs. The privilege is assigned at the site level only.

approved

An **approval status** assigned to a CRF that indicates a user with the approve privilege certifies that the CRF is an accurate representation of the source data. In RDC Classic, an approval is equivalent to an electronic signature.

ATTACHMENT prefix

Any field in the CRF that has an ATTACHMENT prefix represents an extended text field that supports 10,000 characters instead of the normal maximum of 200 characters. You can enter and update data in these fields only in Oracle Clinical Remote Data Capture Onsite (RDC Onsite).

audit history

The set of all audit records for a given datapoint.

See also: **audit record**, **data point**

audit record

A set of information that describes an instance of data update. Each audit record includes the following information:

- the current value of the datapoint
- the previous value of the datapoint
- the username that changed the datapoint
- the timestamp the data update occurred
- the change reason
- an optional comment.

automatic progression

A feature of RDC Classic that enhances user data entry, monitor verification, and investigator approval sessions. When automatic progression is enabled, as you complete work on the current CRF focus moves to the next CRF in a sequence specified by the settings in the Preferences Window. The next CRF may be: within the current patient record, across Spreadsheet tabs; within the current patient, within the current event tab; or within the current CRF column.

Note that, based on system administrator settings, the Preferences window may not be available in your session.

awaiting re-approval

This is a system-generated **approval status** that indicates the CRF is **approved**, but that one or more response values were updated. A CRF in this approval status can be re-approved or the approval can be undone.

The CRF changes that cause the change in approval status include:

- response value update
- update to an investigator comment
- initiation of a new investigator comment
- update to a discrepancy
- initiation of a new discrepancy

awaiting re-verification

This is a system-generated **verification status** that indicates the CRF is **verified**, but that one or more response values were updated. A CRF in this verification status can be re-verified or the verification can be undone.

The CRF changes that cause the change in verification status include:

- response value update
- update to an investigator comment
- initiation of a new investigator comment
- update to a discrepancy
- initiation of a new discrepancy

B

batch loaded data

A designation that specifies response values were entered into a CRF by electronic means, as opposed to manually entered via a user performing data entry.

blank

An RDC Classic **entry status** designation that is assigned to a CRF a user has defined as blank. A Blank CRF does not contain data, nor can data be collected while it is marked as blank.

blank flag

A check box **GUI** component used in the Data Entry window. The Blank Flag, or check box, is used to designate a CRF as **blank**. It is a standard item in the CRF Header area of a Data Entry window and may also be present in the CRF section, especially in multi-section CRFs.

book

See **case book**.

Boolean expression

In RDC Classic, a statement that uses a **Boolean operator** to construct a search string by combining two or more search strings.

Boolean operator

A key word that is used to logically join two search strings in a **Boolean expression**. RDC Classic accepts the following Boolean operators:

- AND

- OR

browse

1) A user action that entails reviewing existing data without adding new data or changing existing data.

2) A **privilege**, specific to manually entered CRFs, that provides the user with the ability to view existing data, but not to add new data or update existing data in CRFs. All RDC Classic users must be assigned this privilege or a higher-level privilege that incorporates it.

browse batch

A **privilege**, specific to batch loaded CRFs, that provides the user with the ability to view existing data, but not to add new or update existing data in CRFs. This is the minimum privilege required for a user to view batch loaded CRFs.

C

cancel

A user action that halts the current process or action and reverts to the state of the application that immediately preceded the process or action, without changing the status of the system or data.

Cancel button

In a dialogue or pop-up window, a Cancel button causes the application to dismiss the window, disregard changes made in the window, and revert to conditions that existed before the window opened.

case book

The set of CRFs that are used to collect data for a patient over the course of the study. Each **patient** is assigned to a particular case book.

case report form

A paper or electronic record associated with a patient in a clinical study. Its purpose is to facilitate accurate collection of clinical data. In RDC Classic, CRFs are depicted electronically, through the Data Entry window.

See also: **CRF**

change history

A listing of the values that have been assigned to data or information. Each list item includes information that uniquely identifies it. Specifically, a timestamp and the username of the person who made the change are recorded. In RDC Classic, a change history can be associated with the following:

- **response value**

- **investigator comment**

- **discrepancy**

change reason

A constituent of an **audit record**. A standardized entry that explains why a datapoint changed. The change reason can be supplied either automatically (system-provided) or manually (user-provided).

In RDC Classic, a user-supplied change reason is required when patient data changes after the CRF reaches **entry complete** data entry status.

clinical planned event

An occurrence, usually a **visit**, that is scheduled as part of a protocol to collect clinical data for a patient. In RDC Classic, visits appear in the context of a case book.

closed

A **discrepancy status** that indicates the relevant discrepancy is not actionable by any **user group**. The discrepancy has been resolved, either by a user or the system.

See also: **discrepancy status**, **user group**, **active**, **other**, **obsolete**, **discrepancy state**

CPE

An acronym for **clinical planned event**.

CRA

An acronym for contract research associate.

In Oracle Clinical and RDC Classic, a defined **role** that can be assigned to a user for the purpose of discrepancy management.

created

An RDC Classic entry status designation that is assigned to a CRF when all required CRF header data has been entered and saved, and no other data, i.e., response data, has been entered.

This is used when your internal process involves an administration person who logs the paper as received in-house, but the data have not yet been entered by the Data Entry staff.

CRF

See **case report form**

criterion

In reference to the RDC Classic Search window, one of the components that can be altered so that a certain set of study data is retrieved to the Spreadsheet. Each criterion is comprised of a set of parameters that allow you to make choices about the data you wish to retrieve.

The Search Window is comprised of seven criteria:

1. Book Criterion
2. Site Criterion
3. Patients Subsearch Window
4. Visit/Page Range Subsearch Window
5. CRF Status Subsearch Window
6. CRF/Visit Dates Subsearch Window
7. Data Subsearch Window

Each criterion is comprised of a certain number of parameters. With the exception of the book criterion, all Search window criteria have a default setting that retrieves the maximum amount of data. (The default for the Site criterion, for example, is "All Sites").

You modify a criterion from its default by changing one or more of the parameters that comprise it.

- The Book and Site criteria each have a single parameter, which you access and modify from the Search window.

- All other criteria have multiple parameters, which you access and modify in the Subsearch window that is specific to each criterion.

CRF header

An area of a CRF which consists of information that identifies that the CRF and the data that it collects. The information pertains to the patient, visit, investigator, and site.

In the Data Entry windows, certain fields in the CRF header are required, that is, you must record that information before the system allows you to save the CRF.

A component of a CRF as it is displayed in the Data Entry window. It consists of one or more **header field**s, in which you collect information that uniquely describes and defines the current CRF. There is one header for each CRF.

RDC Classic will not save a CRF to the study database until all required CRF header and CRF section header fields are collected.

CRF section

In RDC Classic, a constituent of a CRF that is comprised of a set of related questions. Each CRF contains at least one section and may contain more than one. In Oracle Clinical terms, a section equates to a **data collection module (DCM)**.

current

A discrepancy state that indicates action can be taken on the discrepancy – either by a user or by the system. It has not been made **obsolete** by the system.

See also: **discrepancy state**, **obsolete**, **open**, **active**, **other**, **closed**

current study

The data set that is active in RDC Classic. The name of the current study is displayed in the title bar of the Main Application Window.

D

data collection instrument (DCI)

(General) The Oracle Clinical term that correlates to an RDC Classic **CRF**. A DCI is composed of one or more DCMs.

See also: **case report form**, **data collection module (DCM)**, **CRF**

data collection module (DCM)

(General) The Oracle Clinical term for a CRF **section**.

(Oracle Clinical) A set of one or more related groups of questions that pertain to a single clinical study visit.

See also: **section**

data entry

A designation that describes the method that is used to enter data into a CRF and save it to the study database.

data entry status

A designation that describes the current state of data entry for a CRF. In RDC Classic, there are four data entry statuses:

1. **created**

2. **blank**

3. **entry started**

4. **entry complete**

data field

A location in the Question area of the Data Entry window in which you type a value that is the response to a CRF question.

data point

A location in a form where a data value may be entered. In most cases, a data point corresponds to a field in the Data Entry window.

data selection tool

Either of two RDC Classic components that allow you to specify the patient data you want to include in a **workset**. The Search Window, which is available to all users, provides the capability to specify parameters that can result in narrowly defined worksets. The Activity List Window, which is made available in the RDC Classic session by the administrator through a setting in the RDC Classic Configurator, defines the workset indirectly, based on the activity the user selects.

data update

In RDC Classic, the process of changing a CRF that has been **created** and saved to the database by altering a **data point** and saving the new version of the CRF to the database.

See also: **created**, **data point**, **CRF**, **initial data entry**

DCM

An acronym for **data collection module (DCM)**.

default search

The saved search that is designated to be used as the default search criteria for the Search window and the default filter for the Activity List window.

default study

The preferred study associated with your username. RDC Classic automatically selects the default study when you initiate a session.

- If you have access to one study, that is your default study.

- If you have access to more than one study, the study that was active when you closed the previous session is the default study.

- If you have access to more than study, but have not initiated a previous session in the current database, the system administrator can specify a default study.

- If the a default study is not specified, the system presents the Change Study Window when you logon, which allows you to choose a study from among those to which you have access.

discrepancy

Data that falls outside of an expected range of values or is otherwise 'flagged' during the edit check process.

See also: **discrepancy management**, **manual discrepancy**, **multivariate discrepancy**, **univariate discrepancy**

discrepancy action

A process that changes the status of a discrepancy. There are two types of actions:

1. routing

2. resolution

discrepancy change history

The listing associated with a discrepancy that provides details of each update that was made it. The specific components of the discrepancy change history that are available to RDC Classic users are:

1. timestamp of update

2. error text

3. discrepancy comment

4. current status

5. resolution

6. resolution comment

7. change by

discrepancy management

A process that systematically addresses discrepancies generated within a study. Discrepancy management attempts to identify the cause and assess the implications of each discrepancy and determine an appropriate action for the discrepancy. Its goal is to satisfactorily resolve all discrepancies associated with each CRF.

See also: discrepancy, multivariate discrepancy, univariate discrepancy, manual discrepancy

discrepancy record

An entry which is part of the study database that defines the pertinent aspects of a discrepancy, from its initial occurrence and through each action that is taken on it.

discrepancy review

A mode of the Data Entry window that is accessible from the Individual Discrepancy Tab of a **multivariate discrepancy**. The system uses the window to display the data field of a discrepancy variable that is not in the currently open CRF. In this mode, the title bar is highlighted in red and the words "Discrepancy Review" are appended to the normal title bar information.

discrepancy state

The highest level designation of a discrepancy. A discrepancy can be in one of two states:

1. **current**

2. **obsolete**

discrepancy status

1) A designation that describes a current discrepancy

A designation that describes the current state of a CRF with regard to discrepancies. In RDC Classic there are four discrepancy statuses:

1. none

2. **closed**

3. **active**

4. **other**

discrete value group

(Oracle Clinical) A set of responses that are acceptable for a given question. A DVG constrains the responses to a question to a distinct set of values. It may also allow the same question to be used in multiple instances.

It is also possible for one DVG to be a subset of another DVG. In this case, the child DVG is made up of responses that are part of the parent.

document

In RDC Classic, the equivalent of a **CRF**.

document number

A system-assigned unique identifier for a particular collected CRF.

DVG

(Oracle Clinical) An acronym for **discrete value group**.

E

EDC

An acronym for **electronic data capture**.

electronic data capture

A method of data collection for clinical trials that uses computers at investigator sites as a mechanism to submit patient data and information to a centralized study database.

Remote Data Capture is an electronic data capture application.

See also: **EDC**

entry complete

An **entry status** that is assigned to a CRF in which all required fields have been entered, including CRF header fields and Question area response data points.

entry started

An **entry status** that is assigned to a CRF in which data entry has been initiated but is not complete. CRFs that are assigned this entry status, some required data fields are complete, while some are not; the document has been saved in an incomplete status.

entry status

Formal stages of data entry, delineated in Oracle Clinical and RDC Classic, that track the progression of a CRF from no data entered ("Created") through entry complete.

See also: **blank**, **created**, **entry started**, **entry complete**

F

filter

A **saved search** that is applied to the Activity List window to limit the scope of the Navigation pane and/or the activities that are available in the Task pane. It allows you to generate a more discrete and focused **workset** that is still based on an activity.

focus

In RDC Classic, where the cursor is currently active. Focus may change from window to window, as when the cursor moves from the Main Application window to the first data field in the Data Entry window when you click a CRF cell.

How focus changes is a consideration when you are modifying the settings on the Preferences window to enhance the efficiency of your data entry or verification/approval sessions.

frozen

A designation that is applied to a patient which indicates that all data has been received, entered, reviewed, and cleaned for the patient, CRF, or visit.

G

Graphical User Interface

The screen representation of a software application that uses graphical components, such as windows, icons, and menus, to effect user interaction, rather than typing command line entries.

GUI

An acronym for **Graphical User Interface**.

H

header field

A location in the CRF header or the CRF section header in which you collect values that provide information about the CRF. A header field may either be required or optional. All required header fields must be collected before the system permits a CRF to be saved to the study database.

In the CRF Header, the following header fields are available:

- visit date

- visit time

- comment

- **blank flag**

In CRF Section Headers, the following fields are available:

- date

- time

- **blank flag**

- **clinical planned event**

- lab

- **qualifying value**

Note: The preceding lists are specific to RDC Classic only.

See also: **required field**

I

indicator question

A question used with certain **question group**s that allows "branching" during data entry based on the response.

For example, in a Drug Allergy question group, an indicator question could be, "Allergic to any drug?"

- If the response is "Yes", the remaining questions in the question group, such as "Drug Name" and "Type of Reaction", require responses.

- If the response is "No", the rest of the question group is not collected.

initial data entry

The step in the RDC Classic workflow during which the CRF is initially opened and created. During this process all required CRF and CRF section header information is collected. Response data may or may not be collected.

installation reference codelist

(Oracle Clinical) A reference codelist that is defined and populated upon initial installation of the application.

See also: reference codelist

internal

A **discrepancy status** that can be assigned to a **section discrepancy** through a **routing** action. This type of discrepancy can be configured so that it is "hidden" from one or more user groups.

investigator comment

A textual explanation that is written by the investigator. It provides the investigator with the opportunity to include additional information with a response value. Each investigator comment is saved as part of the response with which it is associated.

RDC Classic provides visual cues to alert the user to the presence of an investigator comment associated with a datapoint:

- the response field is displayed with a yellow background color

- the data value is displayed in a green font

- when focus is in the relevant response field, the Data Entry window header includes an entry: **<Inv>**, to indicate the presence of the investigator comment.

L

list of values

A set of possible values for a data field. The list of values can generally be displayed by either clicking the button that is associated with list of value fields, pressing the List button or by pressing the F9 key.

See also: **LOV**, **discrete value group**

lock

a) a privilege that may be assigned that enables a user to lock a CRF or a set of CRFs

See also: **privilege**

b) A process that prevents subsequent update of a CRF. Under most circumstances, a locked CRF cannot be 'unlocked,' although administrators may permit, on a limited basis, a user to unlock a single CRF so that data may be updated.

locked

A status assigned to a CRF that indicates all data has been collected, approved, and verified. A locked CRF may be viewed in browse mode and may be included in PDRs, however, its data may not be updated under normal circumstances.

See also: **patient data report**, **data entry status**

lock status

A designation that describes the current state of a CRF, with regard to whether or not it may be updated. In RDC Classic, there are two lock statuses:

- **locked**

- **unlocked**

LOV

An acronym for **list of values**.

M

mandatory response field

A response field in the question area of CRF section that should be completed before the CRF is saved in the Entry Complete status. Failure to do so results in the generation of a discrepancy, which is associated with the relevant response field.

See also: **required field**

mandatory field discrepancy

A **discrepancy** associated with a **mandatory response field** that is generated by the system when a CRF is saved. The discrepancy triggers when data for the field is not collected.

manual discrepancy

A **discrepancy** that is generated by a user, rather than a **data point** value. In RDC Classic, a manual discrepancy may be associated with an entire CRF, a CRF section header or a specific response in the question area of a CRF.

See also: **discrepancy**, **discrepancy management**, **section discrepancy**

menu bar

The section of the Main Application window that provides access to RDC Classic commands.

Refer to "Main Application Window" on page 11-3 and "Menu Bar" on page 11-3 for further information.

See also: **menu command**, **menu item**

menu command

Each menu command is displayed in either black or grey font. If the command is displayed in black font, it is available and may be invoked under the current application conditions. If the command is displayed in grey font, it is not available under the current application conditions. If you attempt to use a menu command that is displayed in grey font, the system does not respond.

menu item

Each label (e.g., "File" or "Insert") that is used to categorize commands that are available from the **menu bar**. When a menu is accessed, either by clicking the label or using its **access key**, it drops down to display the list of menu commands that are associated with it.

multivariate discrepancy

A **discrepancy** that is dependent on two or more **data point** values, which can be within a single CRF or across multiple CRFs and/or visits. A multivariate discrepancy is generated when a CRF is saved, which causes the system to run the validation procedures that locate this type of discrepancy.

See also: **discrepancy**, **discrepancy management**, **manual discrepancy**

N

Navigation pane

In the Activity List Window, the section, or frame, that comprises the left-hand portion of the window and presents a hierarchical listing of the current study, the sites to which you have access. When you click a Site node the patients assigned to each site to which you have access are displayed under the site name.

See also: **node**, **scope**, **Task pane**

news item

A message that is communicated by the study sponsor to some portion of its RDC Classic users. News items are displayed in the News Window.

node

An item in the hierarchical tree in the Navigation pane of the Activity List Window. When you select a node, the tasks that are associated with it are displayed in the Task pane.

Each node represents one of three scopes: study, site, or patient. Within the Navigation pane, there is only one Study node displayed. However, depending on the security settings associated with your username, there may be more than one Site node displayed under the Study node, and generally many Patient nodes listed under each Site node.

See also: **scope**

non-repeating question group

A set of questions that are related, but for which there is not a single set of possible answers.

See also: **question group**, **repeating question**

not approved

An **approval status** assigned to a CRF that indicates the CRF has never been **approved**.

See also: **approval status**, **approved**, **not approved**, **awaiting re-approval**

not verified

A **verification status** that indicates the CRF has not yet been verified.

See also: **verification status**, **verified**, **not verified**, **awaiting re-verification**

O

obsolete

A system-generated **discrepancy state** assigned to a discrepancy that is associated with a response that is a constituent of a:

- **repeating question** row that was deleted
- a question that was deleted
- a CRF section that was deleted
- a CRF that was deleted.

A section discrepancy is made obsolete when its parent CRF is deleted or made blank. A data discrepancy is also made obsolete if the validation procedure upon which it is based is retired.

open

1) A designation for a **discrepancy** that indicates it is either in the **active** or **other** discrepancy status; that is, it is actionable by a **user group**.

2) A designation for a CRF that indicates it contains at least one **active** or **other** discrepancy.

optional CRF

A CRF that is planned in a visit, but which the protocol does not require to be collected. Optional CRFs are not included when the system determines whether there

are missing pages. The information in the CRF Column Header of optional CRFs is displayed in italic font to distinguish each from required CRFs.

other

A **discrepancy status** that indicates the discrepancy is actionable by a **user group** other than yours.

See also: **discrepancy status**, **discrepancy**, **active**, **other**, **closed**

P

parameter

In reference to the Search Window, a component of a **criterion** that you use to define a specific property of the data you wish to comprise the **workset**. A parameter may be comprised of settings that represent a value or range of values that, when combined with any other parameters in the same criterion, define specific data.

See also: **criterion**, **setting**, **search phrase**, **workset**

pass 2 complete

A **data entry status** that assigned to CRFs that originate in the Oracle Clinical data entry system. It indicates that two-pass data entry was required for the CRF and that the second pass is complete.

pass 2 started

A **data entry status** that assigned to CRFs that originate in the Oracle Clinical data entry system. It indicates that two-pass data entry was required for the CRF and that at least one response field has been recorded in the second pass.

patient

A human participant in a clinical study. Each patient in a study is assigned a unique patient number that is associated with a particular site. In addition, the patient number is also assigned to a particular case book.

See also: **case book**

patient data

The data that is collected about a participant in a clinical study. This includes demographic information and clinical results.

See also: freezing, locking, subject

patient data report

In Oracle Clinical or RDC Classic, a generated **PDF** document that is a compilation of data collected about a patient. There are two basic types of PDR: reports that contain blank CRFs and reports that contain response data, audit history records, and/or discrepancy data.

PDRs that include response data provide a snapshot of a dataset that you specify. This type of PDR includes investigator comments and long data values, notes deleted CRFs, and provides the option for you to specify an extensive set of parameters that control the data that is included in the report.

patient list

The set of patients that contain at least one CRF which satisfies the search criteria.

patient number

A designation for a a set of patient data that is unique across a given study. Patient numbers are assigned to a study as part of the Oracle Clinical Design process. Alternative terms include: enrollment number, allocation number, and randomization number.

The following rules apply to all patient numbers:

1. Each patient number must always be assigned to a site.

2. Each patient number may not be assigned to more than one site at a time.

3. The first character in the patient number string may be a non-zero numeric or an alphabetic character.

4. If the first character in the patient number string is alphabetic, the second character must be a non-zero numeric character.

5. Only the first character may be alphabetic.

PDF

An acronym for **Portable Document Format**.

pending changes

Changes that are made to a CRF that have not yet been committed to the study database. The changes that may be pending are response value, investigator comments, or discrepancies. The **save** action commits pending changes to the database.

phase

An attribute of a book that denotes a stage of a study. Phases are used to divide the study into logical groupings of visits. Examples of phases include: Screening, Dosing, and Follow-up.

You can use the RDC Classic Spreadsheet to view CRFs by phases. To do this, select the Phase Spreadsheet view from the Spreadsheet View drop-down list box.

Portable Document Format

A type of file format.

Portable Document Format is a universal file format published by Adobe Systems, Inc., that preserves all of the fonts, formatting, graphics, and color of a source document that is generated on with any application on any operating system.

See also: **PDF**

privilege

The ability for an RDC Classic user to perform a certain task. In RDC Classic, privileges are granted to users in the RDC Classic Administration study and site maintenance windows by administrators. In general, users within a **user group**, that is, those that are given the same **role**, are assigned the same set of privileges.

The following privileges may be assigned to RDC Classic users:

1. **browse**

2. **browse batch**

3. **update**

4. **update batch**

5. **update discrepancy**

6. **verify**

7. **approve**

8. **lock**

9. **unlock**

progression sequence

The order that RDC Classic uses to navigate to and open CRFs. There are three different modes available in RDC Classic:

1. By patient

2. By patient, within Spreadsheet view

3. By CRF column

The specific sequence that is employed at any time is defined by the Progression to next CRF setting in the Preferences window. The system uses the progression sequence when other progression settings are selected.

Q

qualifying value question

A question that differentiates between sets of identical questions. In a multi-section CRF, where the same section, containing the same set of questions, is collected more than once, a qualifying question is used in each such section. The purpose of the qualifying question is to elicit a unique response, called a **qualifying value**, which allows differentiation of the responses in the sections.

When you respond to a qualifying value question, you select from a discrete set of values that are specified in the question definition.

An example of a qualifying question is a multi-section CRF that collects vital sign data multiple times in a single visit. Each set of vital sign data comprises a section. Each section is differentiated by "time post dose" question. The result is a set of vital signs collected at specific times.

qualifying value

The value assigned to a **qualifying value question** that is associated with a CRF section. For multi-section CRFs, where each section includes a qualifying question, the qualifying value is used to differentiate between the sections.

query

1) A procedure that is run against a database with the goal of returning a subset of a data that satisfy the query criteria.

2) An industry term that is a synonym for the Oracle Clinical term, **discrepancy**.

question definition

The set of information that delineates what data a question collects. Among the information is:

- question name

- data type

- length

- lower bound

- upper bound

question group

A set of questions in a CRF that are related due to similarity or study protocol considerations.

An example of a question group is Demographics, which collects such data as: sex, race, and date of birth.

See also: **non-repeating question group**, **repeating question**

question name

The label that describes a question. It may be in the form of a question or it may simply be a word or phrase that serves as the prompt for a response.

R

RDC administrator

A user who able to set or modify the privileges associated with other RDC users, either via Oracle Clinical or the RDC Admin application. Within the RDC application, a user who is an RDC administrator is able to maintain saved searches for any RDC user.

A user is designated as RDC administrator through any one of these actions:

- selecting the Admin? check box in the Study Security or Site Security windows

- assigning the user one of these database roles:

  - RXC_ADMIN

  - RXC_SUPER

  - RXC_SUPER_NOGL

Refer to the *Oracle Clinical Administrator's Guide* for additional information.

repeating question

A question that usually consists of more than one response. The responses are generally situated in a single row and are referred to as a "repeating question row". For each response, there may be a default value, which is a system-provided value that entered automatically when you open the CRF. A repeating question is usually one of a set, each of which are distinguished by the initial response or by a question label.

An example is a question group titled, "Body Systems". Each repeating question row collects data about a different body system with three response values. The first response in each row identifies the part of the body, for instance, chest, or head. The next response in each row requires one of three values: "Normal", "Abnormal", or "Not Done". If the response to this question is "Abnormal", the third response, "Explanation", is required.

See also: **question group**, **non-repeating question group**

required CRF

A CRF that the protocol specifies as a planned CRF in a visit, for which data must be collected. Planned CRFs are analyzed when the system determines whether there are missing pages. The information in the CRF Column Header of optional CRFs is displayed in regular font to distinguish each from **optional CRF**s.

See also: **CRF**, **optional CRF**

required field

An RDC Classic designation for a CRF datapoint that indicates data must be collected for that field before the system will save the CRF. In RDC Classic, required fields occur in

resolution

A type of **discrepancy action** that causes the status of the discrepancy to change from **active** to **closed**.

See also: **discrepancy**, **discrepancy status**, **discrepancy action**, **routing**, **user role**

resolution reason

A parameter associated with a **discrepancy action** that provides a sponsor-defined reason when a user closes a discrepancy.

response value

The value that is assigned to a datapoint. This term usually refers to fields in the Question area of a CRF.

See also: **CRF**, **data point**

response sequence

The order in which the system expects data entry to proceed, from one field to the next. Also termed *tab order*, this is determined for each question during the CRF design phase of study setup. It is used when you use the Tab key to navigate from one field to another. The system also uses it to facilitate the Auto Skip and Auto Fill features of the Data Entry window.

role

See **user role**

routing

A type of **discrepancy action** that causes the status of the discrepancy to change from **active** to **other** for your **user group** and from other to active for a different user group.

See also: **discrepancy**, **discrepancy status**, **discrepancy action**, **resolution**, **user role**

S

save

An action that commits pending data changes to the study database.

In RDC Classic, there are two modes of save action: explicit and implicit. The former is a result of user action, for example, clicking the Save button. The latter is the result of a system action.

saved search

A set of **search criteria** that have been saved to the study database, which can be re-used at a later time to quickly and consistently generate a workset.

See also: **search criteria**, **workset**, **RDC administrator**

scope

In the **Activity List Window**, a category or classification of a set of tasks; there are three scope levels that are available in the Activity List window:

1. study

2. site

3. patient.

These are listed and identified in the Navigation Pane. When you select an item in the Navigation pane, the activities that are associated with its scope are listed in the Task Pane. Because only one study can be active in RDC Classic at any given time, the study scope is listed once. The site scope is listed once for each site to which you have access for the current study. The patient scope is listed once for each patient to which you have access for the site.

search criteria

The settings that determine the CRFs that comprise the **workset**. These settings can be defined directly, through the **Search window**, or indirectly, through the Activity List window.

search phrase

The group of **setting**s that, when taken together, define a searchable property. An example is, "search all CRFs named 'Vitals' for systolic BP values that are greater than or equal to 120,". You use several drop-down lists in the Subsearch window to construct the search phrase.

Search window

A GUI component in RDC Classic that allows a user to define directly the **search criteria** that is displayed in the RDC Classic Spreadsheet. The Search window provides access to seven criteria, which are can be modified from default values, that the system combines to retrieves CRFs from the study database.

section

1) In RDC Classic, a constituent of a CRF that is comprised of a set of related questions. Each CRF contains at least one section and may contain more than one. In Oracle Clinical terms, a section equates to a **data collection module (DCM)** (DCM).

2) In the **Graphical User Interface** - a part of a window or other informational feature that contains related information and/or data fields. It is often delineated by a descriptive label and a border that surrounds its related components.

For example, the different views that are available in the Summary Task tab are differentiated by the sections that comprise each view. In some cases, the sections are used in more than one view. Refer to "Summary Task Tab" on page 13-2 for examples of sections.

section discrepancy

A user-generated **discrepancy** that is associated with a **CRF section**. There can be multiple discrepancies associated with a CRF section. This is the only type of discrepancy can be routed as an **internal** discrepancy.

The system displays "<Oper>" as an indication of the presence of a section discrepancy in the title bar of the Data Entry window when focus is in the discrepant CRF section.

See also: **discrepancy**, **CRF section**

session

The period that starts when you successfully log in to RDC Classic and ends when you exit RDC Classic. This is also referred to as an **RDC Classic session**. It is constricted by limitations that are imposed by the following conditions:

- only one username is granted access to a session

- the role and privileges assigned to the username determine the patient data and functionality that is available within a session

- only one database can be accessed during a given session – if you want to access a different database, you must initiate a new RDC Classic session

- only one study can be open at a time during a session, however, unlike the restriction on the active database, you can change to another study within an RDC Classic session – if you want to access a different study you must close the current study and select another.

- only one book can be active at a given time, however, you can change to another book within an RDC Classic session

- one or more sites can be active during a given session and the privileges assigned to the username may vary from site to site.

setting

The value of a **parameter** in the Search Window, which is a contributor to a the value of a **criterion**. Usually, the default setting for a parameter is "ALL", which means that the parameter does not limit the data that is retrieved. When the value of a parameter is set to something other than "ALL", it generally limits the number of CRFs that are retrieved.

See also: **criterion**, **parameter**

sequence number

In the Discrepancy Task Tab, the ordering number that is assigned to each discrepancy associated with the current CRF or CRF section (if the current CRF is multi-section). Discrepancies are listed in the List of Discrepancies Tab in numerical order, according to the sequence number. The number assigned to each discrepancy is not static. It is based on the following parameters: the current status, the timestamp, and the location of the response field within the CRF or section.

shortcut key

A key or key combination that allows you to implement a function in the application by using the keyboard.

See also: **access key**

site

1) A **criterion** that contributes to the generation of **search criteria** based on the sites to which the user has **access**. The criterion can have a value of either:

- <ALL> – includes all sites to which the user has access

- single site – limits search criteria to one site to which the user has access.

2) A clinical location that participates in a study.

source data

The first place that patient data is recorded. This may be in a hospital chart or a paper CRF at an investigative site. Alternatively, it may be collected in an electronic CRF via RDC Classic data entry.

In RDC Classic, the verification process entails source data verification. That is, ensuring that the source data matches what has been collected in RDC Classic.

spreadsheet view tab

In the RDC Classic Spreadsheet, these determine how the system displays the workset data. There are three different tabs that each provide a different view of the workset:

- Study

- Phase

- Visit

You select the type with the Spreadsheet view drop-down list that is located above the patient listings in the Spreadsheet. (Note that the presence of this component is dependent on a sponsor-specified configuration.)

subsearch window

A window that is accessed from the Search window that allows a user to change the values of parameters. Changes in the subsearch window affect a Search window criterion.

T

Task pane

In the Activity List Window, the section, or frame, that comprises the right-hand portion of the window and presents a listing of activities, or tasks, associated with the currently selected node in the **Navigation pane**. When you click a task, RDC Classic retrieves the data necessary to complete the task from the study database and displays it in the RDC Classic Spreadsheet.

See also: **node**, **scope**, **Navigation pane**

test mode

A method of using RDC Classic during study design, prior to the initiation of the protocol. Under normal circumstances, RDC Classic runs with Production mode active. This mode mirrors the look and feel of production mode but uses a separate set of tables to store the data.

timepoint

A significant event in the history of a CRF. Used as criterion when viewing the Audit Trail tab. Examples of timepoints include:

- creation date

- verification dates

- approval dates.

timestamp

A value assigned to a datapoint that provides a chronology for significant events during a study. Such events include: the date/time when a value was created, the date/time when a value was updated, etc.

TMS

An acronym for the Oracle Thesaurus Management System application

U

Uniform Resource Locator

An Internet address that points to a specific resource on the World Wide Web by its location. The address is described in combinations of syntax and special characters that, when combined, represent a unique string. In general, URLs make up a subset of URIs. Common URLs are those that point to Web pages or to FTP sites. The former are identified by an "http:" prefix string, the latter are identified by an "ftp:" prefix string.

univariate discrepancy

A **discrepancy** that is dependent on the value of a single **data point**. This type of discrepancy is usually when the value recorded for a response does not meet certain criteria that is deemed acceptable by the study sponsor.

See also: **discrepancy**, **discrepancy management**, **manual discrepancy**, **multivariate discrepancy**

unlock

a) A privilege that is assigned to a user to unlock a CRF. The privilege can only be assigned at the **site** level.

See also: **privilege**, **lock**

b) A process that allows a user with unlock privilege to assign to another user the capability to update a CRF that is in the **locked** status.

unlocked

A **lock status** that indicates a CRF may be updated.

unplanned

A designation attributed to any event or CRF that was not part of the protocol schedule or which occurs at a time other than was originally specified in the protocol schedule.

See also: **unplanned CRF**, **unplanned visit**

unplanned CRF

A CRF collected at a visit at which it was not planned, that is, it is not part of the case book.

unplanned visit

A clinical event which occurs that was not scheduled by the protocol.

update

1) A process or condition in which CRF data or information, which has previously been saved, is changed.

2) A **privilege** that allows a user to initiate data entry, update data, initiate discrepancies, and update discrepancies.

update batch

A **privilege** that allows a user to initiate or update a discrepancy in CRFs that are batch-loaded.

update discrepancy

A **privilege** that allows a user to initiate or update a discrepancy in CRFs that are no batch-loaded.

URI

An acronym for Uniform Resource Identifier.

URL

An acronym for **Uniform Resource Locator**.

user group

In RDC Classic, a set of users that are assigned to the same **user role**.

user role

A database role that is granted to a user or user group. In RDC Classic, there are five default user roles, however, any given study database may include some or all of these, and may include sponsor-specific roles. RDC Classic allows privileges to be assigned independently of user role assignment.

The roles that RDC Classic ships with are:

1. Super User (SU)

2. Data Manager (DM)

3. Clinical Research Associate (CRA)

4. Site Coordinator (SITE)

5. Site Investigator (INV)

See also: **privilege**, **user group**

> **Note:** The RDC Classic documentation uses this default set of user roles to describe various functionality that is dependent on certain sets of privileges.

V

validation

An action that entails the initiation and processing of sponsor-defined procedures, in the case of multiple datapoints, or edit checks, in the case of a single datapoint, that analyze collected data and return an query, or discrepancy, for each datapoint that does not meet the criteria defined in the procedure. Such a data-generated discrepancy is also referred to as a **validation error**.

validation error

A condition associated with one or more datapoints that indicates the value does not meet the criteria defined in a question definition or validation procedure. It is equivalent to a data-generated **discrepancy**.

value

When used in the context of criteria and parameters, the choice that you assign to a parameter, which was chosen from a list of possible values.

verification history

A record, or set of records, associated with a CRF that lists each change in **verification status** starting with the initial verification action.

verification status

A designation that describes if a CRF has been verified. In RDC Classic, there are four verification statuses:

1. **not verified**

2. **verified**

3. **awaiting re-verification**

4. **verification undone**

verification undone

A **verification status** that indicates the CRF was verified but subsequently the verification was undone. This status is equivalent to the **not verified** status, with the exception that a **verification history** exists for a CRF in verification undone status.

verified

A **verification status** that indicates the CRF has been verified by a user with the verify privilege.

verify

A **privilege** assigned to a user name that allows the user to alter the **verification status** of a CRF or a group of CRFs. The privilege can be assigned at the study level or the site level.

visit

A clinical event, which generally denotes the occurrence of a meeting between a patient and clinical staff at a study site. In the course of a visit, data related to the study is collected, which at some point is recorded and saved to the study database.

In RDC Classic, a visit consists of one or more CRFs. By default, the system displays Spreadsheet Visit view in the RDC Classic Workspace, which displays, for the current patient list, all of the CRFs collected for a single visit.

W

workset

The collection of patient data that is currently displayed in the **RDC Classic Spreadsheet**. You use either the **Search Window** or the "Activity List Window" to select the data that you want to view in the Spreadsheet. This may include, but is not limited to, the following:

- patients
- CRFs, including entry, approval, verification, and lock statuses
- response data
- investigator comments
- discrepancies
- audit trail history

This term may also be called a *dataset*.

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