

Oracle® Clinical
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Oracle Clinical Administrator Glossary

Index

Preface

This *Oracle Clinical Administrator's Guide* describes activities that may be required of a system or database administrator to maintain an Oracle Clinical site. For installation and one-time tasks, see the *Oracle Clinical Installation Guide*. For information on configuring Remote Data Capture Onsite (RDC Onsite), see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

This preface contains the following topics:

- [Audience](#) on page xiii
- [Documentation Accessibility](#) on page xiv
- [Finding Information and Patches on My Oracle Support](#) on page xiv
- [Finding Oracle Documentation](#) on page xvi
- [Related Documents](#) on page xvi
- [Conventions](#) on page xvii

Audience

To administer an Oracle Clinical installation you need to be able to carry out the tasks listed below. If you lack the necessary skills, one alternative is to engage Oracle Consulting.

Oracle Database Administrators

To perform Oracle Clinical database tasks, you should have a level of knowledge equivalent to what is taught in Oracle's DBA Architecture and Administration course. You must be able to read, edit, and run SQL scripts and review log files. For ongoing administration, additional DBA training is essential.

System Administrators

A general understanding of the operating system and networking is required, including:

- For UNIX:
 - Creating and managing user accounts and groups
 - Installing Oracle RDBMS software and patches
 - Identifying space on a file system for Oracle database tablespaces
 - Setting and using environment variables

- For Microsoft Windows:
 - Creating and managing user accounts and groups
 - Creating and managing services
 - Installing Oracle software
 - Managing settings through the Control Panel applets
 - Adding network printers

Documentation Accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at

<http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit

<http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info> or visit

<http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

Finding Information and Patches on My Oracle Support

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

Before you install and use Oracle Clinical, 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.
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 Name 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 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 xvi.

- *Oracle Clinical Installation Guide* (Part A83779)
- *Oracle Clinical Administrator's Guide* (Part A83791)
- *Oracle Clinical Getting Started* (Part B12308)
- *Oracle Clinical Creating a Study* (Part A85200)
- *Oracle Clinical Conducting a Study* (Part A85201)
- *Oracle Clinical Interfacing from Oracle Clinical* (Part A83793)
- *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* (Part E11064)
- *Oracle Clinical Remote Data Capture Onsite User's Guide* (Part B31158)
- *Oracle Clinical Remote Data Capture Classic Data Entry User's Guide* (Part B13921)

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

In addition, Oracle Clinical 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.
<i>italic</i>	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

Configuration Tasks

This section includes tasks that you perform when you install Oracle Clinical or the Remote Data Capture option.

- [Chapter 1, "Setting Up User Accounts"](#)
- [Chapter 2, "Oracle Clinical Menu-Based Security"](#)
- [Chapter 3, "Configuring Discrepancy Management"](#)
- [Chapter 4, "Configuring the Mass Changes Utility"](#)
- [Chapter 5, "Configuring Data Entry and User Preferences"](#)
- [Chapter 6, "Configuring Data Extract"](#)
- [Chapter 7, "Reference Codelists"](#)

Setting Up User Accounts

This section contains the following topics:

- [Creating an Administrator User Account](#) on page 1-1
- [Setting Up Required Accounts and Directories](#) on page 1-2
- [Running the Add User Script](#) on page 1-5
- [Maintaining Oracle User and Group User Accounts](#) on page 1-9
- [Granting Data Access to User and Group User Accounts](#) on page 1-11
- [Granting Data Access to RDC Users](#) on page 1-13
- [Granting Additional Database Roles to User Accounts](#) on page 1-15
- [Setting Up Data Extract Users](#) on page 1-16
- [Setting Up Power Users](#) on page 1-17
- [Setting Up Passwords](#) on page 1-18

Creating an Administrator User Account

To create an administrator user account with which you can perform all the functions under the Oracle Clinical Admin menu:

1. Log on to SQL*Plus as SYSTEM and run the Add User script; see "[Running the Add User Script](#)" on page 1-5.
2. Add one of the following database roles; see "[Granting Additional Database Roles to User Accounts](#)" on page 1-15. By default, these roles have access to menus as follows:
 - RXC_ADMIN: Provides access to all Admin menu items.
 - RXC_SUPER: Provides access to all menu items.
 - RXC_SUPER_NOGL: Provides access to all menu items except the Global Library.
 - RXC_DES: Provides access to the RDC Administration tool as well as Oracle Clinical Design menu items
 - RXC_DMGR: Provides access to the RDC Administration tool as well as Oracle Clinical Definition and Conduct menu items
3. Add privileges, if required; see "[Setting Up Power Users](#)" on page 1-17.

Setting Up Required Accounts and Directories

To add a user account to Oracle Clinical, you run the Add User script. In that script you are prompted to supply information about the servers, queues, and directories the user will use. You must either set these up in advance and enter the correct information as you run the script, or enter the information in the script and do the required setup afterward.

- **Set up the Reports Server**; see the *Oracle Clinical Installation Guide* for instructions.
- [Setting Up a Report Server Log Directory](#) on page 1-2
- **Determine which database roles** the user needs; see [Chapter 2, "Oracle Clinical Menu-Based Security"](#)
- **Parameterized Submission (PSUB) user requirements.** The following are required only for users who need to use the PSUB utility; see ["Who Needs PSUB?"](#) on page 1-2:
 - [Creating an Operating System Account](#) on page 1-3.
 - [Creating a PSUB Log Directory](#) on page 1-3
 - [Ensuring PSUB Execution Permission \(UNIX Only\)](#) on page 1-4
 - [Modifying the RXCPROD Account's Profile](#) on page 1-4

Who Needs PSUB? Some of the user setup tasks are required only if the user needs to be able to run Oracle Clinical's Parameterized Submission (PSUB) batch utility. PSUB is required to:

- Run batch data load
- Run batch data delete
- Run batch validation
- Generate a default, character-based DCM layout
- Run the following reports: Randomization Report by Treatment, Patient DCI/DCM Matrix, Generate Study Report, Missing and Overdue DCMs, Investigator Corrs & Missing Pgs, Study/Investigator DCM Summary Matrix, Display Treatment Assignments
- Run Validate Study or Validate Site in RDC—the only RDC users who need PSUB

PSUB is not required to:

- Perform basic data entry in either Oracle Clinical or RDC
- Generate graphic layouts and DCI forms
- Run most reports, including the Patient Data and Audit History reports

PSUB initiates batch jobs on the operating system of the database server through the account of a dedicated user, RXCPROD. This account places the logs and output of the PSUB job into a directory that is accessible to the user who submits the job. Oracle Clinical users must therefore have operating system accounts on the database server.

Setting Up a Report Server Log Directory

During Oracle Clinical installation you create a Report Server root directory (see the *Oracle Clinical Installation Guide* for instructions). You can either use the root directory for all users' report output, or you can create a separate subdirectory for each user under the root directory. In either case, a user's access is restricted to the reports

generated by that user in Oracle Clinical or RDC—regardless of whether or not there is a user-specific subdirectory.

In order for users to view reports through Oracle Clinical and RDC, enter the full path to the root directory or user-specific subdirectory when you execute the Add User script or in the Oracle Accounts window.

Note: The full path cannot exceed 35 characters.

Creating an Operating System Account

Users who need to run PSUB (see ["Who Needs PSUB?"](#) on page 1-2) need an operating system account on the database server. Users who want to run Data Extract jobs and SAS must also have an account on the server that runs SAS, if it is a different machine from the PSUB server.

For setting the password for a user, see ["Changing the Password for a User"](#) on page 1-19.

Accounts on UNIX Systems

When you create a user account, ensure that the path to the user's login directory does not contain uppercase characters. PSUB changes all path specifications to lowercase on UNIX platforms.

If you must have uppercase characters in the path, you can provide lowercase and uppercase versions of the paths by using symbolic links, as needed.

For example, if the standard path to user bsmith's account is:

```
/usr1/home/Clinical/bsmith
```

You can create this link:

```
% cd /usr1/home
% ln -s Clinical clinical
```

Accounts on Windows Systems

For security reasons, when you set up local accounts for users on the Windows database server, do not use the same password as the user's domain account.

Creating a PSUB Log Directory

Create a PSUB root directory on the database server and user-specific log subdirectories for users who need PSUB. When a PSUB batch job runs, the system writes the log and output files associated with the job to the log directory of the user who ran the job.

UNIX On UNIX servers, Oracle suggests you create a directory named **log** as a subdirectory of each user's home directory. For example, for user bsmith

```
/u01/home/bsmith/log
```

Windows On Windows servers, Oracle suggests you create a directory named **oc_users**, and beneath that create a subdirectory for each user, which is named for that user. In each user-specific directory, create a log subdirectory.

You must give each user read/write access to their directory.

For example, for user bsmith:

```
d:\oc_users\bsmith\log
```

Making the PSUB Root Directory Accessible

Each user has a PSUB log directory under the PSUB root directory. Therefore the root directory must be accessible to all users. In the previous examples, the shared PSUB root directories are "/u01/home" (UNIX) and "d:\users" (Windows). In addition, the root directory must be accessible to the Oracle Clinical middle tier. You do this differently, depending upon whether you choose the UNC or HTTP protocol, as described below.

FTP Protocol If you chose FTP as the file viewing protocol, you can skip this step.

UNC Protocol If you chose UNC as the file viewing protocol, you must create a UNC for the PSUB root directory and make the PSUB root directory readable by the network domain account that is used to start the application server.

HTTP Protocol If you chose HTTP as the file viewing protocol, you must set up the PSUB root directory as a virtual directory on the Web Server. Generally, you would setup that Web Server on the same computer as the PSUB root directory. Oracle Database ships with an Oracle HTTP Server that you can use as a Web Server.

Note: Refer to "[Setting Up File Viewing](#)" on page 11-1 for additional information.

Ensuring PSUB Execution Permission (UNIX Only)

On UNIX database servers, the PSUB utility works by having one operating system account, RXCPROD, use rsh (remsh on HP-UX) to submit batch jobs on behalf of the actual user's operating system account. To submit these jobs on the user's behalf, RXCPROD must have permission to access the user's account. You can grant this permission either: through an entry in /etc/hosts.equiv, which grants RXCPROD the permission for all users, including new users as they come to be created, or through an entry in each account's .rhosts file.

- **For all users at once:** If the database server has an /etc/hosts.equiv file, add `official_host_name rxcprod` as a line in the file. This grants RXCPROD the permission for all users, including new user accounts as they are created.
- **For each user individually:** Create a file named rhosts in the user's login directory and include `official_host_name rxcprod` as a line in the file.

where `official_host_name` is the official name of the computer on which you are installing Oracle Clinical. You must use the official name — not an alias — for the server. The official name is the first listing after the IP address in the /etc/hosts file.

Modifying the RXCPROD Account's Profile

RXCPROD is the dedicated PSUB account. Enable RXCPROD to find the programs that PSUB runs by doing the following:

Open the RXCPROD account's **.profile** file and edit the PATH command:

```
PATH=$PATH:opapps_home/bin:oracle_home/bin
```


where *oracle_home* is the path of the Oracle home directory and *opapps_home* is the path of the Oracle Clinical home directory.

Running the Add User Script

Create a database account for the user in each database instance to which the user connects by running the script `ocl_add_user.sql` in SQL*Plus.

This section contains the following topics:

- [About the Add User Script](#)
- [Running the Add User Script in UNIX](#)
- [Running the Add User Script in Windows](#)
- [Required Parameters](#)
- [Optional Parameters](#)

About the Add User Script

The `ocl_add_user.sql` script performs the following tasks:

- creates an Oracle database account for the user, with the specified password

Note: If you use SQL*Plus to create a Oracle Clinical database account, do *not* use the IDENTIFIED EXTERNALLY clause; rather, assign an explicit password.

- sets the user's temporary tablespace to "temp" and default tablespace to "users"
- grants default Oracle Clinical database roles to the user; you can edit the script to assign additional database roles
- grants the RXC_SUPER role for data access to all studies, if specified
- grants RXC_RDC and RDC_ACCESS if access to RDC is required
- makes the RXCLIN_MOD role a non-default role
- creates a record in the Oracle Clinical table ORACLE_ACCOUNTS.

Note: You can copy and customize this script, or create different versions of it for different types of users. For example, you can change temporary and default tablespaces, provide default values for some parameters instead of entering a value for each user at a prompt. You can add a call to `crusrq.sql` to create the USER_QUERIES table (see "[Creating a Queries Table for a Data Extract User](#)" on page 1-17).

However, if you decide to customize the script, it is important not to modify the line: `alter user &&ops_id default role all except rxclin_mod;`

Note: You can give users additional database roles directly in SQL*Plus; see "[Granting Additional Database Roles to User Accounts](#)" on page 1-15.

Running the Add User Script in UNIX

1. Log on with your UNIX account.

2. Set the environment.

For UNIX servers, C shell, enter the following:

```
opa_setup database_instance_name code_environment_designation
```

For example: %opa_setup burlma9 22

For UNIX servers, Bourne shell, enter the following:

```
p1 = database_instance_name  
p2 = code_environment_designation  
opa_setup
```

3. Change to the RXC_TOOLS directory:

```
cd $RXC_TOOLS
```

4. Call SQL*Plus and log in as SYSTEM:

```
sqlplus system
```

5. Run the Add User script:

```
start ocl_add_user.sql
```

See [Table 1-1, "Add User Script Required Parameters"](#) and [Table 1-2, "Add User Script Optional Parameters"](#) for a description of the prompts output by the Add User script, valid entries, and examples.

Running the Add User Script in Windows

1. Log on with your local account.

2. Open an MS-DOS window.

3. Set the server environment:

```
set p1=db_name  
set p2=code_env  
opa_setup
```

where *db_name* is a database instance name and *code_env* is a code environment designation.

4. Change to the RXC_TOOLS directory:

```
cd %RXC_TOOLS%
```

5. Call SQL*Plus and log in as SYSTEM.

```
sqlplus system
```

6. Run the Add User script:

```
start ocl_add_user.sql
```

Required Parameters

The following table describes the required Add User script parameters:

Table 1–1 Add User Script Required Parameters

Prompt/Equivalent in Oracle Accounts Window	Description	Rules and Examples
User ID, starting with OPS\$ /Account Name	Defines the login name for the user. Names are not case sensitive. OPS\$ is required at the beginning of the account name if the user needs to run PSUB processes in Oracle Clinical; see "Who Needs PSUB?" on page 1-2. The letters after OPS\$ (if OPS\$ is included) must be identical to the user's operating system account name on the database server. If OPS\$ is not included, the user ID you enter here must be identical to the user's operating system account name on the database server.	OPS\$bsmith bsmith
Password Not in the Oracle Accounts window	Defines the login password for the user. Passwords are not case sensitive. See "Changing the Password for a User" on page 1-19.	farrier
Last Name /Last Name	Specifies the user's surname (family name). Names are not case sensitive; names are automatically capitalized.	Smith
First Name First Name	Specifies the user's given name. Names are not case sensitive; names are automatically capitalized.	William
PSUB Log Directory /PSUB Directory	Specifies the directory where PSUB places output and log files from PSUB jobs. See "Who Needs PSUB?" on page 1-2. RDC users need a PSUB log directory only if they run Validate Study or Validate Site. You create the root directory during installation.	UNIX: /users/bsmith/log Windows (use UNC): \users\bsmith\log
Report Server Log Directory /Report Server Directory	Specifies the designated location for saving output from the Report Server. Required for generating and viewing Patient Data Reports and most Oracle Clinical reports. You create the directory as part of setting up the Report Server during Oracle Clinical installation.	Must be specified in UNC format. String length cannot exceed 35 characters. \oc_srvr\users\bsmith

Table 1–1 (Cont.) Add User Script Required Parameters

Prompt/Equivalent in Oracle Accounts Window	Description	Rules and Examples
Grant RXC_Super Menu Role (Y/N) Not in the Oracle Accounts window	Specifies whether to grant superuser menu privileges to this user. With this privilege, the user can access all Oracle Clinical menus. In general, Oracle recommends that you restrict the RXC_SUPER role to system administrators. This setting does not correspond to a field in the Oracle Clinical accounts table.	Y — Gives superuser menu privileges to this user. N — Does not give superuser menu privileges to this user. You should always answer N for non-Oracle Clinical users.
Grant Super-User Status to access all studies (Y/N) /Super User?	Specifies whether to grant superuser status to this user. With this privilege, the user can access all clinical studies in the database, in both Test and Production modes. This setting corresponds to the Super User? check box in the Oracle Clinical accounts table. You can change this setting and grant access to programs, projects, and studies in the Oracle Accounts window; see " Granting Data Access to User and Group User Accounts " on page 1-11.	Y — Allows this user to access all clinical studies. N — By default, the user does not have access to any studies. You must explicitly grant access to particular studies, projects, or programs.
Does user require access to RDC (Y/N) Not in the Oracle Accounts window	Specifies whether this user can log in to and use the RDC Onsite application. A Y value grants the RDC_ACCESS and RXC_RDC roles to the user. The RDC_ACCESS role lets the user initiate an RDC Onsite session and the RXC_RDC role lets the user enter and modify data (subject to study- and site-level security privileges).	Y — Lets this user access the RDC Onsite application. N — Denies access to the RDC Onsite application for this user.

Optional Parameters

The remaining parameters are optional. In addition, you can use the Maintain Oracle Accounts form to manage these optional parameters; see "[Maintaining Oracle User and Group User Accounts](#)" on page 1-9.

Table 1–2 Add User Script Optional Parameters

Prompt/Equivalent in Oracle Accounts Window	Description	Rules and Examples
Custom Doc Dir /Custom Help Directory	Specifies the location of your site-specific context-sensitive HTML help files.	
Printer for PSUB /Default PSUB Printer	The printer to which PSUB print jobs are routed, in upper case. This response must match the Short Value of an active entry in the PRINT QUEUE NAME local reference codelist. Required for RDC users only if they run Validate Study or Validate Site.	RXC_PRINTER (This is the default value for the database shipped in the OCL_JOB_PREF local reference codelist.)
Queue /Default PSUB Queue	The designation for the queue in which PSUB batch jobs are executed. This response must match the Short Value of an active entry in the BATCH QUEUE NAME local reference codelist. Must be entered in upper case. Required for RDC users only if they run Validate Study or Validate Site.	RXC_BATCH_QUEUE (This is the default value for the database shipped in the OCL_JOB_PREF local reference codelist.)

Table 1–2 (Cont.) Add User Script Optional Parameters

Prompt/Equivalent in Oracle Accounts Window	Description	Rules and Examples
Printer for the Report Server /Default RS Printer	The printer to which print output from a report server job is routed. This response must match the Short Value of an active entry in the PRINT QUEUE NAME local reference codelist. Must be entered in upper case.	<code>RXC_PRINTER</code> (This is the default value for the database shipped in the OCL_JOB_PREF local reference codelist.)
Report Server /Default Report Server	Specify a value if you want to override the system default for a specific user. When the user prepares to submit a report request, this response specifies which report server is offered as the default. This response must match the Short Value of an active entry in the REPORT_SERVER local reference codelist.	<code>REPORT_SERVER</code> (This is the default value for the database shipped in the OCL_JOB_PREF local reference codelist.)
Job Set Report Server /Default Job Set Server	When the user prepares to submit a job set request, this response specifies which report server is offered as the default. This response must match the Short Value of an active entry in the REPORT_SERVER local reference codelist. Required for RDC users only if they run Validate Study or Validate Site.	<code>REPORT_SERVER</code> (This is the default value for the database shipped in the OCL_JOB_PREF local reference codelist.)
PSUB Scheduler Report Server /Default PSUB Scheduler Report Server	When the user prepares to submit a scheduled PSUB job request, this response specifies which report server is offered as the default. This response must match the Short Value of an active entry in the REPORT_SERVER local reference codelist. Required for RDC users only if they run Validate Study or Validate Site.	<code>REPORT_SERVER</code> (This is the default value for the database shipped in the OCL_JOB_PREF local reference codelist.)

Maintaining Oracle User and Group User Accounts

After you create a user with the Add User script, the user account appears in the Oracle Accounts window. Use this window to:

- Create group user accounts
- View and modify settings for individual user accounts

Do not use this window to create new individual user accounts because you cannot assign database roles to users here. Use the Add User script.

You can access other windows from Oracle Accounts to do the following tasks:

- [Adding a User to a Group User Account](#) on page 1-11; use this window to assign a user to a group user account. You can then grant data access to all the users assigned to the group user account at the same time.
- [Granting Data Access to a Study](#); use this window to grant access to one study at a time to a single user or group user account
- [Granting Data Access to Programs and Projects](#) on page 1-12; use this window to grant a access to all the studies in a program or project at the same time to a single user or group user account

To create a group user account:

1. From the **Data** menu, select **Insert Record**.
2. Enter values in the fields.

The window contains the following fields:

Account Type If set to Oracle, the record is an individual user account. To create a group user account, set to Group.

Account Name For an individual user account, the user ID; for a group user account, its name.

Last Name Family name or surname of the user with the individual user account; not required for group user accounts.

First Name Given name of the user with the individual user account; not required for group accounts.

Super User? If checked, the user or group user account has superuser status and can see data in all studies on the database. If not checked, the user or group user account can see data only for studies to which they are explicitly allowed access; see "[Granting Data Access to User and Group User Accounts](#)" on page 1-11.

PSUB Directory Location for log and output files from Parameterized Submission jobs; see "[Creating a PSUB Log Directory](#)" on page 1-3.

Report Server Directory Location for log and output files from Oracle Clinical reports jobs; see "[Setting Up a Report Server Log Directory](#)" on page 1-2.

Note: The location designation for any report server log directory, whether directory path or UNC, cannot exceed 35 characters

Custom Help Directory Location of company-specific context-sensitive html files, if any.

Default PSUB Printer The printer to which PSUB print jobs are routed, in upper case. This response must match the Short Value of an active entry in the PRINT QUEUE NAME local reference codelist.

Default RS Printer The printer to which print output from a report server job is routed. This response must match the Short Value of an active entry in the PRINT QUEUE NAME local reference codelist. Must be entered in upper case.

Default PSUB Queue The designation for the queue in which PSUB batch jobs are executed. This response must match the Short Value of an active entry in the BATCH_QUEUE_NAME local reference codelist. Must be entered in upper case.

Default Report Server When the user prepares to submit a report request, this response specifies which report server is offered as the default. This response must match the Short Value of an active entry in the REPORT_SERVER local reference codelist.

Default Job Set Report Server When the user prepares to submit a job set request, this response specifies which report server is offered as the default. This response must match the Short Value of an active entry in the REPORT_SERVER local reference codelist. See "[Using Job Sets to Control Execution Order](#)" on page 8-11 for information on job sets.

Default PSUB Scheduler Report Server When the user prepares to submit a scheduled PSUB job request, this response specifies which report server is offered as the default. This response must match the Short Value of an active entry in the REPORT_SERVER local reference codelist.

Note: The location designation for any report server log directory, whether directory path or UNC, cannot exceed 35 characters.

Adding a User to a Group User Account

You can add all the users who should have access to the same set of studies, programs, or projects to the same group user account and assign data access to all the users at the same time through the group user account. An individual user can belong to multiple group user accounts.

To add a user to a user group:

1. Navigate to **Admin, Users**, and then **Oracle Accounts**. The system opens the Oracle Accounts window.
2. Query for the individual user you want to add to a user group.
3. Click **Group Membership**. The system displays the Group Membership window.
4. From the **Group Membership** field's list of values, select the group to which you want to assign the user. If you want to assign the user to multiple user groups, use multiple rows.
5. Save your work.

Granting Data Access to User and Group User Accounts

You must explicitly give users access to study data, either by granting them Superuser status, which allows access to all studies, or explicitly granting access to specific studies or groups of studies (programs and projects). For RDC users, you can use either the Oracle Accounts window or the Study and Site Security windows; see ["Granting Data Access to RDC Users"](#) on page 1-13.

To allow an Oracle Clinical or RDC user—even a user who will work exclusively in RDC—to view study data, you must grant study or superuser access in Oracle Clinical. You can grant data access to a user or group user account in several ways:

- Grant access to data in all studies by granting the user or group user account superuser status, either in the Oracle Accounts window or, for individual users, when you run the Add User script.
- If the user or group user accounts does not have superuser status, you can grant access to data in one or more studies, either to one study at a time or to all studies in a program or project.

You can grant data access at several levels:

- [Granting Data Access to Programs and Projects](#) on page 1-12
- [Granting Data Access to a Study](#) on page 1-12

See also ["Superuser and Study Access Interaction"](#) on page 1-13 and ["Revoking User Access"](#) on page 1-13.

Granting Data Access to Programs and Projects

Assigning program or project access to a user or group user account enables either the individual user or the set of users in the group to have access to all studies associated with the program or project.

1. Navigate to **Admin, Users**, and then **Oracle Accounts**. The system opens the Oracle Accounts window.
2. Query for the account with which you want to work.

Note: You cannot assign project or program access to a user or user group whose **Super User?** flag is checked. That account already has access to all programs and projects.

3. Click **Programs/Projects**. The Programs window displays.
4. In the **Program** field, from the list of values select the name of the program to which you want the user or user group to have access.
5. In the **Project** field, from the list of values select the program to which the user will have access. If the user should have access to all projects within a program, enter a percent sign (%) in the project field.

If you want to assign multiple programs to the account, or multiple (but not all) projects within a program, use multiple rows. There is no limit to the number of programs to which the user can have access.

6. Save your work.

Granting Data Access to a Study

To assign study data access to a user or user group:

1. Navigate to **Admin, Users**, and then **Oracle Accounts**. The system opens the Maintain Oracle Accounts window.
2. Query for the account with which you want to work.

Note: You cannot assign study access to a user or user group whose Super User flag is checked. That account already has access to all studies.

3. Click **Studies**. The Studies window displays.
4. In the **Study** field, from the list of values select a study to which you want the user or user group to have access. If you want to assign multiple studies to the account, use multiple rows. There is no limit to the number of studies you can specify.
5. Save your work.

Note: If a user creates a new study and does not have access to it through the project and/or program it belongs to, the system automatically gives the user access to the study he or she has just created.

Superuser and Study Access Interaction

You cannot assign project or program access to a user or user group whose **Super User?** flag is checked. That account already has access to all programs and projects.

However, if you assign access to programs, projects, or studies to a user whose **Super User?** flag is not checked, and then check that user's **Super User?** flag, the superuser status overrides the existing specific privileges, but the existing privileges are still displayed in the Projects, Programs, and Studies windows.

If an RDC user has superuser status in the Oracle Accounts window and has access to only a subset of RDC studies in the Study Security window, the superuser status overrides the study-specific privileges and the user has access to all studies. However, you can use the Study Security window to limit the type of access to a particular study. See the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for information.

Revoking User Access

Note: If a user has both superuser status and access to specific studies defined, you must revoke the superuser status before you can revoke his/her access to a specific study.

When you revoke access to a program, you revoke access to all projects within that program.

To revoke a user's study, user group, project, or program access:

1. Navigate to **Admin, Users**, and then **Oracle Accounts**. The system displays the Oracle Accounts window.
2. Query for the account with which you want to work.
3. Click either **Studies, Programs/Projects**, or **Group Membership**.
4. Select the study, program/project combination, or user group from which you want to remove the user.
5. From the Data menu, select **Delete Record**.
6. Save your work.

Granting Data Access to RDC Users

This section contains the following topics:

- [Granting Automatic Access in RDC to Studies Granted in Oracle Clinical](#) on page 1-13
- [Configuring Study and Site Security Privileges](#) on page 1-14
- [Changing the Default Access to DCIs](#) on page 1-14

Granting Automatic Access in RDC to Studies Granted in Oracle Clinical

You can use a reference codelist setting to determine whether users who have access to data for a particular study in Oracle Clinical automatically have access to the study in RDC.

In the OCL_STATE local reference codelist, set the DMGR RDC ACCESS short value as follows:

- When set to **YES**, a user with no study privileges defined for RDC but with study access defined in Oracle Clinical is automatically given RDC Onsite access to the study as well, in both Test and Production modes. The user has all RDC privileges except APPROVE and VERIFY. UPD_LOCK_OC, an Oracle Clinical-specific privilege, is also excluded. You can restrict such a user's access to RDC Onsite by limiting privileges at the study or site level; see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for further information.
- When set to **NO**, a user granted access to a study in Oracle Clinical does not automatically have access to that study in RDC Onsite. You can use the Study Security form to assign specific privileges to the user; see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for further information.

Users with the **Super User?** flag selected in the Oracle Accounts form in Oracle Clinical have access to all studies in both Oracle Clinical and RDC, and in both Test and Production modes.

Configuring Study and Site Security Privileges

You can give RDC users specific privileges for particular studies and sites in the Study and Site Security windows, which are included in both Oracle Clinical and in the RDC Onsite Administrator's Tool; see "[Configuring Study and Site Security for Discrepancy Management](#)" on page 3-26.

Changing the Default Access to DCIs

RDC Onsite includes a predefined set of user roles. By default, these roles have UNRESTRICTED access to all DCIs. You can change the default access for any role to RESTRICTED.

- Users assigned to a role with UNRESTRICTED access to DCIs can access any DCI in RDC Onsite unless access has been denied to a particular DCI in a particular study through the DCI Access window in the Oracle Clinical Definition menu; see *Oracle Clinical Creating a Study* for study-level information.
- Users assigned to a role with RESTRICTED access to DCIs cannot access any DCIs in RDC Onsite unless access has been granted to a particular DCI in a particular study.

You may want to create custom database roles specifically for the purpose of restricting access to certain DCIs to smaller groups of people (see "[Creating Custom Database Roles](#)" on page 2-6 for more information and an example). If you do, you must add the new role in the Maintain DCI Access by Role window and specify a default access of RESTRICTED or UNRESTRICTED for it.

Caution: If you create a new user role but do not specify a default value for DCI access, users assigned to that role cannot log in to RDC Onsite. You must define the default access to DCIs for every user role you plan to assign.

If you assign a user to more than one role, and those roles have conflicting DCI access, the user cannot log it to RDC Onsite.

Before you can change the default DCI access for a user, the user role must exist (must be valid). You cannot change the default DCI access if the user role does not exist.

To define the DCI access for a user role:

1. Open Oracle Clinical.
2. Navigate to **Admin** and then select **Users and Roles**.
3. Select **Default DCI Access by Role**.

Alternatively, you can select one of the following menu options depending upon your administrator privileges and current task:

- Select **Test Default DCI Access** if you want to try out DCI access before implementing the feature in a live study.
 - Select **Query Default DCI Access by Role** if you only want to view the current settings but make no changes.
4. Enter a valid user role in the **User Role** field. You can:
 - Type the name of a valid user role into the field.
 - Click the **List of Values** button, and then select a user role from the list. The list includes all the user roles currently defined in the USER GROUP ROLES installation reference codelist.
 5. Enter the default DCI access for the selected user role. Valid entries are:
 - **UNRESTRICTED** — Allows study/site access to all DCIs unless otherwise restricted in the DCI Access form for the study.
 - **RESTRICTED** — Does not allow access to any DCIs unless you specify exceptions in the DCI Access form for the study.

You can type a valid entry directly into the field. Alternatively, you can click the **List of Values** button, and then select from the list.

6. Continue to enter each user role and the type of DCI access allowed.
7. Save your changes.

For each record in the Maintain Default DCI Access by Role form, Oracle Clinical creates and maintain an audit trail.

Upon initial entry to the form, Oracle Clinical populates the form with all the user roles defined in the USER GROUP ROLES reference codelist. For each user role, the Default DCI Access field is set to UNRESTRICTED. You must add any new user roles that you create.

Granting Additional Database Roles to User Accounts

This section contains the following topics:

- [Additional Database Roles for RDC Users](#) on page 1-16
- [Additional Database Roles for RDC Users](#) on page 1-16

The Add User script grants the minimum database roles required for a user to access Oracle Clinical and, if you specify that RDC access is required, RDC.

- Oracle Clinical default database roles: CONNECT, RESOURCE, RXCLIN_READ, RXC_ANY, AND OCL_ACCESS
- RDC default database roles: RXC_RDC and RDC_ACCESS

Users require additional database roles to do meaningful work in either Oracle Clinical or RDC.

To grant one or more database roles to a user:

1. Log in to SQL*Plus as SYSTEM.
2. Grant a role to a user:

```
grant database_role to user_name
```

For example: `grant rxc_site to BSMITH`

Additional Database Roles for RDC Users

You must explicitly grant every RDC Onsite user at least one database role. You can use the predefined database roles listed in [Table 1–3](#), selecting the role that matches the user's job function, or define additional database roles if you need to further fine-tune security privileges; see ["Creating and Modifying Database Roles"](#) on page 2-3.

These database roles are mapped to user roles in the installation reference codelist `USER_GROUP_ROLES`. Those user roles are used to define security privileges and to customize various aspects of the user interface. See [Chapter 3, "Configuring Discrepancy Management"](#) for further information.

Table 1–3 Default Database Roles Defined for RDC Users

Database Role	Typical User Profile
RXC_DMGR	Data manager
RXC_SUPER	Data manager
RXC_CRA	Clinical Research Associate (CRA)
RXC_SITE	Site user, 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

Additional Database Roles for Oracle Clinical Users

The database roles assigned to a user determine which tasks a user can perform by controlling which menu paths the user can see in the user interface—for example, Study Design, Data Entry, or Administration—and within those areas, finer distinctions such as whether the user can make changes or only view existing data. Oracle Clinical includes many predefined database roles for this purpose. You can also define your own database roles; see [Chapter 2, "Oracle Clinical Menu-Based Security"](#) for more information.

The roles in [Table 1–3](#) apply to the Oracle Clinical discrepancy management system as well as to RDC. Give one of the above roles to each user who has one of the corresponding job functions and who will be working with discrepancies in Oracle Clinical's Maintain Discrepancy Database window.

Setting Up Data Extract Users

Oracle Clinical users who need to generate Data Extract views and write macros require additional setup:

- [Creating an Operating System Account on the SAS Server](#) on page 1-17
- [Adding User to the OCLSASCR User Group \(UNIX only\)](#) on page 1-17
- [Creating a Queries Table for a Data Extract User](#) on page 1-17

Creating an Operating System Account on the SAS Server

User who need to generate SAS Data Extract view need an operating system account on the SAS server. If they do not already have one, create one; see instructions in ["Creating an Operating System Account"](#) on page 1-3.

Adding User to the OCLSASCR User Group (UNIX only)

Add the user to the OCLSASCR user group to give the user access to the RXC_USER directories that hold the SAS Data Extract Views. The OCLSASCR user group is created as part of the Oracle Clinical installation and has all the privileges required to use SAS. Refer to the *Oracle Clinical Installation Guide* for instructions on creating the OCLSASCR group.

You can add the user to the OCLSASCR user group by:

- using the `usermod` command, or
- editing the `/etc/group` and `/etc/logingroup` files, if these files are not linked; if these files are linked, it is only necessary to modify the `/etc/group` file.

Creating a Queries Table for a Data Extract User

Oracle provides a script, `crusrq.sql`, that creates a table called `USER_QUERIES` in an individual user's schema. The table provides a location to save the SQL code the user creates using data extract functions. Run the script for each user who will write data extract functions.

To create this table:

1. Change directories to the `RXC_INSTALL` directory.
2. Run this command:

```
sqlplus @crusrq
```

Alternatively, you can modify the Add User script to create the `USER_QUERIES` table automatically by adding these lines:

```
connect &&ops_id/&&pwd
@rxcl_install:crusrq.sql
```

Setting Up Power Users

Most end users do not require additions to a login script for Oracle Clinical purposes. Only power users who want to run `opa_setup` from the command line (in order to condition their environment to point to a particular database, or a code environment, or both), must add commands to a login script on that machine, in order to configure their environments.

A power user might use `opa_setup` to set environment variables for such tasks as:

- running client applications other than Oracle Clinical (such as SQL*Plus, SAS, or a reporting program) against an Oracle Clinical database
- installing patches to Oracle Clinical server code or databases
- running Oracle Clinical administrative SQL scripts

For users who will perform these tasks, commands must be added to the login scripts that:

- define `RXC_LOG`

- add SAS
- add source (on C shell).

UNIX

Bourne/Korn shell Edit the user's `.profile` file. In the following example, `SAS_home` is the directory where the SAS executable is located.

```
# Include OPA directories
PATH=$PATH:/opa_home/bin:/sas_home; export PATH
# Define RXC_LOG for command line utilities
RXC_LOG=$HOME/log; export RXC_LOG
```

C shell Edit the user's `.cshrc` file. For example:

```
# Include OPA directories
set path=( $path /opa_home/bin /sas_home )
# Define RXC_LOG for command line utilities
setenv RXC_LOG $HOME/log
# Create alias for opa_setup
source /opa_home/bin/copa_setup_alias
```

Windows

No changes to a login script are required. In order to run `opa_setup`, ensure that `opapps_home/bin` is in the `PATH` environment variable.

Setting Up Passwords

Changing passwords depends on whether they are for a schema, a role, or for a user.

The section is comprised of the following topics:

- [Changing the Password for a Schema or Role](#) on page 1-18
- [Changing the Password for a User](#) on page 1-19
- [Enforcing Password Security](#) on page 1-20
- [Auditing Passwords](#) on page 1-20
- [Operating System Passwords](#) on page 1-20

Note: Passwords cannot contain these characters: { | } @ ;

Changing the Password for a Schema or Role

Certain Oracle Clinical database objects are protected by password. These objects are listed and described in [Table 1–4, "Password-protected database objects"](#).

Table 1–4 Password-protected database objects

Name	Type	Description
RXC_MAA	Schema	Required for Data Extract.
RXC_PD	Schema	Required for Procedure generation.
RXC_REP	Schema	Required for replication.
RXC_DISC_REP	Schema	Required for disconnected replication.

Table 1–4 (Cont.) Password-protected database objects

Name	Type	Description
RXCLIN_MOD	Role	Enables Oracle Clinical users to write to the database. This role is set for users when they log in through the application.
RXC_SERVLETSP	Schema	Used for accessing study data from Data Entry window in Production mode.
RXC_SERVLETST	Schema	Used for accessing study data from Data Entry window in Test mode.

Encrypted versions of the passwords associated with these objects are stored in two locations:

1. an Oracle dictionary table, and
2. an Oracle Clinical passwords table.

If you want to change any of these passwords, you must change the encrypted value in both locations. You can change the passwords in both places at once with the SET_PWD utility, following these steps:

1. Log on to the database server using an account that is set up to run Oracle Clinical back end jobs.
2. Set environment variables for the database and code environment. For example, for database **test** and code environment **46**:

a. UNIX: `opa_setup test 46`

b. Windows:

```
set p1=test
```

```
set p2=46
```

```
opa_setup
```

3. Enter a command in the following format:

```
set_pwd rxc/rxc_password db_object_name db_object_password
```

where *rxc_password* is the password for the rxc account, *db_object_name* is the name of the database object from [Table 1–4](#), "Password-protected database objects", and *db_object_password* is the new password for that object. For example:

```
set_pwd rxc/notrxc rxclin_mod r2d2c3po
```

Changing the Password for a User

Users can change their own database passwords either in SQL*Plus or with the Oracle Clinical menu by choosing **Admin**, then **Users**, and then **Database Password**.

In the Oracle Database Password window:

1. Type your password in **Enter Password** text box.
2. Type it again in the **Confirm Password** text box.
3. Click **OK**.

Administrators can change the password for an Oracle Clinical user in SQL*Plus as usual:

1. In SQL*Plus, connect to the database as the SYSTEM user.

2. Reset the password for the user:

```
alter user user identified by user_password;
```

Enforcing Password Security

Oracle enables a database administrator to enforce various rules about passwords at the database level, including setting a password lifetime, after which users must set a new password; disallowing reuse of previous passwords; locking an account after a user attempts to logon a specified number of times; and creating complexity rules for passwords through a PL/SQL function.

All rules that you set at the database level apply when a user connects through Oracle Clinical. If the password has expired, a dialog box that prompts the user for a new password automatically appears. For further details, refer to your Oracle *Administrator's Guide*.

Auditing Passwords

Oracle recommends that you turn on the auditing system for roles. For information on the AUDIT command, refer to the Oracle *SQL Reference* manual.

To track failed attempts to create, alter, drop, or set a role, issue the following statement:

```
audit role by access whenever not successful
```

Operating System Passwords

A system-level account must exist on the database server computer in order for Oracle Clinical users to run PSUB jobs. On UNIX, you can choose whether to allow users to store their UNIX account passwords in the Oracle Clinical database in an encrypted format. On Windows, users *must* store their passwords to be able to run any PSUB job.

You use the Operating System Password window to change whether your system password is stored in Oracle Clinical. This window is accessible either:

- by selecting **Admin**, then **Users**, and **OS Password**, or
- by selecting the **Server OS Password** button in the **Submission Details** window.

The Operating System Password window consists of an **Enter password** text box and a check box entitled, **Save encrypted password in the database?**

The behavior of the check box depends on your operating system and is described in the following subsections:

- ["UNIX Passwords"](#) on page 1-21
- ["Windows Passwords"](#) on page 1-21

Note: If the PSUB server belongs to a Windows domain, users' local accounts on that server must match the passwords of their domain accounts. In this way, the correct authentication is passed to the server and access is allowed to the domain resources. Otherwise, users' PSUB jobs do not print.

UNIX Passwords

On UNIX servers, you control the **Save encrypted password in the database?** check box with the Short Value of the USR_SAVE_OSPASS entry in the **OCL_STATE** local reference codelist. The default value of USR_SAVE_OS_PASS is "N" (No). In this case, the check box the system displays in the Operating System Password window is clear and not updateable. If you change the value of USR_SAVE_OS_PASS to "Y" (Yes), the check box is still clear, but it is updateable, which allows the user to select it.

Windows Passwords

On Windows servers, a stored password is required for any PSUB server-side job. When end users see the Server OS Password dialog box, the **Save encrypted password in the database?** check box is selected and cannot be updated. The first time a user runs a PSUB job, the system prompts for a password if it has not already been stored in the database.

Oracle Clinical Menu-Based Security

This section includes the following topics:

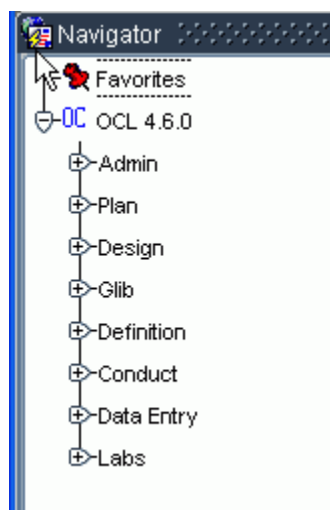
- [Creating and Modifying Database Roles](#) on page 2-3
- [Adding Menu Items to Oracle Clinical](#) on page 2-8

You control which users have access to which menu items in the Oracle Clinical Navigator (see [Figure 2-1](#)) by assigning database roles to users.

Oracle Clinical includes a set of predefined database roles that allow access to a predefined set of Oracle Clinical menu items, including second- and third-level menu items (see [Figure 2-2](#)). You can enforce security by assigning users only the database roles they need to do their work, preventing them from seeing other parts of the system and taking actions they are not authorized to take.

If necessary, you can modify the menu items associated with the predefined database roles or create entirely new database roles.

Figure 2-1 Oracle Clinical Navigator with Top-Level Menu Items Displayed



Although each company distributes Oracle Clinical tasks differently among its personnel, following is a guideline for which users need which menu items:

- Administrators need some or all of the Admin menu.
- Study designers need some of the Admin menu and the Plan, Design, and Definition menus. They may also need Glib (Global Library), or you may have people who use only the Global Library.

- Data Managers need the Conduct, Data Entry, and Labs menus. They may also need some or all of the Definition menu.
- Data entry operators need the Data Entry menu.
- Programmers who write validation and derivation Procedures and data extract macros need parts of the Definition menu.

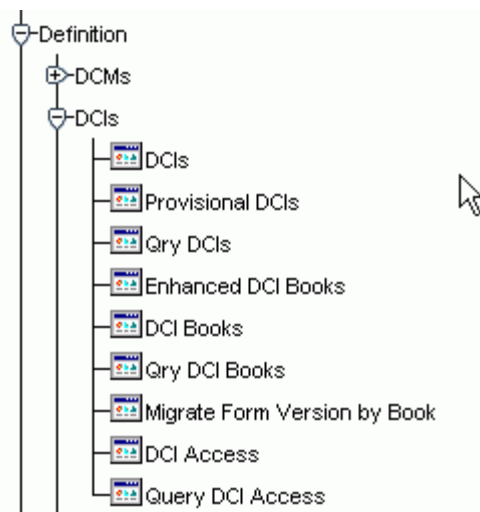
For information about the tasks in each menu, see the following Oracle Clinical user documentation:

- *The Oracle Clinical Administrator's Guide* has information on the Admin menu.
- *Oracle Clinical Creating a Study* has information on the Plan, Design, and Definition menus.
- *Oracle Clinical Conducting a Study* has information on the Conduct, Data Entry, and Labs menus.

In many cases, there are two menu items for the same form associated with different database roles. In this way you control user's privileges through menu access. Menu items based on the same form may differ as follows:

- **Query and Read-Write Versions:** One menu item allows read-only privileges and the other allows write privileges as well. If a user has access only to the Query version of the form, he or she cannot view the data there but cannot make any changes.
- **Provisional and Active Definitions.** Definitional objects can have a status of Provisional or Active. Some menu items allow the user read and write access only to Provisional objects, while a different version of the same form allows access to Active objects, which may be currently in production use, as well.
- **Test and Production Patient Data.** One menu items allows read and write access to test data and the other allows read and write access to production data.

Figure 2-2 Oracle Clinical Navigator with the Definition DCIs Menu Displayed



Predefined Database Roles

To see a complete list of the predefined database roles and the menu items to which they allow access, run the Menu Roles report in the Developer's Toolkit.

To run the Menu Roles report, navigate to **DTK**, then **Menu Roles**. To see the Developer's Toolkit (DTK menu item) you must have the DTK_ADMIN database role. See "[Granting Additional Database Roles to User Accounts](#)" on page 1-15.

If you create custom roles for your Oracle Clinical database and set up menu security for these roles, you can run the Menu Roles report to confirm that you have set up these roles correctly. The Menu Roles report describes, for both default and custom roles, the menu items to which each role gives a user access. This report applies to the current database only.

Note: If the Menu Roles report does not show a custom role you have defined, you may not have defined a record for that role in the OPA_MENU_ROLES codelist. See "[Adding a Custom Role to OPA_MENU_ROLES](#)" on page 2-8.

Creating and Modifying Database Roles

To modify menu security, you must access the Developer's Toolkit (DTK) menu in the Oracle Pharmaceutical Applications Navigator window. Entries on the DTK menu are accessible only to those database accounts granted the DTK_ADMIN role. The DBA should grant this role to those accounts with the responsibility for maintaining Oracle Clinical roles. This section assumes that your account has the DTK_ADMIN role.

This section is comprised of the following topics:

- [Viewing Menu-Role Associations](#) on page 2-3
- [Modifying Menu-Role Associations](#) on page 2-6
- [Creating Custom Database Roles](#) on page 2-6
- [Associating Roles with Menus](#) on page 2-7
- [Granting a Custom Role Access to a Custom Module](#) on page 2-8
- [Adding a Custom Role to OPA_MENU_ROLES](#) on page 2-8

Viewing Menu-Role Associations

This section contains the following topics:

- [Organization of the Menu Module Tree](#) on page 2-3
- [Navigating the Menu Modules](#) on page 2-5

To view the activities covered by a particular database role, from the Navigator, expand Developer's Toolkit and select Maintain Menu Modules. In the form, press the Query by Role button for a list of values. Choosing a role causes a display of all activities associated with that role. A complete list of database roles and their relation to menu items can be generated by running the Menu Roles report from the Developer's Toolkit.

Organization of the Menu Module Tree

This section describes the internal structure of the Navigator's menus, and the roles and role associations provided by Oracle Clinical.

Internal Menu Module Structure All activities accessible through the Navigator are organized in a tree, with the root "OPA". Descending from OPA, a node exists for each installed application. For your installation, there will, at a minimum, be nodes for OCL (for Oracle Clinical activities), OPA (for menus and activities generic to all products of Oracle Health Sciences, formerly known as Oracle Pharmaceutical Applications), and DTK (for the Developer's Toolkit). In turn, each of node is the parent of other menu nodes, and ultimately of leaf nodes, which correspond to executable modules.

Figure 2-3 Maintain Menu Modules Window

Module Id	Application	Type Code	Label	Name	File Name	Sub Env	Lang.	# Roles
163600	TMS	TOPMENU	TMS	TMS			All	1
171200	OCL	TOPMENU	OCL	OCL			All	1
171300	OPA	TOPMENU	Favorites	FAVORITES			Eng	1
180400	DTK	TOPMENU	Developer's Toolkit	DTK			Eng	1
199400	PHD	TOPMENU	PhD	PHD			Eng	6

Buttons: Exit, Save, Menu entries, Roles, Query by Role, Query Top Menus

Many executable modules can perform more than one task, so to completely define an activity, there is also a task name and a query-only flag. For instance, the same form module, RXCRCMAI, performs both query and maintenance of local, installation, and system reference codelists. Consequently, there are six leaf nodes for this module — one for each combination.

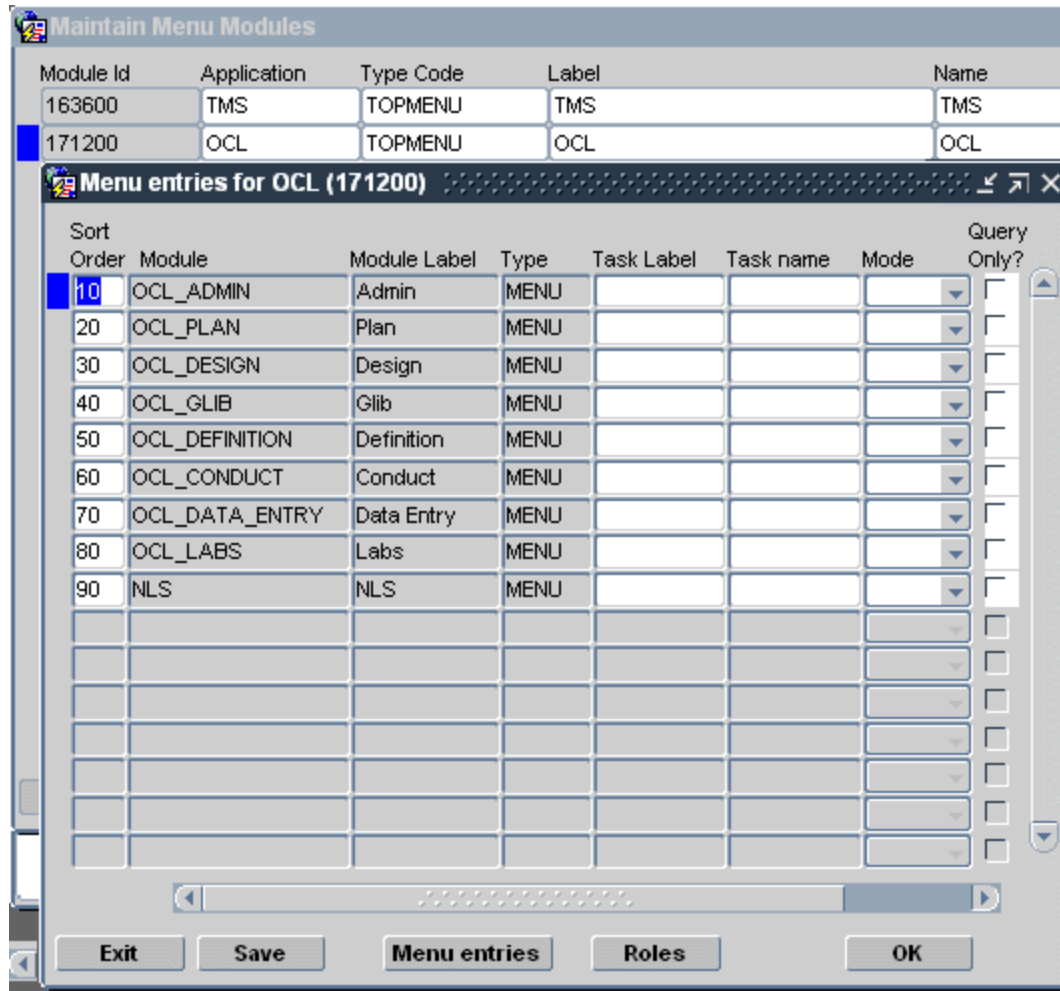
The concatenation of nodes, starting at OPA, ending at the leaf node, and including the task and the query mode, is the internal analog of the Navigator menu path to the activity. For instance, the menu path **OC**, then **Data Entry**, and **Initial Log-In**, plus **Entry** corresponds to the series of nodes OPA:OCL:OCL_DATA_ENTRY:RXCDLEMLI, plus the task name INITIAL LOG-IN AND FIRST-PASS ENTRY, and a clear ("no") query-only flag.

Role Association Structure The access an application user has to each node in the menu-module tree is determined by the database role. Each node of the menu tree has associated with it one or more database roles that are allowed access to that node. A user that is not associated with the appropriate role cannot view its corresponding menu or module. The following examples illustrate how the role associated with a user account affects the access the user is given to different menus:

- To view the OCL application menu, a user's Oracle account must be granted the OCL_ACCESS role. This is typically an automatic grant when an Oracle Clinical account is created, along with CONNECT, RESOURCE, RXCLIN_READ, RXCLIN_MOD, and RXC_ANY.
- When Oracle-defined menu-role associations have not been modified, to see the **Data Entry** menu option of **OCL** your account must have one of these roles: RXC_DE; RXC_DE2; RXC_DMGR; RXC_SUPER; or RXC_SUPER_NOGL.
- The Initial Log-In and Entry activity requires the same roles, according to the module-role association created in the database by Oracle. So, in order to run

Initial Log-In and Data Entry, your account needs at least two roles: OCL_ACCESS, and one of: RXC_DE, RXC_DE2, RXC_DMGR, RXC_SUPER, RXC_SUPER_NOGL.

Figure 2–4 Menu Entries for Module Window

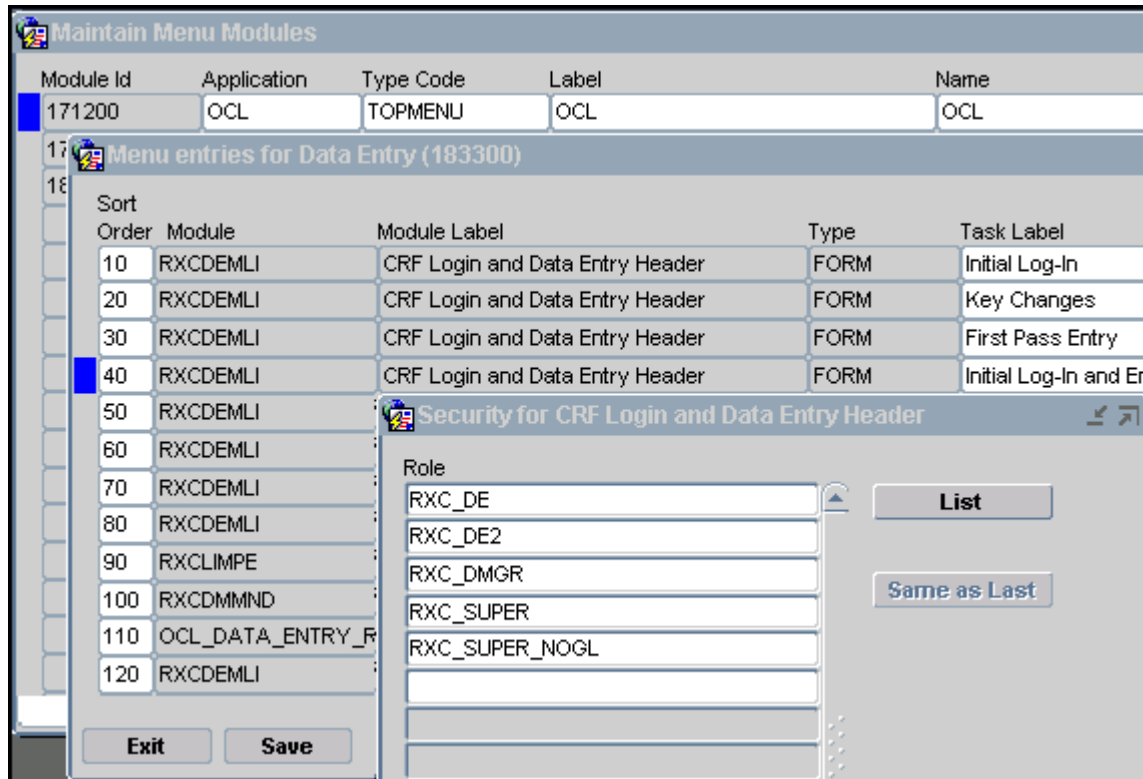


Navigating the Menu Modules

To view or modify the roles permitted access to the Oracle Clinical menus and activities, navigate to **DTK**, then **Maintain Menu Modules**. A Maintain Menu Modules window opens, as shown in [Figure 2–4, "Menu Entries for Module Window"](#), with one entry per top-level menu node in the OPA Navigator menu. The record with a blue mark to its left has focus. Change focus by clicking once anywhere on the record of the node you want to examine.

To drill down into the menu nodes from the currently selected node, click **Menu Entries**, or double-click anywhere in the node's record. Doing this from the Maintain Menu Modules window brings up a new window, as in [Figure 2–4](#), with a title bar naming the parent node, and with records describing the child nodes of that parent. You can continue to drill down within this window until you reach a leaf. If the record that has focus is a module, you have reached a leaf of the tree and the **Menu entries** button is disabled, as in [Figure 2–5](#).

Figure 2-5 Security for Task Dialog Box



Modifying Menu-Role Associations

At any node of the menu-module tree, you can see or modify the database roles associated with the node by pressing the Roles button. This button brings up a Security for *task* dialog box where the roles enabling access to this node are listed and can be modified. Figure 2-5, "Security for Task Dialog Box" illustrates this process for Initial Log-In and Entry.

You can also query the nodes accessible via a role through the Query by Role button, available in the Maintain Menu Modules and Menu Entries for *module* windows. If you click on this button, you are prompted for a role (an list of values is available). When you enter a role, all menu-module tree nodes accessible via that role are displayed. The Query Top Menus button returns you to a list of the application menu nodes (Figure 2-5).

Creating Custom Database Roles

This section describes how to create a new database role. This may be required if the database roles that are supplied as part of installation do not fit or cannot be modified to fit your business model.

After you create a new database role, grant it access to menu items (see "Modifying Menu-Role Associations" on page 2-6) and add it to a reference codelist (see "Adding a Custom Role to OPA_MENU_ROLES" on page 2-8).

Menu and module access role names must start with the three-letter designator of the application to which they will apply, as shown in Table 2-1, "Prefixes for Role Name, by Application".

Table 2–1 Prefixes for Role Name, by Application

Prefix	Application
DTK	Developer's Toolkit
OCL or RXC	Oracle Clinical
OPA	Oracle Pharmaceutical Applications
TMS	Thesaurus Management System

Examples of valid role names are: OCL_CRA, RXCBROWSER, DTK_HELP. The Oracle Clinical Remote Data Capture module has no special prefix; its role names are preceded by RXC.

To create a new database role, you must create the role in the database and explicitly grant all the database privileges required for users with the role to do the tasks you intend, including privileges on the related Oracle Clinical tables.

Log in to SQL*Plus as SYSTEM and enter the following:

```
create role role_name;
grant privilege on table to role_name;
```

For information on Oracle Clinical tables, see the Oracle Clinical Technical Reference Manual.

Creating Custom Roles for Restricting DCI Access

You may want to create additional database roles to use in restricting access to DCIs. There is only one predefined role for investigators: RXC_INV. If you want to hide one investigator's observations from another's you need more than one investigator role, for example Neurologist (RXC_NEUR, for example) and Oncologist (RXC_ONC, for example). You can create these two roles, create CRFs that are specific to each of those types of observations, and allow one investigator role access to the DCI corresponding to one CRF and the other investigator role access to the other.

Note the following additional tasks required:

- Define default DCI Access for the role; see ["Changing the Default Access to DCIs"](#) on page 1-14. You must do this before any users assigned the role try to log in to RDC.
- Assign the roles to users; see ["Granting Additional Database Roles to User Accounts"](#) on page 1-15. Be careful not to assign roles with conflicting DCI access to the same user.

Associating Roles with Menus

Once a new database role has been created and is accessible, select the **Maintain Menu Modules** option of the **DTK** menu to identify those menus and activities to which the role gives a user access.

Navigate to each node in the menu-module tree (see ["Modifying Menu-Role Associations"](#) on page 2-6) to which this role should give access, then click the **Roles** button. This brings up a dialog box where the roles that enable access to the node are listed. Add the new role to the list.

Adding a Custom Role to OPA_MENU_ROLES

Custom roles do not appear in the Menu Roles report until you add them to the OPA_MENU_ROLES installation reference codelist. To add a custom role to this codelist:

1. Choose **DTK**, then **Maintain all Codelists**.
2. Query for the OPA_MENU_ROLES codelist.
3. Insert a new record, and define the short value and long value of the codelist. The long value must match the full name of the new database role exactly, and the short name must be three characters or fewer, and unique in that database. The system uses the short name of the role when it generates the Menu Roles report.

Granting a Custom Role Access to a Custom Module

Use these instructions if you are assigning a custom role to a custom module; see ["Adding Menu Items to Oracle Clinical"](#) on page 2-8. This procedure allows you to grant the role access to the module as well as to the individual menu items.

1. Open the appropriate menu module file in Oracle Developer 10g Forms Builder.
2. Connect to the database as RXC.
3. In the Object Navigator, highlight the RXCUSER *module* (not the menu).
4. In the Menu Security property, add the new role. Use the same name as in the database.
5. Assign your new role to the appropriate menu items as described elsewhere in this section.
6. Save, compile, and distribute the resulting .mmx file.

Note: If you want to assign a new role to a standard Oracle Clinical module, refer to the ["Modifying Menu-Role Associations"](#) section on page 2-6.

Adding Menu Items to Oracle Clinical

You can add your own menu items (Developer modules) to the Users and Roles menu, thus extending the functionality of Oracle Clinical. Since you control the Users and Roles menu, you can preserve changes to it across releases of Oracle Clinical. See the *Installation Guide* for instructions.

Replace the files rxcuser.mmb and rxcuser.fmb with your own menu and form, which will be what is brought up by choosing **Admin**, and then **Users and Roles**.

Configuring Discrepancy Management

Both Oracle Clinical and the Remote Data Capture (RDC) option use the discrepancy system, which is described in *Oracle Clinical Conducting a Study*. This section describes the tasks for configuring the discrepancy management system:

- [Mapping Database Roles to User Roles](#) on page 3-1 (Oracle Clinical and RDC)
- [Specifying User Roles for the Oracle Clinical Discrepancy Database](#) on page 3-2 (Oracle Clinical only)
- [Customizing Layout Definitions](#) on page 3-4 (Oracle Clinical only)
- [Customizing Profiles](#) on page 3-5 (Oracle Clinical only)
- [Customizing Flexfields](#) on page 3-9 (Oracle Clinical only)
- [Defining Reason Codes for Discrepancies](#) on page 3-11
- [Defining the Possible Review Statuses for Discrepancies](#) on page 3-14
- [Defining Resolution Reasons for Discrepancies](#) on page 3-16
- [Setting Values in the OCL_STATE Local Reference Codelist](#) on page 3-17
- [Configuring Role-Specific Discrepancy Management for RDC](#) on page 3-17 (RDC only)
- [Configuring Study and Site Security for Discrepancy Management](#) on page 3-26 (Oracle Clinical and RDC)
- [Setting Up Data Clarification Forms \(DCFs\)](#) on page 3-28 (Oracle Clinical only)
- [Creating Reusable Standard Text for Discrepancies and DCFs](#) on page 3-34 (Oracle Clinical and RDC)

See the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for information on setting up Study/Site discrepancy management privileges.

Mapping Database Roles to User Roles

This section applies to all RDC users and to Oracle Clinical users who need to work with discrepancies in Oracle Clinical's Maintain Discrepancy Database window.

User Roles are important because:

- RDC uses them to define access privileges; see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for more information.
- You can customize RDC discrepancy management, news, and activities for different user roles; see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for more information.

- You can customize the layout of the Maintain Discrepancy Database window for different roles; see ["Customizing Layout Definitions"](#) on page 3-4
- You can customize profiles for different roles; see ["Customizing Profiles"](#) on page 3-5.

For these customizations and access privileges to be available to a user, the user must have a database role that is mapped to the relevant user role in the User Group Roles installation reference codelist.

There are five default user roles. You can create additional roles if necessary, and map them in the User Group Roles reference codelist to make them available for customizing features in RDC and Oracle Clinical discrepancy management; see ["Creating Custom Database Roles"](#) on page 2-6.

[Table 3-1](#) shows the default mapping of database roles to user group roles. The Long Value is not used.

Table 3-1 Default Values for the USER GROUP ROLES Codelist

Database Role (Short Value)	User Group Name (Long Value)	Description
RXC_DMGR	DM	Data management role
RXC_SUPER	DM	Data management role
RXC_CRA	CRA	CRA role
RXC_SITE	SITE	Site user
RXC_BIOS	BIOSTAT	Biostatistics role
RXC_QC	QUALITY CONTROL	Quality control role
RXC_INV	INV	Investigator

Note: The USER GROUPS reference codelist is used in Oracle Clinical discrepancy management only. It contains a subset of the User Group Roles in the USER GROUP ROLES reference codelist and determines which of them are available for use in Oracle Clinical discrepancy management; see [Chapter 3, "Configuring Discrepancy Management"](#)

Specifying User Roles for the Oracle Clinical Discrepancy Database

In the USER GROUPS installation reference codelist, you specify which of the roles mapped to database roles in the USER GROUP ROLES reference codelist will be available for use in customizing aspects of the discrepancy management system in Oracle Clinical, including profiles and layouts for use in the Maintain Discrepancy Database window.

The position of a database role in the codelist is important if users have more than one database role. In the case of a user with more than one role, the system uses the database role closest to the top (seq=1) in the codelist as the default; for example, as the default profile when the user opens the Maintain Discrepancy Database window.

The long value is not used.

Table 3–2 Default Values for the USER GROUPS codelist

Seq	Short Value (Database Role)	Long Value (User Group Name)	Description
1	DM	—	Data managers
2	CRA	—	Clinical research associates
3	BIOSTAT	—	Biostatistics group
4	QUALITY CONTROL	—	Quality control department

Note: *User groups* is a misleading term here. This codelist is used only in discrepancy management (including data clarification forms). The term used for groups of users who have access to the same studies, programs, or projects is *group user account*.

Assigning Function Privileges and Layouts

You control user group discrepancy function privileges and layout definitions in the User Group Admin window. From the **Admin** menu, select **Discrepancy Mgmt**, then select **User Group Administration**.

The window displays a list of existing user group names and their mapped database roles. Select a user group name to view its defined function privileges and layouts.

Assigning and Removing Function Privileges

In the Function Privileges display, you can add or remove privileges for the selected user group. If a group lacks a particular privilege, the system prevents members of that group from performing the function. (The system reference codelist DISCREPANCY FUNCTIONS controls the list of values; you cannot modify it.)

To add a privilege:

1. Click in an empty row. An ellipsis (...) appears.
2. Click the ellipsis. The list of values appears.
3. Select a privilege and click **OK**. The system adds the privilege.

To remove a privilege, select it and then select **Delete Record** from the **Data** menu.

The following table describes the function privileges.

Table 3–3 Function Privileges for Discrepancy Management

Name	Privilege Granted and Method of Use
UPD DATA ENTRY	Enables the Update Patient Data Special menu item in the Discrepancy Database window, and allows updates while in the Data Entry subsystem.
BRWS DATA ENTRY	Enables the Browse Patient Data Special menu item in the Discrepancy Database window for read-only access to patient data.
MANUAL	Enables the Add Manual button in the Maintain Discrepancy Database window, which allows users to create manual discrepancies and manual header discrepancies.
DCF PRINT DRAFT	Displays the Draft option in the DCF Print Options window; enables the user to print a draft version of a Data Clarification Form (DCF) report..
DCF PRINT COPY	Enables the Copy option in the DCF Print Options window; enables the user to print a copy of a DCF.

Table 3–3 (Cont.) Function Privileges for Discrepancy Management

Name	Privilege Granted and Method of Use
DCF PRINT FINISH	Enables the Final option in the DCF Print Options window; enables the user to print a final version of a DCF report.
DCF REPRINT	Enables the Reprint option in the DCF Print Options window; enables the user to reprint a final version of a DCF report.
CREATE DCF	Enables the Create DCF option in the group selection menu in the Maintain Discrepancy Database form.

Assigning Custom Layouts

If you define one or more custom layouts for the Discrepancy Database window (see "[Customizing Layout Definitions](#)" on page 3-4, assign it to a user group to allow the user group to use it. Users can select the layout they want to use from the **User Group Layouts** item in the Special menu of the Discrepancy Database window.

To assign a layout to a user group:

1. Click in an empty row. An ellipsis (...) appears.
2. Click the ellipsis. The list of values appears.
3. Select a layout and click **OK**. The system adds the layout.

To remove a layout, select it and then select **Delete Record** from the **Data** menu.

Customizing Layout Definitions

This section applies to Oracle Clinical only; not RDC.

Oracle Clinical provides the Layout Definitions utility for creating different representations of the Maintain Discrepancy Database window for different user groups. You can then assign layouts to different user groups. A user group can have more than one layout, and a layout can be used by multiple user groups.

A layout definition specifies which discrepancy details appear in the Master, or upper section, of the Maintain Discrepancy Database window in multi-record view, and which appear in the Detail, or lower section. The layout also determines the display location of each discrepancy detail, relative to the others in the same section of the window.

The Master section of the Maintain Discrepancy Database window in multi-record view is displayed above all the discrepancies. The system populates the fields in the upper section with values from the discrepancy that is highlighted in the lower section. All the fields in the Master section are visible without scrolling.

Of the discrepancy details that remain in the lower section of the window, put those that are most useful at the top of the list, so that they are displayed farthest left in the window. They, too, will be visible without scrolling.

To open the Layout Definitions window, from the **Admin** menu, select **Discrepancy Mgmt Admin**, then select **Layout Definitions**. You can also open this form directly from the User Group Admin form by clicking the **Layout Definitions** button. Users can create their own temporary layout directly in the multi-record view of the Maintain Discrepancy Database window; see "Changing Discrepancy Display Layout and Filtering the Data Displayed" in *Oracle Clinical Conducting a Study*.

To view the definition of an existing layout, select its name in the top section, labeled "Layout."

To create a new layout:

1. Enter a name for the new Layout in the top section, labeled "Layout." If no line is available, select **Data**, then select **Insert Record**.
2. One by one, select the fields you want to move into the other section and move them, using the sideways arrows:
 - Use the Left arrow to move the selected field into the Master, or upper, section of the window in multi-record view.

The system allows only eight fields in the Master section, specifically: **Patient, Visit, Subevent Number, DCM Name, Review Status, DCF ID, CRF Page, and Investigator**. To maximize the number of fields visible without scrolling, put all eight fields into the Master section.
 - Use the Right arrow to move the selected field from the Master section into the Detail, or lower, section of the window.
3. Use the Up and Down arrows to adjust the display order of the items. The topmost item in either the Master or Details list appears farthest left in the appropriate section of the Maintain Discrepancy Database window. The second item from the top appears second to the left, and so on.

In the Details section, the display order determines which fields are visible without scrolling. The number of fields that are visible without scrolling depends on the size of the fields you select.
4. Click OK to save your changes or click Back to return without saving your changes.

Users have access to the same utility for customizing the layout of the Maintain Discrepancy Database form. For a more comprehensive description of this utility, see "Using the Maintain Discrepancy Database Window" in *Oracle Clinical Conducting a Study*.

Customizing Profiles

This section applies to Oracle Clinical only; not RDC.

To open the Maintain Discrepancy Database form, a user must have a user role with a defined *profile*. Profiles control access to discrepancy records and fields, review status codes, data entry, layout definitions, and printing and tracking Data Clarification Forms (DCFs).

You can create *master* profiles for different user roles; individual users can modify their profile when they open the Maintain Discrepancy Database form.

See "[Mapping Database Roles to User Roles](#)" on page 3-1 for information about user roles.

To open the Profile Administration window, from the **Admin** menu, select **Discrepancy Mgmt Admin**, then select **Profile Administration**. The Profile Administration window opens in multi-mode view. You can toggle between modes by clicking the **View Mode** button in the upper right corner of the form.

Filtering Profile Views

The Profile Administration form includes a Profile Criteria section. You can specify the available criteria to suit different audiences. In multi-view mode the criteria are

columns of fields. In single-view mode, these fields are in the middle panel, labeled Profile Criteria.

Specifying Default Profile Criteria

You can refine a profile group's view by specifying default profile criteria values in the Profile Administration form. Many of the fields have lists of values. If you do not specify a particular criterion, the system allows a user with that profile to query all possible values. If you do not lock a profile criterion, (see the following section), users can override the Master profile's default settings.

Locking Profile Criteria

Profile users can customize their profiles, and thereby modify their views of the discrepancy database. You control the extent to which they can modify a profile by locking or unlocking each criterion. The locks are boxes that, in single-view mode reside between each criterion name and its field, and in multi-mode view reside to the right of each criterion's field. (See [Figure 3-1](#) and [Figure 3-2](#) for examples of each view mode, with diagonal arrows indicating the box positions.) The lock prevents users from modifying the default profile settings. If you do not lock a profile criterion, a profile user can override the profile's default setting.

In multi-view mode, for criteria like *Accessible Data Only?* where toggle boxes control viewing, the Lock box is to the right of the criteria names. (See [Figure 3-1](#) on page 3-6.)

In single-view mode, for criteria like *Accessible Data Only?* where toggle boxes control viewing, the Lock box is to the left of each criterion's toggle box. (See [Figure 3-2](#).)

Example 3-1 Profile Administration Form in Multi-View Mode

[Figure 3-1](#) on page 3-6 is a screen capture of a region of the Profile Administration form in multi-view mode. (Many of the intervening criteria fields have been scrolled out of view in order to include the *Accessible Data Only?* column in the illustration.) The diagonal arrows point to the Lock box columns for the *Creation Ts To* column's Lock box, near the top-center of the capture, and the *Accessible Data Only?* Lock box on the right. The table following [Figure 3-1](#) on page 3-6 describes how the settings in [Figure 3-1](#) control profile criteria viewing for the four listed profiles.

Figure 3-1 Sample Multi-View Region of the Profile Administration Form

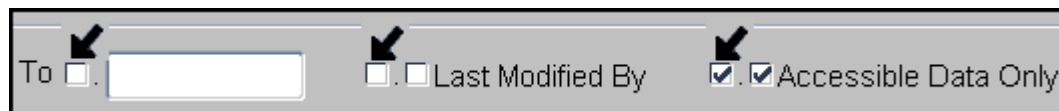
Profile Name	Creation Ts To		Accessible Data Only?	
BIOSTAT Master Profile	12-NOV-2003	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CRA Master Profile	12-NOV-2003	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DM Master Profile		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
QUALITY CONTROL Master		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Table 3–4 Legend for Figure 3–1

Profile Name	Creation Ts To Access Criterion Access	Accessible Data Only? Criterion Access
BIOSTAT Master Profile	Only records dated before 12-NOV-2003 appear by default, but users can change this date because it is not locked.	Because the left box is not selected, both data types appear by default. But users can limit their view to accessible data because the criterion is not locked (the Lock box to its right is not selected).
CRA Master Profile	Only records dated before 12-NOV-2003 appear, and users cannot change this date because it is locked.	Because the left box is not selected, only accessible data appears by default. But users can include inaccessible data in their view because the criterion is not locked.
DM Master Profile	All data appears, regardless of creation date, because the creation date is not specified. But because the criterion is not locked, users can filter by creation date if they choose.	Both data types appear by default, and because this setting is locked, users cannot change it.
QUALITY CONTROL Master Profile	All data appears, regardless of creation date, because the creation date is not specified. Because the criterion is locked, users cannot filter their view by creation date.	Only accessible data appears by default, and because this setting is locked, users cannot change it.

Example 3–2 Profile Administration Form in Multi-View Mode

Figure 3–2 depicts a portion of the single-view Profile Administration window. The arrows point to the Lock boxes for, from left to right, the (*Creation Ts*) To criterion, the *Last Modified By* criterion, and the *Accessible Data Only?* criterion.

Figure 3–2 Sample Single-View Region of the Profile Administration Window

In single-view mode, for criteria like *Accessible Data Only?* where toggle boxes control viewing, the Lock box is to the left of the toggle box.

Adding SQL Statements

In addition to defining access to discrepancy details in the Profile Criteria fields, you can further limit data access by entering SQL statements in the SQL Text section. To prevent users from bypassing the SQL statements, check the locking box for each entry. (In single-view mode the locking box is to the right of the SQL Text label. In multi-view mode, the locking box is to the left of the SQL Text column's fields.) Your SQL statements have a size limit of 2000 characters.

Filtering Profile Views by Review Status

You can limit a profile's view of discrepancy records according to the records' current review status classifications. Select a profile in the Profile Administration form, then click the Review Status button to open the Discrepancy Review Status Codes dialog box. (To define the codes you see in this box, see "[Defining the Possible Review Statures for Discrepancies](#)" on page 3-14.) The dialog box contains rows with three

columns: the **Selected?** box column, the **Status Name** column and the **Locked?** box column.

Each **Selected?** box controls a profile's default access to records that have that review status classification code. Select a code's **Selected?** box to include discrepancy records; deselect it to prevent viewing records with its code.

Users can override each of these settings in their personal profiles unless you lock them. If you lock a review status code, profile users cannot override the profile's default setting.

[Table 3-5](#) on page 3-8 describes the outcome for the four possible combinations of **Selected?** and **Locked?** boxes:

Table 3-5 Selecting and Locking Review Status Profile Criteria

Selected?	Locked?	Result
Unchecked	Unchecked	Not viewed by default, but profile user can reveal it.
Checked	Unchecked	Viewed by default, but the profile user can hide it.
Unchecked	Checked	Not viewed by default, and profile user cannot reveal it.
Checked	Checked	Viewed by default, and profile user cannot hide it.

Updating Status Codes

If the values in the DISCREPANCY REV STATUS CODE reference codelist change, you can update all profiles with the new values by clicking the **Add Review Status** button. (To edit the codelist, see ["Defining the Possible Review Statuses for Discrepancies"](#) on page 3-14.)

Filtering Profile Views by Discrepancy Field

You can control a profile's access to discrepancy review status types and individual discrepancy fields by setting its privileges. By default, a new profile has no update privileges; you must add review status codes, and then discrepancy field values to each master profile. To open the Privileges for DM Master Profile window, from the Admin menu, select Discrepancy Mgmt Admin, and then select Profile Administration. Select a master profile, then click the Privileges button.

Adding Update Privileges by Review Status Code In the Update Discrepancy records... Review Status column, add the discrepancy record review status types that you want to be accessible by users of the currently selected profile. You can select from an list of values. (To define the review status codes that appear in this dialog box, see ["Defining the Possible Review Statuses for Discrepancies"](#) on page 3-14.)

Note: Adding an update code does not make its discrepancy fields accessible. You must also specify each field. See the following section.

Setting Update Privileges by Discrepancy Field In the Update Discrepancy Fields panel there are two columns: Field Name and Privilege. Add the field names for fields that users of this profile can update. You can select them from an list of values. In each corresponding Privilege field, add the type of privilege. If you do not add a field name, users of the profile cannot update the data in the Maintain Discrepancy Database form. You can select from lists of values for both fields. [Table 3-6](#) shows the

corresponding field names for each field status value. (The Update Discrepancy Fields section contains the list of fields the profile has access to change if the current discrepancy record's review status is on the Update Discrepancy Records list. For Oracle Clinical Release 4.6, the only allowable value for the Privilege field is *Update*.)

Table 3–6 Field Status Values

Field Status Value	Field in the Maintain Discrepancy Database Form or Description
REVIEW STATUS	Review Status
RESOLUTION STAT	Resolution Status
COMMENT TEXT	Comment Text
INT COMMENTS	Internal Comments
RESOLUTION TEXT	Resolution Text
ASSOCIATED ID	Associate a discrepancy for passive review field
CRF PAGE NUMBER	CRF Page Number
FLEXFIELD1	User-definable field (See "Customizing Flexfields" on page 3-9.)
FLEXFIELD2	User-definable field (See "Customizing Flexfields" on page 3-9.)

Setting Review Status Updating Privileges

The Can Change Review Status To section contains the allowable values for the review status if it can be updated. The Own Manual Only flag identifies allowable values for the Review Status field for manual discrepancy records owned by the same group as the current user. For example, you could specify that users of the CRA profile could only close discrepancies that they manually created.

Note: If users can choose an IRRESOLVABLE status, they must also have access to the Resolution Status; whenever the status is Irresolvable, the Resolution Status is required. Otherwise users cannot enter a value for lack of privileges.

Customizing Flexfields

The Maintain Discrepancy Database window includes two editable fields that have the default labels **Flexfield1** and **Flexfield2**. You can use them to store information you need. You can change their labels, make the fields mandatory if you want, and create a dynamic or static list of values for each field:

- **Static List of Values.** By default, the fields get their list of values from a database view that references the installation reference codelists DISC_FLEX1_VALUES and DISC_FLEX2_VALUES. You can populate these reference codelists to create lists of values for the two fields.
- **Dynamic List of Values.** Alternatively, you can reprogram the view to reference another Oracle Clinical table or even an Oracle table outside Oracle Clinical, such as an adverse event code maintained in a different Oracle system. In each field you can display any column value or concatenation of column values.

The views, DISCREP_FLEX1 and DISCREP_FLEX2, respectively, are created during installation as follows:

```
create or replace view discrep_flex1 as
select  ref_codelist_value_short_val VALUE,
        long_value DESCRIPTION
from    reference_codelist_values
where  ref_codelist_name = 'DISC_FLEX1_VALUES'
and    active_flag='Y';
```

DISC_FLEX1 and DISC_FLEX2

Use these local reference codelists to customize the label for Flexfield1 or Flexfield2, to enable the field, make the field mandatory or not, and to specify whether or not there is a list of values for the field.

Table 3-7 DISC_FLEX1 and DISC_FLEX2 Settings

Short Value	Long Values	Description
enabled	Y or N	Set the long value to Y to allow users to enter values in the field. Set to N to prevent users from entering values in the field.
required	Y or N	Set the long value to Y to require users to enter text in this field. Set to N to make the field optional.
prompt	Y or N	Enter freeform text as the long value. This text becomes the flexfield's label in the Discrepancy Database window.
lov_validate	Y or N	Set the long value to Y to require the system checks the entry against an list of values. An invalid entry triggers the system to display the associated list of values.

DISC_FLEX1_VALUES and DISC_FLEX2_VALUES

If you set LOV_VALIDATE to Y in DISC_FLEX1, you can create a static list of values by entering each allowed value in a row in this codelist. When a user displays the list of values in the Discrepancy Database window, the system displays the short value and description for each row you enter here. (Alternatively, create a dynamic list of values; see "Customizing Flexfields" on page 3-9.)

The long value is used as the description in the Flexfield1 (or 2) field's list of values. The short value is stored in the FLEX_FIELD1 (or 2) column in the DISCREPANCY_ENTRIES table in the database. The default value has no effect.

Table 3-8 DISC_FLEX1_VALUES and DISC_FLEX2_VALUES Codelists

Field name	Description
Seq	Determines the order of the values in the flexfields' lists of values.
Short Value	Is the stored value when the user selects the row from the list of values.
Long Value	Can duplicate the short value; not displayed in the list of values.
Active box	Check an entry's Active box to have the entry appear in the list of values.
Default	The default value.
Description	Description of the value; displayed in the list of values.

Example

To customize Flexfield1 to ask the creator of a manual discrepancy record if the record is finished, and test the response entry against a list of three values, you would set the flexfield1 codelist values to the values in the following two tables, with the three values defined in the second. (Values that differ from the default values are in *italics*):

Table 3–9 DISC_FLEX1 Settings to Make a Finished? Prompt

Seq	Short Value	Long Value	Active	Default	Description
1	ENABLED	Y	3		Flexfield1 Displayed
2	REQUIRED	N	3		Flexfield1 Required
3	PROMPT	<i>Finished?</i>	3		Flexfield1 Prompt
4	LOV_VALIDATE	Y	3		Flexfield1 list of values Validate

Table 3–10 DISC_FLEX1_VALUES Settings for a Finished? List of Values

Seq	Short Value	Long Value	Active	Default	Description
1	Y	<i>Yes</i>	3		
2	N	<i>No</i>	3		
3	U	<i>Undetermined</i>	3	3	

Defining Reason Codes for Discrepancies

This section contains the following topics:

- ["Reason Codes and Descriptions for Manual Discrepancies"](#)
- ["Reason Codes and Descriptions for Univariate Discrepancies"](#)
- ["Reason Codes and Descriptions for Multivariate Discrepancies"](#)

You define reason codes to separate discrepancies into categories. Reasons provide an explanation of why the discrepancy exists. They are called **Reasons** in RDC and **Category** in Oracle Clinical.

Reason Codes and Descriptions for Manual Discrepancies

When a user creates an Operator Comment (a manual field or section discrepancy in RDC Onsite), the system prompts the user to select a reason code from a list of reasons that is populated by the MANUAL SOURCE TYPE CODE reference codelist in Oracle Clinical. The user can also enter an additional explanation for the discrepancy.

You can add and remove values in the reference codelist (see [Figure 3–3](#)):

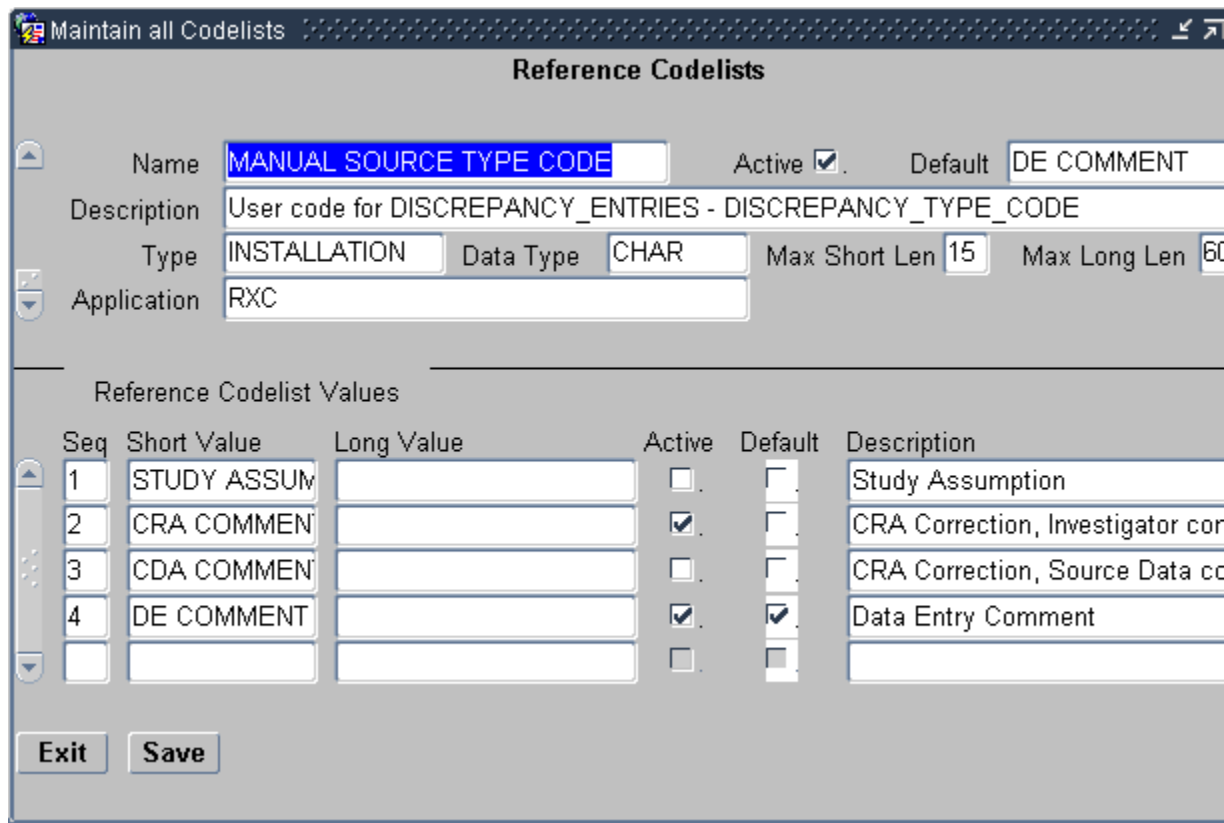
- For each reason you add, enter a value in the Short Value field and the Description field.
- Set one reason to Default. The first time the user creates a manual discrepancy during a login session, the system inserts the default reason. The user can select a different reason. For subsequent manual discrepancies, RDC Onsite displays the last entered reason. The user can always select a different reason.

Oracle Clinical stores the short value in the database.

Table 3–11 Values for MANUAL SOURCE TYPE CODE Reference Codelist

Seq	Short Value	Long Value	Description
1	STUDY ASSUMP		Study assumption
2	CRA COMMENT		CRA Correction, Investigator consulted
3	CDA COMMENT		CRA Correction, Source Data consulted
4	DE COMMENT		Data Entry Comment
5	SOURCE DATA REV		Source Data Review

Figure 3–3 Defining Reasons for a Manual Discrepancy



Reason Codes and Descriptions for Univariate Discrepancies

The system creates a univariate discrepancy when the data entered does not match the requirements defined in the underlying question, such as data type or length. You cannot change these underlying causes, but you can change the reason text or define more than one reason associated with a single underlying cause, from which the user can choose.

The system automatically populates the reason code and description when it raises the discrepancy.

To define reason codes and descriptions for univariate discrepancies:

1. Open Oracle Clinical.

2. Select **Admin, Discrepancy Mgmt Admin**, and then select **Standard Text Maintenance**. See [Figure 3-4](#).

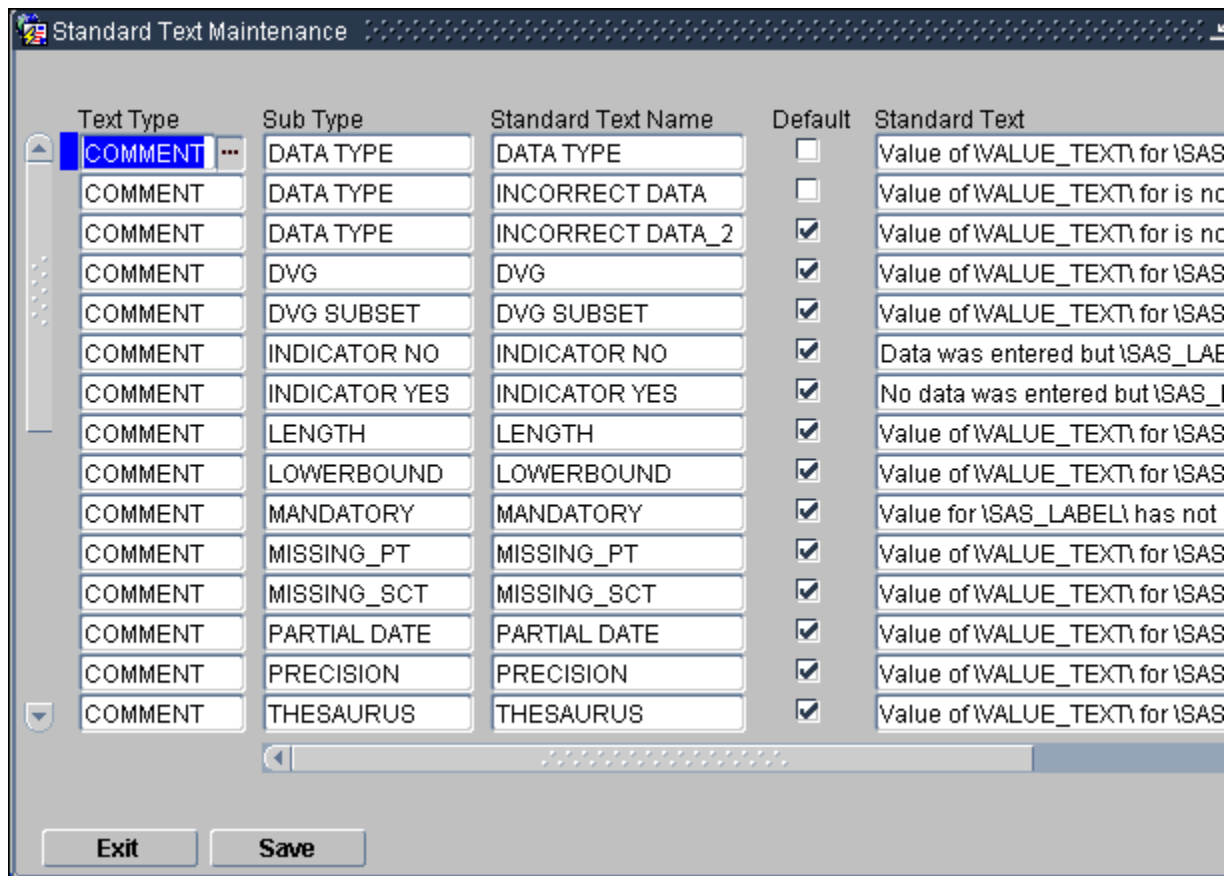
You use the fields in the Standard Text Maintenance form to define descriptions for each type of univariate discrepancy as follows:

- **Text Type** — Select COMMENT to specify descriptions for univariate discrepancies.
- **Sub Type** — Select from the list of valid univariate discrepancy types. RDC Onsite uses the text in the Sub Type field to populate the Reason field when a discrepancy of that type is raised.
- **Standard Text Name** — Ordinarily, you specify a name to match the Sub Type. However, if you want to specify more than one description for a discrepancy type, use this field to specify a unique identifier.
- **Default** — If you choose to create a selection of multiple descriptions for a certain discrepancy type, select which description is the default value. RDC Onsite uses the default value the first time a discrepancy of that type is raised. The user can always select one of the alternative descriptions provided.
- **Standard Text** — Specify the description that you want RDC Onsite to display for the discrepancy type raised. Note that you can use variables to include the data value of the discrepant response as well as the definitional components of the question; for example:

```
Value of \VALUE_TEXT\ for \SAS_LABEL\ is not a valid \DATA_TYPE\.
```

where VALUE_TEXT is the data response entered, SAS_LABEL is the SAS label defined for the Question, and DATA_TYPE is the data type defined for the Question.

Figure 3–4 Defining Descriptions for Univariate Discrepancies



Reason Codes and Descriptions for Multivariate Discrepancies

Oracle Clinical raises multivariate discrepancies when user-defined validation procedures detect invalid or inconsistent data. You specify the reason for multivariate discrepancies in the procedure definition; see *Oracle Clinical Creating a Study* for details. Oracle Clinical displays the reason; RDC Onsite does not.

Defining the Possible Review Statuses for Discrepancies

When a user takes **action** on a discrepancy, the discrepancy goes to a new **review status**. For system-generated discrepancies (univariate and multivariate), the system assigns the default review status. For manual discrepancies, the user selects the review status.

Both the Oracle Clinical and RDC discrepancy management systems use the DISCREPANCY REV STATUS CODE installation reference codelist to define all the discrepancy statuses possible to use in your discrepancy management workflow.

RDC Onsite uses the text string in the Description field to display the status of a discrepancy in any discrepancy management-related window, form, page, or report. Oracle Clinical uses the text string in the Short Value field to display the status of a discrepancy.

You can edit the review status codes available and sequence the order in which they appear in lists of values. If you add a status, you must do the following as well:

- In **Oracle Clinical**, update all profiles with the new status by clicking the **Add Review Status** button; see ["Customizing Profiles"](#) on page 3-5.
- In **RDC**, add the new status' short value to each DISCREPANCY STATUS ROLE codelist. In addition, if you want users of a particular role to be able to route discrepancies *to* the status, add the status to the relevant DISCREPANCY ACTIONS ROLE codelist. See ["Configuring Discrepancy Display by User Role"](#) on page 3-18 and ["Configuring the Actions Allowed on Discrepancies"](#) on page 3-23.

Default Entries for the DISCREPANCY REV STATUS CODE Codelist

Table 3–12 lists the entries in the DISCREPANCY REV STATUS CODE codelist following the initial installation of Oracle Clinical.

Table 3–12 Default Entries for the DISCREPANCY REV STATUS CODE Codelist

Short Value	Long Value	Description
CRA REVIEW	Null	Under CRA Review
INV REVIEW	Null	Under Investigator Review
RESOLVED	IRRESOLVABLE	Closed - resolved
IRRESOLVABLE	IRRESOLVABLE	Irresolvable (That is, closed. Cannot be resolved.)
TMS EVALUATION	TMS EVALUATION	TMS Evaluation
UNREVIEWED	Null	Not yet reviewed
TMS IN PROGRESS	TMS IN PROGRESS	TMS in Progress - Set/Reset by system
DM REVIEW	Null	Under DM Review
INT DM REV	Null	Internal - Under DM Review
INT CRA REV	Null	Internal - Under CRA Review

Rules for the DISCREPANCY REV STATUS CODE Codelist

When entering and modifying values in the DISCREPANCY REV STATUS CODE reference codelist, you must follow these rules:

- The codelist must contain at least one short value entry with a long value of IRRESOLVABLE, which indicates that a user must specify a resolution reason when setting a discrepancy to this status. By default, the codelist contains the short values RESOLVED and IRRESOLVABLE, which are each assigned the long value IRRESOLVABLE.
- The codelist must contain a short value entry of UNREVIEWED. The Active check box corresponding to the value must always be selected. The UNREVIEWED value is the system-coded default status of any newly created discrepancy, except multivariate discrepancies, whose initial review status is defined in the Details block of the Oracle Clinical validation procedure that generates the discrepancy.
- The codelist must **NOT** contain a short value entry of CLOSED. The system reserves the CLOSED value as the status for any system-resolved discrepancy, that is, a data discrepancy that was resolved as the result of an update to a non-discrepant value.

- The Description field must be entered for each short value. In RDC, the system uses this value to display the status of discrepancies in any discrepancy management-related windows, forms, tasks tabs, or reports. In Oracle Clinical, the system uses the short value to describe the status of a discrepancy.
- The Active checkbox must be selected for each review status that you want to allow for a certain user role. In other words, if you set an entry in a DISCREPANCY STATUS *role* codelist to active, then you must also set the corresponding entry in the DISCREPANCY REV STATUS CODE codelist to active. Conversely, if you set an entry in the DISCREPANCY REV STATUS CODE codelist to inactive, you must also set the corresponding entry in each DISCREPANCY STATUS *role* codelist to inactive. If not, users receive an error message that problems exist with the discrepancy management system.

Defining Resolution Reasons for Discrepancies

Users can manually resolve discrepancies. When doing so, the user must also provide an explanation — a reason — for resolving the discrepancy. The user must select a resolution reason from the list that you define in the DISCREPANCY RESOLU TYPE CODE installation reference codelist.

Enter values in the Description field and the Short Value field. The system displays the text string that you specify in the Description field to display the list of resolution reasons to the user. The corresponding short value is stored in the database.

Note: Oracle reserves the CND BLK DELETED value as the resolution for a manual discrepancy associated with a conditional block that was deleted. The value is hard-coded. Do not add this value to the DISCREPANCY RESOLU TYPE CODE codelist.

Table 3–13 lists the default entries in the DISCREPANCY RESOLU TYPE CODE codelist.

Table 3–13 Values for the DISCREPANCY RESOLU TYPE CODE

Short Value	Long Value	Description
CRA VERIFY	CONFIRMED	CRA Correction
CRA VERIFY-INV	CONFIRMED	CRA Correction, Investigator consulted
CRA VERIFY-SRC	CONFIRMED	CRA Correction, Source Data consulted
INV VERIFY	CONFIRMED	Investigator Correction
STUDY ASSUMP	CONFIRMED	Study Assumption
NO ACTION REQD	CONFIRMED	No Action Required
ELIMINATED	IRRESOLVABLE	Data value changed. Disc no longer applicable.
OVERRULED	NON DISCREPANT	Disc not considered a validation error.
DATA MODIFIED	IRRESOLVABLE	Data value changed. Disc no longer applicable.
INV-NO INFO	IRRESOLVEABLE	Investigator queried. No further information available.

If you add a value, select a long value from the following:

- NULL: No value entered.
- CONFIRMED
- IRRESOLVABLE: Used for values which correspond to manually closed discrepancies. This makes the RESOLUTIONTYPE CODE and COMMENT available when user selects an IRRESOLVABLE status.
- NOT DISCREPANT. Used for manual discrepancies only; indicates that the discrepancy was raised for a comment, not because there was a problem with the data.

Setting Values in the OCL_STATE Local Reference Codelist

The local reference codelist OCL_STATE includes several parameters that control discrepancy database and DCF functions, as well as many other parameters. The following table describes the discrepancy management parameters.

Table 3–14 Codelist OCL_STATE Settings for Discrepancy Database Functions

Short Value (Parameter Name)	Long Value (Settings)	Description
DISC_DCM_PROMPT	default_prompt or question_name or sas_label	The single-record mode of the Maintain Discrepancy Database form's Characteristics panel has a button that toggles the three long value settings. Choose the value to display by default.
DCF_TEXT_SYNC	y or n	If set to y, changes to comment and resolution text entries in DCFs automatically propagate to the discrepancy database
DISC_AUTO_HDFE	y or n	If set to y, the system automatically populates header and footer text fields with the default values set in the Standard Text Admin form.
DISC_AUTOR_CRFP	y or n	If set to y, the system automatically populates the CRF Page Number field of the Maintain Discrepancy Database form.

Configuring Role-Specific Discrepancy Management for RDC

This section includes the following topics:

- [Defining Reason Codes for Discrepancies](#)
- [Configuring Discrepancy Display by User Role](#)
- [Configuring the Actions Allowed on Discrepancies](#)
- [Preventing Update to OTHER Discrepancies](#)

You use the reference codelists in Oracle Clinical to define your discrepancy management system for both Oracle Clinical and RDC Onsite.

To configure most settings for your discrepancy management system, you use the **installation** reference codelists in Oracle Clinical.

To access the installation reference codelists:

1. Open Oracle Clinical.
2. Select **Admin, Reference Codelists**, and then select **Installation Codelists**.

See [Chapter 7, "Reference Codelists"](#) for general information on setting reference codelist values.

Configuring Discrepancy Display by User Role

This section contains the following topics, which apply only to RDC:

- [How RDC Indicates Discrepancies in the User Interface](#) on page 3-19
- [Rules for the DISCREPANCY STATUS role Codelists](#) on page 3-20
- [Comparison of the Default Values for the DISCREPANCY STATUS role Codelists](#) on page 3-21
- [DISCREPANCY STATUS CRA](#) on page 3-21
- [DISCREPANCY STATUS DM](#) on page 3-22
- [DISCREPANCY STATUS INV](#) on page 3-22
- [DISCREPANCY STATUS SITE](#) on page 3-22

RDC uses the DISCREPANCY STATUS *role* installation reference codelists to determine how discrepancies with a particular status are displayed for users with a particular role. There is a different reference codelist for each default user role: CRA, DM, INV, and SITE.

Use these codelists to ensure that discrepancies are displayed appropriately for users of different roles. For example, a discrepancy with a review status of **Under CRA Review** should appear as ACTIVE to a CRA, but as OTHER to an investigator.

Note: These reference codelists do not determine what actions a user can perform on discrepancies or their underlying patient data. The DISCREPANCY ACTIONS *role* codelists determine what routing and resolution actions each user role can take on a discrepancy.

Note: If you create additional roles for use in discrepancy management you must create a new reference codelist called DISCREPANCY STATUS *role* for each of them and set it up the same way that these reference codelists are set up.

Every status defined in the DISCREPANCY REV STATUS CODE codelist must be included in the DISCREPANCY STATUS *role* codelist for each role, with a long value that determines how the discrepancy is presented (or not) to the user. The possible long values are:

- **ACTIVE:** (For open discrepancies) The current user can take action against this discrepancy.
- **OTHER:** (For open discrepancies) The discrepancy is assigned to a user with a different role. For RDC Onsite, you can prevent users from taking action on OTHER discrepancies with the reference codelist DISCREPANCY NO OTHER UPDATE; see "[Preventing Update to OTHER Discrepancies](#)" on page 3-25.
- **CLOSED:** (For closed discrepancies) System-closed discrepancies cannot be re-opened by users with any role. If the discrepancy was manually closed by a user, any user with UPDATE or UPD_DISCREP privilege can re-open the discrepancy.
- **HIDDEN:** (For open discrepancies) The current user cannot view or take action against this discrepancy. This functionality is intended only for section-type discrepancies. If a user selects a univariate or multivariate discrepancy, the Action

drop-down list excludes any action that would route the discrepancy to a status that is HIDDEN for any role.

There is another technique for hiding any type of discrepancy (section, univariate, multivariate) at a particular status (for example Internal DM Review) from a particular user role (for example SITE). In this example, simply uncheck the 'Active' checkbox for the status Internal DM Review in the codelist DISCREPANCY STATUS SITE.

Note: If you change the long value to HIDDEN for a status that has already been applied to univariate or other types of discrepancies, these existing discrepancies are hidden to users with the relevant role, even though only section discrepancies are intended to allow hiding.

Note: Long values must be in uppercase.

How RDC Indicates Discrepancies in the User Interface

RDC uses the settings of these codelists to indicate to the current user whether a CRF, patient, or individual response is associated with a discrepancy and if so, whether it is a discrepancy that requires action by the current user. The table below describes the colors that RDC uses for this purpose. RDC uses these colors to highlight the patient icon, the CRF icon, and the individual fields in a CRF that have one or more discrepancies.

Note that:

- HIDDEN discrepancies are not highlighted in any color because they are not visible to particular user roles.
- RDC uses green to highlight the fields in a CRF that have a discrepancy that was manually closed by the user. Fields with a system-closed discrepancy are not highlighted.

Table 3–15 Colors Used to Indicate Discrepancy Access Status

Color	Access Status	Implication
Red	ACTIVE	The CRF contains at least one open discrepancy that requires attention by the user role to which the current user is assigned.
Yellow	OTHER	The CRF contains only open discrepancies that require the attention of a user role different from the one to which the current user is assigned.
White	CLOSED	The CRF contains no visible open discrepancies. Three conditions may be true for a white CRF or patient icon: <ul style="list-style-type: none"> ■ The CRF may contain discrepancies that are hidden from the current user's user role. ■ The CRF may have contained discrepancies at one time, but all discrepancies are closed or obsolete. ■ The CRF never had any discrepancies.

Rules for the DISCREPANCY STATUS *role* Codelists

When entering and modifying values in a DISCREPANCY STATUS *role* codelist, you must follow these rules:

- Each DISCREPANCY STATUS *role* codelist must include all short values that appear in the DISCREPANCY REV STATUS CODE codelist, and must not contain any values not in that codelist. When you add a short value to one codelist, you must add the same short value to the other codelist. (An exception is the CLOSED status, described below).
- Each codelist must contain the short value CLOSED, which has a corresponding long value CLOSED. This is the status that is used for any system-resolved discrepancy, that is, a data discrepancy that was resolved as the result of an update to a non-discrepant value.
- The RESOLVED and IRRESOLVABLE short values must have a long value of CLOSED for all roles.
- If a review status is CLOSED for one user role it must be either CLOSED or HIDDEN for all other user roles. Note also that for any review status that appears as CLOSED in a DISCREPANCY STATUS *role* codelist, the DISCREPANCY REV STATUS CODE codelist must represent the review status with a long value of IRRESOLVABLE.
- Do not change any long value with a default value of CLOSED.

Note: Both RDC Classic and RDC Onsite use these reference codelist values. RDC Classic does not support the CLOSED display status for any review status except RESOLVED and IRRESOLVABLE.

- The setting of the Active check box determines whether discrepancies of that status are visible to users with the relevant role. If the Active check box is not selected, users with the role cannot see discrepancies of that status. If the Active check box is selected, users with the role can see discrepancies of that status. The way discrepant values are displayed depends on the long value.

Note: Either disabling the Active check box or setting the long value to HIDDEN has the effect of hiding discrepancies of the relevant status from users with the relevant role. However, use of the text string 'HIDDEN' only works for hiding section discrepancies. The technique of unchecking the 'Active' checkbox can be used to hide any type of discrepancy: section, manual field, univariate, or multivariate.

- If an entry in a DISCREPANCY STATUS *role* codelist is active, then the corresponding entry in the DISCREPANCY REV STATUS CODE codelist must also be active. If not, the discrepancy configuration is invalid. RDC Onsite will display an error message to alert users to the problem.
- The Description field is optional for all entries.
- The setting of the Default check box has no effect. The default status of a new discrepancy is always UNREVIEWED.

Comparison of the Default Values for the DISCREPANCY STATUS role Codelists

Table 3–16 provides a comparison of how each default discrepancy status is displayed by default for each user role.

Table 3–16 User Roles and the Default RDC Onsite Discrepancy Access Statuses

Short Value – Oracle Clinical Discrepancy Review Status	Long Value – RDC Onsite Display			
	CRA	DM	INV	SITE
UNREVIEWED	ACTIVE	ACTIVE	ACTIVE	ACTIVE
CRA REVIEW	ACTIVE	OTHER	OTHER	OTHER
INV REVIEW	OTHER	OTHER	ACTIVE	OTHER
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
INT CRA REV	ACTIVE	OTHER	HIDDEN	HIDDEN
INT DM REV	OTHER	ACTIVE	HIDDEN	HIDDEN
INT RESOLVED	CLOSED	N/A	CLOSED	CLOSED

DISCREPANCY STATUS CRA

This codelist contains discrepancy status groupings for the CRA role.

Table 3–17 Values for the DISCREPANCY STATUS CRA Reference Codelist

Seq	Short value	Long value	Active Check box
1	UNREVIEWED	ACTIVE	Y
2	CRA REVIEW	ACTIVE	Y
3	INV REVIEW	OTHER	Y
4	DM REVIEW	OTHER	Y
5	TMS EVALUATION	OTHER	Y
6	TMS IN PROGRESS	OTHER	Y
7	RESOLVED	CLOSED	Y
8	IRRESOLVABLE	CLOSED	Y
9	CLOSED	CLOSED	Y
10	INT CRA REV	ACTIVE	Y
11	INT DM REV	OTHER	Y

DISCREPANCY STATUS DM

This codelist contains discrepancy status groupings for the Data Management role.

Table 3–18 Values for the DISCREPANCY STATUS DM Reference Codelist

Seq	Short value	Long value	Active Check box
1	UNREVIEWED	ACTIVE	Y
2	CRA REVIEW	OTHER	Y
3	INV REVIEW	OTHER	Y
4	DM REVIEW	ACTIVE	Y
5	TMS EVALUATION	OTHER	Y
6	TMS IN PROGRESS	OTHER	Y
7	RESOLVED	CLOSED	Y
8	IRRESOLVABLE	CLOSED	Y
9	CLOSED	CLOSED	Y
10	INT CRA REV	OTHER	Y
11	INT DM REV	ACTIVE	Y

DISCREPANCY STATUS INV

This codelist contains discrepancy status groupings for the INVESTIGATOR role.

Table 3–19 Values for the DISCREPANCY STATUS INV Reference Codelist

Seq	Short value	Long value	Active Check box
1	UNREVIEWED	ACTIVE	Y
2	CRA REVIEW	OTHER	Y
3	INV REVIEW	ACTIVE	Y
4	DM REVIEW	OTHER	Y
5	TMS EVALUATION	OTHER	Y
6	TMS IN PROGRESS	OTHER	Y
7	RESOLVED	CLOSED	Y
8	IRRESOLVABLE	CLOSED	Y
9	CLOSED	CLOSED	Y
11	INT CRA REV	HIDDEN	Y
12	INT DM REV	OTHER	Y
11	INT RESOLVED	CLOSED	N

DISCREPANCY STATUS SITE

This codelist contains discrepancy status groupings for the SITE role.

Table 3–20 Values for the DISCREPANCY STATUS SITE Reference Codelist

Seq	Short value	Long value	Active Check box
1	UNREVIEWED	ACTIVE	Y
2	CRA REVIEW	OTHER	Y

Table 3–20 (Cont.) Values for the DISCREPANCY STATUS SITE Reference Codelist

Seq	Short value	Long value	Active Check box
3	INV REVIEW	OTHER	Y
4	DM REVIEW	OTHER	Y
5	TMS EVALUATION	OTHER	Y
6	TMS IN PROGRESS	OTHER	Y
7	RESOLVED	CLOSED	Y
8	IRRESOLVABLE	CLOSED	Y
9	CLOSED	CLOSED	Y
10	INT CRA REV	HIDDEN	Y
11	INT DM REV	HIDDEN	Y
12	INT RESOLVED	CLOSED	N

Configuring the Actions Allowed on Discrepancies

In RDC Onsite, a user changes the review status of a discrepancy by selecting an option from the list in the Action field. You use the DISCREPANCY ACTIONS *role* codelists to define the set of routing and resolution actions that each user role can take against discrepancies with a particular status.

Each DISCREPANCY ACTIONS *role* codelists specifies allowed actions for one of the default user roles:

- DISCREPANCY ACTIONS CRA
- DISCREPANCY ACTIONS DM
- DISCREPANCY ACTIONS INV
- DISCREPANCY ACTIONS SITE

Only RDC uses the set of DISCREPANCY ACTIONS *role* codelists.

Note: RDC disallows routing of all but section discrepancies to a HIDDEN status as follows: at run time, if the user selects a univariate or multivariate discrepancy, the Action drop-down list excludes any action that would route the discrepancy to a status that is HIDDEN (that is, has a long value of HIDDEN in the DISCREPANCY STATUS *role* codelist) for any role.

However, the same restriction does not apply if you use the alternative method for hiding discrepancies from one or more user roles. That is, simply uncheck the 'active' checkbox in the DISCREPANCY STATUS *role* codelist for the 'blinded' user role.

To enable users of the relevant role to route discrepancies to a particular status:

1. In the **Short Value** field, enter the name of the discrepancy status—as it appears in the DISCREPANCY REV STATUS CODE codelist—to which you want users of the role specified in the reference codelist name to be able to route discrepancies.

Note: The codelist must contain one and only one row with 'CLOSED' as a short value.

2. In the Long Value field, enter the Actions drop-down item text that should appear for users with the role.
3. Be sure the Active check box is checked.

Note: To remove the item from the Actions drop-down list, uncheck the Active check box.

The Description field is optional.

4. Save your work.

Rules for the DISCREPANCY ACTIONS *role* Codelists

When entering and modifying values in a DISCREPANCY ACTIONS *role* reference codelist, you must follow these rules:

- Each DISCREPANCY ACTIONS *role* codelist must contain a subset of the short values (the statuses) defined in the DISCREPANCY REV STATUS CODE codelist. The long value specifies an action that the user can take against a discrepancy. The corresponding short value, which must match a short value in the DISCREPANCY REV STATUS CODE codelist, identifies the status RDC Onsite assigns to the discrepancy when the user selects the action.
- CLOSED should **not** appear as a short value in any DISCREPANCY ACTIONS *role* codelist.
- You must specify text in the Long Value field. RDC Onsite displays this text in the Action drop-down list.

DISCREPANCY ACTIONS CRA

This codelist contains discrepancy actions for the CRA role. The initial short and long values are:

Table 3–21 Values for the DISCREPANCY ACTIONS CRA Reference Codelist

Seq	Short value	Long value	Description
1	DM REVIEW	Null	Send to Data Mgt
2	RESOLVED	IRRESOLVABLE	Closed - Resolved
3	IRRESOLVABLE	IRRESOLVABLE	Irresolvable
4	INT DM REV	Null	Internal Data Mgt review

DISCREPANCY ACTIONS DM

This codelist contains discrepancy actions for the DATA MANAGER role. The initial short and long values are:

Table 3–22 Values for DISCREPANCY ACTIONS DM Reference Codelist

Seq	Short value	Long value	Description
1	INT REVIEW	Null	Send to site
2	TMS REVIEW	Null	Send for classification
3	RESOLVED	IRRESOLVABLE	Closed - Resolved
4	IRRESOLVABLE	IRRESOLVABLE	Irresolvable
5	INT CRA REV	Null	Internal CRA review

DISCREPANCY ACTIONS INV

This codelist contains discrepancy actions for the INVESTIGATOR role. The initial value is:

- DM REVIEW — Send to Data Mgt

DISCREPANCY ACTIONS SITE

This codelist contains discrepancy actions for the SITE role. The initial value is:

- DM REVIEW — Send to Data Mgt

Preventing Update to OTHER Discrepancies

Only RDC Onsite uses the DISCREPANCY NO OTHER UPDATE installation codelist.

You can use the DISCREPANCY NO OTHER UPDATE codelist to specify which user roles do not have access to and cannot update discrepancies that appear to them with a status of OTHER; see "[Configuring Discrepancy Display by User Role](#)" on page 3-18.

By default, the DISCREPANCY NO OTHER UPDATE codelist has no values. All users can update discrepancies with a status of OTHER. To prevent users from updating OTHER discrepancies, you add one or more user roles to the codelist.

To prevent users with a particular role from updating OTHER discrepancies:

1. Open the DISCREPANCY NO OTHER UPDATE codelist.
2. Enter the role name in the Short Value field. The value you enter must be exactly the same as one of the long values in the USER GROUP ROLES reference codelist. For example, CRA, INV, or SITE.

Caution: The system does not check the validity of your entries. You must be careful to specify only valid user roles. If the values do not match exactly, users with the role will still be able to update OTHER discrepancies.

3. Select the **Active** check box. An active entry indicates the user role cannot update OTHER discrepancies.
4. Save your work.

The Seq, Long Value, Default, and Description fields are not used by RDC Onsite.

You can grant this privilege to any number of roles.

To allow the update of OTHER discrepancies for a role that you added to the DISCREPANCY NO OTHER UPDATE codelist, you can either:

- Delete the record by using the command on the Data menu.
- Make the value inactive by clearing its Active check box.

Configuring Study and Site Security for Discrepancy Management

Once you open either the Maintain Access to Studies form or the Maintain Access to Sites within a Study form, you can use the standard menu commands, toolbar icons, or shortcut keys to:

- Query for one or more records. You can use the % sign as a wildcard search character.
- Add a new record or update existing records.
- Delete one or more records.
- Switch to a different study or site.

For the Study field, Site field, and User field, you can type directly into the field. You can also open a list of valid values and select from the list.

To add or modify the privileges for a user:

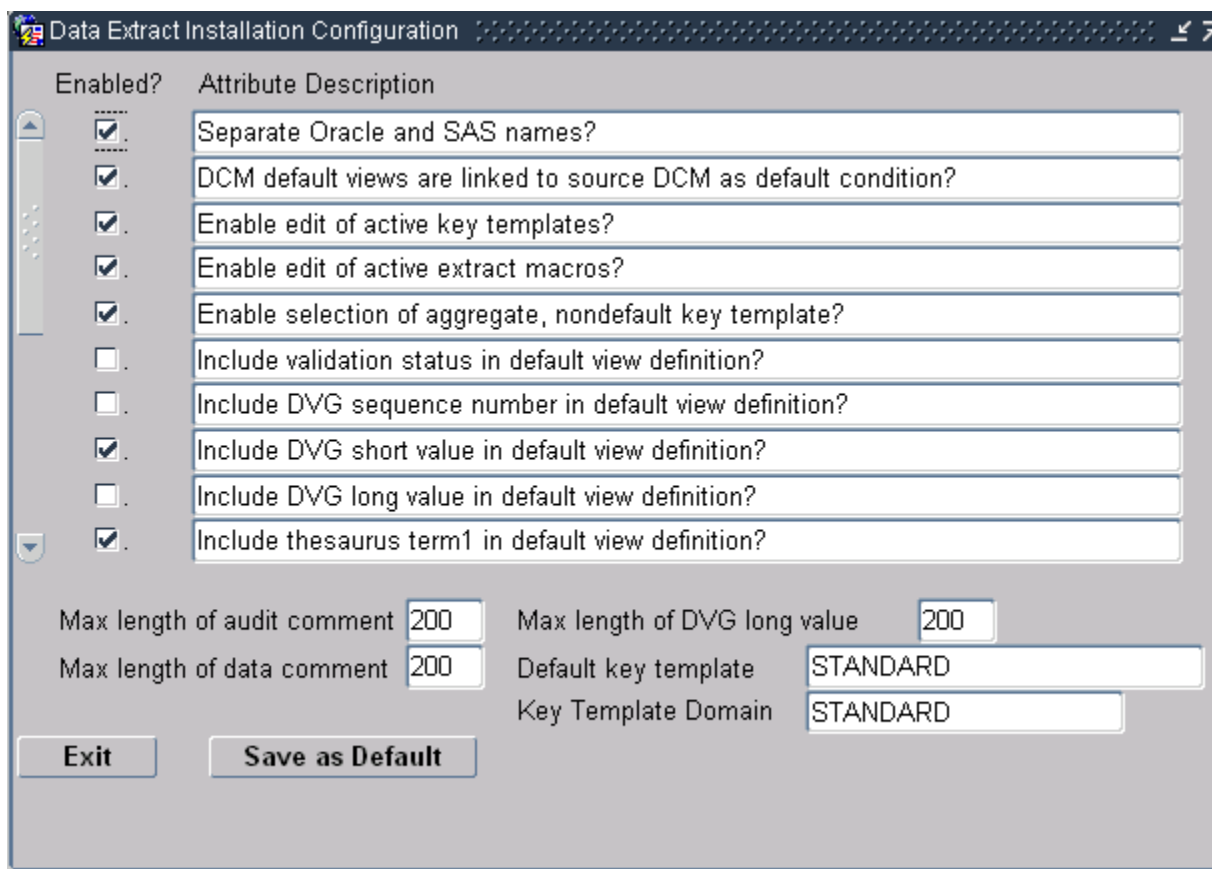
1. Open either RDC Administration or Oracle Clinical.
 - In RDC Administration, navigate to **Maintain**.
 - In Oracle Clinical, navigate to **Admin, Users and Roles**.
2. Open the correct form:
 - To grant privileges to a user for a particular study, select **Study Security**.
 - To grant privileges to a user for a particular site, select **Site Security**.
3. Query for a particular record or query all records and navigate to the record you want to update. Alternatively, press F6 to insert a blank row and add a new record.
4. Click the **Privilege** column for the user whose privileges you want to update. The dialog box for configuring privileges opens. See [Figure 3-5](#).
5. Select the privileges to assign to the user:
 - To select one privilege, click that privilege.
 - To select several privileges, **Ctrl-click** each privilege. Ctrl-click also toggles the selection on and off.
 - To select a range, **Shift-click** the first and last privilege in the range.
6. Click **OK** to save the privileges for the selected user. Add or modify privileges for other users, as appropriate. Save your changes when finished.

Note: A user granted access to a study can see the study in RDC only if the study has at least one site with an investigator assigned and has at least one patient enrolled. Similarly, a user can see a site only if the site has an investigator and patient enrolled.

Table 3–23 Function Privileges for Discrepancy Management

Name	Privilege Granted and Method of Use
UPD DATA ENTRY	Enables the Update Patient Data menu item under the Special menu, and allows updates while in the Data Entry subsystem.
BRWS DATA ENTRY	Enables the Browse Patient Data menu item under the Special menu for read-only access to patient data.
MANUAL	Enables the Add Manual button in the Maintain Discrepancy Database window, which allows users to create manual discrepancies and manual header discrepancies.
DCF PRINT DRAFT	Displays the Draft option in the DCF Print Options window; enables the user to print a draft version of a Data Clarification Form (DCF) report.
DCF PRINT COPY	Enables the Copy option in the DCF Print Options window; enables the user to print a copy of a DCF.
DCF PRINT FINISH	Enables the Final option in the DCF Print Options window; enables the user to print a final version of a DCF report.
DCF REPRINT	Enables the Reprint option in the DCF Print Options window; enables the user to reprint a final version of a DCF report.
CREATE DCF	Enables the Create DCF option in the group selection menu in the Maintain Discrepancy Database form.

Figure 3–5 Assigning Privileges to a User for a Particular Study



Updating a Discrepancy

For a user with the requisite function profile privilege(s) assigned, the system permits the user to update the discrepancies under the following circumstances:

- If there are no privileges assigned to any site and to the study, the user has the UPD_DISCREP privilege.
- If any privilege is assigned to the user at the current site, then the UPDATE or UPD_DISCREP must be assigned to the user at the site level in order for the user to update a discrepancy.
- If the user is not assigned any privileges at the current site-level, but is assigned one or more privileges at the study-level or another site within the study, then the user must be assigned the UPDATE or UPD_DISCREP at the study level.

Navigating to Data Entry

For a user with the requisite function profile privilege(s) assigned, the system permits that user to navigate to data entry and either browse data or update data under the following circumstances. If the user is not able to either browse or update data, the system does not permit navigation to data entry.

In contrast to other study- and site-level security settings, only the site-level BROWSE and/or UPDATE privileges, in conjunction with the function profile privileges, affect a user's ability to browse or update data.

- To update data:
 - UPDATE is assigned at the site-level and UPD DATA ENTRY is assigned as a function profile privilege
 - no privileges are assigned at any site in the study and UPD DATA ENTRY is assigned as a function profile privilege
- If update data is not permitted, to browse data:
 - BROWSE is assigned at the site-level **and** either UPD DATA ENTRY or the BRWS DATA ENTRY is assigned as a function profile privilege
 - UPDATE is assigned at the site-level and BRWS DATA ENTRY is assigned as a function profile privilege
 - no privileges are assigned at any site in the study and BRWS DATA ENTRY is assigned as a function profile privilege

Setting Up Data Clarification Forms (DCFs)

Oracle Clinical includes a utility for printing and tracking Data Clarification Forms (DCFs) as a way of resolving discrepancies in a clinical trial's response data. Setting up DCFs for your organization requires that you define DCF status codes and lay out the DCF report.

This section includes the following topics:

- [Defining DCF Statuses and their Behavior](#) on page 3-29
- [Laying Out the DCF](#) on page 3-30
- [Creating New Standard Text](#) on page 3-34

Defining DCF Statuses and their Behavior

There are several Installation Reference Codelists that affect DCF Statuses. You can modify them if you want to for your organization's needs.

DCF STATUS CODES The DCF Status reflects the stage in the review process of the DCF as a whole. Oracle Clinical comes with many review statuses defined in this reference codelist. You can make them inactive if you do not want to use them or create new ones, with the following limitations:

- You cannot make these statuses inactive: Sent, Received, and Closed.
- Do not make status Created inactive unless you also make it optional in the DCF OPTIONAL STATUS CODES reference codelist.
- Do not make statuses Incomplete, Part Received, or Received inactive if you want the system to automatically update the DCF Status when users update the status of individual DCF Pages.
- If you add a status, you must set its DISPLAY_SN, which determines the order in which the statuses can be set. If you adjust the DISPLAY_SN, you may need to adjust the DCF LOCK CONDITIONS and the DCF OPTIONAL STATUS CODES installation reference codelists, both of which refer to DCF Statuses by their number in the DCF STATUS CODES installation reference codelist.

DCF OPTIONAL STATUS CODES This installation reference codelist refers to the DCF Statuses listed in the DCF STATUS CODES reference codelist. The number in the Short Value column refers to the display number of the status in the DCF STATUS CODES codelist. (Note that the description is incorrect for numbers 7 and 8, which should be Incomplete and Part Received.)

All status codes referenced and active in this codelist are optional. All that are inactive or not entered here are mandatory, meaning that a DCF must be assigned to that status before it can be assigned a subsequent status, as defined in the Seq column. As shipped, only CREATED, SENT and CLOSED are mandatory (no rows exist with short values 2, 6, or 12).

To make a status mandatory if it is included in this reference codelist, uncheck its Active box.

DCF LOCK CONDITIONS This installation reference codelist determines what actions can be taken on discrepancies and DCFs where the DCF has a particular status. The Long Value refers to the number of the status in the DCF STATUS CODES codelist. As shipped, the codelist sets the following behavior, in order:

- Discrepancies belonging to a DCF whose status is Final (#4) or higher cannot be deleted.
- Discrepancies belonging to a DCF whose status is Ready (#5) or higher cannot be modified.
- DCFs whose status is Ready (#5) or higher cannot be deleted (unless the status exceeds or equals a status with a DISPLAY_SN of 1000; see last point).
- DCFs whose status is Ready (#5) or higher cannot be modified.
- DCFs whose status is #1000 or higher cannot be closed. We recommend that you do not change DCF_CLOSE.

To stop enforcing any of these rules, set the Long Value to a high value. To change the DCF Status that prevents any of the actions described in the Short Value column,

change the number in the Long Value column to the number in the DCF STATUS CODES codelist of the status you prefer.

Laying Out the DCF

Laying out the DCF's contents and arranging its fields includes the following tasks:

- [Replacing the DCF Place-holder Graphic](#) on page 3-30
- [Modifying Codelist DCF REPORT LABELS](#) on page 3-30
- [Modifying the DCF Views](#) on page 3-31
- [Defining DCF Headers and Footers](#) on page 3-32

See the [Default DCF Layout Diagram](#) on page 3-32 for a geographic representation of the DCF's default values and their placements.

OPA views `dcf_rpt_master` and `dcf_rpt_detail` control much of the content and the appearance of DCFs. Local codelist DCF REPORT LABELS controls the report's label text. DCFs also include several unchangeable parameters, such as the Revision # and other values that print along the bottom of each DCF page.

Replacing the DCF Place-holder Graphic

Oracle Clinical includes a placeholder graphic file located, typically, in your installation's `.. \OPArelease_number\oc` directory, and named `rxcdcf.bmp`. You can replace `rxcdcf.bmp` with your own graphic file, but you must name it `rxcdcf.bmp`. We recommend that your graphic does not exceed 200 pixels in height.

Modifying Codelist DCF REPORT LABELS The labels for the value fields of the DCF views correspond to their position on the report. The following table describes each of the columns on the report. For field labels, it identifies the codelist member in the DCF REPORT LABELS local codelist and their default table and column values.

Table 3–24 DCF Labels and Field Mappings

Default Field Label from DCF_ REPORT_LABELS		Default Data Value from DCF_RPT_MASTER and DCF_RPT_DETAIL	
Short Value	Long Value	Table.Column	Description
line1_left	To:	ocl_sites.name	Site name's short value
line3_left	Date:	sysdate	Date of this DCF's creation: mm/dd/yyyy
line3_right	Reviewer	oracle_accounts.firstname (and) .lastname	Reviewer's initials
line2_left	Investigator:	ocl_investigators.first_name (and) .lastname	Investigator's first and last name.
line1_right	Patient #:	patient_positions.patient	Patient position
line2_right	Patient Initials:	patient_positions.reported_first_name (and) .reported_last_name	Patient's initials
q_field1	Form Name/ Visit Name:	dcms.description	Mapped to view value qline1_1
q_field2	Page #:	discrepancy_entries.crf_page_number	CRF page number Mapped to view value qline1_2

Table 3–24 (Cont.) DCF Labels and Field Mappings

Default Field Label from DCF_ REPORT_LABELS		Default Data Value from DCF_RPT_MASTER and DCF_RPT_DETAIL	
Short Value	Long Value	Table.Column	Description
q_field3	Date:	discrepancy_entries.creation_ts	Discrepancy timestamp date: mm/dd/yyyy Mapped to view value qline1_3
q_field4	Questions/ Comments:	dcf_discrepancies.comment_text	Mapped to view value qline1_4
q_field5	Resolution:	dcf_discrepancies.resolution_text	Mapped to view value qline1_5
mstr_sort_ order ¹	line1_right	patient_positions.patient	Controls the default sort order of view DCF_RPT_MASTER
dtl_sort_order ¹	q_line1_1	dcm.description	Controls the default sort order of view DCF_RPT_DETAIL
rpt_ orientation ¹	Landscape		Landscape or Portrait Controls the default action of the Print button in the DCF form.

¹ Not a label

Modifying the DCF Views

Table 3–25 and Table 3–26 describe all of the parameters in the two DCF report views. The view scripts for the DCF are in file rxviews.sql. You can map other discrepancy values to the DCF parameters, or comment out the parameters to remove them from the DCF output. Note that if you remap parameters, you may have to change their labels (See "Modifying Codelist DCF REPORT LABELS" on page 3-30).

Caution: Do not change parameter values that have a **_DNC** suffix.

Table 3–25 View DCF_RPT_MASTER Parameters

Parameter	Default Data Value (Table.Column)	Comments
dcf_id_dnc	data_clarification_forms.dcf_id	A system-generated number.
title1	clinical_studies.short_title	Prints the study's title.
title2	'Data Clarification Form'	Prints the text string Discrepancy Clarification Form.
line1_left	ocl_sites.name	Site name's short value
line3_left	sysdate	Date of this DCF's creation: MM/DD/YYYY
line3_right	oracle_accounts.firstname <i>and</i> .lastname	DCF creator's account name
line2_left	ocl_investigators.first_name (<i>and</i>) .lastname	Investigator's first and last name.
line1_right	patient_positions.patient	Patient position
line2_right	patient_positions.reported_first_name (<i>and</i>) reported_last_name	Patient's initials
header_text	header_text	Prints the discrepancy's header text. Define header text in the Standard Text Maintenance form.

Table 3–25 (Cont.) View DCF_RPT_MASTER Parameters

Parameter	Default Data Value (Table.Column)	Comments
footer_text	footer_text	Prints the discrepancy's footer text. Define footer text in the Standard Text Maintenance form
clinical_study_id_dnc	clinical_studies.clinical_study_id	
current_status_dnc	data_clarification_forms.current_status	
site_id_dnc	data_clarification_forms.site_id	
investigator_id_dnc	ocl_investigators.first_name (and) .last_name	Investigator's initials
owning_user_dnc	data_clarification_forms.owning_user	

Table 3–26 describes the values of the DCF_RPT_DETAIL view, and its default data values. In DCF report printouts, the system draws a rectangular border around the output of this view, and may include more than one discrepancy's details.

Table 3–26 View DCF_RPT_DETAIL Parameters

View Parameter	Default Data Value (Table.Column)	Comments
dcf_id_dnc	data_clarification_forms.dcf_id	
q_line1_1	dcms.description	Value for q_field1 label
q_line1_2	discrepancy_entries.crf_page_number	Value for q_field2 label
q_line1_3	received_dcms.dcm_date	Value for q_field3label
q_line1_4	dcf_discrepancies.comment_text	Value for q_field4label
q_line1_5	dcf_discrepancies.resolution_text	Value for q_field5label
q_line2_1	clinical_planned_events.description	
discrepancy_entry_id_dnc	discrepancy_entries.discrepancy_entries	
status_dnc	dcf_discrepancies.status	
disc_type	discrepancy_entries.de_sub_type_code	
disc_rev	discrepancy_entries.discrepancy_rev_status	

Defining DCF Headers and Footers

You can define standard text headers and footers in the Standard Text Maintenance form (see "Creating New Standard Text" on page 3-34). You can define any number of standard headers and footers and designate one header and one footer as the default. When you create a DCF, the system assigns it the default header and footer. You can use the list of values in the Header and Footer fields to choose a different standard header or footer.

You can also modify the standard text of the header or footer by clicking the Text button in the main DCF screen and editing the displayed text.

Default DCF Layout Diagram

The following diagram shows the relative position of the labels (in bold font), and the default data values of a default DCF printout. The section between the rxcdcf.bmp graphic and the ruled rectangle contains most of the data defined in the DCF_RPT_MASTER view. The DCF_RPT_DETAIL view populates the contents in the rectangle. A

DCF can accommodate the descriptions of more than one discrepancy on each page. The legend for the DCF layout diagram precedes the diagram itself.

Default field label> 10: ocl_sites.name <=Default data value for the field
 Default field label short value> line1_left

rxcacr.bmp

status_dnc		title1	
dcf_discrepancies.status		clinical_studies.short_title	
		title2	
To:	ocl_sites.name	Patient#:	patient_
line1_left		line1_	positions.patien
		right	
Investigator:	ocl_	Patient	patient_
line2_left	investigators.fi	Initials:	positions.report
	rst_name (and)	line2_	ed_first_name
	.lastname	right	(and) .reported_
			last_name
Date:	sysdate	Reviewer:	oracle_
line3_left		line3_	accounts.firstname
		right	(and) .lastname

header_text

Form Name/ Visit Name	Page #	Questions/Commen ts	Resolution
q_field1	q_field2	q_field4	q_field5
	Date		
	q_field3		

dcf_id_dnc	q_line1_2	q_line1_4	q_line1_5
data_	discrepancy_	dcf_	dcf_
clarification	entries.crf_	discrepancies.c	discrepancies.resolution_
_forms.dcf_id	page_number	omment_text	text
q_line1_1	q_line1_3		
dcms.descript	received_		
ion	dcms.dcm_date		
	Closed:	status_dnc	
		dcf_	
		discrepancies.s	
		tatus	
Disc ID:	discrepancy_		
	entry_id_dnc		
	discrepancy_		
	entries.discrepa		
	ncy_entries		
Type:	disc_type		
	discrepancy_		
	entries.de_sub_		
	type_code		

status_dnc	title1
dcf_discrepancies.status	clinical_studies.short_title
footer_text	
Page <i>x</i> of <i>x</i>	DCF ID: discrepancy_
	discrepancy_
	entry_id_dnc
	discrepancy_
	entries.discrep
	ancy_entries
	Revision #: (0 for DRAFT and FINAL, and incremented for each reprint by the system)

Creating Reusable Standard Text for Discrepancies and DCFs

This section includes the topics:

- [Creating New Standard Text](#) on page 3-34
- [Inserting Replacement Parameters](#) on page 3-35
- [Customizing Default Standard Text Entries](#) on page 3-36

The standard text utility allows you to create uniform, reusable text for discrepancy comments and error messages and for DCF headers and footers. Using standard text saves time and promotes consistency. There are four types of standard text, used as follows by the system:

- **Comment.** Displayed as an error message during Data Entry and Data Entry Update for univariate discrepant responses; also displayed in the Comment field in the Maintain Discrepancy Database window for univariate discrepancies. Oracle Clinical ships with a set of default univariate error messages, one for each type of univariate discrepancy. You can edit the existing default and/or create alternatives to be available for use in Data Entry, Data Entry Update, and discrepancy management; see "[Customizing Default Standard Text Entries](#)" on page 3-36.

Comment-type standard text is also available by pressing F9 in the Comment field of the Maintain Discrepancy Database window. Comment text is displayed in the Create DCF window List of Values to help the user choose which discrepancy to include in a DCF when creating a DCF by discrepancy number.
- **Internal Comment.** In the Maintain Discrepancy Database window, users can enter an original comment in free form text or, by pressing F9 in the **Inter Com** field, choose from the internal comments you define here.
- **Resolution.** In the Maintain Discrepancy Database window, users can enter an original comment in free form text when they resolve a discrepancy or, by pressing F9 in the **Res Com** field, choose from the resolution comments you define here.
- **Header and Footer Text on DCFs.** The header and footer text you define appears on each page of a DCF. See "[Defining DCF Headers and Footers](#)" on page 3-32.

For each type of standard text definition, you can include *replacement parameters*, or variables. When the system displays the standard text, it substitutes the actual value of the parameter; see "[Inserting Replacement Parameters](#)" on page 3-35.

Creating New Standard Text

To create new standard text entries:

1. From the **Admin** menu, select **Discrepancy Mgmt**, then select **Standard Text Maintenance**.

The Standard Text Maintenance form opens, with columns for Text Type, Sub Type, Standard Text Name, a Default box, and a line for the standard text string.

2. Choose a text type. The text type identifies where the system uses the definition: In DCF headers or footers or discrepancy comments and Data Entry. The choices are: Comment, Footer, Header, Internal Comment, Resolution. For further information, see the introduction to this section, "[Creating Reusable Standard Text for Discrepancies and DCFs](#)" on page 3-34.
3. Choose a subtype only if you are creating an alternative univariate error text (you must have chosen a Text Type of Comment as well). See "[Customizing Default Standard Text Entries](#)" on page 3-36. Choose the subtype corresponding to the univariate error type for which you are creating a standard text.

For discrepancy comments, internal comments, and resolution comments, and DCF headers and footers, do not enter a subtype. If you do, the text will not be available for use even though it is successfully saved.

4. Name the entry in the **Standard Text Name** field. Each standard text definition must have a unique name. Users see the name and the text definition in the list of values for Comments, Internal Comments, and Resolution Comments of the Maintain Discrepancy Database.
5. Toggle the **Default** box. For the COMMENT type, the box controls which standard text value the system displays during Data Entry and DE Update. For HEADER and FOOTER types, a check identifies the default when a new DCF is created. Only one entry can be checked as default for each text type/subtype combination.
6. Write the text in the **Standard Text** field.

You can embed variables in your standard text that the system replaces with values from individual records. Press F9 to see the list of values, select and insert a variable. For further information, see "[Inserting Replacement Parameters](#)" on page 3-35 and, for examples of how the system replaces variables with actual values, [Table 3-29, "Examples of Alternative Standard Text for Univariate Errors"](#) on page 3-37.

Inserting Replacement Parameters

Standard text definitions can contain standard *replacement parameters*, or variables. You can insert one of the replacement parameters shown in [Table 3-27](#) into your standard text. When the system displays the standard text, it displays the actual value of the parameter. The replacement parameters are in UPPERCASE and are delimited by backslashes (\); for example, \SAS_LABEL\.

To insert a parameter in a standard text string, put your cursor in the location in the text where you want to insert the variable, press F9 or click the ellipsis (...) to display the list of values, and select it from the list of values. [Table 3-27, "Replacement Parameters"](#) describes each available variable and its source table or view and column.

Table 3-27 Replacement Parameters

Parameter Name	Description	Source
assoc_id	Associated Id for the discrepancy	discrepancy_management.associated_id
crf_page_no	CRF Page number for the discrepancy	discrepancy_management.crf_page_number
data_type	Data Type of the question	dcm_questions.question_data_type_code
date_time_format	Precision for Date and Time	dcm_questions.date_time_type_code
dcm_name	DCM Name for the discrepancy	discrepancy_management.name

Table 3–27 (Cont.) Replacement Parameters

Parameter Name	Description	Source
dcm_prompt	DCM Prompt of the question	discrepancy_management.default_prompt
dcm_subset	DCM Subset name for the discrepancy	discrepancy_management.dcm_subset_sn
decimal_places	Decimal places for a numeric question	dcm_questions.decimal_places
descriptor1	First descriptor for question group	dcm_question_groups.repeat_descr1_label
descriptor2	Second descriptor for question group	dcm_question_groups.repeat_descr2_label
discrete_values	Comma-delimited list of values	discrete_values.discrete_value_value
dvg_name	DVG Name of the question	discrete_value_groups.name
length	Length of the question	dcm_questions.length
lower_bound	Lower bound of the question	dcm_questions.lower_bound
repeat_sn	Repeat sequence number for the discrepancy	responses.repeat_sn
sas_label	SAS Label of the question	discrepancy_management.sas_label
sas_name	SAS Name of the question	dcm_questions.sas_name
upper_bound	Upper Bound of the question	dcm_questions.upper_bound
value_text	Value Text of discrepancy responses.	value_text or responses.exception_value_text

Customizing Default Standard Text Entries

You can modify the default standard text in the Standard Text Maintenance form. From the Admin menu, select Discrepancy Mgmt Admin, then select Standard Text Maintenance. The window is populated with the default values for each type of univariate error message shipped with Oracle Clinical. [Table 3–28](#) lists the default standard text definitions for Oracle Clinical Release 4.6.

Table 3–28 Default Univariate Discrepancy Messages

Discrepancy Type	Default Text
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 the 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 the maximum value of \UPPER_BOUND\

Example 3-3 Standard Text

The following table illustrates how you can use standard text definitions with different replacement parameters to create appropriate alternative error messages for DVG univariate discrepancies.

The system generates a different error message from same standard text definition by populating the replacement parameters with values from the question definition and entered data. The first column contains standard text definitions using replacement parameters. The second column shows the error message that would appear during data entry if the operator entered "X" as a response to the question PATIENT_SEX, which has a DVG containing the values M(ale) and F(emale). The third column shows the error message that would result from the same standard text if an operator entered "X" for the question SMOKING, which has a DVG containing the values Y(es) and N(o).

Table 3-29 Examples of Alternative Standard Text for Univariate Errors

Standard Text	Sex Example	Smoking Example
Value '\VALUE_TEXT\' for question \SAS.LABEL\ is not in expected list '\DISCRETE_VALUES\.'	Value 'X' for question SEX is not in expected list 'M,F.'	Value 'X' for question \SMOKING\ is not in expected list 'Y,N.'
Value of \VALUE_TEXT\ does not exist in Discrete Value Group \DVG_NAME\.'	Value of X does not exist in Discrete Value Group PATIENT_SEX.	Value of X does not exist in Discrete Value Group Yes/No.
Value of \VALUE_TEXT\ for \SAS.LABEL\ is invalid.	Value of X for SEX is invalid.	Value of X for SMOKING is invalid.

Configuring the Mass Changes Utility

Setting up the Mass Change Utility (MCU), which is described in *Oracle Clinical Conducting a Study*, requires performing the following general steps, each described in the following sections:

- [Creating and Assigning Mass Changes Roles](#) on page 4-1
- [Customizing Mass Changes Local Codelists](#) on page 4-1
- [Customizing the Field Display on the Candidate Data Set Form](#) on page 4-2

Creating and Assigning Mass Changes Roles

Oracle Clinical supplies two default database roles for the Mass Changes Utility: RXC_MC and RXC_MC_TEST. RXC_MC has access to all production mass change options and RXC_MC_TEST has access to the test mass change options only. Your organization can also choose to create your own roles.

Assign these roles to the users that work with the Mass Changes Utility.

Customizing Mass Changes Local Codelists

The Mass Changes Utility uses the local reference codelists described in the following table. You can modify them to suit your organization's needs. The *affected tablename.columnname* column indicates the database columns that are affected by or use each reference codelist. From the **Admin** menu, select **Reference Codelists**, then select **Local Codelists** and query the codelists named in the following table.

Table 4–1 Mass Changes Utility Reference Codelists

Name	Description	Affected Tablename.Columnname
MC CDS SORT ORDER ¹	Default sort order for viewing and applying the candidate data set (CDS); the columns you can order.	mass_changes.order_by_cols
MC COLUMNS ²	The list of columns that can be used in LHS or RHS of criteria, such as RDCI.SITE	mass_change_criteria.col mass_change_criteria.value
DISC COLS2	Columns available for the LHS and RHS of the CDS Criteria form, regardless of the discrepancy type specified, such as DE.CREATION_TS	mass_change_criteria.col mass_change_criteria.value
UNI DISC COLS2	Columns available for the LHS and RHS of the CDS Criteria form, where the discrepancy type specified is UNIVARIATE, such as DE.DISCREPANCY_TYPE_CODE	mass_change_criteria.col mass_change_criteria.value
IND DISC COLS2	Columns available for the LHS and RHS of the CDS Criteria form, where the discrepancy type specified is INDICATOR	mass_change_criteria.col mass_change_criteria.value

Table 4–1 (Cont.) Mass Changes Utility Reference Codelists

Name	Description	Affected Tablename.Columnname
MULTI DISC COLS2	Columns available for the LHS and RHS of the CDS Criteria form, where the discrepancy type specified is MULTIVARIATE, such as PROCEDURES.NAME	mass_change_criteria.col mass_change_criteria.value
MANHD DISC COLS2	Columns available for the LHS and RHS of the CDS Criteria form, where the discrepancy type specified is MANUAL HEADER	mass_change_criteria.col mass_change_criteria.value
FLD RXCMCMCD RDCI KEY	Candidate Data Set fields to be displayed on the Candidate Data Set form when called for RDCI KEY changes, their order of display, width, and prompt.	N/A
FLD RXCMCMCD RDCM KEY	Candidate Data Set fields to be displayed on the Candidate Data Set form when called for RDCM KEY changes, their order of display, width, and prompt	N/A
FLD RXCMCMCD RDCI DELETE	Candidate Data Set fields to be displayed on the Candidate Data Set form when called for RDCI DELETE changes, their order of display, width, and prompt	N/A
FLD RXCMCMCD RESPONSE	Candidate Data Set fields to be displayed on the Candidate Data Set form when called for Responses changes, their order of display, width, and prompt	N/A
OCL MC PREFS ³	Sets the default maximum number of records to change in a Candidate Data Set. Its initial long value is 1000.	mass_changes.max_cds_records

¹ Only the display sequence and whether the field should be sorted in ascending or descending order should be changed. New fields should not be added and existing ones should not be removed.

² The values in this reference codelist determine the contents of the list of values for mass change criteria. Additional values may be added to the reference codelist but they must be from one of the existing tables already defined for values, and they must use the alias provided for the table. No validation occurs against the values in this codelist. If a value is not in the list of values it can still be added as a criterion for specifying the candidate data set.

³ OCL MC PREFS currently has one value, MAX_CDS_RECORDS, which controls the default maximum number of records to include in a Candidate Data Set.

Customizing the Field Display on the Candidate Data Set Form

These local codelists control the display of fields on the Candidate Data Set form for the four Mass Changes Utility change types:

- FLD RXCMCMCD RDCI KEY
- FLD RXCMCMCD RDCM KEY
- FLD RXCMCMCD RDCI DELETE
- FLD RXCMCMCD RESPONSE

From the Admin menu, select Reference Codelists, then select Local Codelists, and query FLD% in the Name field. The following table describes how the codelist values control all four codelists:

Table 4–2 CDS Display Codelist Fields

Codelist Field Name	Description
Seq	Sequence number: Orders each value's column position in either the fixed (the lowest numbers), or scrolling sections of the Mass Changes Utility form. (See Description, below)
Short Value	The name of the field in the form. You must not change these values.
Long Value	The display length for the field on the Candidate Data Set form.

Table 4–2 (Cont.) CDS Display Codelist Fields

Codelist Field Name	Description
Active box	Check a value's Active box to display to include its field on the Mass Changes Utility form.
Default box	N/A
Description	<p>The value's assignment to the non-scrolling or scrolling sections of the Mass Changes Utility form, and its prompt label. The description field has the following syntax:</p> <p><i>F:promptlabel</i> or <i>S:promptlabel</i></p> <p>Where:</p> <p><i>F</i>: locates the field in the left-side, non-scrolling section of the Candidate Data Set form. <i>S</i>: locates the field on the scrolling, right-side section of the Candidate Data Set form.</p> <p><i>promptlabel</i> The field label on the Candidate Data Set form.</p> <p>If all fields are non-scrolling, you must still use the <i>F:promptlabel</i> syntax.</p> <p>For Response data and data comment fields, the prompt is the default prompt for the DCM question concatenated with <i>promptlabel</i>.</p>

Oracle Clinical has default values for these codelists that reflect the most likely scenario for displaying the Candidate Data Set. You can modify the default values. The following table lists all possible column values. You can add, remove, modify, or rearrange the display fields. Footnotes and a legend with descriptions of all of the table's symbols follows the table.

Table 4–3 Candidate Data Set Form Codelist Values

Column Value	Short Name	Display Settings by Mass Changes Utility Change Type				
		Recom- mended	Set by Default	Can be Set	List of Values	Update- able
cdr_status_code	cdr_status_code	All	All			
validate_comment	val_comment	All	All			
change_reason_code ¹ (Must be valid in codelist)	c_reason_code	All	All		All	All
audit_comment	audit_comment	All	All			All
how_updated	how_updated	I, M, R	I, M, R			
received_dci_id	received_dci_id			All		
document_number	doc_number	All	All			
document_number_new	doc_number_new	I	I			I
investigator	investig	I	All			
investigator_new	investig_new	I	I		I	I
site	site	I	All			
site_new	site_new	I	I		I	I
patient	patient	I	All			
patient_new	patient_new	I	I		I	I
dci_short_name	dci_sh_name	I	All			

Table 4-3 (Cont.) Candidate Data Set Form Codelist Values

Column Value	Short Name	Display Settings by Mass Changes Utility Change Type				
		Recommended	Set by Default	Can be Set	List of Values	Update-able
dci_short_name_new	dci_sh_name_new	I	I		I	I
clin_plan_eve_name	cpe_name	I	All			
clin_plan_eve_name_new	cpe_name_new	I	I, M		I, M--	I, M
visit_number	vis_number	I	All			
subevent_number	sub_number	I	All			
subevent_number_new	sub_number_new	I	All		I, M	I, M
dci_date-	dci_dt	I	I, D, M	R		
dci_date_new-	dci_dt_new	I	I			I
dci_time-	dci_tm	I	I, D, M	R		
dci_time_new-	dci_tm_new	I	I			I
comment_text	cm_txt	I, M	I, D, M	R		
comment_text_new	cm_txt_new	I, M	I, M			I, M
blank_flag	blank_flag	I, M	I, D, M	R		
blank_flag_new	blank_flag_new	I, M	I, M		I, M	I, M
received_dcm_id	received_dcm_id			M, R		
rdci_clin_plan_eve_name	rdci_cpe_name			M, R		
rdci_visit_number	rdci_vis_number			M, R		
rdci_subevent_number	rdci_sub_number			M, R		
rdci_comment_text	rdci_cm_txt			M, R		
rdci_blank_flag	rdci_blank_flag			M, R		
dcm_name	dcm_name	M	M, R			
dcm_subset_name	dcm_subset_name		M	R		
dcm_layout_sn	dcm_layout_sn		M	R		
dcm_date*	dcm_dt	M	M	R		
dcm_date_new*	dcm_dt_new	M	M			M
dcm_time*	dcm_tm	M	M	R		
dcm_time_new*	dcm_tm_new	M	M			M
qualifying_value	qual_value	M	M, R			
qualifying_value_new	qual_value_new	M	M		M	M
data_comment_text	dta_cm_txt	M	M	R		
data_comment_text_new	dta_cm_txt_new	M	M	R		M
repeat_sn	repeat_sn	R	R			
response_id1	response_id1			R		
validation_status1	valid_status1		R			

Table 4–3 (Cont.) Candidate Data Set Form Codelist Values

Column Value	Short Name	Display Settings by Mass Changes Utility Change Type				
		Recommended	Set by Default	Can be Set	List of Values	Update-able
exception_value_text1	e_val_txt1			R	R†	
value_text1	val_txt1			R	R∅	
full_value_text1	f_val_txt1	R	R		R`	
full_value_text1_new ²	f_val_txt1_new	R	R		R`	R
data_comment_text1	dta_cm_txt1	R	R			
data_comment_text1_new	dta_cm_txt1_new	R	R			R
response_id2	response_id2			R		
validation_status2	valid_status2		R			
exception_value_text2	e_val_txt2			R	R†	
value_text2	val_txt2			R	R∅	
full_value_text2	f_val_txt2	R†	R†		R`	
full_value_text2_new ²	f_val_txt2_new	R†	R†		R`, as per data entry	R
data_comment_text2	dta_cm_txt2	R†	R†			
data_comment_text2_new	dta_cm_txt2_new	R†	R†			R
response_id3	response_id3			R		
validation_status3	valid_status3		R			
exception_value_text3	e_val_txt3			R	R†	
value_text3	val_txt3			R	R∅	
full_value_text3	f_val_txt3	R†	R†		R`	
full_value_text3_new	f_val_txt3_new	R†	R†		R`, as per data entry	R
data_comment_text3	dta_cm_txt3	R†	R†			
data_comment_text3_new	dta_cm_txt3_new	R†	R†			R
response_id4	response_id4			R		
validation_status4	valid_status4		R			
exception_value_text4	e_val_txt4			R	R†	
value_text4	val_txt4			R	R∅	
full_value_text4	f_val_txt4	R†	R†		R`	
full_value_text4_new	f_val_txt4_new	R†	R†		R`, as per data entry	R
data_comment_text4	dta_cm_txt4	R†	R†			
data_comment_text4_new	dta_cm_txt4_new	R†	R†			R

¹ Validation issue: Value must be valid in the reference code list.² Validation issue: Must pass field validation in data entry.

Table 4–4 Legend for Table 4–3

Symbol	Description
	A blank cell indicates that the value does not qualify for any of the change types.
L	RDCI KEY change type
D	RDCI DELETE change type
M	RDCM KEY change type
R	RESPONSE change type
All	Applies to all change type codes: RDCI KEY, RDCI DELETE, RDCM KEY, RESPONSE
-	The system does not display this field. Instead a display field is used as with the Data Entry Log-in form. This field displays the data retrieved into the base table field in the appropriate format and translates the information entered into the new fields to the format needed by the base table fields. This field contains an list of values, or is update-able, pertains to the display field, with the update of the base table fields by the system. It is necessary for the reference codelist to have the display fields rather than the base table field. For these fields, the labels, <i>Column value</i> refers to the base table field and <i>short name</i> refers to the display field.
--	The <code>clin_plan_eve_name_new</code> field list of values contains the visit number as well, for reference purposes only.
†	Responses and associated old and new values are required and present by default, if they exist.
‡	An list of values is present for <code>exception_value_text</code> if an alpha data code discrete value group exists for the DCM question, and values from this group are part of the list of values.
∅	An list of values is present for <code>value_text</code> if a discrete value group exists for the DCM question, and values from this group will appear in the list of values
`	There is an list of values for the <code>full_value_text</code> if any discrete value group exists for the DCM question, and values from these groups appear in the list of values.

Configuring Data Entry and User Preferences

This section includes the following topics:

- [Customizing Data Entry Behavior](#) on page 5-1
- [Customizing the Oracle Clinical Log-in Window Layout](#) on page 5-7
- [Setting DCI Form Default Values for RDC Data Entry and the Patient Data Report](#) on page 5-10
- [Customizing Flex Fields for DCI Forms](#) on page 5-20
- [Customizing CRF Column Headers in the RDC Classic Surround](#) on page 5-22
- [Customizing Online Help](#) on page 5-24

Customizing Data Entry Behavior

A number of features, behaviors, and even the appearance of the Log-In and Data Entry screens can be configured depending on configuration settings, user preferences, and special layout editing tools. This section provides an overview of these features; more detail on each feature is available in later sections.

The features discussed in this section are:

- [Define Data Entry Configuration Settings](#) on page 5-1
- [Configuring Additional Data Entry User Preferences](#) on page 5-5
- [Configuring Privileged Update](#) on page 5-7

Define Data Entry Configuration Settings

Data entry configuration settings, such as whether univariate validation failures alert the First-Pass and Second-Pass data entry operators, can be set at the local database level, the study level, or the user level.

Data entry configuration settings can be set at the:

- **Database Level** through the Maintain Installation Configuration window; see [Configure Database-Level Data Entry Settings](#) on page 5-2
- **Study Level** through the Maintain Study Configuration window (via Maintain Clinical Study States window); see [Configure Study-Level Data Entry Settings](#) on page 5-4

- **User Level** through the Maintain Oracle Accounts window; [Configure User-Level Data Entry Settings](#) on page 5-4

As the configuration level becomes more specific, from database to study to user, its settings usually take precedence over the more general level. At the local database level, each setting is either enabled or disabled. At the study and user levels, each setting is either enabled, disabled, or not set. If the value of a setting is "Not Set" it serves as a "pass-through" to the next higher level value for that setting. Initially, all values at the study- and user-level are set to "Not Set" so that the database level, which is set up during installation, is in effect until you modify the settings for a given study or user.

Study-level configuration settings affect all users who have access to that study, except when user-level configuration or Study/Site security settings are set up for a user. If a setting at this level has a value of Not Set, all users who access the study use the database-level setting, unless the value for the setting at the user level is Enabled or Disabled for a specific user.

Note that certain privileges that are assigned via the Study and/or Site Security windows take precedence over user-level data entry configuration settings.

The settings available at each level are identical; the only difference is the availability of the "Not Set" value at the study- and user-levels. Refer to [Table 5-1, "Local Database-Level Data Entry Configuration Settings"](#) for a complete list of settings.

Configure Database-Level Data Entry Settings

Local database configuration settings are maintained in the Maintain Installation Configuration window. You can customize the configuration settings for the local database by changing the default shipped values for the configuration settings.

At the local level, configuration settings are either enabled, disabled, or have a numeric value, as applicable. [Table 5-1](#) describes each setting.

Use this procedure to change the local settings:

1. INavigate to **Admin**, then **DE Admin**, and **DE Config Settings**. The Maintain Installation Configuration window opens.
2. Navigate to the configuration setting that you want to modify, and change its value. The default page height and width settings allow numeric values within upper and lower bounds. The other settings can be set to either enabled or disabled.
3. Click **Save** to commit changes.

Table 5–1 Local Database-Level Data Entry Configuration Settings

Configuration parameter	Description	Values	Default setting
Second-Pass Comparison Failure Alert	(Oracle Clinical only) Controls whether the data entry operator is notified when a first-pass/second-pass comparison error occurs. When this setting is not enabled, the operator is in "silent" mode during second-pass data entry, and any first/second pass comparison failures that occur must be resolved during comparison reconciliation.	Enabled/ Disabled	Enabled
Manual Discrepancy in Browse	(Oracle Clinical only) Whether the data entry operator can create or modify a manual discrepancy (operator comment) in browse mode (only applicable if the user has access to Browse mode).	Enabled/ Disabled	Enabled
Resolve Discrepancies in Data Entry	(Oracle Clinical and RDC) Whether the data entry operator has authority to resolve discrepancies during data entry, that is, the permission to set a discrepancy to closed status. For RDC Classic, set this parameter to Enabled.	Enabled/ Disabled	Enabled
Privileged Update	(Oracle Clinical and RDC) Whether the data entry operator can perform the following while in update mode: <ul style="list-style-type: none"> ▪ update data for locked RDCMs and RDCIs, ▪ override protected repeating defaults, and ▪ exceed the Maximum # of Repeats to a Repeating Question Group, even when Enforce Repeats is set (Oracle Clinical and RDC Classic only). 	Enabled/ Disabled	Disabled
List of Values for Thesaurus Questions	(Oracle Clinical only) Whether a list of values is available for thesaurus questions based on external dictionaries.	Enabled/ Disabled	Disabled
Univariate Failure Alert	(Oracle Clinical and RDC Classic) Whether the data entry operator is notified when a univariate validation error occurs. When this setting is disabled, the operator is in "silent" discrepancy mode. Univariate discrepancies are still created in "silent" mode, but the operator is not notified of their creation. RDC Onsite does not use this setting. Instead, it uses a configuration setting in the RDC Administration tool, which can be over-ridden by the end user, if Preferences are made available	Enabled/ Disabled	Enabled
Initiate DE session using DCI Book	(Oracle Clinical only) Whether DCI book sequencing is the default sequencing mode during log-in and data entry.	Enabled/ Disabled	Enabled
Unenrolled patient alert	(Oracle Clinical only) Whether the data entry operator is notified when a received DCI is logged in for a patient not enrolled in the study.	Enabled/ Disabled	Enabled
Prevent Second-pass Entry by First-pass operator	(Oracle Clinical only) Whether Oracle Clinical prevents the data entry operator who did first-pass entry on a given RDCI from performing second-pass entry on the same RDCI.	Enabled/ Disabled	Disabled
Browse accessible data only	(Oracle Clinical only) Determines if data entry operators can browse data.	Enabled/ Disabled	Disabled

Table 5–1 (Cont.) Local Database-Level Data Entry Configuration Settings

Configuration parameter	Description	Values	Default setting
DCI and DCM Date Required	(Oracle Clinical and RDC) The data entry must enter the DCI and DCM Visit date.	Enabled/ Disabled	Enabled
Default height for Data Entry page in DCM	(Oracle Clinical only) Default value for the Data Entry Page Height for DCMs. This setting determines only the value that is supplied as the default, which can be overridden during DCM definition.	Number between 10 and 60	22
Default width for Data Entry page in DCM	(Oracle Clinical only) The default value for the Data Entry Page Width for DCMs. This setting determines only the value that is supplied as the default, which can be overridden during DCM Definition.	Number between 10 and 240	80

Configure Study-Level Data Entry Settings

If you require that a particular study have different data entry configuration settings from those set at the local database level, you can change the settings at the study level by modifying the Clinical Study State record for that study. Study-level configuration settings override local database-level configuration settings for that study.

The study-level configuration settings are identical to the local database-level data entry configuration settings, but at the study level, an additional value, "Not Set", is available for all configuration settings. If a setting is not set, it is not defined and the next higher configuration setting takes effect. Because study-level settings take precedence over database-level, by default, all study-level configuration settings are set to "Not Set", which results in the local-level settings taking effect. Refer to [Table 5–1, "Local Database-Level Data Entry Configuration Settings"](#) for a listing of the settings.

Values for each non-numeric setting are available from the list of values and can be either "Enabled", "Disabled", or "Not Set". The default page height and width settings allow numeric values within upper and lower bounds.

To change a study-level data entry configuration setting:

1. Navigate to **Conduct**, then **Security**, and then **Clinical Study States**. The Maintain Study States window opens.
2. Query for the study you want to update. Choose **DE Configs** in the **Special** menu. The Maintain Study Configuration window opens.
3. For each configuration setting that you want to modify, change its value as necessary.
4. Save the changes and click Back to return to the Maintain Clinical Study States window, or click Back without saving to abandon your changes.

Changes at this level affect all users working in the study, unless user-level data entry configuration settings are defined for a user. Refer to ["Configure User-Level Data Entry Settings"](#) for information on modifying these settings.

Configure User-Level Data Entry Settings

User-level settings affect all studies to which the user has access.

If you require that a user have different data entry configuration settings from those set at the study or the database level, you can change specific settings at the user level that supersede those higher level settings.

The user-level configuration settings are identical to the study- and database-level data entry configuration settings. As with the study level settings, an additional value of Not Set is available for all nonnumeric settings. If a setting is Not Set, the next higher configuration setting takes effect. Because user-level settings take precedence over database-level, by default they are set to Not Set, which results in the local-level settings taking effect. [Table 5-1, "Local Database-Level Data Entry Configuration Settings"](#) has a complete list of settings.

Note: The [DCI and DCM Date Required](#) setting is inactive at the user-level.

Values for each nonnumeric setting are available from the list of values and can be either Enabled, Disabled, or Not Set. The default page height and width settings allow numeric values within upper and lower bounds.

To change user-level data entry configuration settings, follow this procedure:

1. Navigate to **Admin**, then **Users**, then **Oracle Accounts**. The Maintain Oracle Accounts multi-view window displays.
2. Query the user record you want to modify. Choose **Special, DE Configs**. The Maintain User Configuration window displays.

To define a user-level configuration setting, change the value of the configuration setting in this window to any value other than not set. You can change the value of a configuration setting without changing all of them.

3. Change the any setting, as needed.
4. Save the changes and then click **Back** to return to the Maintain Oracle Accounts form, or click **Back** without saving to abandon your changes.

Configuring Additional Data Entry User Preferences

Oracle Clinical supplies a set of default values for user preferences, which are displayed in [Table 5-2](#). These preferences remain in effect for all data entry operators unless operators override the defaults and save their own values (see Chapters 3 and 4 in *Oracle Clinical Conducting a Study*).

To change the default values for user preferences:

1. Navigate to **Admin**, then **DE Admin**, and then **DE User Prefs**. The Maintain Installation Preferences window opens.
2. Navigate to the user preference that you want to modify, and change its value. Values for each user preference are represented either as checkboxes or in Lists of Values.
3. Click **Save as Default** to save the changes, then click **Exit** to close the window.

Table 5–2 Local dAta Entry User Preference Settings

User preference	Description	Values	Default setting
Auto Skip	On fields that have been defined as Auto Skip fields in DCM definition, determines whether the cursor automatically skips to the next field when the current field is filled to its predefined length.	Enabled/Disabled	Enabled
Auto Fill	Applicable only for fields that have lists of values (DVG- or thesaurus-based). Determines whether entering a few unique characters of a valid value will result in the system's filling in the rest of the value upon navigation out of the field.	Enabled/Disabled	Enabled
Univariate Beep	Determines whether an audible signal will accompany the Univariate validation failure pop-up window. Not applicable if the Univariate validation failure alert configuration setting is disabled.	Enabled/Disabled	Enabled
Comparison Beep	Determines whether an audible signal accompanies the First-Pass/Second-Pass Comparison Failure pop-up window. Not applicable if the second-pass comparison failure alert configuration setting is disabled.	Enabled/Disabled	Enabled
End of Form Beep	Determines whether you receive an audible beep when you reach the end of a form.	Enabled/Disabled	Enabled
Data Entry Input Format	For all log-in and data entry tasks, for DCI and DCM dates and data entry fields of type date, determines how date formats are applied to interpreting data that is input to the field. Must be the same as data entry display format (see below), unless display format is standard. standard format (see below) is always accepted.	us (mm-dd-yyyy) european (dd-mm-yyyy) swedish (yyyy-mm-dd)	US
Data Entry Display Format	For DCI and DCM Dates, the Display Format configuration determines the date format used for displaying dates. For data entry fields, the format is controlled by the date order of the DCM, which is either DYNAMIC or is one of the four date formats (US, EUROPEAN, SWEDISH, or STANDARD). If the DCM's date order is DYNAMIC, data entry fields that are dates are displayed using the same data entry configuration Display Format setting used for DCI and DCM dates. Otherwise, data entry fields are displayed using the format indicated by the Date Order for the DCM. Additionally, whether the day and month portion of a data entry field date is displayed is controlled by the Date Time Format of the DCM question on which it is based. There are four possible Date Time Formats for a date field: DMY (day, month, and year are displayed), MY (day is not displayed), and Y (only year is displayed).	US (MM-DD-YYYY) European (DD-MM-YYYY) Swedish (YYYY-MM-DD) Standard (DD-MON-YYYY)	US
RDCI Sort Order	For query sequencing, determines the ordering for the RDCIs retrieved by a query for data entry processing.	Document Number Patient - Visit - DCI Name - DCI Date Entry Order	Entry Order

Configuring Privileged Update

This section includes the following topics:

- [Set Privileged Update Using Configuration Settings](#) on page 5-7—applies to Oracle Clinical and RDC
- [Set Privileged Update Using Study/Site Security](#) on page 5-7—applies to Oracle Clinical only

Users with privileged update can perform the same tasks on a locked document that they can on an unlocked document. in all data entry modes: log in, first pass, second pass, update, reconciliation, and key changes.

Within RDC, enabling privileged update means that the user can take any action consistent with the study- or site-security privileges assigned to the user's name. For RDC purposes, privileged update can only be assigned through the data entry configuration settings.

In Oracle Clinical you can assign privileged update through data entry configuration settings and through study/site security.

- If Privileged Update is not enabled for a user through the data entry configuration settings, you can use the UPD_LOCK_OC privilege to grant Privileged Update access to a user. The advantage of this approach is that you can grant the privilege for a specific site within a study, while the Data Entry Configuration settings allow specification only at the database, study, or user level.
- If Privileged Update is enabled through the data entry configuration settings, the UPD_LOCK_OC privilege assigned through study/site security is not applicable.

Set Privileged Update Using Configuration Settings

By default, privileged update is not enabled for a user. In most circumstances, you set the Privileged Update data entry configuration setting at the user level. To do this, refer to "[Configure User-Level Data Entry Settings](#)" on page 5-4.

- To set privileged update at the study level, refer to "[Configure Study-Level Data Entry Settings](#)".
- To set privileged update at the local database level, refer to "[Configure Database-Level Data Entry Settings](#)".

These settings apply to Oracle Clinical and RDC users.

Set Privileged Update Using Study/Site Security

For Oracle Clinical users only, when Privileged Update is not enabled for a user in the data entry configuration settings, you can grant Privilege Update access by assigning the user the UPD_LOCK_OC privilege for a particular study or site within a study.

Navigate to **Admin, Users and Roles, Study Security** or **Site Security**.

Customizing the Oracle Clinical Log-in Window Layout

Oracle Clinical data entry operators use the log-in and data entry windows to enter and display the patient data defined by Study DCMs and DCIs (see *Oracle Clinical Creating a Study*). (Once entered, patient data, or documents, are called received DCIs (RDCIs) and received DCMs (RDCMs).) The appearance of these windows can be modified by the log-in layout editor tool to resemble the received DCI and DCM header information that appears on the CRF. You can change the header information

field prompts, change the field sequences, or even hide fields after supplying them with default values.

This section includes the following topics:

- [Using the Log-in Layout Editor](#)
- [Modify the Received DCI window](#)
- [Modifying the Received DCM Window](#)
- [Modifying the Smart Received DCM Window](#)

Using the Log-in Layout Editor

The header information in CRFs is captured in the received DCI and received DCM windows. The Log-in Layout Editor allows you to match online screens with header information on the paper CRF that you may use for source data entry.

The log-in layout editor is a different tool from the DCM layout editor. You use the log-in layout editor to match the online Log-In windows with common CRF header information. You can change the header information field prompts, change the sequence of the fields, or hide fields that have default values.

"[Customizing the Oracle Clinical Log-in Window Layout](#)" on page 5-7 describes the log-in layout editor. Use the DCM layout editor to modify the appearance of the Data Entry windows (see "Laying out the data entry screen" in the *Oracle Clinical Creating a Study* manual).

The log-in layout editor can modify three windows:

- the Received DCI (RDCI) window,
- the Received DCM (RDCM) window, and
- the Smart Received DCM (Smart RDCM) window.

During log-in and data entry, the Received DCI window is the first screen that the system presents to a data entry operator. In all modes, under normal navigation, the window displayed immediately after the Received DCI window is the Smart RDCM window. This window displays underneath the Received DCI window and shows only the received DCM information required for context. To view all received DCM information, the user must navigate to the Received DCM window by invoking the function [RDCM].

To access the Log-in Layout Editor, navigate to **Admin**, the **DE Admin**, and **Log-In Layout Editor**. The RDCI window displays. Note the drop-down list field in the bottom-left corner of your screen. Use this window selection field to navigate between the windows. When you click on the arrow to the right of the drop-down list field, the names of all the windows are displayed. To change to another window, select it from the drop-down list. If you have changes pending when you attempt to change to another window, you are prompted to save your changes, or you can discard them.

Modify the Received DCI window

To modify the Received DCI window, select RDCI window from the drop-down list. The Received DCI window displays, showing all the received DCIs fields and their default prompts.

When you click on a field or on its prompt, the following information about the field or prompt is displayed to the right of the window selection window:

- the prompt or field name (depending on whether you clicked on the field or on its prompt),
- the X and Y coordinates for the field or prompt, and
- the length of the prompt or field.

These fields are display-only and cannot be updated.

You can change the length of a prompt or of a field by clicking on the prompt or on the field and then clicking on the Increase Width or Decrease Width buttons, which increase or decrease the length of the prompt or the field.

You can change the screen position of the field and its prompt by clicking on the prompt and dragging it to a new location. The field follows the prompt. If you click on the field itself and drag it, it moves separately from the prompt.

You can modify the prompt text by clicking on the prompt and then editing the text.

In the RDCI window, you are limited to six lines of vertical screen space, and 80 characters of horizontal space. In the data entry form, the window will only display the height of the screen occupied by fields or their prompts. For example, if you configure the RDCI window in the log-in layout editor such that you have fields and prompts on only the first four lines, only those four lines are displayed at data entry time, leaving more room for the data entry fields.

You can hide a field by dragging it to the Items Not Displayed section of the form. This field is not visible to the data entry operator during normal data entry functioning.

You can make a field non-updateable by the data entry operator by double-clicking on the field. When a field has been made non-updatable, it is displayed in red in the RDCI window. You can make it updateable by double-clicking on the field again.

Save pending changes by selecting **Save**. If you want to discard changes that you have made but have not yet saved, you can select **Revert**, which rolls back your changes to your last save. To close the form, select **Exit**.

To edit the layout of another window, click the arrow to the right of the **Window Selection** drop-down list field, and then select the window whose layout you next want to edit. If you have pending changes when you try to change windows, you are prompted to save your changes.

Modifying the Received DCM Window

The **RDCM** window is displayed to the data entry operator when the [RDCM] function is invoked.

To modify the **RDCM** window, select RDCM Window from the window selection drop-down list. You can modify the information that is displayed for the received DCM in the RDCM window in the same way that you modified the information in the RDCI window. All navigation and other behavior is identical. The only difference is that for RDCMs, you have twelve lines to work with vertically, rather than the six lines allotted to RDCIs. The horizontal restriction remains 80 characters for rdcms, the same as for RDCIs.

Modifying the Smart Received DCM Window

In all log-in and data entry modes, the Received DCI window is the first window the data entry operator sees. This window may be used to capture RDCI information in

Log-In modes, or it may be used only to display RDCI information, as in the data entry modes.

Additional RDCM-level information may need to be captured, or displayed for context. For this purpose during log-in and data entry, instead of the entire RDCM window, the Smart Received DCM window is displayed underneath the Received DCI window. The Smart RDCM window contains only those RDCM fields that may require user input, or that provide minimal context for the user. In addition, page fields are displayed to indicate which RDCM of the parent RDCI is currently being displayed. Full RDCM information is available to the data entry operator by invoking the [RDCM] function.

To modify the **Smart RDCM** window, choose it in Window Selection drop-down list field. The Smart RDCM window is displayed

The following fields are displayed in the Smart RDCM window:

- Qualifying Value
- Clinical Planned Event Name
- Subevent Number
- Visit Number
- DCM Date
- DCM Time
- Lab Name

Because of the unique character of the Smart RDCM window, there are limitations on the changes that you can make to the fields in this window, as follows:

- You cannot change any characteristics of the Qualifying Value field.
- You cannot change the position of any of the fields.
- You cannot choose not to display one of the fields.

All six fields must be displayed, and their location can not be changed. For Smart RDCM window fields other than the Qualifying Value, you can change the field prompt and length.

After you save your changes, the next time that a data entry operator performs a log-in function in that study, the changes that you made will be visible.

Setting DCI Form Default Values for RDC Data Entry and the Patient Data Report

This section consists of the following topics:

- [Setting and Enforcing Values](#) on page 5-12
- [Settings](#) on page 5-12
 - [DCI Form Definition](#)
 - [DCI Form Runtime](#)
 - [General](#)
 - [Graphic Layout Editor/Updater](#)
 - [Graphic Layout Generator - General](#)

- [Graphic Layout Generation - DCMS](#)
- [DCI Form Generation Defaults](#)
- [Default Settings for Showing DCM Header Fields](#)
- [Default DCM Header Field Prompts](#)
- [Version Migration](#)
- [Patient Data Report](#)
- [Validation](#)

You set the default values for DCI Form and Graphic Layout settings for all studies in the current database in the DCI Form Local Database Settings window. These settings affect the appearance of data entry windows in RDC Onsite and the PDF output of the Patient Data Report and Blank Casebook Report in Oracle Clinical and RDC.

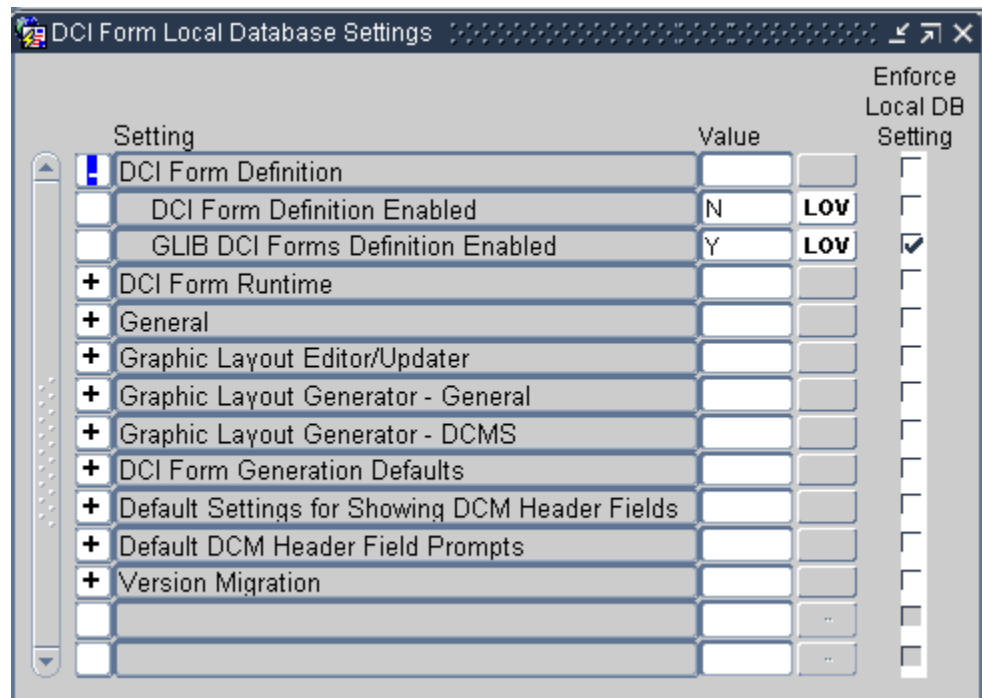
For each setting, you can choose to enforce the value across all studies or allow modification on the study level in the DCI Form Local Study Settings window (under **Design**).

By default the roles that have access to this form are RXC_USER, RXC_SUPER_NOGL, RXC_ADMIN. There is also a read-only Query version of this form (QRY Global Settings, in the same path). To query the form you must have either the RXC_SUPER or RXC_ANY role.

Access the window by navigating to **Admin**, then **DCI Form Local Database Settings**.

Settings are logically grouped, and when you open the window only the groups are displayed. To see individual settings, click the + node.

Figure 5–1 DCI Form Local Database Settings Window



Setting and Enforcing Values

For each individual setting you can choose to:

- Change the default value
- Select the **Enforce Local DB Setting** check box

If you select **Enforce Local DB Setting** here, study designers cannot change the value at the study level in the DCI Form Local Study Settings window. If you do not select **Enforce Local DB Setting** here, the value is modifiable at the study level.

For further information about the DCI Form Local Study Settings window, refer to the *Oracle Clinical Creating a Study* manual.

Settings

This section describes the following groups of settings:

- [DCI Form Definition](#)
- [DCI Form Runtime](#)
- [General](#)
- [Graphic Layout Editor/Updater](#)
- [Graphic Layout Generator - General](#)
- [Graphic Layout Generation - DCMS](#)
- [DCI Form Generation Defaults](#)
- [Default Settings for Showing DCM Header Fields](#)
- [Default DCM Header Field Prompts](#)
- [Version Migration](#)
- [Patient Data Report](#)
- [Validation](#)

DCI Form Definition

The settings for this category are:

- **DCI Form Definition Enabled** If set to **Y**, DCI Form definition—the use of graphic layouts—is enabled by default for all studies in the database. The study-level setting is not in the DCI Form Local Study Settings window but in **Clinical Study States** (under **Conduct**, then **Security**). The Easy Study Design feature does not include an explicit setting for enabling DCI Form definition; if study designers want to change the default value, they can use the Clinical Study States form.
- **GLIB DCI Forms Definition Enabled** If set to **Y**, DCI Forms can be defined in the Global Library (under **Glib**, then **DCMs DCIs Procedures**, then **DCMs** or **DCIs**). There is no corresponding study-level setting.

DCI Form Runtime

The settings for this category are:

- **Label for Customizable Patient Identifier** If you are using a customizable patient identifier and you would like to display a label other than Reference (the default) in RDC Onsite, enter the label text you prefer. The label appears next to the field in the Search screen of the Home and Casebooks pages. You can use this setting only

if **Use customizable patient identifier?** is set to **Y**. See the *RDC Administrator's Guide* for further information.

- **DCI Form Entry Enabled** If set to **Y**, data entry in RDC Onsite is enabled. The study-level setting is not in the DCI Form Local Study Settings window but in the **Clinical Study States** window (under **Conduct**, then **Security**). The Easy Study Design feature does not include an explicit setting for enabling DCI Form definition; if study designers want to change the default value, they can use the Clinical Study States window.
- **DCI Form Field Length Restriction** If set to **Y**, users cannot enter more characters in a field than specified by the Length attribute on the DCM Question definition for that field. If set to **N** and a user enters more characters than specified, the system creates a discrepancy. Overflow data that cannot be displayed on the output prints into an overflow section.
- **Display Label for DCM Question** Select the source for the label of each field in the CRF; either the **SAS label**, the **question name**, or the **default prompt** of the corresponding question definition. The label is then used as a reference in the Discrepancies, Investigator Comments, and Audit History Navigators in the RDC Onsite data entry window.
- **Display Visit Owning Interval on MPC Page?** If set to **Y**, the Casebooks page in RDC Onsite displays the interval—phase, period, or subperiod—to which the displayed visit belongs.
- **Enable Entry of Investigator Comments** If set to **Y**, Investigator comments are allowed in RDC Onsite.
- **Page Labeling Compatible with Page Tracking?** If set to **Y**, the page label in a physical page uses the same syntax as the page identification in the page tracking system. This setting applies only to studies that use Page Tracking; refer to *Oracle Clinical Creating a Study* for more information.
- **Represent Disabled Blocks as** This setting applies to studies using conditional in-form branching. Select **Greyed** if you want conditional fields that are not expected for a patient to be displayed but grayed out. Select **Hidden** if you do not want such fields to be displayed at all. In this case, the next expected fields, if any, are displayed in the same area, so that there is no empty space in the middle of the page. The empty space appears at the end of the page.
- **Suppress Change Reason for new Responses** If set to **Y**, the data entry user is not prompted for a Change Reason the first time a response is entered even if the CRF has been previously saved.
- **Suppress Change Reason Prompt for New Investigator Comment** If set to **Y**, the Investigator is not prompted for a Change Reason the first time he or she enters a comment on a particular response.
- **Suppress Warning for Non-migrated CRFs** If set to **Y**, the data entry user does not receive a warning when working on a CRF that was entered via another user interface—Oracle Clinical, RDC Classic, or Batch Data Load—and the CRF has not been migrated to a DCI Form version. Also refer to the setting **Allow Migration of Classic RDCIs?** under the [Version Migration](#) category.

Note: You cannot uncheck Enforced for this setting. There is no corresponding setting at the study level, so the value you set here is automatically enforced.

- **Use customizable patient identifier?** If set to **Y**, the system allows you to customize an additional patient identifier field for Search purposes in RDC Onsite. Values determined by your customization are stored in the Reported Reference column of the Patient Positions column in Oracle Clinical. You can change the label for the field using the **Label for Customizable Patient Identifier** setting. See the *RDC Administrator's Guide* for further information.

General

The settings for this category are:

- **Default Unplanned Use Allowed for DCIs not in Book** If set to **Y**, DCIs not included in a DCI Book are available for unplanned use; the default setting in the DCI Book Constraints window for the **Unplanned Use Allowed if not listed below** field is checked.

This setting has no effect on existing DCI Books or on DCIs already listed in the DCI Book Constraints window.

Refer to the section on DCI Books in the *Oracle Clinical Creating a Study* manual for more information.

- **Layout Unit of Measurement** Select the unit of measurement to be used when dimensions related to layouts are displayed. The options are: **inches**, **centimeters**, and **points**.

Graphic Layout Editor/Updater

This category has one setting: **Enforce Length as Field Size**. If set to **Y**, the system uses the character length defined for the question to set the minimum size of the field in the layout editor. When set to **Y**, if you increase the question's length in the **Study DCM Questions** window, the system sets the **Needs Update** flag to indicate the field width needs to be increased.

Note: This setting has no effect if the **DCM Question Attribute for Determining Field Width** setting, which is a constituent of [Graphic Layout Generation - DCMS](#) is set to **DISPLAY LENGTH**.

Graphic Layout Generator - General

The settings in this category are:

- **Default Checkbox Check Style** Select the default value for the **Checkbox Style** field in the startup dialog for the DCM Graphic Layout generator, which determines the symbol used in selected checkboxes. The default options are: **Check**, **Circle**, **Cross**, and **Square**.
- **Default Checkbox Shape** Select the default value for the **Checkbox Shape** field in the startup dialog for the DCM Graphic layout generator, which determines the checkbox shape. The options are: **Circle** and **Square**.
- **Default Checkbox Size** Select the default point size for checkboxes. The options are: **10**, **12**, **15**, **20**.

Note: You can change the set of options by modifying the [DCIF CHECKBOX SIZE](#) installation reference codelist.

- **Default Landscape Form Layout Template** Select the default layout template that the system uses for horizontal layouts. The list of values is populated by the templates that are available in the database.
- **Default Portrait Form Layout Template** Select the default layout template that the system uses for vertical layouts. The list of values is populated by the templates that are available in the database.
- **Field Font Size** Select the default font point size for fields. The option are: 8, 9, 10, 11, 12, 14.

Note: You can change the set of options by modifying the [DCIF FONT TYPESIZE](#) installation reference codelist.

- **Field Font Typeface** Select the default font for fields; must be a monospace font. This list is based on the DCIF Typefaces table, which is not modifiable. In Oracle Clinical Release 4.6, this list includes only Courier.
- **Prompt Font Size** Select the default font point size for prompts. The option are: 8, 9, 10, 11, 12, 14.

Note: You can change the set of options by modifying the [DCIF FONT TYPESIZE](#) installation reference codelist.

- **Prompt Font Typeface** Select the default font for prompts. The options are: Arial, Courier New, Symbol, and Times New Roman.

Graphic Layout Generation - DCMS

This category has one setting: **DCM Question Attribute for Determining Field Width**. Select the question attribute to use to determine the size of the field:

- If set to **Length**, the display area accommodates the maximum number of characters allowed for the question, without scrolling. If the page is not wide enough to accommodate the field on one line, the layout generator changes it to a multi-line field.
- If set to **Display Length**, the display area may not be large enough to see the full response at one time. If the page is not wide enough to accommodate the field, the layout generator will extend the field to the page margin, but will not change it to a multi-line field.

The user can scroll to view or edit the overflow of text that might occur. A Patient Data Report (PDR) that includes such a field displays the entire value in the Overflow Section of the report.

Note: Refer also to the [Enforce Length as Field Size](#) setting.

DCI Form Generation Defaults

The settings in this category are:

- **Default Landscape Page Definition** Select a default page size for horizontal pages: either US letter (OCL_USL_L) or A4 (OCL_A4_L).
- **Default Portrait Page Definition** Select a default page size for vertical pages: either US letter (OCL_USL_P) or A4 (OCL_A4_P).

Note: These settings have the same list of values, which is populated by the [DCIF PAGE DEFINITION](#) installation reference codelist. Be careful to select a landscape value for the landscape setting and a portrait value for the portrait setting.

Default Settings for Showing DCM Header Fields

This category controls the default display of DCM header field definitions.

Note that you use next category, [Default DCM Header Field Prompts](#), to define default text for these fields' labels.

The settings for this category are:

- **Default for Show Blank Flag?** If set to **Y**, the DCM header includes a Blank Flag field.
- **Default for Show Comment?** If set to **Y**, the DCM header includes a Comment field, also known as the DCM Internal Comment. The DCM header data comments are available only in the Oracle Clinical Data Entry subsystem. You cannot modify the field in RDC Data Entry. Set this option to **Y** only if you want to produce Patient Data Reports that show RDCM header comments entered in through Oracle Clinical Data Entry.
- **Default for Show Data Comment?** If set to **Y**, the DCM header includes a Data Comment field. The DCM header data, which is the same as internal comments, is only available in the Oracle Clinical Data Entry subsystem. You cannot modify the field in RDC Data Entry. Set this option to **Y** only if you want to produce Patient Data Reports that show RDCM header data comments entered in through Oracle Clinical Data Entry.
- **Default for Show Lab?** Set to **Y** to enable displaying and entering the lab for an RDCM by default if the lab has any lab questions. If there are no lab questions for a DCM, **Show Lab** is set to **N** regardless of this setting.
- **Default for Show Qualifying Value?** Set to **Y** to display the qualifying value. If there is a qualifying question for the DCM but there is no default value, **Show Qualifying Value** has a value of **Y** even if this value is set to **N**. If there is no qualifying question for a DCM, **Show Qualifying Value** has a value of **N** for the DCI module record regardless the value of this setting.
- **Default Visit Display Code** Select the way you want the DCM header to display visit information. The options are:
 - NAME /SUB# - Visit Name, Subevent Displayed in separate fields
 - NAME+ SUB# - Visit Name, Subevent both displayed in Visit field
 - NAME ONLY - Visit Name
- **Hide Visit by Default?** If set to **Y**, the DCM header does **not** include the visit identifier. The system sets **Visit Display Code** to **HIDDEN** by default, overriding the previous setting. Exceptions: if there is no defined clinical planned event, or the **Use DCI Date** setting is not selected, you cannot select value **HIDDEN** for the Visit Display for a DCM, and **Visit Display Code** defaults to the value you set for the previous setting.

Default DCM Header Field Prompts

You control the default display prompts of DCM header field definitions in this category. You control the display of these definitions in the previous category, see "[Default Settings for Showing DCM Header Fields](#)" on page 5-16.

- **(Internal) Comment prompt** Enter prompt text for an internal comment field.
- **Blank Flag prompt** Enter prompt text to identify a header indicator that a DCM is blank.
- **Data Comment prompt** Enter prompt text to identify a DCM header data comment field.
- **Date prompt** Enter prompt text to identify a DCM header Date field.
- **Generate DCM Header Divider?** If set to **Y**, the system generates a line between the DCM Header and the DCM.
- **Lab prompt** Enter prompt text to identify a DCM header Lab identifier field.
- **Length for (Internal) Comment Prompt** Enter a number to determine the maximum number of characters a comment field can hold.

Note: This field is misnamed. It is not the length of the prompt, but the length of the comment field itself.

- **Length for Data Comment** Enter a number to determine the maximum number of characters a data comment field can hold.
- **Length of Visit Name** Enter a number to determine the maximum number of characters a Visit Name field can hold.
- **Subevent Prompt** Enter prompt text to identify a DCM subevent identifier field.
- **Time prompt** Enter prompt text to identify a Time field.
- **Visit Name Prompt** Enter prompt text to identify a Visit Name field.
- **Visit Name+Sub# Prompt** Enter prompt text to identify the Visit Name and subevent identifier field combination.

Version Migration

If the data definitions that comprise a DCI Form change after a study has gone into production, you need to create a new layout version. These settings control whether and how to allow existing data to be migrated.

- **Allow Migration of Approved Documents?** If set to **Y**, approved RDCIs (collected patient data) are included whenever patient RDCIs are migrated to new DCI Form versions.
- **Allow Migration of Classic RDCIs?** If set to **Y**, patient RDCIs entered in Oracle Clinical or RDC Classic data entry are included whenever RDCIs are migrated to new DCI Form version(s).

Note: It is not necessary to migrate such RDCIs in order to open them in RDC HTML data entry.

If set to **N**, such RDCIs are not included in the migration. There are two other settings dictating whether or not users can open non-migrated CRFs, and if they can, whether a warning message will be issued.

- **Allow HTML data entry for non-migrated CRFs** This setting is available in the RDC Administration form under RDC Configuration models. If set to **N**, non-migrated CRFs cannot be opened in HTML data entry.

- [Suppress Warning for Non-migrated CRFs](#) This setting is found under the category DCI Form Runtime. If set to **N**, whenever a user opens a non-migrated CRF in HTML data entry, a warning message is issued: "Please Note: The data displayed on this form was originally entered using another interface."
- **Allow Migration of Locked Documents?** If set to **Y**, locked RDCIs (documents) are included whenever patient RDCIs are migrated to new DCI Form versions.
- **Default Reason to Retain Approval Verification** Select the default reason to supply if approvals or verifications are retained during DCI Form version migration.
You must create the available values in the [APPROVE VERIFY RETAIN CODE](#) installation reference codelist.
- **Default Reason to Reverse Approval/Verification** Select the default reason to supply if approvals or verifications are reversed during DCI Form version migration.
You must create the available values in the [APPROVE VERIFY REVERSE CODE](#) installation reference codelist.
- **Default Setting for Reverse Approval Status** If set to **Y**, DCI Form version migration changes approved RDCIs' approval status to Unapproved. If set to **N**, DCI Form version migration keeps approved RDCIs' approval status as Approved.
- **Default Setting for Reverse Verification Status** If set to **Y**, DCI Form version migration changes verified RDCIs' verification status to Unverified. If set to **N**, DCI Form version migration keeps verified RDCIs' approval status as Verified.
- **Last Migrateable Entry Status** Specify the highest status at which CRFs are included in version migration. The possible statuses are, in order from lowest to highest, with the Oracle Clinical term given first and the RDC equivalent following:
 - Received (Blank)
 - (not applicable) (Created)
 - Pass 1 Started (Entry Started)
 - Pass 1 Complete (Entry Complete)
 - Batch Loaded (not applicable)
 - Pass 2 Pending (not applicable)
 - Pass 2 Started (not applicable)
 - Pass 2 Complete (not applicable)

In addition to these statuses, the keyword ALL allows RDCIs at any status to migrate, and the keyword NONE disallows any RDCI from migrating.
- **User Override to Reverse Approvals?** If set to **Y**, the user running Form Version Migration can specify whether that particular execution of Form Version Migration should reverse the status of all approved RDCIs migrated and can select a different reason for the reversal, if another option is available.
If set to **N**, the user running the migration cannot change the setting you selected for [Default Setting for Reverse Approval Status](#) and cannot change the default reason you set in [Default Reason to Retain Approval Verification](#) or [Default Reason to Reverse Approval/Verification](#).
- **User Override to Reverse Verifications?** If set to **Y**, the user running Form Version Migration can specify whether that particular execution of Form Version

Migration should reverse the status of all verified RDCIs migrated and can select a different reason for the reversal, if another option is available.

If set to **N**, the user running the migration cannot change the setting you selected for [Default Setting for Reverse Approval Status](#) and cannot change the default reason you set in [Default Reason to Retain Approval Verification](#) or [Default Reason to Reverse Approval/Verification](#).

Patient Data Report

The settings in this category are:

- **Bookmark Ancillary Data Section** If set to **Y**, the system generates bookmarks for the Ancillary Data sections of the Patient Data Report (PDR).
- **Bookmark Subevents** If **Y**, the system generates bookmarks for Visit Subevents in the PDR.
- **Bookmark Title for Ancillary Data Section** Specify a title to be used for bookmarks to the ancillary data section for a CRF (if **Bookmark Ancillary Data Section** is set to **Y**). The default value is "Ancillary Data Section". In the bookmark, the system appends the word "for" followed by the bookmark label of the CRF to the value specified. Therefore with the default value the bookmark text is "Ancillary Data Section for *CRF bookmark label*."
- **Exclude Overflow for Hidden Protected Repeating Defaults** The Patient Data report includes all default text for repeating questions in the ancillary pages. Set to **Y** if you do not want to include text for repeating default questions if they are hidden.

If set to **Y** and the CRF response field for a protected repeating default is less than one character long, the Overflow section of a Patient Data Report does not list the default values for the field. This setting provides support for a mechanism to hide certain fields in a CRF simply by restricting the field length to less than 1 character.
- **Include Approval Information** If set to **Y**, approval information for the CRF is included in the ancillary data section. A line appears under the title of the report stating that the document was approved, who it was approved by and the date and time of approval. If the CRF is approved but has no other ancillary data, the ancillary data page is included with just the approval information.
- **Include Audit History for Fields Not Displayed in CRF** This setting has effect only when Audit History is selected when the PDR is submitted. If set to **Y**, the audit history for CRF fields that are not displayed in the CRF is displayed at the end of the Ancillary Data Section. It is not attached to a superscript but lists all audit information for fields that are not displayed on the form—for example, if the blank flag was changed for a CRF but the blank_flag is not displayed in the form. If set to **N**, the audit history is not displayed for undisplayed fields.
- **Include TOC in Page Numbering** If set to **Y**, the cover page and table of contents are counted when determining PDR page numbers. For example, if CONMED is the first domain, and the cover page and table of contents each consisted of one page, CONMED would begin on page 3 if **Include TOC in Page Numbering** is set to **Y** and on page 1 if it is set to **N**.
- **PDR Bookmark Data Domain** Select DCI if you want Patient Data Report bookmarks to be at the DCI level, or DCM if you want bookmarks at the DCM level. See *Oracle Clinical Creating a Study* for information on DCIs and DCMs. **Enforce Local DB Setting** is checked and cannot be unchecked. The setting cannot be changed at the study level. The default value is DCI.

Validation

This category contains one value: **Execute TMS validation during site/patient validation?**. If set to **Y**, TMS processing is executed during site and patient validation. If a question is defined as a TMS parent question, the value is sent to TMS immediately and, if the value can be autoclassified in TMS, the derived responses are sent back. However, during patient validation TMS processing is always performed for the study as a whole, including for sites to which the current user may not have access, and the audit trail represents the changes as having been made by the user who invoked patient validation.

To avoid this, turn off TMS validation entirely in the context of patient validation by setting this parameter to **N**. TMS processing still occurs during batch validation.

Customizing Flex Fields for DCI Forms

The purpose of flex fields is to allow the CRF designer to include fields in the CRF header and/or footer that display data based on functions that you define. The input parameters to the function include data specific to the current document, such as document number, investigator id, etc., which allows you to include information based on these parameters in the document.

You add flex fields to your CRF design using the Form Layout Template (FLT) Layout Editor. The system allows you to define up to ten flex fields, any or all of which can be included in an FLT. Refer to *Oracle Clinical Creating a Study* for information about the procedure to insert a flex field in a FLT.

This section describes the flex fields that are defined by default and outlines the procedure you use to customize and activate additional flex fields.

- [How Flex Fields Work](#) on page 5-20
- [Flex Field Components](#) on page 5-21

How Flex Fields Work

Each flex field is customized through the use of a function in the package `rdocpb_client.sql`. When the flex field is properly configured, it can be added to the header and/or footer, using the FLT layout editor.

The function is called by the FLT layout editor.

- RDC Onsite runtime uses Flex Field Name (pKey) and Value (pValue).
- The GLE uses the Flex Field Name (pKey) and Description (pDescription) parameters to populate the

At runtime, any flex fields that are in the DCI header or footer are displayed and are populated with the value returned by a call to the function that is associated with the field. By default, if there is an error in the function, the system returns NULL. No error message is provided. You can modify the program for debugging purposes so that if there is an error in the function, the system returns an error message, which it displays in the relevant flex field.

There is no separate audit history for flexfield values that change due to modifications of the underlying function call or as the result of changes to any data points upon which a function is based.

Flex Field Components

The functions associated with flex fields are declared in `rdcps_client.sql` and are written in `rdcpb_client.sql`. These files are copied to the `$RXC_INSTALL` directory during the server installation. They are executed against the database when you upgrade or install it.

The flex field functions are defined as follows:

- Function name is of the form "FLEX_FIELD*n*", where *n* is an integer from 1 to 10, inclusive
- Flex field name is of the form "RDCI_FLEX_FIELD*n*", where *n* is an integer from 1 to 10, inclusive, and links the flex field name to the function name.

The parameters that are available in the flex field functions are listed and described in

Table 5-3 Flex Field Function Parameters

Parameter	Description
pTestProd	Describes the current mode; value is "P" if called from production mode, "T" if called from test mode. Refer to the shipped functions for examples of usage.
pRdcPopulating	Describes if the function is called during runtime or from the layout editor.
pUserId	The Oracle account of the person logged in to the system.
pUserRole	The RDC role of the user who is logged in to the system. If the user has multiple roles, it takes the first one on the list.
pStudy	The name of the current study.
pStudyId	The ID associated with the current study.
pStudyVerId	The version of the live study.
pDocNum	The document number of the CRF.
pBook	The name of the book to which the CXRF is assigned.
pBookId	The Book ID of the book to which the CRF is assigned.
pDci	The name of the DCI for the CRF.
pDciId	The DCI ID of the DCI for the CRF.
pSite	The site of the CRF.
pSiteId	The Site ID of the site for the CRF.
pInv	The name of the investigator for the site.
pInvId	The investigator ID of the investigator for the site.
pPatient	The patient associated with the CRF.
pPatientId	The patient ID of the patient associated with the CRF.
pCpeName	The name associated with the clinical planned event (CPE) for the CRF.
pCpeId	The CPE ID of the CPE for the CRF.
pSubNo	The subevent number for the CPE.
pKey	The name of the flex field, for example, "FLEX_FIELD1".
pValue	The value that is displayed in the flex field. This is only applicable when

Table 5-3 (Cont.) Flex Field Function Parameters

Parameter	Description
pDescription	The prompt that is used to designate the flex field in the

pRdcPopulating

This parameter returns "Y" if it is called from the runtime environment. It returns "N" if it is called from the layout editor. When it is set to "N", most of the other parameters are "NULL". The select statements that you use to return a flex field value should only be executed when the value of this parameter is "Y". SQL statements based on the parameters that process successfully during runtime (pRdcPopulating = 'Y') will generally fail when called from the layout editor (pRdcPopulating = 'N'). Refer to FLEX_FIELD1 and FLEX_FIELD2 in `rdcpb_client.sql` for examples of this parameter's usage.

Shipped Functions

Oracle Clinical ships with two "starter" functions and seven undefined functions:

1. FLEX_FIELD1 – Patient Initials
2. FLEX_FIELD2 – Investigator Name
3. FLEX_FIELD3 through FLEX_FIELD10 – Null

The purpose of the shipped functions is to give you an example of how to write the functions to return values based on input parameters that come from the current document. You can modify the undefined functions or the defined functions to create flex fields functions that match your particular business needs.

The functions are coded so that exceptions in the SQL statements are handled silently. This ensures that errors in flexfields do not prevent RDC data entry. For de-bugging, we recommend that you use `opa_trace.tableon`, `opa_trace.debugon`, and `opa_trace.debugmsg(msgstring)` functions to record debug information in the `opa_debug` table.

The select statements used for deriving values based on the key parameters (from pStudy to pCpeName) are inside the 'IF' clause, "if pRdcPopulating='Y'". If you put the statements outside of this 'IF' clause, the function will fail when called from the layout editor when these values are null.

Customizing CRF Column Headers in the RDC Classic Surround

You can customize the three rows of information in the CRF Column Header in the RDC Spreadsheet using functions that are supplied.

- [Default Behavior](#) on page 5-23
- [Functions Used to Modify CRF Column Headers](#) on page 5-23

Figure 5–2 CRF Column Header for Planned and Unplanned CRFs

Default Behavior

The CRF Column header consists of three lines of information, which, when taken together, uniquely identify a set of CRFs. When a column intersects a Patient row, it results in a CRF cell, which uniquely identifies a CRF for which data has been, or will be, collected for a specific patient.

By default, the information displayed in a CRF Column header is:

- Line 1 – Visit name; if the visit is unplanned (such that the subevent is not zero), it also includes the subevent number, using dot notation
- Line 2 – Page number
- Line 3 – DCI/CRF name

The character width of Line 1 is 11 characters. If the display value is greater than 11 characters, it is truncated. If the display value is 11 characters or less and the font size and width of characters cause the value to extend beyond the physical length of 11 characters, the user must scroll to view the entire value.

Note: *Scrolling* in this case refers to placing the insertion point in the row and using the arrow keys to move it to the right.

Lines 2 and 3 are not truncated. If the value of either exceeds the physical width of the column header, it is wrapped to a new line.

Functions Used to Modify CRF Column Headers

You have the option to modify any or all of the CRF Column Header lines using a separate set of functions.

Functions

You have the option to modify any or all of the CRF Column Header lines using a separate set of functions, which are included in the file `rdcpb_client.sql`. When you customize all three lines, the values are displayed in full and are not truncated. Wrapping may occur depending on the font, the font size, and the width of the characters returned in the value. If wrapping occurs on either Line 1 or 2, the subsequent lines are displayed lower down in the CRF Column Header area. This may result in making all or part of the Line 3 value unviewable in the RDC Spreadsheet.

Although you have the option of customizing all three lines of the column header, if the combined length of text for the three values exceeds 50 characters, the system

displays a warning message (number 988300) and the combined text is truncated at 50 characters. The RDC user will then have to exit the application.

The three functions that can be customized are:

1. `GetReadableColumnHeaderLine1` – customize Line 1 (Visit Name)
2. `GetReadableColumnHeaderLine2` – customize Line 2 (Page No)
3. `GetReadableColumnHeaderLine3` – customizes Line 3 (DCI/CRF Name)

Note: The `GetReadableColumnHeaderLine1` function takes precedence over `GetReadableVisitName`. That is, if both functions are customized, the system displays the value returned by `GetReadableColumnHeaderLine1`.

All three functions have the same input parameters, which are as follows:

<code>vTabType</code>	Spreadsheet view tab type; like VISIT, STUDY or PHASE
<code>vStudy</code>	The name of the study
<code>vBook</code>	The name of the book
<code>vVisit</code>	The name of the visit
<code>vSubno</code>	The subevent number for the visit.
<code>vPage</code>	The page number
<code>vDciSName</code>	The short name of the DCI
<code>bPlanned</code>	A boolean operator that indicates whether the CRF is planned or unplanned.
<code>vDefault</code>	The default value for the line that would normally be displayed in the RDC Spreadsheet.

Customizing Online Help

Oracle Clinical provides utilities for implementing a customized version of the system's extended help (Xhelp), which is HTML-based and context-sensitive. By setting up custom help through the system, you can activate a button in Oracle Clinical's field help window that, when clicked by an end user, displays your information. The system determines the user's environment by determining the form, block, and task for the current focus. You can activate or deactivate both Oracle Clinical's help (the **More** button) and your own (the **Custom Help** button).

Oracle Clinical's help system has a three-frame HTML interface that has embedded Java script macros and XML metadata. However, the application should work with any file type that your computers recognize. You can write topic files to suit your needs and completely ignore our help system, or you can copy our system into a new directory, rewrite the topic files of your choice, and then configure calls to them.

- [Modifying Calls to Online Help Topic Files](#) on page 5-25
- [Copying Xhelp Topic Files](#) on page 5-26

Modifying Calls to Online Help Topic Files

You can create customized HTML online help files with a context sensitive call from any window in Oracle Clinical. To see your online help, user click Help and then Custom.

You must create your own HTML files, put them in an accessible location, and insert the URL for the Help for each window in the OCL_DOC_INDEX table in the Developer's Toolkit.

The Oracle Clinical Help engine determines which topic file to open by comparing the user's current environment to environments listed in table OCL_DOC_INDEX. The environment is the combination of module, task, and block values. You change these calls with the Document Index form. To access this form, you must have access to the Oracle Clinical Developer's Toolkit. Navigate to **Admin**, then **Client Doc Index**. The Maintain Client DOC Index window displays. It has these fields:

- **Module Name:** The code module, or form name. You can find this value in any form by navigating to **Action**, then **Environment**.
- **Task Name:** A case-sensitive string that often resembles the screen name. Many forms have task names that distinguish browse mode from write mode. You can find this value in any form by navigating to **Action**, then **Environment**.
- **Block Name:** A subdivision within the form. Some forms have one block. Others have many. You can find this value in any form by navigating to **Action**, then **Environment**.
- **Field Name:** You can make calls that are context sensitive to the field level. If you leave this field blank, the system drops through to the block level. You can find this value by invoking Help and reading the value from the field window.
- **Show Oracle Clinical Help:** This check box controls the More button. If you un-check it, you deactivate Oracle Clinical's packaged help topic for the current environment.
- **Oracle Clinical Doc Name:** This is Oracle Clinical's topic identifier. Our calls contain several parameters for invoking our help system. The Oracle Clinical Doc Name is the second half of a URL. The first half is the value of a Web Server registry variable. The help engine concatenates the two parts, invokes a new browser instance, and passes the URL to the browser.
- **Show Client Help:** This check box activates the Custom button.
- **Client Doc Name:** This is the value you enter to create a custom call to your help topic. The Client Doc Name is the second half of a URL The first half is the value of Web Server registry variable OPA_CUSTOM_DOC_DIR.
- **Product:** The value can be AERS, RXA, RXC, or TMS.

Note: Context-sensitive calls to custom help is available from within Oracle Clinical only. There is no similar mechanism for RDC.

To modify a call to the Xhelp topic files:

1. Navigate to **Admin**, then **Client Doc Index** to open the Maintain Client DOC Index window.
2. Query the module, task, or block name field for the form with the help you want to modify. (This information is available by opening the form and choosing **Environment** in the **Action** menu to display the Environment window.)

3. Set the **Show Oracle Clinical Help** and **Show Client Help** checkboxes as necessary for your system.
4. Enter your path/filename in the **Client Document Name** field, in the same row as the environment it references.

Note:

- Calls are case sensitive. Windows Explorer may not give an accurate view of the case of a filename, or a directory name.
 - Browsers use forward slashes (/) as directory separators. If a call displays the HTML file at the end of the file, the call probably contains a backslash (\).
-
-

Copying Xhelp Topic Files

If you copy the shipped Xhelp to a separate directory, you can customize the content in those files, yet retain their HTML hyperlinks. You then activate your system by setting your OPA_CUSTOM_DOC_DIR registry string value to point to the duplicate directory.

Creating Custom Help Files

The Oracle Clinical Xhelp system provides flexibility to link to files that you create from within the online help. However, if you do create custom help files do not place them under the \html\xhelp directory. This directory may be over-written during product and/or documentation upgrades. We suggest you create another directory under \html, for example, \html\custom_xhelp.

Note: If you placed custom help files in the \html\xhelp\oc or the \html\xhelp\rdc directory trees in earlier versions of Oracle Clinical/RDC, you must create backups of these directories during the upgrade process.

Configuring Data Extract

This section contains the following topics:

- [Configuring Default Installation Data Extract Settings](#) on page 6-1
- [Setting Values in Data Extract-Related Reference Codelists](#) on page 6-5
- [Creating Tablespaces for Data Extract Tables and Indexes](#) on page 6-5
- [Customizing Data Extract Views](#) on page 6-6
- [Generating Data Extract Views](#) on page 6-7
- [Enabling the View Builder and Converting Views](#) on page 6-8
- [Controlling Access to Data Extract Views](#) on page 6-9

Configuring Default Installation Data Extract Settings

In the DX Installation Configuration window, you determine the default settings for new studies. To launch the Data Extract Installation Configuration window, navigate to Admin and select DX Installation Configuration.

The DX_CONFIG installation reference codelist includes exactly the same settings. When you change a setting here, the change is reflected in the reference codelist. When you change a setting there, the change is reflected here.

Figure 6–1 Data Extract Installation Configuration Window

Enabled?	Attribute Description
<input checked="" type="checkbox"/>	Separate Oracle and SAS names?
<input checked="" type="checkbox"/>	DCM default views are linked to source DCM as default condition?
<input checked="" type="checkbox"/>	Enable edit of active key templates?
<input checked="" type="checkbox"/>	Enable edit of active extract macros?
<input checked="" type="checkbox"/>	Enable selection of aggregate, nondefault key template?
<input type="checkbox"/>	Include validation status in default view definition?
<input type="checkbox"/>	Include DVG sequence number in default view definition?
<input checked="" type="checkbox"/>	Include DVG short value in default view definition?
<input type="checkbox"/>	Include DVG long value in default view definition?
<input checked="" type="checkbox"/>	Include thesaurus term1 in default view definition?

Max length of audit comment Max length of DVG long value

Max length of data comment Default key template

Key Template Domain

You can enable or disable the attributes described in the upper part of the window by selecting or clearing the appropriate box. The lower part of the window enables you to reduce the size of comments and the DVG long value, and to choose the default Key Template and the default Key Template domain.

The settings in the Data Extract Installation Configuration window are:

Separate Oracle and SAS Names?

When enabled, you can specify different names for Oracle and SAS view columns. Oracle views take the long name; SAS takes the short name. The default is deselected.

In earlier versions of SAS (such as version 6.12), the maximum length for variables (columns or views) was 8 characters, while Oracle names could be as long as 30 characters. If you wanted to keep the same names for the Oracle and SAS variables (for consistency or some other business need), you had to choose a name short enough to fit in the SAS variable length. If you wanted to have a longer Oracle name, the names had to be different. Data Extract creates the Oracle and SAS views based on the decision you make in this field.

DCM Default Views Are Linked to Source DCM as Default Condition?

This setting controls whether a view definition is linked to its source DCM if the view definition's link mode is DEFAULT. If this setting is enabled, a view definition with DEFAULT link mode will be linked to its DCM, meaning that changes to the DCM will propagate to the view definition as well. If this setting is not enabled, these view definitions are not linked, so they will not change when the source DCM changes.

Enable Edit of Active Key Templates?
Enable Edit of Active Extract Macros?
Enable Edit of Active View Templates?

Each of these settings enables you to choose whether users can modify one type of active component in a view definition. Your organization may want to freeze definitions like Key Templates, extract macros, and View Templates that are used across many view definitions in the global library.

Enable Selection of Aggregate, Nondefault Key Template?

Choose this setting if you want to be able to choose alternative Key Templates for different view definitions within a study.

Include Validation Status in Default View Definition?
Include DVG Sequence Number in Default View Definition?
Include DVG Short Value in Default View Definition?
Include DVG Long Value in Default View Definition?
Include Thesaurus Term1 in Default View Definition?
Include Thesaurus Term2 in Default View Definition?
Include Thesaurus Term3 in Default View Definition?
Include Full Value Text in Default View Definition?

These settings all control attributes that you might want to include in the default view definition. All are part of what you can add through the Extended Attributes button when defining a simple question in the Global Library, or through the Template Attributes button when building a template in the Maintain View Templates window.

- **Validation Status** is an attribute of the RESPONSES table. By choosing to display another attribute, you can tell how clean your data is. The default is deselected.
- The **DVG Sequence Number** indicates the order the discrete values appear in the list of values for data entry. The **DVG Short Value** is the data as entered. The **DVG Long Value** is a longer form than the short value of the data as entered. You need at least one, but you may pick all, of the following: the DVG Long Value, the DVG Sequence Number, or data values for the DVG questions.
- The **Thesaurus Term** configuration preferences involve the same kinds of choices as for the DVG, except that data can come from several different tables. You must still choose at least one term, and you may choose all three. The default is selected.
- Oracle Clinical stores valid responses in the Value Text field, and invalid ones in the Exception Value Text field. When the response is valid, the **Full Value Text** field contains the Value Text; when it is invalid, **Full Value Text** contains the Exception Value Text.

Enable Update of SAS and Oracle Column Names?

When you bring a question from the Global Library into a View Template, the SAS column names and Oracle column names in the View Template default to the names defined in the Global Library. If this option is selected, you can change the names at the View Template level; if not selected, you cannot modify the names from their Global Library-derived defaults. The default setting is deselected.

Enable View Builder as Default in New Studies?

The View Builder enables you to automatically generate views of the data and metadata included in a single Data Collection Module (DCM). If this setting is enabled, the **VB Enabled?** setting in the Clinical Study States window is selected by default for new studies.

Use DCM Question-Specific DVG Subset for DVG Attributes?

This setting determines whether the Discrete Value Group (DVG) attributes that are included in the view come from the DVG subset that has been assigned to the DCM question or from the base DVG subset. Selecting this box makes the views include the DCM question DVG's subset information; clearing the box makes the views include the base subset information. For information on DVGs and DVG subsets, see the chapter on questions in *Oracle Clinical Creating a Study*.

Use DCM SAS Label as Seed for Attributes in Default View Definition?

This setting determines which SAS labels the system uses for all the attribute columns of a default view definition. By default, this setting is not enabled, so the SAS labels of the attribute columns are created using the SAS label of the question attributes in the Global Library. However, when you enable this setting, the system creates the SAS labels of the attribute columns of the View Template within the context of a view definition by using the corresponding DCM question's SAS label as the seed when the View Template Question is mapped.

Max Length of Audit Comment

The default Audit Comment length is 200 characters. You can reduce this value if you typically use no more than a few characters for this comment.

Max length of Data Comment

The Oracle Clinical default Comment length is 200 characters. You can reduce this value if you typically use no more than a few characters for this comment.

Max Length of DVG Long Value

The default DVG Long Value length is 200 characters. You can reduce this value if you typically use no more than a few characters for this comment.

You can also create the DVG Long Value column with a maximum width equal to the DVG values specified for a given question. This behavior is enabled when the maximum length of the DVG Long Value is set to zero.

Default Key Template

The default Key Template for custom and default view definitions. You can choose a new default Key Template from the list of values.

Data extract users can choose a non-default Key Template for their view definition only if the [Enable Selection of Aggregate, Nondefault Key Template?](#) box is selected.

Note that study-specific Key Templates achieve the same goal. You can supply a study-specific Key Template in the Clinical Study States window (From the Conduct menu, select Security, then choose Clinical Study States).

Key Template Domain

The Key Template Domain indicates the Global Library domain in which the default Key Template is stored. You cannot assign or change the domain of the default Key Template in this window.

Build Fast Views?

Enables building fast views.

Setting Values in Data Extract-Related Reference Codelists

Check the settings of the following reference codelists, described in [Chapter 7, "Reference Codelists"](#):

- [DX_CONFIG](#)
- [DX_EXTENDED_ATTRIBUTES](#)
- [DX_INDEX_TABLESPACE](#)
- [DX_KEY_NAME](#)
- [DX_ROLES](#)
- [DX_VIEW_TABLESPACE](#)

Creating Tablespaces for Data Extract Tables and Indexes

This section contains the following topics:

- [Creating Tablespaces](#) on page 6-5
- [Entering Tablespace Names in Reference Codelists](#) on page 6-5
- [Creating Data Extract Access Accounts Using Local Tablespaces](#) on page 6-6

Creating Tablespaces

You must create tablespaces to contain the tables and indexes required for data extract. Oracle recommends creating a separate tablespace for tables and for indexes, and for creating each tablespace:

- as locally managed
- with autoallocate on
- with automatic segment space management
- with a block size of 16 kb

Use the following command:

```
CREATE TABLESPACE dxtables DATAFILE
'/u02/oracle/data/dxtables01.dbf' SIZE 500M EXTENT MANAGEMENT
LOCAL AUTOALLOCATE SEGMENT SPACE MANAGEMENT AUTO;
```

For further information, see the *Oracle Database Administrator's Guide*.

Entering Tablespace Names in Reference Codelists

In order to enable users to create tables using the Data Extract View Builder, you must specify to which tablespace and tablespace index you want to add tables for each Study Access Account. You specify these tablespaces and index tablespaces in two installation reference codelists that store data extract tablespace information:

- [DX_INDEX_TABLESPACE](#)
- [DX_VIEW_TABLESPACE](#)

Note: You must also remove invalid values from the reference codelists to prevent users from selecting them for study access accounts. See "[DX_INDEX_TABLESPACE](#)" on page 7-25 and "[DX_VIEW_TABLESPACE](#)" on page 7-26 for information.

Creating Data Extract Access Accounts Using Local Tablespaces

You must create a Data Extract Access Account (under Conduct, navigate to Data Extract, then Study Access Accounts) and specify a tablespace for the account's tables and for its indexes. When the tablespace is defined as locally managed, the View Builder creates tables and indexes for that account as follows:

- The extract tables are created in a single step rather than the previous approach that created a temporary table and then, after determining the size of the table, a second permanent table. This feature capitalizes on the ability to use locally managed tablespaces with the `AUTOALLOCATE` feature that automatically sizes the table.
- The tables are created using the Oracle database table compression feature. Since data extract tables tend to have many repeated keys and values, this should result in significantly less space usage and more efficient data access.
- The indexes are created with leading key compression that results in significantly more compact and efficient indexes.
- Index statistics are now computed as the indexes are created, which results in faster statistics calculation.
- Repeated account maintenance of the `ROLLSNAP` account will take advantage of the more efficient space allocation method used in Locally Managed Tablespaces when it drops and recreates tables.
- Tables are created with the `NOLOGGING` attribute. This reduces the table creation time significantly by avoiding writing to the redo logs. The price of this option is that recovery from database failure using redo logs will not recreate extract tables that have not been otherwise backed up and restored. Since the tables can be recreated from the extract views at any time by rerunning account maintenance in `FULL`, this trade-off is usually acceptable. However, if you do not want to use the `NOLOGGING` behavior, you can override it by creating the locally managed tablespace with the `FORCE LOGGING` attribute.

Customizing Data Extract Views

Oracle Clinical ships with two scripts in the `INSTALL` directory that you can use to customize data extract views.

- `rxcptdxvb.sql` populates the data extract tables `EXTRACT_KEYS` and `EXTRACT_MACROS` and creates the standard key template.
- `pop_vb_static_views.sql` creates the standard view templates, which include views for responses and RDCMs.

For example, if you want to include the investigator's country in the data extract views, add a key for Investigator Name in `rxcptdxvb.sql` and modify the `SELECT`, `FROM` and `WHERE` clauses of the `RDCMS_VIEW` creation statement in `pop_vb_static_views.sql`. The scripts contain comments that show exactly what lines to add for this example.

Note: Oracle Clinical does not support changes you make to these scripts. You must contact Oracle Consulting for help.

Generating Data Extract Views

The `gen_views` utility performs the same operations as the Maintain Data Extract Views batch job within Oracle Clinical (under **Conduct** select **Data Extract** and then **Data Extract Views**) for all accounts in FULL maintenance mode.

Use the `gen_views` utility to regenerate views for all accounts in one or all studies. For example, if a change is made to a key template, all views based on that template in that study must be regenerated for all the study access accounts.

The general sequence for this task is:

- run `opa_setup`, which defines the `RXC_TOOLS` directory
- change to the `RXC_TOOLS` directory
- run `gen_views`.

Variables include:

- `study` enter either the name of a study or ALL for all studies
- `sas_queue` enter the name of the queue where SAS jobs execute or NULL (on Windows only)
- `view_creation_mode` valid values are: `DATA_ONLY`, `COMBINED_VIEW`, or `SEPARATE_VIEW`.

Operating system-specific instructions follow:

Running `gen_views` on UNIX Platforms

To run `gen_views` on a UNIX platform:

1. Log on to the server in your user account and set the environment:

Shell	Command sequence
C Shell	<code>opa_setup db_name code_env</code>
Bourne	<code>p1 = db_name</code> <code>p2 = code_env</code> <code>. opa_setup</code>

where `db_name` is a database instance name and `code_env` is a code environment designation.

2. Change directories to `$RXC_TOOLS`.
3. Set the output directory:

Shell	Command sequence
C Shell	<code>setenv RXC_LOG usr_log_dir</code>
Bourne	<code>RXC_LOG=usr_log_dir</code> <code>export code_env</code>

4. Run the script. For example:

```
% gen_views ALL UNIX DATA_ONLY
```

Running gen_views on Windows

To run `gen_views` on Windows:

1. Log on to the server using your local account.
2. In an MS-DOS window, set the server environment:

```
set p1=db_name
```

```
set p2=code_env
```

```
opa_setup
```

where `db_name` is a database instance name and `code_env` is a code environment designation.

3. Change directories to `%RXC_TOOLS%`
4. Set the output directory:

```
set rxc_log=user_log_folder
```

5. Run the command file. For example:

```
gen_views ALL NULL DATA_ONLY
```

Enabling the View Builder and Converting Views

The View Builder was an enhancement in Oracle Clinical Release 3.1. If you are still using pre-View Builder views, you can convert them to View Builder-style views by running two scripts, `vb_pop_view` and `enable_vb`, for each study.

Converting Views

Running `vb_pop_view` converts a study's existing old-style data extract views to the new view builder style. For example:

```
cd $RXC_INSTALL  
sqlplus rxc/notrxc  
start vb_pop_view
```

The script prompts you for the name of the study.

Note: You can run `vb_pop_view` only once per study.

Enabling the View Builder in a Study

To make view builder-style the default for future views in a study, use the `enable_vb.sql` script. For example:

```
cd $RXC_INSTALL  
sqlplus rxc/notrxc  
start enable_vb.sql
```


When you execute this script it performs the following actions:

- prompts you for the name of the study.
- updates the CLINICAL_STUDY_STATES table, setting VB_ENABLED to "Y".
- sets the default key template in CLINICAL_STUDY_STATES to STANDARD.

After running enable_vb, commit the changes to the database, then rerun view creation.

You can also enable view builder interactively for individual studies within the Oracle Clinical interface. However, using the command line may be more convenient.

Controlling Access to Data Extract Views

Access to individual views at the access account level can be controlled by granting access via roles. You can create your own company-specific roles so that appropriate choices appear in the list of values in the View Definition window.

Do the following:

1. Create as many database roles as you need; see ["Creating Custom Database Roles"](#) on page 2-6.
2. Add these roles to the [DX_ROLES](#) reference codelist. All the roles in that reference codelist appear in the list of values in the View Definition window.
3. Grant the database roles to users who need them; see ["Granting Additional Database Roles to User Accounts"](#) on page 1-15.

Reference Codelists

This section describes Oracle Clinical reference codelists. It is comprised of the following topics:

- [Overview](#) on page 7-1
- [Adding a Value to a Reference Codelist](#) on page 7-2
- [Modifying a Value in a Reference Codelist](#) on page 7-3
- [Running the Reference Codelists Report](#) on page 7-3
- [Local Reference Codelists](#) on page 7-7
- [Installation Reference Codelists](#) on page 7-19
- [Design Installation Reference Codelists](#) on page 7-31
- [System Reference Codelists](#) on page 7-31

Overview

Oracle Clinical uses reference codelists for a wide range of functionality. Certain codelists are used internally by the application, while others set the values the system present to users performing various tasks in the application. There are different types of reference codelists that are used by different subsystems. Some types of codelists are set during the installation of the application and others are set by users during various tasks.

Although the values of certain codelists are listed and described in this section, you can quickly view the values of any codelist by running the Reference Codelist report. Refer to the "[Running the Reference Codelists Report](#)" section on page 7-3 for instructions.

Depending on your assigned roles, you can perform the following types of reference codelist maintenance tasks:

- Add a new value to a local, installation, or design installation codelist.
- Activate or deactivate a codelist value for a local, installation, or design installation codelist.

Accessing and Modifying Reference Codelists

You may have authority to access only some of the types of codelist values. In any case, you cannot create new codelists; you can only add values to existing codelists.

You may modify only the following types of codelists:

- Installation codelists, such as the type codes for clinical planned events, DCIs, DCMs, and question groups.
- Design installation codelists, which are used to setup treatments and study designs, should be maintained by clinical (rather than system administration) personnel. The design installation codelists are actually a subset of the full set of installation codelists. If you choose, you can grant access to the design installation codelists for users to whom you would not grant access to the full set of installation codelists.
- Local codelists specific to your site within the company, such as the codelist for batch and print queue names.

System codelists are used internally by Oracle Clinical, and cannot be modified.

Viewing Original Reference Codelist Settings

To see the initial settings for a codelist shipped with Oracle Clinical, go into the Developer's Toolkit, Maintain All Codelists, and query for a codelists. You can access all types of codelists through this window, including local, installation, design, and system codelists.

Adding a Value to a Reference Codelist

Follow this procedure to add values to an existing local, installation, design, or installation codelist:

1. Select **Admin**, then **Reference Codelists**. Choose one option to display the Reference Codelists window for one of these codelist types:
 - Local Codelists
 - Installation Codelists
 - Design Installation Codelists
2. To find the reference codelist you want, start a query, enter query criteria in one or more enterable fields to define the search, and then execute the query. Use the arrow keys to scroll to the codelist you want.
3. Click **Next Area** to move to the **Reference Codelist Values** block.

If there are no records, the record lines are blank and you can go to step 5.

If there are records, place focus in a field that is one row above the row you want to add. Select **Data**, then **Insert Record**.

4. Enter information about the new value in the following fields:
 - **Seq** – The order in which the value appears. Used for presentation and in reports.
 - **Short Value** – Shortened name of the value; used to fill in the application field when selected from a list of values.
 - **Long Value** – Complete name of the value; used if short value is truncated.
 - **Active** – For reference codelists that provide a list of values, only those entries whose Active checkbox is selected appear in the list.

- **Default** – For reference codelists that provide a list of values, the entry whose Default box is checked may be highlighted when the list appears.
 - **Description** – Description of the value.
5. Click the **Save** button. The system adds the new value to the codelist.

Modifying a Value in a Reference Codelist

You cannot delete a value, but deactivating it (clearing the Active check box) means it will not appear in a list of values, and Oracle Clinical will not include it as an acceptable value during validation. Follow this procedure to modify an existing value in a reference codelist:

1. Perform steps 1 through 3 in "[Adding a Value to a Reference Codelist](#)" on page 7-2 to select a reference codelist, then place focus in the value record you want to change.
2. Make your changes. You cannot change the Short Value field. Changing the Active checkbox activates or deactivates the value. Only active values appear in the list of values for the relevant field and are used in field validation.
3. Click **Save**. Oracle Clinical modifies the changed codelist records in the database.

Make sure the Long Value of the entry `SERVER_OS` in the local reference codelist `OCL_STATE` is correct for your operating system—that is, set to Windows or UNIX.

Note: On UNIX systems, the Long Value of the `server_name` entry (also in `OCL_STATE`) must be in lowercase letters.

Running the Reference Codelists Report

Oracle Clinical includes a large number of reference codelists, many of which you can modify. In order to obtain the current values in any codelist, or to view the codelist values at any point in time, run the Reference Codelist report. This report summarizes all of the values in one or more reference codelists. You use the Report Submission window, which is depicted in [Figure 7-1](#), to set the values of four parameters and specify the information you want to include in the report.

Figure 7–1 Report Submission Window for Reference Codelist Report

Description	Current Value	Mand- atory?	LOV ?	Patt- ern ?
Modification Date		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reference Codelist Name		<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Reference Codelist Type	INSTALLATION	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Active Flag	Y	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

To run the Reference Codelists report:

1. Navigate to **Admin, Admin Reports**, and then **Reference Codelists**. The system opens that Report Submission window with a set of parameters specific to the Reference Codelists report.
2. In the list of parameters, set that values of the four parameters to setup the report you want to run. Only the **Active Flag** parameter value is mandatory.
 - a. the **Modification Date** parameter allows you to limit the report to include codelists modified on or after a certain date; use the "DD-MON-YYYY" date format for this field
 - b. use the **Reference Codelist Name** parameter to specify a codelist; the list of values allows you to select from the list of codelists
 - c. the **Reference Codelist Type** parameter allows you to limit the report to certain types of codelists
 - d. ensure that the **Active Flag** parameter is set to its default value of "Y".
3. Click **Job Details**. The system opens the Submission Details window.
4. In the Submission Details window:
 - a. Set the **Output Type**, **Output Format**, and **Printer** (if applicable) fields to appropriate values.
 - b. Ensure that the **Mode of Execution** and the **Report Server** fields are set correctly.
5. Click **Submit Job**.

Maintain/Query Reference Codelists Windows

When you query or maintain a codelist, the system displays the Reference Codelists window. The graphic in [Figure 7–2, "Maintain Reference Codelists Window"](#), depicts a typical "maintain" reference codelist window, which allows you to modify the values in a codelist.

Figure 7-2 Maintain Reference Codelists Window

Seq	Short Value	Long Value	Active	Default	Description
1	CRA CORR		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	CRA Correction
2	DATA ENTRY E		<input checked="" type="checkbox"/>	<input type="checkbox"/>	Data Entry Error
5	BATCH		<input checked="" type="checkbox"/>	<input type="checkbox"/>	Batch
6	CRA CORR-INV		<input checked="" type="checkbox"/>	<input type="checkbox"/>	CRA Correction, Inv consulted
7	CRA CORR-SR		<input checked="" type="checkbox"/>	<input type="checkbox"/>	CRA Correction, Src Data

Access

You access the reference codelist windows through the menu paths that are available under the **Admin, Reference Codelists** path. The available selections are:

- Local Codelists
- Qry Local Codelists
- Installation Codelists
- Qry Installation Codelists
- Design Installation Codelists
- Qry Design Installation Codelists
- Qry System Codelists

The selections that are prefixed "Qry" open the window in query mode, that is, you can view the codelists only. The other selections open the window in maintenance mode, in which the system allows you to modify the codelist. Note that you can only open the System Reference Codelists in query mode because that set of codelists cannot be modified.

Components

The reference codelist windows consist of two sections: an upper section that identifies the current codelist and provides information about it; and a lower section that lists the values associated with the current reference codelist. The components that

comprise the upper section of the window are listed and described in [Table 7-1, "Components of the Reference Codelist section"](#).

Table 7-1 Components of the Reference Codelist section

Component	Type	Description
Name	Field	Displays the name of the current reference codelist; the field can also be used to query for a specific codelist.
Active	Check box	Specifies if the codelist is active. This component cannot be updated.
Default	Field	Lists the default value, which is the value for which the Default checkbox in the Values section is selected.
Description	Field	A system-specified description of the current reference codelist
Type	Field	Displays the type of current codelist
Data Type	Field	Displays the data type for the values in the codelist
Max Short Len	Field	The maximum number of characters allowed for the Short Value of each reference codelist value
Max Long Len	Field	The maximum number of characters allowed for the Long Value of each reference codelist value
Application	Field	Displays the subsystem with which the codelist is associated

The lower portion of the window contains the values that are associated with the current reference codelist. In the maintenance windows, you use this section to modify the values. The components in this section are list and described in [Table 7-2, "Components of the Reference Codelist Values section"](#).

Table 7-2 Components of the Reference Codelist Values section

Component	Type	Description
Seq	Field	Displays the sequence number of the value
Short Value	Field	Displays the short value for the value
Long Value	Field	Displays the long value for the value
Active	Check box	Specifies if the value is active, that is, if it is included when the system accesses the reference codelist
Default	Check box	Specifies if the value is the default value for the reference codelist
Description	Field	A text explanation of the value
Exit	Button	Closes the window
Save	Button	Commits all pending changes to the database

Usage

This section provides instructions for basic tasks you can use the reference codelists windows.

Query a reference codelist To search for a specific reference codelist:

1. With focus in the Name field, press the F7 key. This puts the system in query mode.
2. Type the name of the codelist, using the wildcard ("%") as necessary, to construct the search string.
3. Press the F8 key. The system runs the query and displays the first codelist returned in the Name field.

Navigate a list of codelists If more than one codelist is returned, there are several methods you can use to navigate to a specific entry:

- Use the Page Up/Page Down or the Up/Down arrow keys to move one entry up or down in the list.
- Use the **Move**, then **Last Record** to move to the bottom of the list.
- Use the **Move**, then **First Record** to move to the top of the list.

Add a value To add a value to the current reference codelist, you must be working in the Maintain Reference Codelist window.

1. Place focus in the row immediately above the location in which you want to add the value.
2. Select the **Data**, then **Insert Record** menu command. The system places a blank row below the current row.
3. Modify the fields for the row, as appropriate.

Local Reference Codelists

Local codelists control the behavior of some Oracle Clinical features in the selected database only. You can modify local codelists if your user role has one of the following schema: RXC_ADMIN, RXC_SUPER, or RXC_SUPER_NOGL.

Local codelists are listed here alphabetically:

BATCH QUEUE NAME

This codelist contains batch queue names to be used by the Parameterized Submission (PSUB) utility for this Oracle Clinical instance.

The reference codelist ships with a short value of RXC_BATCH_QUEUE, and a long value of a. This short value is in turn found in the OCL_JOB_PREF reference codelist, indicating that this is the default batch queue to be used by PSUB.

You can set a different default queue for a particular user by specifying any short value from the BATCH QUEUE NAME reference codelist when you create or modify the user's account. When adding entries, the short value specifies a symbolic name for the queue, and the long value specifies a single character queue like a, d, e. b and c are excluded, as these are reserved.

You can modify the long value for the `RXC_BATCH_QUEUE` entry in one of 2 ways:

- change the value to another single-character queue name
- enter the value `RXC_BATCH_QUEUE`

If you choose the latter option, PSUB interprets this as an environment variable, whose value is set in the `opa_settings` file; see [Appendix A, "Environment Variables and Registry Settings"](#).

DB_LINKS

This codelist contains the names of database links for replication.

Replication is a "pulling" operation; that is, the database location requesting the data must initiate the action. Each database in the installation maintains its own local `DB_LINKS` reference codelist. There should be an entry in the Short Value field for each of the other database locations in the installation. The Long Value contains the name of the private database link to that database, owned by the Oracle user `RXC_REP`.

DCF COMMENT TEXT

This codelist contains values you can use as the initial text for the DCF comment field.

DCF DEFAULT FOOTERS

This codelist contains values you can use as the footer text to be inserted into the DCF Footer field. See ["Defining DCF Headers and Footers"](#) on page 3-32.

DCF DEFAULT HEADERS

This codelist contains values you can use as the header text to be inserted into the DCF Header field. See ["Defining DCF Headers and Footers"](#) on page 3-32.

DCF REPORT LABELS

This codelist contains user-configurable labels for the DCF Report.

DISC COLS

This codelist contains the variables that can be specified for MCU CDS Discrepancy criteria; see ["Customizing Mass Changes Local Codelists"](#) on page 4-1.

DISC_FLEX1 and DISC_FLEX2

See ["Customizing Flexfields"](#) on page 3-9 for information.

DISC_FLEX1_VALUES and DISC_FLEX2_VALUES

See ["Customizing Flexfields"](#) on page 3-9 for information.

FLD RXCMCMCD RDCI DELETE

This codelist contains the display and order of RDCI Delete Candidate Data Set fields; see ["Customizing Mass Changes Local Codelists"](#) on page 4-1.

FLD RXCMCMCD RDCI KEY

This codelist contains the display and order of RDCI Key Change Candidate Data Set fields; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1.

FLD RXCMCMCD RDCM KEY

This codelist contains the display and order of RDCM Key Change Candidate Data Set fields; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1.

FLD RXCMCMCD RESPONSE

This codelist contains the display and order of response Candidate Data Set fields; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1.

IND DISC COLS

This codelist contains variables that you can specify for MCU CDS Ind discrepancy criteria; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1.

MAN DISC COLS

This codelist contains variables that you can specify for MCU CDS manual discrepancy criteria; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1.

MANHD DISC COLS

This codelist contains variables that you can specify for MCU CDS manual header discrepancy criteria; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1.

MC CDS SORT ORDER

This codelist contains the sort order of CDS fields; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1 for information.

MC COLUMNS

This codelist contains variables that you can specify for MCU CDS criteria; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1.

MULTI DISC COLS

This codelist contains variables that you can specify for MCU CDS multivariate discrepancy criteria; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1.

NLS_CONFIG

This codelist contains settings that control behavior in Oracle Clinical with NLS Option. See the *Oracle Clinical with NLS Option User's Guide* for details.

OCL MC PREFS

This codelist enables you to set preferences for Mass Changes.

OCL_DE_CONFIG

This codelist controls Data Entry configuration settings. The entries for values are listed and described in [Table 7-3](#).

Note: The settings with sequence numbers 1-9, 12-14, and 17 are also updateable in the Maintain Installation Configuration window under Admin, DE Admin, DE Config Settings; see "[Define Data Entry Configuration Settings](#)" on page 5-1.

Table 7-3 Values for the OCL_DE_CONFIG Reference Codelist

Seq	Short Value	Long Value	Description
1	2ND PASS ALERT	Y	Determines if the alert for a 2nd Pass comparison failure is enabled
2	DISC IN BROWSE	Y	Determines if the user is allowed to initiate a manual discrepancy when working in browse mode
3	DISC RES IN DE	Y	Determines if the user is allowed to resolve discrepancies during data entry.
4	PRIV UPDATE	N	Determines if the privileged update is enabled at the database level.
5	THESAURUS list of values	Y	Determines if the DVG, which populates the list of values, for thesaurus questions is enabled.
6	UNIVAR ALERT	Y	Determines if the univariate validation alert, which prompts the user to a validation error during data entry, is enabled.
7	USE DCI BOOK	N	Determines if the system initiates a data entry session using a DCI book.
8	UNENROLL ALERT	Y	Determines if the system alerts the user to a patient that has been unenrolled.
9	P2 NOT BY P1	N	Determines if the system prevents a Pass 1 data entry operator from performing Pass 2 data entry.
10	OCL THES DISC	N	Determines if system alerts the user to OLC Thesaurus discrepancies during data entry.
11	OCL THES list of values	N	Determines if the lists of values for OCL Thesaurus questions are enabled.
12	BROWSE ACC ONLY	N	Determines if data in accessible documents is browse only.
13	DEF PAGE HEIGHT	22	Sets the default height of the DCM data entry page in points, pixels, inches, or centimeters, depending on the unit of measure selected in the Maintain Installation Configuration window under Admin, DE Admin, DE Config Settings; see " Define Data Entry Configuration Settings " on page 5-1. Applies only to Oracle Clinical and to RDC Classic.
14	DEF PAGE WIDTH	78	Sets the default height of the DCM data entry page in points, pixels, inches, or centimeters, depending on the unit of measure selected in the Maintain Installation Configuration window under Admin, DE Admin, DE Config Settings; see " Define Data Entry Configuration Settings " on page 5-1. Applies only to Oracle Clinical and to RDC Classic.
15	P2 ALWAYS ALERT	Y	Determines if the system alerts the user whenever Pass 2 data differs from the corresponding Pass 1 data.
16	AUTO SEQ DFLT	Y	Sets the default auto sequence behavior; when a user presses tab in the last field of a DCM/CRF Section, the system opens the next DCM for data entry.

Table 7–3 (Cont.) Values for the OCL_DE_CONFIG Reference Codelist

Seq	Short Value	Long Value	Description
17	DCI DATE REQ	Y	Sets the default as to whether the DCI date is required in the Log-in form.
18	DVGSEQOVERALPHA	N	This setting is used only when a question has both an internal and an alpha DVG assigned, Enter By Sequence is enabled for the internal DVG, and both the internal and the alpha DVG have values with the same sequence number. When the user enters a sequence number that exists in both DVGs, the system records the internal DVG value if this reference codelist value is set to Y. If it is set to N, the system records the alpha DVG value with the same sequence number.
19	DVG List of Values STYLE	SEQ	This value determines how the system displays the list of values for DVG and Alpha DVG questions.
20	COMMCHGREAS_REQ	Y	Determines if a change reason is required for updates to RDCI comments in accessible documents.
21	JUSTENTERP1TIME	0	Sets the time period (in minutes) during which a Pass 1 Complete RDCI/RDCM can be modified in Pass 1 mode.
22	JUSTENTERP2TIME	0	Sets the time period (in minutes) during which a Pass 2 Complete RDCI/RDCM can be modified in Pass 2 mode.
23	SEQUENCEBUFFER	1000000	The sequence buffer that is used to prevent the sequence from reaching its maximum value. At this setting, when a sequence number is within 1,000,000 of 2,147,483,647, the system displays a warning message when a user attempts to use a relevant subsystem and the system exits the current screen.
24	RSTRCT LCKD CRF	N	Determines if some actions are permitted on a locked CRF. Applies to RDC Onsite only.

DVG List of Values STYLE

This value determines how the system displays the list of values for DVG and Alpha DVG questions. The options for this value are SEQ and SHORT.

Note: If "Enter by Sequence" is not selected in the DVG definition, this reference codelist setting (SEQ or SHORT) has no effect. The list of values does not display the sequence number, sorts records by the DVG value, and displays these columns in this order:

1. Short Value, which is titled "DVG Value" in the list of values
 2. Alpha Column, which contains "A" if it is an Alpha DVG value or is null for all others
 3. Long Value, which is titled "Description" in the list of values.
-

SEQ If the Long Value is set to "SEQ" and "Enter by Sequence" is selected in the DVG definition, the columns in the list of values are displayed in this order:

1. Display SN (prefixed with "A" if it is an Alpha DVG value)
2. Short Value, which is titled, "DVG value" in the list of values
3. Long Value, which is titled "Description" in the list of values.

The records are sorted by DVG sequence number.

SHORT If the Long Value is set to "SHORT" and "Enter by Sequence" is selected in the DVG definition, the columns in the list of values are displayed in this order:

1. Short Value, which is titled "DVG Value" in the list of values
2. Display SN (prefixed with "A" if it is an Alpha DVG value)

Note: The sequence number is displayed only if there is an alpha DVG associated with the question.

3. Long Value, which is title "Description" in the list of values.

The records are sorted by DVG sequence number.

COMMCHGREAS_REQ

This value determines if the system requires a change reason when the RDCI comment is updated and the document is internally accessible. The options for this value are "Y" and "N". The default value is "Y", which causes the system to require a change reason for an update to the RDCI comment.

JUSTENTERP1TIME

This value defines time period (in minutes) during which a user can modify or query a previously Pass 1 Complete RDCI/RDCM in Pass 1 mode.

The initial value of this entry is "0".

JUSTENTERP2TIME

This value defines the time period (in minutes) during which a user can modify/query a previously Pass 2 Complete RDCI/RDCM in Pass 2 mode.

The initial value of this entry is "0".

RSTRCT LCKD CRF

By default, RDC Onsite restricts access to locked CRFs. You can use the RSTRCT LCKD CRF setting in the OCL_DE_CONFIG local reference codelist to allow some users to take actions on locked CRFs.

- **Y** — Specifies that users cannot update discrepancies for a locked CRF, verify a locked CRF, or approve a locked CRF unless the CRF is specifically unlocked for them.
- **N** — Specifies that any user with UPD_DISCREP privileges can work on discrepancies in a locked CRF, any user with VERIFY privileges can verify a locked CRF, and any user with APPROVE privileges can approve a locked CRF.

OCL_DE_PREFS

This codelist enables you to set the default data entry preferences for this instance. The default entries are displayed and described in [Table 7-4, "Values for the OCL_DE_PREF reference codelist"](#). You can also set almost all of these values in the Maintain Installation Preferences under Admin, DE Admin, DE User Prefs. The exceptions, which you can set only here, are: AUTO NEXT FORM and AUTO SEQ DEFLT.

Table 7–4 Values for the OCL_DE_PREF reference codelist

Seq	Short Value	Long Value	Description
1	AUTO SKIP	Y	Determines if auto skip is enabled
2	AUTO FILL	Y	Determines if auto fill is enabled
3	UNIVAR BEEP	Y	Determines if the system sounds a beep when a recorded response value generates a validation error
4	COMPARISON FAILURE	Y	Determines if the system sounds a beep when a response value generates a comparison failure.
5	END FORM BEEP	Y	Determines if the system sounds a beep when the user navigates from the last field in a form.
6	DATE ENTRY FMT	US	Determines the default format for dates that the system assumes during data entry
7	DATE DISPLAY FMT	STANDARD	Determines the format the system uses to present dates in the display
8	RDCI ORDER	PATIENT	The "order-by" the system uses for RDCI queries.
9	AUTO NEXT FORM	Y	Determines if the system automatically displays the next data entry form in the sequence.
10	AUTO SEQ DEFLT	Y	Determines if auto-sequence is set by default.

OCL_JOB_PREF

This codelist sets default values in the Oracle Clinical PSUB job window.

Oracle Clinical ships default system-wide values in the local reference codelist OCL_JOB_PREF. Each entry refers to a specific row in another reference codelist, which must be updated with correct values for your installation. The long value in this reference codelist is populated from the short value in the other reference codelist. [Table 7–5](#) lists the defaults you can set.

Table 7–5 Entries in the OCL_JOB_PREF Reference Codelist

Short Value	Description	Refers to reference codelist
PSUB_PRINTER	Default PSUB Printer	PRINT QUEUE NAME
DFLT_PSUB_QUEUE	Default PSUB Queue	BATCH QUEUE NAME
DFLT_REPORT_RS	Default Reports Server	REPORT_SERVER
DFLT_JOBSET_RS	Default Job Set Reports Server	REPORT_SERVER
DFLT_PSUBSCH_RS	Default for PSUB Scheduling, generating DCI Forms, and previewing	REPORT_SERVER
DFLT_RS_PRINTER	Default Reports Server Printer	PRINT QUEUE NAME

For example, to set a printer as the default for reports at an installation:

1. Navigate to **Admin**, then **Reference Codelists**, and **Local Codelists**.

2. Insert a record in the [PRINT QUEUE NAME](#) codelist:
 - Short Value – Name of the printer, for example, `boston09`
 - Long Value – Printer specification, for example, `\\oc1dsn1\boston09`
 - Description – Information about the printer that may be helpful to the end user

(Note that all three values display in the Submission Details screens.)
3. In the OCL_JOB_PREF codelist, update the Long Value of the DFLT_RS_PRINTER entry with the Short Value of the printer from Step 3.

OCL_MC_PREFS

This codelist's single value, `MAX_CDS_RECORDS`, sets the default maximum number of records to change using the Mass Changes utility. Its initial value is 1000; see "[Customizing Mass Changes Local Codelists](#)" on page 4-1.

OCL_MENU_ACCESS

This codelist contains settings that support configuration of menu options.

Table 7-6 OCL_MENU_ACCESS Default Values

Seq	Short Value	Long Value
1	PRPJ	Y
2	ORUN	Y
3	REGION	Y
4	STUDY	Y
5	FACTOR	Y
6	STRATA	Y
7	ACSU	Y
8	DRUG	Y
9	REGIMEN	Y
10	SITES	Y
11	INVEST	Y
12	PATTEN	Y

OCL_STATE

OCL_STATE tracks information about the database, such as its name, operating system, and RDBMS version, which Oracle Clinical requires to complete certain processes. Some of the short values are described in more detail following the table.

Table 7-7 Values for the OCL_STATE Reference Codelist

Seq	Short Value	Long Value	Description
1	DB_NAME	<i>name of database</i>	Name of the database
2	SERVER_OS	Server operating system	
3	LOCATION_CODE		Client name for the current location

Table 7-7 (Cont.) Values for the OCL_STATE Reference Codelist

Seq	Short Value	Long Value	Description
4	PRINTER_TYPE		Default type of printer used - ASCII
5	DB_VERSION		The database version, this is used by Data Extract to determine optimization.
6	INVOKE_IMAGE	N	
7	BDL_R_SE		Specifies the rollback segment for Batch Data Load processes. Set to active and enter a long value of Y if you have created a database rollback segment for use in batch data load.
8	DFLT_PAGE_TRACK	N	Specifies the default value of the "Page Tracking Enabled" study level setting.
9	FILE_VIEWER	Y	Used by PSUB to view the log and output files
10	SERVER_NAME		Used by PSUB to open FTP sessions
11	DB_BLOCK_SIZE		The database block size from init.ora
12	TEMP_TABLES		Temporary Tablespace for use in new account creation activities
13	DM_PROMPT		Prompt for the DM window.
14	INVOKE_WORKFLOW	N	Used by the Login form to determine if a workflow system can be used.
15	USR_SAVE_OCPASS	Y	Determines if the user can save the OS password in the database; see "UNIX Passwords" on page 1-21.
16	PROC_LAB_ALIAS	LAB	The name of the lab variable for the standard Procedure question group prompt.
17	DISC_DCM_PROMPT	QUESTION_NAME	The single-record mode of the Maintain Discrepancy Database form's Characteristics panel has a button that toggles the three long value settings. Choose the value to display by default: question_name (displays the name of the question associated with the discrepancy),
18	DCF_TEXT_SYNC	N	Edits comments and resolutions text DCFs propagates to disc mgmt
19	DISC_AUTO_HDFT	Y	Auto Generation of Header/Footer Text
20	DISC_AUTO_CRFPG	Y	Auto Generation of CRF Page Number
21	BOOK_USAGE	IGNORE	(Applies only to RDC Classic) If set to IGNORE (the default) the system allows the user to use any book for the patient, regardless of the patient's book assignment. If set to PROMPT, the system allows the use of any book but gives a warning. If set to ENFORCE, the system does not allow using any book other than the one to which the patient is assigned.
23	BOOK_CHANGE	ALLOW	Change of DCI Book for patient: ALLOW, DISALLOW, or DISALLOW IF DATA

Table 7-7 (Cont.) Values for the OCL_STATE Reference Codelist

Seq	Short Value	Long Value	Description
25	BOOK_ASSIGN	N	Assign DCI book to patient on first data entry: Y or N
25	TMS_FAIL_BV_ACT	FAIL	Determines whether Batch Validation continues when TMS derivation fails during Batch Validation: WARN or FAIL.
26	DB_HOST		Host name for the database, as entered in tnsnames.ora file
27	DB_PORT	1532	Port number for the database as entered in tnsnames.ora file
28	DMGR RDC ACCESS	YES	"Granting Automatic Access in RDC to Studies Granted in Oracle Clinical" on page 1-13
29	UPD_FV_INCREM	N	Y or N - Y means do only incremental PDR Templates and HTML Forms gen

SERVER_NAME

Set the SERVER_NAME value in this codelist to the database/PSUB server.

LOCATION_CODE

For replication, the specific piece of information required is the LOCATION_CODE value, which is the client name for the current location. The system collects and stores this value during database creation.

DB_BLOCK_SIZE

This entry is used by the DX table code to obtain the block size, which is used for space calculations. It is used for the dictionary-managed tablespace algorithm.

TEMP_TABLES

This entry specifies the name of the temporary tablespace the system users when creating DX study_access_accounts.

DM_PROMPT

This entry is used by the Discrepancy Management form as the prompt to use for Study site.

DISC_DCM_PROMPT

Specifies the source of the question in a discrepancy. The options for the Long Value are:

- DEFAULT_PROMPT
- QUESTION_NAME
- SAS_LABEL

PROC_LAB_ALIAS

This entry is used during procedure generation to determine the alias of the standard RDCM Question LAB in the Procedure Question Group declarations. The system sets

this to a default value of "LAB". This default value for the alias will conflict with the Question QGalias.LAB if you have a study question named "LAB".

If there is a conflict with the study question named LAB, you should redefine PROC_LAB_ALIAS to a different name, such as, "RDCM_LAB", to avoid errors during procedure generation. In this case, any references to the standard Received DCM Lab question must be changed to RDCM_LAB, or a generation error will occur. When you do this, procedure references to QGalias.LAB will relate to the study question LAB and references to QGalias.RDCM_LAB will relate to the standard Received DCM Lab.

BOOK_ASSIGN

If set to Y, the system automatically assigns the DCI Book defined as the default for the study (in DCI Books or Enhanced DCI Books, under Definition) to each patient when data is first entered for the patient.

TMS_FAIL_BV_ACT

Use this entry to indicate whether batch validation should continue or stop after a TMS-related error is encountered. The two values are 'WARN' and 'FAIL,' which is the default value. It causes batch validation to fail when there is a TMS failure; for example, when either an invalid dictionary or an invalid domain is defined. Irrespective of the value for TMS_FAIL_BV_ACT, if a TMS-related error occurs, the batch validation status is always failure and batch validation completes the process with a TMS warning.

UPD_FV_INCREM

This setting pertains to the upgrade utility provided with Oracle Clinical/RDC 4.5.3 and above that allows you to migrate from PDF to HTML data entry forms. By default, the Upgrade utility generates the HTML data entry forms and the PDR templates for all DCI Form Versions in the study that have PDF data entry forms generated.

There may be times when you have problems with the form or template generation. For example, perhaps some images used in the form layout are no longer in the correct location so the Upgrade utility does not generate a few of the DCI Form versions. For such cases, you can temporarily change the utility to run in incremental mode. In incremental mode, the Upgrade utility only creates the HTML data entry forms and the PDR templates if they do not already exist.

Set the long value to Y or N:

- Y — Forces the Upgrade utility to run in incremental mode. In incremental mode, the utility will not regenerate HTML data entry forms and PDR templates for form versions that already exist.
- N (default) — Forces the Upgrade utility to generate all form versions.

This setting applies only to running the Upgrade utility for existing DCI Form versions.

Note: Running the Upgrade utility in incremental mode is for resolving problems. Oracle recommends that you do not continue to run the utility in incremental mode. Be sure to change the UPD_FV_INCREM value back to N after you generate the forms you need

PRINT QUEUE NAME

This codelist populates the list of printers that you can use when you submit a batch job or a reports job and when you set up a user account.

Oracle Clinical users can select a printer name from a list of values when they submit a job. You specify that list by defining entries in this local reference codelist. Both the long and short values appear in the list of values.

The short value is a code or abbreviation for the printer. The long value of the printer name is the printer specification. You can use either an absolute path or an environment variable for the long value. For example:

- `\\opaprtsrv\waltprt9` where `waltprt9` is the printer name
- `%RXC_PRINTER%` where `RXC_PRINTER` is the environment variable

The Default setting in the reference codelist has no effect. The `OCL_JOB_PREF` reference codelist determines the default printer. You can override the default when you set up a user account with any of the values in the `PRINT QUEUE NAME` reference codelist, and a user can override his or her own default when he or she submits a job.

PUBLIC_DB_LINKS

This codelist provides a list of database links for replication; it is used by `RXA_DES`.

Each database in the installation maintains its own `PUBLIC_DB_LINKS` local reference codelist. There should be an entry in the Short Value field for each of the other database locations in the installation. The Long Value contains the name of the public database link to that database.

REPORT_SERVER

This codelist defines the list of reports servers from which the user can select when setting up to run a report.

SAS_QUEUE

This codelist specifies the value(s) in the [BATCH QUEUE NAME](#) codelist that is required to run SAS.

SQL FUNCTIONS

This codelist provides a list SQL functions that you can then use when building queries.

TMS_OPTIONS

This local reference codelist contains TMS-specific options. It is populated only if TMS is installed in the Oracle Clinical database. When TMS is installed, currently the only option defined is `FIRST_REVIEW`. If the Long Value for this option is set to `Y`, and the Review Before TMS flag is also set to `Y` in the question set, then the first review for a thesaurus omission happens in the Oracle Clinical discrepancy management system, rather than in TMS. For more information on the interaction between the Oracle Clinical discrepancy management system and TMS, see the "Defining a question set" topic in the *TMS User's Guide*.

UNI DISC COLS

This codelist contains variables that you can specify for Mass Change Utility CDS Univariate Discrepancy criteria.

Installation Reference Codelists

Installation codelists control Oracle Clinical behavior installation-wide; that is, across an installation of multiple Oracle Clinical databases. They are listed here alphabetically:

APPLICATION AREA CODE

This codelist contains settings for areas on the body where the medication can be given.

APPLICATION SYSTEM NAME

This codelist contains a list of application systems used by Oracle Clinical.

APPROVE VERIFY RETAIN CODE

Enter one or more reasons to supply if CRF approvals or verifications are retained during DCI Form version migration.

You can limit the options available in a particular study in the DCI Form Study Settings window. If [User Override to Reverse Approvals?](#) or [User Override to Reverse Verifications?](#) is set to N in the DCI Form Local Database Settings window, the user running the migration cannot change the default value.

1. In the row with the short value DFLT_RETAIN_R, enter the text you want to appear as the initial default value as the long value.
2. If you want to allow the user to select other reasons for retaining approvals, enter an appropriate short and long value for each reason. Both values appear in the list of values.
3. Set each value to Active.

APPROVE VERIFY REVERSE CODE

Enter one or more reasons to supply if CRF approvals or verifications are reversed during DCI Form version migration.

You can limit the options available in a particular study in the DCI Form Study Settings window. If [User Override to Reverse Approvals?](#) or [User Override to Reverse Verifications?](#) is set to N in the DCI Form Local Database Settings window, the user running the migration cannot change the default value.

1. In the row with the short value DFLT_REVERSE_R, enter the text you want to appear as the initial default value as the long value.
2. If you want to allow the user to select other reasons for retaining approvals, enter an appropriate short and long value for each reason. Both values appear in the list of values.
3. Set each value to Active.

BLIND TYPE CODE

This codelist contains a list of types of blinding that are available in a study.

CLINICAL PHASE

This codelist list the clinical phases that are available in the design of a study.

COUNTRIES

This codelist contains the list of valid countries.

CRF PAGE NUMBERING SCHEME

This codelist contains the list of valid page tracking statuses that is used by the CRF Page Tracking feature.

CRF PAGE STATUS CODES

This codelist contains the list of valid CRF page statuses that is used in Maintain Page Status Tracking form.

CRF PAGE STATUS QUERY

This codelist contains the list of valid statuses for CRF page types that is used in Log-In Query window.

DATA CHANGE REASON TYPE CODE

This codelist contains the list of valid data change reason type codes for data update. The system uses it to provide a default value and to validate user-supplied response change reasons for Oracle Clinical data entry and mass changes (response changes), RDC, and [DCAPI](#).

The default value is presented initially in each user session. If the user selects a different change reason, the system presents the user's last selection as the default. Subsequent changes use the value that was selected last.

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). You can also put a comma-separated list of roles in a single field.

To prevent the reason from appearing at all in RDC Onsite HTML, enter NOTRDC as the long value.

Note: Changing the Long Value of a DATA CHANGE REASON TYPE CODE entry has no effect on data update in Oracle Clinical DE forms. This feature is affects RDC data entry only.

You can customize this codelist. However, the following values are reserved by the system and cannot be used as custom values: 'PASS1', 'PASS2', 'BATCH', 'UPDATE', 'REMOVED', 'TRANSLATION', 'KEY CHANGE', 'BROWSE', 'RECONCILIATION'.

Table 7–8 Values for the DATA CHANGE REASON TYPE CODE Reference Codelist

Short value	Long value	Description
CRA CORR		CRA Correction
DATA ENTRY ERR		Error during data entry
BATCH		Batch-loaded data
CRA CORR-INV		CRA corrected, after consulting with the Investigator
CRA CORR-SRC		CRA correction, after consulting the source data
INV CORR		Investigator correction
STUDY ASSUM		Study assumption
THES CLARIF		Thesaurus clarification
ANALYSIS CORR		Analysis correction
REMOVED		RDCI removed
VAL STATUS CHG		Validation status changed
DATA ENTRY MODE		Data entry mode

Note: Set the LONG VALUE of one the reference codelist values in this list or in [DATA CHANGE REASON2 TYPE CODE](#), to "DCAPIDEL" and another to "DCAPIINV" (comma-separated, if there are other values in the LONG VALUE).

DATA CHANGE REASON2 TYPE CODE

This codelist is used to provide a default value and for validation in **DCAPI**. It works in conjunction with the [DATA CHANGE REASON TYPE CODE](#). It is not used by Oracle Clinical or RDC, but provides a method for you to provide an additional list of values of change reasons that are used by your external applications.

There are no default values for this codelist. Although you can customize this codelist, note that the following set of values are reserved by the system and cannot be used as custom values: 'PASS1', 'PASS2', 'BATCH', 'UPDATE', 'REMOVED', 'TRANSLATION', 'KEY CHANGE', 'BROWSE', 'RECONCILIATION'.

DCF LOCK CONDITIONS

This codelist contains statuses that refer to particular actions that should be limited; see ["DCF LOCK CONDITIONS"](#) on page 3-29 for information.

DCF_OPTIONAL_STATUS_CODES

This codelist contains optional status codes for DCFs; see ["DCF OPTIONAL STATUS CODES"](#) on page 3-29.

DCF STATUS CODES

This codelist contains status codes for DCFs; see ["DCF STATUS CODES"](#) on page 3-29.

DCIF CHECKBOX SIZE

This codelist controls the allowable sizes for checkboxes in DCI Forms. These values are available in the DCI Form Local Database Settings window; see ["Setting DCI Form Default Values for RDC Data Entry and the Patient Data Report"](#) on page 5-10.

The values refer to point sizes. The values are:

- 10
- 12
- 15
- 20

DCIF FONT TYPESIZE

This codelist contains the list of valid font type sizes that can be used in DCI Form graphic layouts in prompts and fields; see ["Setting DCI Form Default Values for RDC Data Entry and the Patient Data Report"](#) on page 5-10.

The default values refer to point sizes. The values are:

- 8
- 9
- 10
- 11
- 12
- 14

DCIF PAGE DEFINITION

This codelist contains the list of page definitions that can be used by the DCI form; see ["Setting DCI Form Default Values for RDC Data Entry and the Patient Data Report"](#) on page 5-10. The four values that are installed are:

- US Portrait
- US Landscape
- A4 Portrait
- A4 Landscape

The long value specifies the height width, and binding offset. With 0 Binding offset, the form layout template appears in the middle of the page. If you specify a non-zero (positive or negative) offset, the FLT moves left/right (for portrait) or up/down (for landscape).

DCM DCI QG TYPE CODE

This codelist contains the values you use to categorize DCMs, DCIs, and Question Groups. The values appear in the lists of values in the DCI Type field in the Maintain DCIs window, the Type field in the Maintain DCMs window, and the QG Type field of the Maintain Question Groups window.

DISCREPANCY ACTIONS *ROLE* Codelists

See ["Configuring the Actions Allowed on Discrepancies"](#) on page 3-23 for information.

DISCREPANCY MESSAGES

This codelist's function has been replaced by the Standard Text Maintenance form under Admin, Discrepancy Mgmt Maintenance. See ["Reason Codes and Descriptions for Univariate Discrepancies"](#) on page 3-12 for information.

DISCREPANCY RESOLU TYPE CODE

See ["Defining Resolution Reasons for Discrepancies"](#) on page 3-16 for information.

DISCREPANCY REV STATUS CODE

See ["Defining the Possible Review Statuses for Discrepancies"](#) on page 3-14 for information.

DISCREPANCY STATUS *ROLE* Codelists

See ["Configuring Discrepancy Display by User Role"](#) on page 3-18 for information.

DISCREPANCY NO OTHER UPDATE

See ["Preventing Update to OTHER Discrepancies"](#) on page 3-25 for information.

DISCRETE VAL GRP TYPE CODE

This codelist lists the severity codes for DVGs.

DISC_STDST_VALUES

This codelist contains discrepancy Study Site Values.

DOSE FORM TYPE CODE

This codelist contains Dosage Form Types.

DOSE FREQUENCY TYPE CODE

This codelist contains frequencies of dose administration.

DX_CONFIG

This codelist contains default settings for data extract.

The DX installation Configuration window includes exactly the same settings. When you change a setting here, the change is reflected there. When you change a setting there, the change is reflected here. For additional explanation of each setting, see ["Configuring Default Installation Data Extract Settings"](#) on page 6-1.

Table 7–9 Values for DX_CONFIG Reference Codelist

Seq	Short Value	Long Value	Description
1	KEY_TEMPLATE	STANDARD	Default Key Template Name
2	DOMAIN	STANDARD	Domain of Default Key Template
3	SEPARATE_SAS_YN	N	Separate Oracle and SAS names?

Table 7–9 (Cont.) Values for DX_CONFIG Reference Codelist

Seq	Short Value	Long Value	Description
4	DCM_LINK_YN	Y	DCM default views are linked to source DCM as default conditions?
5	ACTIVE_KTEDT_YN	N	Enable edit of active key templates?
6	ACTIVE_XMEDT_YN	Y	Enable edit of active extract macros?
7	FREE_KT_SEL_YN	N	Enable selection of nonaggregate, nondefault key template?
8	INC_VALSTAT_YN	N	Include validation status in default view definition?
9	DVGDEFAULT_SN	N	Include DVG sequence number in default view definition?
10	DVGDEFAULT_SV	Y	Include DVG short value in default view definition?
11	DVGDEFAULT_LV	N	Include DVG long value in default view definition?
12	THESAURUS_TERM1	Y	Include thesaurus term1 in default view definition?
13	THESAURUS_TERM2	Y	Include thesaurus term2 in default view definition?
14	THESAURUS_TERM3	Y	Include thesaurus term3 in default view definition?
15	SAS_ATTREDT_YN	N	Enable update of SAS and Oracle column names?
15	INC_FULL_VALTXT	N	Include Full Value Text in default view definition?
16	MAX_AUDIT_LEN	200	Maximum length of Audit Comment
17	MAX_DATCOM_LEN	200	Maximum length of Data Comment
18	DVG_LNG_LEN	200	Maximum length of DVG long value
19	ACTIVE_VTEDT_YN	N	Enable edit of active view templates?
20	ENABLE_VB	N	Enable View Builder as default in new studies?
22	VB_DVG_SUBSET	N	Use DCM Question-specific DVG attributes?
23	USE_DCM_SAS	N	Use DCM SAS Label as seed for attributes in default view definition?
24	FAST_VIEWS	N	Build fast views?

DX_EXTENDED_ATTRIBUTES

This codelist contains settings for Global Library Questions extended attribute creation.

Oracle Clinical offers the option of enabling additional question or response attributes for use in building views and view templates. The extended attributes are enabled at database creation when a population script, `vb_pop_que_attr.sql`, reads the installation reference codelist [DX_EXTENDED_ATTRIBUTES](#).

If you change the settings in this reference codelist, run the script `vb_def_que_attr.sql` again.

VALIDATION_STATUS and DVG_SHORT_VALUE are enabled by default.

Table 7–10 Extended Attributes for Questions

Attribute	Meaning
AUDIT_COMMENT_TEXT	Audit comment text from the response.
DATA_CHANGE_REASON_TYPE_CODE	Code value for the reason the data was changed.
DATA_COMMENT_TEXT	Data comment text from the response.
DISCREPANCY_INDICATOR	Discrepancy indicator for the response.
DVG_LONG_VALUE	DVG long value, if this is a DVG question.
DVG_NUMBER	DVG sequence number, if this is a DVG question.
DVG_SHORT_VALUE VALUE_TEXT	DVG short value, if this is a DVG question. Value of the response, if not.
EXCEPTION_VALUE_TEXT	Exception value text for the response.
FULL_VALUE_TEXT	Response value, or, if error, the exception text.
VALIDATION_STATUS	Validation status of the response
TERM_COL1	Thesaurus DVG first term column
TERM_COL2	Thesaurus DVG second term column
TERM_COL3	Thesaurus DVG third term column

DX_INDEX_TABLESPACE

This codelist contains a list of index tablespaces for use with the Data Extract View Builder. The long values appear in the list of values for the Index Tablespace field in the Maintain Study Access Accounts window under Conduct, then Data Extract.

You must:

- Uncheck the **Active** check box for the long values `RXC_APP_IDX_TSPA` and `RXC_DCD_IDX_TSPA`. These values are not valid and should not be available to users.
- Enter the names of each tablespace you create for the purpose of containing data extract indexes, and check its Active check box. See "[Creating Tablespaces for Data Extract Tables and Indexes](#)" on page 6-5 for more information.

DX_KEY_NAME

This codelist contains the column alias for a data extract view keys

DX_ROLES

This codelist contains the list of default roles for accessing data extract views. Values set here appear in a list of values in the View Definition window; users with the selected role have access to the view. You can add roles; see "[Controlling Access to Data Extract Views](#)" on page 6-9 for more information.

DX_VIEW_TABLESPACE

This codelist contains a list of view tablespaces for use with the Data Extract View Builder. The long values appear in the list of values for the Tablespace field in the Maintain Study Access Accounts window under Conduct, Data Extract.

You must:

- Uncheck the **Active** check box for the long values RXC_APP_TSPA and RXC_DCD_TSPA. These values are not valid and should not be available to users.
- Enter the names of each tablespace you create for the purpose of containing data extract tables, and check its Active check box. See "[Creating Tablespaces for Data Extract Tables and Indexes](#)" on page 6-5 for more information.

EXECUTION SCHED CODE

This codelist contains the execution schedule, which is used in MODULE_EXECUTIONS.

EXP DESIGN TYPE CODE

This codelist contains experimental design types for studies.

EXTERNAL_TRANS_TYPE

This codelist provides transaction types for the Data Capture API function SetExternalContext.

LAB RANGE SUBSET CODE

This codelist contains the set of Lab Range Subset Codes.

MANUAL SOURCE TYPE CODE

See "[Reason Codes and Descriptions for Manual Discrepancies](#)" on page 3-11 for information.

MAPPING_TYPE

This codelist contains the list of user codes for mapping type. Refer to [Chapter 11, "Setting Up File Viewing."](#)

Table 7-11 Values for MAPPING_TYPE Reference Codelist

Seq	Short Value	Long Value	Description
1	HTTP	HTTP	HTTP Transfer protocol
2	FTP	FTP	FTP Transfer protocol
3	HTTPS	HTTPS	Secure-socket layer HTTP protocol
4	UNC	UNC	Universal Naming Convention protocol

MEDICAL EVAL TYPE CODE

This codelist contains the values you use to categorize Questions. The values appear in the lists of values in the Medical Evaluation Type field in the Maintain Questions window.

OBJECTIVE TYPE CODE

This codelist contains the list of types of Clinical Planned Objective.

OCL_DOMAINS

This codelist contains the installation-wide list of global library domains. For information, see *Oracle Clinical Creating a Study*.

OCL_INSTALLATION

This codelist defines the location code of the database that owns the Global Library. The system requests and stores this value during database creation. Oracle Clinical checks the local reference codelist [OCL_STATE](#) to determine if the location code specified for the current database matches the one for the Global Library stored in OCL_INSTALLATION. If these values match, Oracle Clinical allows updates to the Global Library.

OCL_OPTIONS_TYPE_CODE

This codelist contains a list of Optional Subsystems.

Table 7–12 Default Values for OCL_OPTIONS_TYPE_CODE Reference Codelist

Seq	Short Value	Long Value	Description
1	TMO_INSTALLED	Y	TMO Installed (obsolete).
2	TMS_INSTALLED	Y	Set to Y if TMS installed; to N if not.
3	VAL_STATUS	Y	If set to Y, Batch Validation skips documents that have had a validation status change since the last validation and are currently open (locked) in OC data entry. If set to NONE, Batch Validation processes such documents.
4	SR_INSTALLED	Y	Set to Y if Symmetric Replication installed

OPA_MENU_ROLES

This codelist contains the list of menu roles available in your Oracle Clinical installation. Any custom roles you create are not available until you enter them in this reference codelist; see "[Adding a Custom Role to OPA_MENU_ROLES](#)" on page 2-8 for information.

PATIENT STATUS CODE

This codelist describes patient statuses such as enrolled or terminated.

PLAN STUDY INT TYPE CODE

This codelist describes types of Planned Study Intervals, such as baseline, dosing, and qualifying.

PROCEDURE TYPE CODE

This codelist contains the list of user code for PROCEDURES.

QUESTION CATEGORY TYPE CODE

This codelist contains the list of user codes for QUESTION_CATEGORY_RELATIONS.

RDCI CHANGE REASON TYPE CODE

RDCI change reason code for Oracle Clinical data entry and mass changes (key changes and soft deletes), RDC, and DCAPI applications during key data update and when deleting an accessible CRF. The values in this codelist are listed and described in [Table 7-13, "Initial values for the RDCI CHANGE REASON TYPE CODE Reference Codelist"](#).

The following subsystems use this reference codelist during processing to provide a change reason for audited changes:

1. Patient Transfer
2. Lab Assignment Criteria
3. Mass Changes
4. Data Entry Login

The user is always prompted for a change reason during items 1 through 3. During data entry login, the user is prompted for a change reason when the document is internally accessible. For each case in which a user-supplied change reason is required, the system prompts the user and presents the list of values in this codelist as the set of options from which the user chooses.

The initial set of values in this codelist are copied from the [DATA CHANGE REASON TYPE CODE](#) reference codelist.

You can choose which values should not appear in RDC HTML Data Entry by adding 'NOTRDC' as the long value. HTML Data Entry displays all active values in the reference codelist that do not have 'NOTRDC' specified as the long value.

Although you can customize this codelist, note that the following set of values are reserved by the system and cannot be used as custom values: 'PASS1', 'PASS2', 'BATCH', 'UPDATE', 'REMOVED', 'TRANSLATION', 'KEY CHANGE', 'BROWSE', 'RECONCILIATION'.

Table 7-13 Initial values for the RDCI CHANGE REASON TYPE CODE Reference Codelist

Short value	Long value	Description
CRA CORR		CRA Correction
DATA ENTRY ERR		Error during data entry
BATCH		Batch-loaded data
CRA CORR-INV		CRA corrected, after consulting with the Investigator
CRA CORR-SRC		CRA correction, after consulting the source data
INV CORR		Investigator correction
STUDY ASSUM		Study assumption
THES CLARIF		Thesaurus clarification
ANALYSIS CORR		Analysis correction
REMOVED		RDCI removed

Table 7–13 (Cont.) Initial values for the RDCI CHANGE REASON TYPE CODE Reference Codelist

Short value	Long value	Description
VAL STATUS CHG		Validation status changed
DATA ENTRY MODE		Data entry mode

RDCI CHANGE REASON2 TYPE CODE

An additional set of RDCI change reason codes that are used by DCAPI. This codelist allows you to provide an additional list of valid change reason values that can be used by your external applications.

There are no default values for this codelist. Although you can customize this codelist, note that the following set of values are reserved by the system and cannot be used as custom values: 'PASS1', 'PASS2', 'BATCH', 'UPDATE', 'REMOVED', 'TRANSLATION', 'KEY CHANGE', 'BROWSE', 'RECONCILIATION'.

REGION TYPE CODE

This codelist contains types of region such as state, country, or continents.

RETIREMENT REASON TYPE CODE

This codelist contains the list of user codes for DCIS, DCMS, DVGS, PROCEDURES, QUES, QUES_GROUPS.

ROUTE OF ADMIN TYPE CODE

This codelist contains routes of drug administration such as oral, intravenous, and inhalation.

SAS_FORMATS

This codelist contains a list of optional subsystems.

SINGLE DCI TYPES

This codelist contains DCI types that do not allow duplicates. That is, the user is not permitted to add DCIs in this codelist as unplanned pages to a visit. Also, if the user adds an unplanned visit to the study, only those DCIs that are not listed in this codelist are included in the new visit.

The short value must correspond to a short value in the DCM DCI QG TYPE CODE installation reference codelist because DCIs can only be created of DCI types defined in that codelist.

The default values are listed in [Table 7–14, "Reference Codelist SINGLE DCI TYPES"](#).

Table 7–14 Reference Codelist SINGLE DCI TYPES

Seq	Short Value
1	DEMOGRAPHY
2	COMPLETION

SOURCE LOCATION CODE

This codelist contains the unique location code for each location in the installation.

The Global Library-owning location maintains this codelist. The Long Value field stores the offset in hours of that location from Greenwich Mean Time (GMT). Locations in a time zone east of Greenwich, England have a positive offset and those to the west have a negative offset. This reference codelist is replicated to the other locations as part of Global Library replication.

STANDARDS AFFIL TYPE CODE

This codelist contains the user code for STANDARDS_AFFILIATIONS.

STUDY STATUS TYPE CODE

This codelist contains types of Clinical Study Status.

TMS_CONFIGURATION

This codelist contains settings that control various default behaviors in the Oracle Thesaurus Management System. See the *Oracle Thesaurus Management System User's Guide* for details.

TMS_OMISSIONASSIGNMENT

This codelist controls the default behavior for omission assignment in the Oracle Thesaurus Management System (TMS). See the *Oracle Thesaurus Management System User's Guide* for details.

TMS_OMISSION_STATUS

This codelist controls the default behavior for TMS Omission Status

TMS_QUERY_TYPE

This codelist populates the Query fields in the Oracle Thesaurus Management System (TMS) with default choices for query type. See the *Oracle Thesaurus Management System User's Guide* for details.

TMS_X_SEARCH

This codelist populates the list of values for the Search Type field in Oracle Thesaurus Management System (TMS). It currently has only one value, Cross Search. See the *Oracle Thesaurus Management System User's Guide* for details.

TREAT CHG REASON TYPE CODE

This codelist contains the list of valid Treatment Change Reason Type Codes.

UNITS_OF_MEASURE_TYPE_CODE

This codelist contains units of measure that are available for use in studies in the database.

USER GROUP ROLES

See ["Mapping Database Roles to User Roles"](#) on page 3-1.

USER GROUPS

See ["Specifying User Roles for the Oracle Clinical Discrepancy Database"](#) on page 3-2 for information on this reference codelist.

VALIDATION FAILURE TYPE CODE

User code for DCM_QUESTIONS, PROCEDURE_DETAILS, QUES, QUES_GROUP_QUES

Design Installation Reference Codelists

Design Installation codelists are a subset of the [Installation Reference Codelists](#) relating to study design. Using a database role with access to the appropriate menu item, you can grant a study designer access to either of the Design Installation Codelists windows (Query or normal), and enable the designer to maintain this subset of the reference codelists without providing access to change all of the installation reference codelists.

Each of the design installation codelists is documented in the main Installation Codelists section:

- [APPLICATION AREA CODE](#)
- [BLIND TYPE CODE](#)
- [CLINICAL PHASE](#)
- [DOSE FORM TYPE CODE](#)
- [DOSE FREQUENCY TYPE CODE](#)
- [EXP DESIGN TYPE CODE](#)
- [OBJECTIVE TYPE CODE](#)
- [PLAN STUDY INT TYPE CODE](#)
- [REGION TYPE CODE](#)
- [ROUTE OF ADMIN TYPE CODE](#)
- [STUDY STATUS TYPE CODE](#)
- [TREAT CHG REASON TYPE CODE](#)

System Reference Codelists

System reference codelists provide values for Oracle Clinical's internal use only. You can browse or query for system codelist values, but you cannot change them. System codelists provide standard values across distributed environments.

To access the System codelists, navigate to **Admin, Reference Codelists**, and then **Qry System Codelists**. Alternatively, you can run a Reference Codelist report for one or all system codelists. Refer to the ["Running the Reference Codelists Report"](#) section on page 7-3 for instructions.

Part II

Oracle Clinical Administration Tasks

This section includes tasks involved in running Oracle Clinical:

- [Chapter 8, "Managing Batch Jobs"](#)
- [Chapter 9, "Partitioning and Indexing"](#)
- [Chapter 10, "Utilities"](#)
- [Chapter 11, "Setting Up File Viewing"](#)
- [Chapter 12, "Enabling Image Viewing"](#)

Managing Batch Jobs

The Oracle Clinical parameterized job and report submission facility (PSUB) submits jobs to execute either on the Reports Server or on the back end server. Oracle Clinical uses Oracle Reports for reports, job sets and scheduling. The back end server, also called the PSUB server, handles only jobs implemented in PL/SQL or a third-generation language (3GL). You cannot alter which server is used for a given job; this is determined by the way in which each PSUB job has been coded.

When you take an action runs a report or PSUB job, the job submission form displays the type of job (either PSUB or Reports Server) at the top of the form.

Use the information in this section to manage PSUB jobs, such as:

- reviewing the installation
- diagnosing and recovering from installation failures, and
- understanding how other system changes affect the consistency of the installation.

Note: For information on managing Oracle Reports jobs, see the Oracle Application Server Reports Queue Manager documentation.

This section includes the following topics:

- [User Account Requirements for Batch Jobs](#) on page 8-1
- [How PSUB Handles a Request](#) on page 8-2
- [Managing the PSUB Process](#) on page 8-3
- [Batch Job Reference Codelists](#) on page 8-13

User Account Requirements for Batch Jobs

Before submitting batch job requests, a user should have the following:

- an OPS\$ database account
- an account on the PSUB server
- a record in the Oracle Accounts table
- a log directory on the PSUB server
- a log directory for reports output

For instructions on setting up user accounts, see "[Setting Up User Accounts](#)" on page 1-1.

Note: On Windows only:

- All Oracle Clinical users must also have operating system-level accounts on the Windows server running the PSUB service.
- The Windows server that runs the PSUB service must belong to the same domain as the Windows server that runs the Oracle database.

This Oracle database security feature prevents unauthorized users from logging in over a network connection. For information on database security, see the your Oracle database documentation.

How PSUB Handles a Request

When a client issues a PSUB request to run a job or report, it sends a message, via a database pipe to the PSUB process, that includes the batch job ID and the primary key into the RXC.BATCH_JOBS table.

When the process receives this message from the database pipe, it reads the job information from the RXC.BATCH_JOBS table and submits the job on the user's behalf with the PSUB Launcher (PSLAUNCH).

In submitting the job, the process creates the following files, where *nnnn* represents the batch job ID reported to the user in a dialog box

The system creates these files in the user's RXC_LOG directory, which you can see in the Oracle Accounts form:

Filename format	Description of file contents
<i>lnnnn.log</i>	Log file of a user's PSUB job. Note that the initial character is the letter L, not the number one.
<i>onnnn.out</i>	Output from a report job.
<i>pnnnn.log</i>	Log file for a print request from the Submitted Batch Jobs form.

Asynchronous PSUB Requests

The DBMS_PIPE mechanism is an asynchronous protocol, so messages remain in the pipe until read by the process. This means that if a user makes a PSUB request and the process is not running, the request is read when the process is started again. Also, the DBA can safely stop and restart the process in a production environment, provided the delay is not too long. All nonblocking requests are processed, and all blocking requests start when the process comes up or times out.

Blocking and Nonblocking Jobs

Blocking jobs are usually of short duration and run in a mode where the system does not allow the user to proceed before their completion. Job completion status (SUCCESS or FAILURE) can be reported to the user immediately after the job completes. Blocking jobs in Oracle Clinical include:

- Default layout generation
- Moving a data entry screen to production
- Generating a Validation Procedure

When an application server submits a blocking job, it sends information through a common database pipe and then waits on an application server-specific receiving pipe for completion (execution) information, which it receives from PSUB. The pipe is maintained by the application and is named with a unique session name. Time-out on the receiving pipe for the application server occurs after 5 minutes, at which point the following message appears: *"Failed to get response from server - Batch Job Id <nnnn>"*. Timing out happens for a variety of reasons, including:

- The rxcprod user is not set up properly.
- Job execution is slow, so more than 5 minutes elapse before completion.
- The PSUB process is not running.
- Too many jobs in the batch queue cause the current job to be pending; or it started after the other jobs were completed.
- The server machine is too slow for the current load.
- The job is executing but is waiting for some resource.
- The client is not connected to an OPS\$ Oracle account; or the client does not have an operating system account on the server.
- The queue is in a stopped state.

Nonblocking jobs include all reports, all jobs launched from the PSUB submission screen, and randomization.

Checking a Nonblocking Batch Job

Users are not notified when nonblocking batch jobs complete. To check the job's status, they can execute a query in the Submitted Batch Jobs form, accessible via:

- the Job Status button in the Submission of *module* window
- the Batch Jobs item from the Action in-form menu
- this command, entered from the rxcprod or system manager account:

```
$ at -l
```

Managing the PSUB Process

This section contains the following topics:

- [Starting and Stopping PSUB Manually in UNIX](#) on page 8-4
- [Starting and Stopping PSUB Automatically in UNIX](#) on page 8-4
- [Starting and Stopping PSUB Manually in Windows](#) on page 8-6
- [Starting PSUB Automatically in Windows](#) on page 8-7
- [Changing PSUB Job Number Sequencing](#) on page 8-9
- [Viewing the Status of a Submitted Batch Job](#) on page 8-9
- [Removing the PSUB Service](#) on page 8-9
- [Viewing Log and Output Files on the Screen](#) on page 8-10
- [Using Job Sets to Control Execution Order](#) on page 8-11
- [Tracking PSUB Processes](#) on page 8-12

Starting and Stopping PSUB Manually in UNIX

This section contains the following topics:

- [Starting PSUB Manually in UNIX](#) on page 8-4
- [Stopping PSUB Manually in UNIX](#) on page 8-4

Starting PSUB Manually in UNIX

To start the process on UNIX:

1. Log on as rxcpod to the UNIX back end server computer.
2. Run the startup script.

The startup script has the following syntax:

```
start_psub instance environment verbose
```

where *instance* refers to a generic instance name, and *environment* to a code environment. This starts up PSUB in verbose mode, which means additional information is placed in the process log file to help in debugging PSUB problems.

Log in as rxcpod to start PSUB. For example:

```
$ start_psub prod 46 verbose
```

If the process is already running, the script exits with an error message.

The start_psub shell script is run interactively as part of the user's current shell. This script runs the executable rxcpsdps as a background process, which is the PSUB process. Creating the background process should take only a few seconds.

Search for an instance of the rxcpsdps process.

For example:

```
$ ps -ef | grep -i rxcpsdps
  rxcpod  0 12750 1  0 15:52:43 ? 0:00 rxcpsdps verbose dev 40
  rxcpod  0 22142 1  0 18:50:39 ? 0:01 rxcpsdps verbose test 40
```

If the PSUB process fails to start, check for errors in `rxcpod_instance_environment_1.log` and `rxcpod_instance_environment_2.log` in the `$RXC_CENTRAL_LOG` directory.

Stopping PSUB Manually in UNIX

The preferred way to stop the PSUB process, because it ensures a graceful exit, is with the following utility, from either the opapps or rxcpod account, after setting the correct environment:

```
stop_psub instance environment rxc_password
```

Starting and Stopping PSUB Automatically in UNIX

On UNIX systems, you can automate the process of starting and stopping PSUB.

Starting PSUB Automatically in UNIX

The following example shell scripts for Sun Solaris show how to make the process start automatically at system startup:

```
# File: /etc/init.d/dbora
ORA_HOME=/u01/app/oracle/product/11.1.0.7.0
```



```

ORA_OWNER=oracle
if [ ! -f $ORA_HOME/bin/dbstart -o ! -d $ORA_HOME ]
then
    echo 'Oracle startup: cannot start'
    exit
fi
case "$1" in
'start')
echo 'Starting Oracle...'
su - $ORA_OWNER -c $ORA_HOME/bin/dbstart
su - $ORA_OWNER -c "lsnrctl start"
su - rxcprod -c start_psub
;;
'stop')
echo 'Stopping Oracle...'
su - rxcprod -c stop_psub
su - $ORA_OWNER -c $ORA_HOME/bin/dbshut
;;
esac
# File: start_psub
# Start database 1
start_psub venus 46
# Start database 2
start_psub pluto 46

```

Stopping PSUB Automatically in UNIX

With an OPS\$ Oracle account you can automate the shutdown of the PSUB process on UNIX so that it does not require the entry of a password. For example, you can grant the OPS\$RXCPROD user access to shut down the PSUB process:

```

$ sqlplus rxc/password
SQL> grant execute on stop_psub_daemon to ops$rxcprod

```

The PSUB process may then be shut down with the command:

```

$ rxcptestop.sh /

```

The entire process of starting up and shutting down Oracle Clinical instances can be automated. The following example shell scripts for Sun Solaris show how.

```

# File: /etc/init.d/dbora
ORA_HOME=/u01/app/oracle/product/11.1.0.7.0
ORA_OWNER=oracle
if [ ! -f $ORA_HOME/bin/dbstart -o ! -d $ORA_HOME ]
then
    echo 'Oracle startup: cannot start'
    exit
fi
case "$1" in
'start')
echo 'Starting Oracle...'
su - $ORA_OWNER -c $ORA_HOME/bin/dbstart
su - $ORA_OWNER -c "lsnrctl start"
su - rxcprod -c start_psub
;;
'stop')
echo 'Stopping Oracle...'
su - rxcprod -c stop_psub
su - $ORA_OWNER -c $ORA_HOME/bin/dbshut
;;

```

```

esac
# File: stop_psub
# Stop database 1
stop_psub venus 46
# Stop database 2
stop_psub pluto 46

```

Starting and Stopping PSUB Manually in Windows

This section contains the following topics:

- [Installing PSUB in Windows](#) on page 8-6
- [Installing PSUB in Windows](#) on page 8-6
- [Stopping PSUB Manually in Windows](#) on page 8-7

Installing PSUB in Windows

On Windows, you must first install the PSUB process as a service:

1. Log in to the Windows server as Administrator.
2. Open a Command Prompt window and enter the following commands:

```

set p1=database-connect-string
set p2=code-environment
opa_setup
cd %RXC_BIN%
rxcpsdps -install database-connect-string database-instance-name

```

3. Open the computer's Services control panel.
4. In the Services dialog box, select the PSUB service and open the Properties window.
5. In the General tab window, set the Startup Type to Manual.
6. In the Log On tab window, click This Account, and choose rxcpod. The system prompts you for the password for the rxcpod user.
7. Enter and confirm the password, and click OK.
8. Log out from this Administrator session.

Starting PSUB Manually in Windows

After installing the PSUB service and setting its parameters as Administrator, you start it as rxcpod:

1. Log in as rxcpod.
2. Open the computer's Services control panel.
3. In the General tab window, select the PSUB Service and enter values for the Start Parameters as follows:

```

database-connect-string code-environment [verbose | noverbose] value-of-rxc_root

```

For example:

```

db2x2 46 verbose c:\opapps\oc\46

```

Note that if you need a backslash (\) in the text box, you must double it (\\).

4. Click the Start button.
5. Click OK to close the PSUB Service Properties window.

Stopping PSUB Manually in Windows

Do not use Enterprise Manager to stop rxcpod sessions on Windows; instead, use the Control Panel on the appropriate local machines.

To stop the PSUB service, follow these steps:

1. Log in as rxcpod.
2. Open the Services control panel.
3. In the Services dialog box, select the PSUB service for the particular database and open the Properties window. The PSUB service for db2x2, for example, might appear as:

```
psub service db2x2
```

4. In the Properties window, click Stop.

Starting PSUB Automatically in Windows

This section contains the following topics:

- [Creating a System Environment Variable](#) on page 8-7
- [Creating a Batch File](#) on page 8-8
- [Scheduling the Batch File and Testing the Setup](#) on page 8-8
- [Adding a Shortcut](#) on page 8-8

You must first install PSUB; see "[Installing PSUB in Windows](#)" on page 8-6.

The batch file is required in large databases that take so much time to come up during a server reboot so that the system tries to start PSUB before the database is fully up. In this case the PSUB process does not start and an error like the following appears in the PSUB log file (found in the *drive:\opapps\oc\46\log* directory):

```
ERROR:Daemon error while connecting:/@devoc
ORA-1033: ORACLE initialization or shutdown in progress
```

Creating a System Environment Variable

You can specify that the PSUB service starts automatically when the Windows PSUB server re-boots. The service parameters are read from system environment variable with name PSUBSERVICE concatenated with database name, such as:

```
PSUBSERVICESUN6X2
```

where "SUN6x2" is the database name.

To create a system environment in Windows:

1. Select **System** in the Control Panel.
2. Select the **Advanced** tab, select **Environment Variables**.
3. Define the System Environment variable in the lower portion of the window, using the format: *database id code environment verbose RXC_ROOT*

For example, for the variable "PSUBSERVICESUN6X2":

```
sun6x2 46 verbose t:\opapps\oc\46
```

Creating a Batch File

Create a batch file called 'psub_start1.bat' in the %RXC_ROOT%/log directory (for example, D:\opapps\oc\46\log) with the following contents.

```
cmd /c echo Current Date/time= %DATE% %TIME% > psub_start1.log
cmd /c echo Starting Time Delay > psub_start1.log
ping localhost -n 180 > nul
cmd /c net start "PSUB Service database_id" > psub_start1.log
```

Notes:

- "PSUB Service *database_id*" is the PSUB service name that appears in the Services window (under Administrative Tools from the Control Panel).
- You can repeat the following command for different databases if needed:

```
cmd /c net start "PSUB Service database_id" > psub_start1.log
```
- The 'ping localhost' command introduces a time delay to ensure that the database is up before starting PSUB. You can increase this value—set to 180 seconds (3 minutes) in the example above—if required.

Scheduling the Batch File and Testing the Setup

To schedule batch file execution:

1. Make sure that the Task Scheduler service is started in the Services Window (under Administrative Tools from the Control Panel).
2. Navigate to Scheduled Tasks in the Control Panel.
3. Open the Add Scheduled Task wizard and click Next. The Scheduled Task Wizard window appears.
4. Click on Browse. The Browse window appears.
5. Go to the directory where 'psub_start1.bat' is saved and then select psub_start1.bat. The task name is displayed as psub_start1. You can modify the name.
6. Under 'Perform this task, select 'When my computer starts' and click Next.
7. On the next screen ensure that the ADMINISTRATOR username/password is used.
8. Click Next and click Finish.

To test, shut down the service if necessary (see ["Stopping PSUB Manually in Windows"](#) on page 8-7) and double-click on file 'psub_start1.bat' to test that it starts the PSUB service. Verify that the log file 'psub_start1.log' is created in the same directory unless a different path was specified.

9. In the Services Window under Administrator Tools in the Control Panel, change the Startup Type of the PSUB Service to Manual.

To test, restart the computer and check the Services window to see if the PSUB service has started. If it has, submit a PSUB job such as Batch Validation and check if it runs.

Adding a Shortcut

For convenience add a shortcut for psub_start1.bat on the desktop to manually start PSUB by double-clicking the icon.

Changing PSUB Job Number Sequencing

A sequence generator numbers Oracle Clinical submitted batch jobs. By default, at each submission the generator increments by 10 the database seed number you provide during back end installation. Change the default by running `alter_psub_seq.sql`, found in the `INSTALL` directory, which lists current settings and asks for:

- start value – number to append to the initial job ID
- increment – the value to add to the job ID for each subsequent job.

For example:

Start Value	Increment	Job ID Numbers
1	10	1, 11, 21, 31...
21	100	21, 121, 221, 321...

The value entered for the "start value" for the PSUB batch job number does not need to be the same as the database seed.

Tips: If users are accessing multiple databases, keep the batch job numbers generated by each database unique so that the log files do not collide.

Keep the increment of the batch job numbers as small as possible so that batch job numbers do not grow too large.

Viewing the Status of a Submitted Batch Job

You view the status of submitted batch jobs in the Submitted Batch Jobs window, which you access by selecting: **Admin**, then **PSUB/Reports Jobs**, and **Batch Jobs**. This window provides information about the batch jobs, including logs, output file names, and stop jobs you have submitted. The most recently submitted jobs are listed first.

You cannot use this window to update fields. If you are viewing this form while the job is executing, requery the form periodically to see the statuses change, or press the Auto Refresh button. Press the button again to turn off the auto query.

Batch job execution statuses:

- ENTERED = User has requested submission of the job.
- SUBMITTED = Job has been submitted to the batch queue.
- SUBMIT_FAILED = Job failed to be submitted to the batch queue.
- STARTED = Job is currently executing.
- SUCCESS = Job has completed successfully.
- FAILURE = Job has completed unsuccessfully. Reason displayed in Failure Text field.
- STOPPED = Job has been stopped by the Stop button.
- STOP_FAILED = Job has not responded to the Stop button.

Removing the PSUB Service

On Windows, you can remove (uninstall) the PSUB service as follows:

1. Log in as Administrator.

2. Open a Command Prompt window and enter the following commands:

```
set p1=database-connect-string
set p2=code-environment
opa_setup
cd %RXC_BIN%
rxcpsdps -remove database-connect-string database_instance_name
```

3. Log out from this Administrator session.

Viewing Log and Output Files on the Screen

This section includes the following topics:

- [Viewing Logs That Concern Execution of Psub Processes](#) on page 8-10
- [Viewing Logs for Individual PSUB Jobs](#) on page 8-10

Viewing Logs That Concern Execution of Psub Processes

The PSUB process writes to log files pointed to by the variable `RXC_CENTRAL_LOG`. `RXC_CENTRAL_LOG` is defined as `$rxc_root/log` (on UNIX), or `%rxc_root%\log` (on Windows). Do not redefine this variable to any other values.

Note: On UNIX systems, you must stop the PSUB process to view the contents of this log file, because it will be locked.

However, the following file can be read while the PSUB process is running:

Operating System	Example path/filename for log file
UNIX	<code>\$RXC_CENTRAL_LOG/rxcpsd_instance_environment_1.log</code>
Windows	<code>%RXC_CENTRAL_LOG%\rxcpsd_instance_environment_1.log</code>

If the process is running in verbose mode more information is written to the log file. You cannot switch from non-verbose to verbose modes while the process is running; you must stop and restart the process to switch mode.

Viewing Logs for Individual PSUB Jobs

Log and output files are always placed in the log directory in your home directory on the server on which PSUB is running. You cannot update log and output file names. The names of the files are structured such that the unique batch job ID for the job is given an:

- "l" prefix for the log file
- "o" for the output file.

For example, a batch job ID of 12345 would have an output file name of `$RXC_LOG/o12345.out` (for UNIX), or `%RXC_LOG%\o12345.out` (for Windows), and a log file name of `$RXC_LOG/l12345.log` (for UNIX), or `%RXC_LOG%\l12345.log` (for Windows).

To view the output or log file on the screen, click the View Output or View Log button and enter the relevant information in the window.

Printing Output or Log Files

To print the output or log file, press the Print Output or Print Log button. In the pop-up box, specify the printer.

For printing, PSUB uses the standard `lp` command (on UNIX) or print functions (on Windows). No other environment variables control printing.

Printing from PSUB jobs on a UNIX server to a Windows spooler is not supported.

Using Job Sets to Control Execution Order

You can create a job set to control the execution order when you want jobs that depend on other jobs to execute only if the jobs on which they depend have successfully executed. If any of the jobs in a job set exits with a status of `SUBMIT-FAILED` or `STOPPED`, the whole job set aborts with a status of `FAILURE`. The basic steps are:

1. [Create a Job Set](#)
2. [Submit a Job Set](#)

Note: All jobs included in a job set must have a saved parameter set. No job included in a job set can have a `LOCAL_IMMEDIATE` mode of execution

Create a Job Set

1. Save a parameter set for each job to be included in the job set, if that has not been done already.
2. Select **Admin**, then **PSUB Jobs**, and **Job Sets**.
3. Enter a name for the job set (alphabetic characters only).
4. In the **Job Label** field, enter a short name for the first job in the sequence. You use this name in the fields under **JOB LABEL** to the right.

Note: No jobs included in a job set can have a `LOCAL_IMMEDIATE` mode of execution

5. Enter the name of the saved parameter set for the job. list of values available.
6. Set the timeout limit for the job in minutes. Default: 720 (12 hours).
7. The next three fields set the execution order and conditional branching. Enter the job label for the job you want to run next if the current job runs successfully, fails, or times out. If you leave one of these fields blank, the entire job set will stop executing if the current job has the corresponding result. For example, if you leave the Failure field blank and the current job fails, Oracle Clinical stops executing the entire job set.

Oracle Clinical enters the task name for the parameter set you entered.

Repeat this process for each job in the job set.

Submit a Job Set

1. Select **Admin**, then **PSUB Jobs**, and **Submit Job Set**.
2. Enter a job set name. An list of values is available.
3. Click **Submit Job**.

A job set controls the execution order for a specified set of jobs, so that jobs that depend on other jobs will execute only if the jobs on which they depend have been successfully executed. If any of the jobs in a job set exits with a status of SUBMIT-FAILED or STOPPED, the whole job set aborts with a status of FAILURE. You create job sets by selecting **Admin**, then **PSUB**, and **Job Set**.

Note: It is not necessary to wait until Oracle Clinical has executed one job before you submit another job.

Tracking PSUB Processes

Before starting a PSUB process, you may want to know the answer to such questions as, "Where was PSUB last running?", or "Where was PSUB running on such-and-such a date?" You can query the table RXC.PSUB_PROCESS_LOG to find out, for a given database, the instance, the environment, and the time a PSUB process was started and the time it was stopped.

Name	Type	Description
PSUB_PROCESS_LOG_ID	NUMBER	
HOST	VARCHAR2(64)	
SERVER_OS	VARCHAR2(8)	The type of operating system on the server where PSUB runs
START_TS	DATE	The time stamp when the PSUB process started
CODE_ENVIRONMENT	VARCHAR2(20)	
VERBOSE	VARCHAR2(1)	
STOP_TS	DATE	The time stamp when the PSUB process stopped

For example, this query will give you the host and code environment of the last time PSUB was started against the database:

```
SQL> select start_ts, host, code_environment
  2  from psub_process_log
  3  where start_ts = (
  4  select max(start_ts) from psub_process_log);
```

This query will list all starts and stops, in time order:

```
SQL> select start_ts, stop_ts, host, code_environment
  2  from psub_process_log
  3  order by 1;
```


Batch Job Reference Codelists

Oracle Clinical manages batch jobs through entries in these reference codelists, refer to [Chapter 7, "Reference Codelists"](#) on page 7-1 for additional information:

- [BATCH QUEUE NAME](#) on page 7-7
- [PRINT QUEUE NAME](#) on page 7-18
- [OCL_JOB_PREF](#) on page 7-13
- [REPORT_SERVER](#) on page 7-18
- [SAS_QUEUE](#) on page 7-18

Partitioning and Indexing

Oracle Clinical modifies the required index structure for the Responses table (as well as several other tables), and enables the use of partitioning for the Responses table. The baseline Release 4.6 upgrade does not change the index or partition structure of the Responses table because these changes can be time-consuming and require additional planning. You decide when to upgrade to the new indexes, and whether and when to upgrade for partitioning.

This section covers the following topics:

- guidelines for planning the upgrade process
- background information on partitioning
- procedures for performing the upgrades
- guidelines for maintaining partitioned Oracle Clinical databases.

This does not replace the Oracle technical documentation regarding partitioning or indexes. Oracle strongly recommends that the DBA in charge of the Oracle Clinical database be familiar with partitioning before attempting to convert an existing Oracle Clinical database to a partitioned Responses table.

For detailed and authoritative information on partitioning and on maintaining partitioned tables, refer to the Oracle database documentation, specifically the *Concepts* manual and the *Administrator's Guide*.

Introduction

There are two basic sets of decisions you must make to plan the upgrade:

- Whether and when to convert to a partitioned Responses table
- If you are not partitioning, when and how to upgrade the index structure of the Responses table

These two decisions are inter-related — the conversion to partitioning subsumes the index upgrade. If you decide that you will be partitioning shortly after upgrading, you might want to skip the separate index upgrade. Conversely, if you are postponing partitioning you might want to do the separate index conversion soon after upgrade. If you are not converting to partitioning, you need to consider the path to index upgrade (see [Figure 9-1](#)).

If you have a fresh installation of Oracle Clinical, you do not need the index upgrade. You do need to decide about partitioning.

Timing Considerations and Deferral of Index or Partition Upgrade

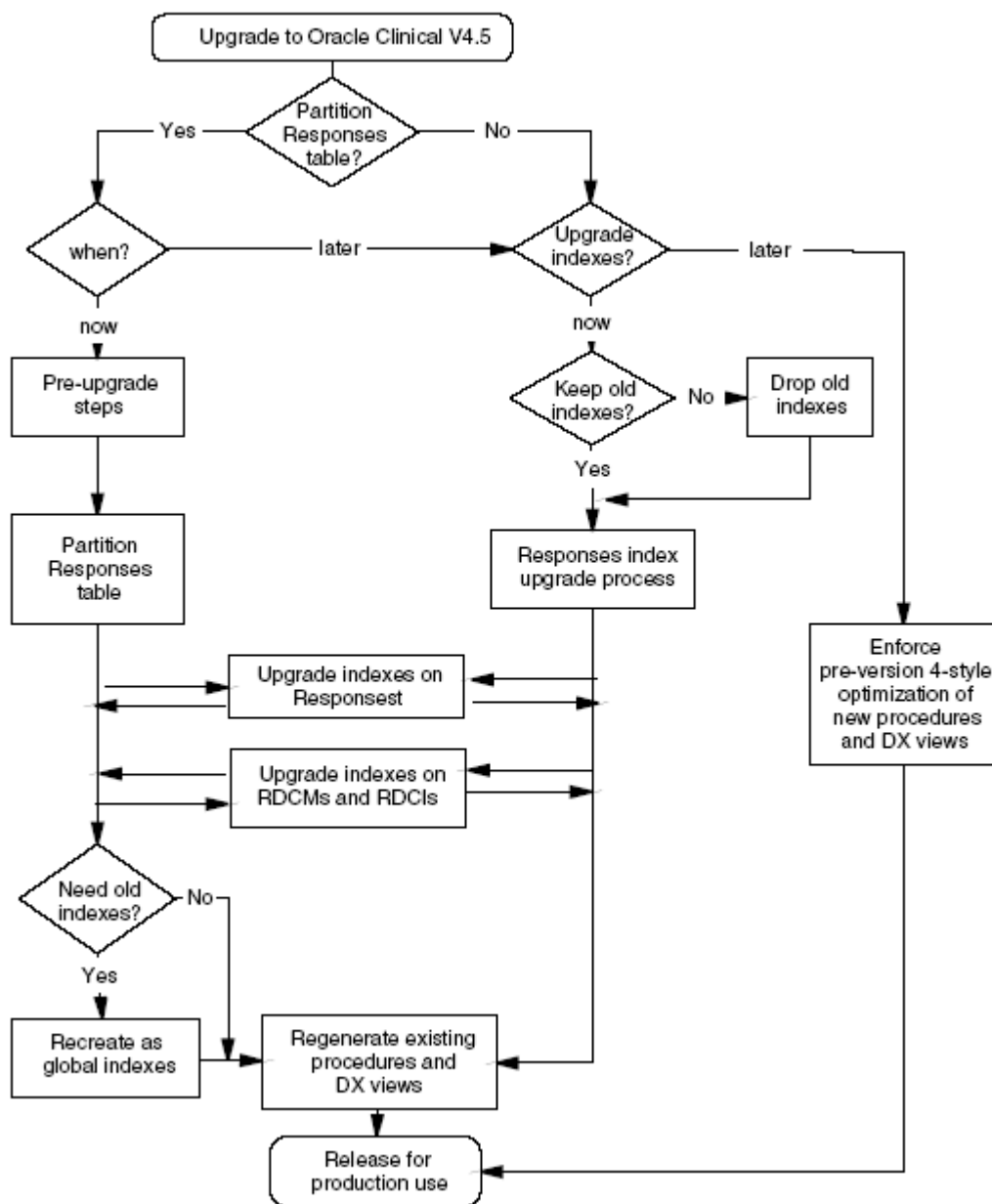
The index upgrade and partitioning both require impact analysis in advance and both can take a significant amount of time to implement. Assuming that the impact analysis is done prior to upgrading and the upgrade path chosen, the primary consideration for when to upgrade is the elapsed time needed to perform the actual upgrades. While either could be done at the same time as the upgrade, deferring the index or partition upgrade to a separate time might reduce the risk and time pressure. The index upgrade is the least time-consuming and is easily performed overnight even on a large database. Partitioning is more time-consuming and, while it can easily be accomplished over a weekend on even the largest Oracle Clinical database, it needs more careful advanced planning.

If you decide to defer both partitioning and the index upgrade, you can force Oracle Clinical to continue to create validation and derivation procedures and data extract views that are optimized for the pre-4.0-style index structure (see "[Enforcing Pre-Version 4.0 Optimization](#)" on page 9-3).

The upgrade for Responsest should be done at the same time as either partitioning or the Responses table index upgrade.

The index upgrade steps are documented in the "[Upgrading Indexes](#)" section on page 9-17. This upgrade can be done at any time that is convenient.

Figure 9-1 Partitioning and Indexing Decision Paths



Enforcing Pre-Version 4.0 Optimization

If you decide to postpone both the partitioning and indexing upgrades, you can force Oracle Clinical to continue to create validation and derivation procedures and data extract views that are optimized for the pre-4.0-style index structure.

You do this by inserting a record in the local OCL_STATE reference codelist with the short value of USE_RESP_DCMQG and a long value of YES.

Later, when you are ready to convert to the new index scheme or partitioning, change the long value to NO before you regenerate views and procedures. The absence of an entry is equivalent to NO.

About Partitioning

Partitioning is an Oracle database capability that allows you to divide a single Oracle table into separate physical partitions, each with its own storage characteristics. The indexes on a table can be partitioned as well. When a table is partitioned, each partition functions physically like a separate table while the table, as a whole, can still be treated as a single table for purposes of data access through SQL. Partitions can be managed like independent tables. They can be reorganized, imported, exported, taken off line and even dropped.

This section provides an overview of partitioning as it has been used for the Responses table in Oracle Clinical. For complete information on partitioning, see the Oracle *Concepts* manual and *Administrator's Guide*.

How Has the Responses Table Been Partitioned?

The response table is range partitioned on `clinical_study_id`. This means that the data is placed into partitions based upon ranges of the internal `clinical_study_id` identifier. The two remaining indexes on the Responses table are equipartitioned with the Responses table on `clinical_study_id`. This means they share the same partitioning scheme as defined for the Responses table. This equipartitioning guarantees partition independence, that is, operations on one partition or its indexes do not affect any other partition or its indexes. Equipartitioning also means that the index partitions are automatically maintained during most partition maintenance operations on the Response table partitions. It is important to note that the Response table partitions and the index partitions have separate storage specifications, so it is still possible to place the index partitions on separate tablespace/physical devices from the table partitions.

Why Partition?

In Oracle Clinical Version 3.1, the Responses table together with its indexes is 20 times larger than the next largest table, Received DCMs. Partitioning the Responses table and reorganizing the indexes accomplish a number of goals:

- [Improves Database and System Management](#)
- [Removes Single Point of Failure](#)
- [Improves Performance](#)
- [Reduces Space Requirements](#)

Improves Database and System Management Partitioning improves database and system management in several ways. First, by dividing the Responses table into many physical segments, you can manage the physical growth and structure of the table at a finer level of granularity. Individual partition segments can be rebuilt independently to consolidate space and improve performance. Partition segments can be placed on separate tablespaces on separate physical devices to improve performance; for example, by moving studies that will be used for intensive reporting onto separate disks from studies with active entry. Studies that are no longer active can be periodically moved to a read-only tablespace on a physical device that need only be backed up after the periodic maintenance and not as part of nightly backups. Similarly, if table export is used as a backup mechanism, only active partitions need to be exported.

Removes Single Point of Failure Prior to partitioning, a single bad index block would require rebuilding the entire index and a bad data block might require rebuilding the entire responses table. Since all of the partitioned indexes are local indexes, with partitioning, a bad index only affects the particular partition and a bad data block only requires the rebuild of that particular partition; the remaining partitions can remain in use while the one with problems is restored.

Improves Performance Both transactional and retrieval performance are improved by partitioning. Transactional performance is improved in two ways: by reducing contention for the data associated with a particular study and reducing transaction overhead. Contention is reduced by distributing inserts, updates, and deletes over different data blocks for each study and by allowing data blocks that are actively being accessed for reporting to be separated from those that are actively being modified by data entry.

Retrieval performance is improved in two ways as well: by physically grouping study data and by allowing physical reorganization on a study basis. By allowing data for each study to be stored their own data and index blocks instead of interspersed with data from many other studies, retrieval by study performs significantly less disk I/O and, in fact, a study can usually be buffered entirely in the SGA. This can produce dramatically improved extract view performance. In addition, when a study is about to be heavily accessed for reporting, the particular partition can be reorganized to consolidate space used by the index and data blocks, thus reducing I/O, and even to place the partition on a separate, perhaps faster, physical device to optimize access.

Reduces Space Requirements The most dramatic reduction in space requirements comes from the re-optimization of Oracle Clinical to do away with the need for three of the indexes on the Responses table. Combined with the Oracle database leading key compression on one of the remaining indexes, this drops the space required by the Responses table and its indexes by over 50%. This benefit can be realized whether or not you partition the Responses table. In addition, the ability to rebuild partitions individually means that space can be recovered from partitions that are no longer being modified by rebuilding them with reduced free space. Since freshly rebuilt indexes are frequently two-thirds the size of an actively growing index, and the free space requirement can be reduced by 10%, the net improvement over time could be an additional 30-40% reduction in space requirements.

Planning for Partitioning Upgrade

Before partitioning the Responses table you must decide how you want to partition it, both initially and on an ongoing basis. To do this, you need to understand how the partitioning is implemented and how this impacts your partition strategy.

Oracle recommends that you place all but the smallest active studies in separate partitions. Small studies that happen to have contiguous `clinical_study_ids` can share a single partition without impacting performance significantly. Inactive studies with contiguous `clinical_study_ids` can be merged into a single partition (see ["Using Read-Only Partitions to Minimize Backup"](#) on page 9-17).

Other partitioning schemes are possible and give differing degrees of performance and problem isolation benefits. One alternate approach is to segment the table into larger partitions that loosely correspond to time-slices based upon sequential `clinical_study_id` allocation. This approach minimizes partition maintenance and gives some problem isolation benefit, but is not likely to give much performance benefit because active studies will tend to share the same partitions.

Pre-upgrade Steps

To assist in the planning process, Oracle Clinical includes several listings and utilities to create the initial partitioning structure. A forms-based user interface is used to perform the actual partition definition prior to generating the partitioned Response table creation script.

Decide Partitions Needed

The following SQL statement provides a listing of all studies with data, the number of responses per study, the most recent response creation in the study, and the flag that indicates whether the study is frozen:

```
SELECT /*+ ordered */ cs.study, cs.clinical_study_id, css.frozen_flag,
        a.resp_count, a.max_date
FROM
    (SELECT count(*) resp_count, clinical_study_id,
        to_char(max(response_entry_ts), 'DD-MON-YYYY') max_date
    FROM responses
    GROUP BY clinical_study_id ORDER BY clinical_study_id) a,
    clinical_studies cs,
    clinical_study_states css
WHERE a.clinical_study_id = cs.clinical_study_id
    AND cs.clinical_study_id = css.clinical_study_id
    AND css.current_flag = 'Y'
ORDER BY clinical_study_id
```

Analyze the resulting list to determine which ranges of `clinical_study_id` can be combined into single partitions and which should be in their own partition. Among the issues to consider are:

1. Identify studies that will never have changes to their data and that are unlikely to have intensive reporting requirements in the future (see ["Using Read-Only Partitions to Minimize Backup"](#) on page 9-17).

Action: Consolidate as much as possible and locate in read-only tablespace (see ["Using Read-Only Partitions to Minimize Backup"](#) on page 9-17).

2. Identify studies that are complete, but may have continued reporting requirements.

Action: Keep in separate partitions, as appropriate by size, but allocate minimal free space. Consider placing tablespace on fast storage devices.

3. Identify contiguous ranges of small studies that will not grow to be large studies.

Action: Consider consolidating into single partitions. This is especially relevant if there are studies that were created but will never contain data.

Define Partition Structure

Once you are prepared to define the initial partition structure, you use the following script to populate the actual table:

```
SQL> @populate_part_map_table.sql log_file_name.log
```

This script populates the mapping table with one row per study with storage clauses based upon the number of responses. The storage clauses are designed to result in a range of 1 to 15 extents for a given table size.

Table 9–1 Default Storage for Oracle Clinical Responses Partitions

Partition Size	Max Responses	Table Extent Size	Index Extent Size
Very Small	<10K	256K	128K
Small	<50K	512K	256K
Medium	<100K	1M	512K
Large	<500K	4M	2M
Very Large	500K+	16M	8M

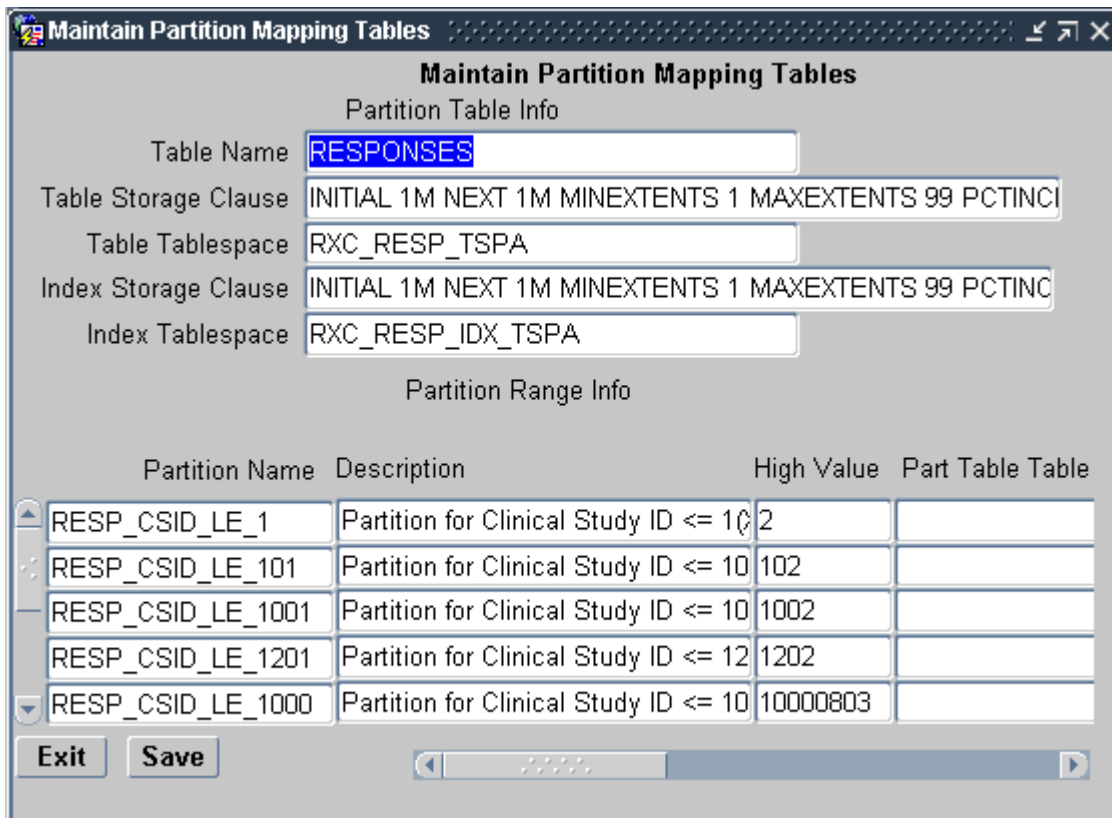
Implement Partition Structure

Once you have executed the script, you can use the Maintain Partition Mapping Tables form, shown in [Figure 9–2](#) (navigate to **Admin**, then **Partition Admin**), to implement the partitioning scheme determined above.

Note: You always specify the maximum `clinical_study_id` included in a partition. The minimum is implicitly one more than the maximum of the previous partition.

You can delete rows to merge partitions. You can edit the storage clauses to reflect consolidation or to adjust the storage because you are aware of factors that affect the size, such as planned rapid growth of a partition. Bear in mind that you can always rebuild a partition later, independent of the upgrade process.

Figure 9–2 Maintain Partition Mapping Tables Window



Generating Table and Index Creation SQL

Once you have completed modifying the partition mapping, you use the script:

```
SQL> @gen_create_part_table.sql part_table_ddl.sql
```

to generate the partitioned table creation script (see [Example 9-1](#)) and:

```
SQL> @gen_create_part_index.sql part_index_ddl.sql
```

to generate a creation script for both partitioned indexes (see [Example 9-2](#) and [Example 9-3](#)). Note that the CREATE statement for RESPONSE_RDCM_NFK_ID uses the *index* tablespace but the *table* storage clause (see "[Sample Responses Foreign Key Index Creation Statement](#)" on page 9-9), because this large concatenated index is approximately 70-80% as large as the data segment while RESPONSE_PK_IDX is 40-50% as large.

Example 9-1 Sample Responses Table Creation Statement

```
CREATE TABLE RESPONSES (
RESPONSE_ID                NUMBER(10,0)                NOT NULL
, RESPONSE_ENTRY_TS        DATE                        NOT NULL
, ENTERED_BY               VARCHAR2(30)              NOT NULL
, RECEIVED_DCM_ID         NUMBER(10,0)              NOT NULL
, DCM_QUESTION_ID         NUMBER(10,0)              NOT NULL
, DCM_QUESTION_GROUP_ID   NUMBER(10,0)              NOT NULL
, CLINICAL_STUDY_ID       NUMBER(10,0)              NOT NULL
, REPEAT_SN               NUMBER(3,0)                NOT NULL
, END_TS                  DATE                        NOT NULL
, VALIDATION_STATUS       VARCHAR2(3)                DEFAULT 'NNN' NOT NULL
, SECOND_PASS_INDICATOR   VARCHAR2(1)                NULL
, VALUE_TEXT              VARCHAR2(200)              NULL
, DISCREPANCY_INDICATOR   VARCHAR2(1)                NULL
, DATA_CHANGE_REASON_TYPE_CODE VARCHAR2(15)         NULL
, DATA_COMMENT_TEXT      VARCHAR2(200)              NULL
, AUDIT_COMMENT_TEXT      VARCHAR2(200)              NULL
, EXCEPTION_VALUE_TEXT    VARCHAR2(200)              NULL)
TABLESPACE RXC_RESP_TSPA
STORAGE (INITIAL 1M NEXT 1M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
PARTITION BY RANGE (CLINICAL_STUDY_ID) (
PARTITION RESP_CSID_LE_1 VALUES LESS THAN (2)
STORAGE (INITIAL 512K NEXT 512K MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_101 VALUES LESS THAN (102)
STORAGE (INITIAL 1M NEXT 1M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_1001 VALUES LESS THAN (1002)
STORAGE (INITIAL 1M NEXT 1M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_1201 VALUES LESS THAN (1202)
STORAGE (INITIAL 4M NEXT 4M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_10000802 VALUES LESS THAN (10000803)
STORAGE (INITIAL 16M NEXT 16M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_10001202 VALUES LESS THAN (10001203)
...
...
, PARTITION RESP_CSID_LE_10242201 VALUES LESS THAN (10242202)
STORAGE (INITIAL 256K NEXT 256K MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_9999999998 VALUES LESS THAN (9999999999)
STORAGE (INITIAL 1M NEXT 1M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
) ENABLE ROW MOVEMENT;
```

Example 9–2 Sample Responses Primary Key Index Creation Script

```

CREATE UNIQUE INDEX RESPONSE_PK_IDX ON RESPONSES (
RESPONSE_ID, RESPONSE_ENTRY_TS, CLINICAL_STUDY_ID)
TABLESPACE RXC_RESP_IDX_TSPA
COMPUTE STATISTICS
NOLOGGING
STORAGE (INITIAL 1M NEXT 1M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
LOCAL (
PARTITION RESP_CSID_LE_1
STORAGE (INITIAL 256K NEXT 256K MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_101
STORAGE (INITIAL 512K NEXT 512K MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_1001
STORAGE (INITIAL 512K NEXT 512K MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_1201
STORAGE (INITIAL 2M NEXT 2M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
...
...
, PARTITION RESP_CSID_LE_10242201
STORAGE (INITIAL 128K NEXT 128K MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_999999998
STORAGE (INITIAL 512K NEXT 512K MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
)
;

```

Once these scripts are generated you should review them and manually make any changes that can not be made through the Maintain Partition Mapping Table form. For instance, if you want to modify the percent free default, for the table as a whole or for particular partitions, you must currently do this by editing the generated creation script. The script generation currently ignores the partition-specific tablespace specification, so you must manually amend the scripts to add this after the partition name and before the storage clause if you want to place a partition in a tablespace other than the one specified for the table or index as a whole.

In addition, you should amend the index creation scripts to add the clauses **COMPUTE STATISTICS** and **NOLOGGING** at the position indicated in **bold** in Examples 9–2 and 9–3. **COMPUTE STATISTICS** allows the cost-based statistics to be computed as the new indexes are created and avoids the time-consuming extra step of separately computing the statistics. **NOLOGGING** avoids the overhead of writing to the Oracle redo log file, which is unnecessary since the database will be backed up after the upgrade (see "[Step 6. Create Indexes on Partitioned Responses Table](#)" on page 9-12 and "[Maintenance of Cost-Based Statistics](#)" on page 9-15).

Example 9–3 Sample Responses Foreign Key Index Creation Statement

```

CREATE INDEX RESPONSE_RDCM_NFK_IDX ON RESPONSES (
CLINICAL_STUDY_ID, RECEIVED_DCM_ID, DCM_QUESTION_GROUP_ID, DCM_QUESTION_ID,
END_TS, RESPONSE_ENTRY_TS, REPEAT_SN, RESPONSE_ID,
VALUE_TEXT, VALIDATION_STATUS, EXCEPTION_VALUE_TEXT, DATA_COMMENT_TEXT)
TABLESPACE RXC_RESP_IDX_TSPA
COMPUTE STATISTICS
NOLOGGING
STORAGE (INITIAL 1M NEXT 1M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
COMPRESS 6
LOCAL (
PARTITION RESP_CSID_LE_1
STORAGE (INITIAL 512K NEXT 512K MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_101
STORAGE (INITIAL 1M NEXT 1M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_1001

```

```
STORAGE (INITIAL 1M NEXT 1M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_1201
STORAGE (INITIAL 4M NEXT 4M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_10000802
STORAGE (INITIAL 16M NEXT 16M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
...
...
, PARTITION RESP_CSID_LE_10242201
STORAGE (INITIAL 256K NEXT 256K MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
, PARTITION RESP_CSID_LE_999999998
STORAGE (INITIAL 1M NEXT 1M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
)
;
```

Partitioning the Responses Table

Once you have prepared the partition table and index creation scripts, you are ready to perform the partition upgrade. The upgrade consists of the following steps:

1. [Back Up the Database.](#)
2. [Export the Responses Table.](#)
3. [Prepare the Database:](#)
 - a. [Drop Responses Table](#)
 - b. [Reorganize Tablespaces and System File Space](#)
 - c. [Create Partitioned Responses Table](#)
4. [Import Responses Data.](#)
5. [Compute Statistics on the Responses Table.](#)
6. [Compile Invalid Objects and, Optionally, Restore Database Trigger.](#)
7. [Back Up the Database](#) (can be deferred to after Step 8).
8. [Regenerate Procedures and Data Extract Views.](#)
9. [Back Up the Database.](#) (Optional, can be deferred to normal backup schedule.)

Note: Conduct all SQL activities while connected to the RXC account, from the tools directory for Oracle Clinical, unless otherwise specified.

Step 1. Back Up the Database

Since the upgrade process involves dropping and recreating the Responses table and since there is a finite chance that the export of the Responses table could be corrupted, Oracle highly recommends that you perform a full database backup before you start the upgrade.

Step 2. Export the Responses Table

The migration of data from the non-partitioned Responses table to a partitioned Responses table is done through the exporting of data into a dump file using the Oracle Export utility and then importing the data into the partitioned table using the Oracle Import utility. During this migration process the Responses table is not available to users.

The Export utility reads the data blocks or rows from non-partitioned Responses table and writes into a dump file (or files). It uses a parameter file `exp_resp_param.dat` which is shipped with Oracle Clinical and located in the tools directory. The DBA in charge of migration at your location should review and make any changes to the parameters they feel are required.

Please note that by default the export includes grants on the Responses table and that the import restores these grants. The upgrade process relies upon this to restore the grants on the newly reconstructed Responses table, so you should not modify the export or import to exclude grants.

```
exp rxc/password parfile=exp_resp_param.dat
```

The `exp_resp_param.dat` file contains the following information:

```
FILE=responses1.dmp, responses2.dmp, responses3.dmp, responses4.dmp
FILESIZE=1G
DIRECT=Y
TABLES=(RXC.RESPONSES)
COMPRESS=y
CONSTRAINTS=N
INDEXES=N
LOG=exp_resp.log
#RECORDLENGTH=64K
STATISTICS=none
```

FILE The names of the files to create. Use multiple files, as shown, but extend or shorten this list to handle the maximum estimated size of your exported database.

FILESIZE As a rough guideline, test exports of a multi-gigabyte Responses table resulted in a total export size approximately 130% of the size of the unpartitioned Responses table's data segment. For full information on Export and its parameters, see the *Oracle Utilities* manual.

Step 3. Prepare the Database

Prior to creating the new Responses table, you should consider restarting the database specifying `NOARCHIVELOG`. Since you will back up the database at the completion of the upgrade and it is easier to restart a failed upgrade than to attempt to recover it from redo logs, there is no reason to pay the overhead of archiving the redo logs.

Drop Responses Table

Drop the existing, unpartitioned Responses table and its indexes:

```
SQL> drop table responses;
```

Reorganize Tablespaces and System File Space

If you are changing the use of tablespaces, for instance, to allocate different partitions to different tablespaces, you might want to drop the existing `RXC_RESP_TSPA` and `RXC_RESP_IDX_TSPA` and associated database files and recreate the new tablespace structure for the partitioned response table and indexes. This is not required, however.

Create Partitioned Responses Table

Create an empty partitioned Responses table by executing the table creation script generated earlier (see [Example 9-1, "Sample Responses Table Creation Statement"](#) on page 9-8). Do not create the indexes.

```
SQL> @part_table_ddl.sql
```

Step 4. Import Responses Data

The Import utility reads the dump file (or files) created by the export step and populates the partitioned Responses table. It uses a parameter file `imp_resp_param.dat` which is shipped with Oracle Clinical and located in the tools directory. The DBA in charge of migration at your location should review and make any changes to the parameters which they feel are required.

```
imp rxc/password PARFILE=imp_resp_param.dat
```

The `imp_resp_param.dat` file contains the following information:

```
FILE=responses1.dmp, responses2.dmp, responses3.dmp
FILESIZE=1G
IGNORE=Y
ANALYZE=N
#BUFFER
COMMIT=Y
TABLES=RESPONSES
INDEXES=N
LOG=imp_resp.log
#RECORDLENGTH
ANALYZE=N
```

FILE The names of the files to create. Make sure you edit this list to match the files created by the Export.

For full information on Import and its parameters, see the *Oracle Utilities* manual.

Step 5. Compute Statistics on the Responses Table

Once the import completes successfully, you should compute the statistics that are used by the cost-based optimizer by executing the ANALYZE command:

```
SQL> analyze table responses compute statistics;
```

While you can perform the analyze step with a small sample size, as illustrated below, the time saved here is relatively small. Because the indexes do not yet exist, the entire ANALYZE is performed by full scans of each partition, which are very efficient.

```
SQL> analyze table responses estimate statistics sample 5 percent;
```

See "[Strategy for Ongoing Partition Maintenance](#)" on page 9-14 for a discussion of the ongoing maintenance of cost-based statistics.

Step 6. Create Indexes on Partitioned Responses Table

Before creating the indexes on the Responses table, amend the index creation script to add the clauses COMPUTE STATISTICS and NOLOGGING, as shown in Examples 9-2 and 9-3, above.

Create the indexes by executing the index creation scripts generated and edited earlier (see "[Generating Table and Index Creation SQL](#)" on page 9-8).

```
SQL> @part_index_ddl.sql
```

These scripts take significant time to execute, proportionate to the size of the Responses table. You can monitor progress by querying the USER_SEGMENTS dictionary view from the RXC account because each index partition is committed separately.

Step 7. Compile Invalid Objects and, Optionally, Restore Database Trigger

Dropping and recreating Responses invalidates some packages and views. Execute the script `compile_all_invalid.sql` to compile all invalid objects in the database.

To run the `compile_all_invalid.sql` script:

1. Set up the environment to point to the correct database and code environment.
2. `cd $RXC_INSTALL`
3. Open a SQL*Plus session as system.
4. Run `compile_all_invalid.sql`:

```
SQL> start compile_all_invalid.sql
```

If you use pre-version 3.1 procedures and replicate study data using a database trigger on the Responses table to ensure that certain data changes occurring during batch validation are replicated, then execute the script `respdrig.sql` in the `install` directory.

```
SQL> @respdrig.sql
```

Step 8. Back Up the Database

After the upgrade is complete, perform your normal full database backup. Re-enable redo log archiving before releasing Oracle Clinical for production use. This backup is mandatory because logging was disabled during the index rebuild and archive logging disabled during the import. You can wait until after Step 8, if you do that immediately after Step 6 and before production use of the database.

Step 9. Regenerate Procedures and Data Extract Views

Once the Response table is partitioned, you must regenerate all procedures and data extract views for active studies. If you have disabled the generation of Version 4-style procedure and view optimization (see "[Enforcing Pre-Version 4.0 Optimization](#)" on page 9-3), you must enable it before regenerating procedures and views.

To regenerate procedures and views, follow the instructions in [Chapter 10, "Utilities"](#). For procedure regeneration you should select the parameters `FULL`, `GENERATE` and `ALL`. Note that in Releases 4.0 and above, procedure regeneration with `GENERATE` no longer causes discrepancies to be closed and reopened.

Step 10. Back Up the Database

If you performed Step 7, you can defer this backup to your normal schedule.

If you skipped Step 7, do a full backup now. Remember to re-enable redo log archiving before releasing Oracle Clinical for production use.

Partition Maintenance

This section includes the following topics:

- [Prospective Allocation of `clinical_study_ids` for Partitioning](#)
- [Strategy for Ongoing Partition Maintenance](#)
- [Instructions for Partition Maintenance](#)
- [Rebuild Indexes after Partition Maintenance](#)

- [Using Read-Only Partitions to Minimize Backup](#)

Prospective Allocation of clinical_study_ids for Partitioning

1. Ensure that distributed studies do not intersperse clinical_study_ids arbitrarily.

If you intend to collapse studies into single partitions or to consolidate dormant studies into read-only partitions, you must ensure that new studies do not get created whose clinical_study_ids lie between existing studies. This can occur in distributed installations of Oracle Clinical when studies are created at multiple locations using database seeds that differ only in their trailing digits. To address this you should either share clinical_study_id sequence across locations by replicating OCL_STUDIES and creating studies centrally or, alternatively, you should ensure that sequences do not overlap by seeding at non-overlapping starting seed values, not just separate trailing digits. For instance, start location 1 at id 101 and location 2 at id 1000102 rather than 102.

2. Preallocate planned studies to achieve grouping of small studies.

If you want to consolidate small studies in single partitions, you should make sure that they have contiguous ranges. For instance, for a new project, create placeholder planned studies for all phase 1 and phase 2 studies so that they have contiguous ids. This allows them to be grouped into a single partition.

Strategy for Ongoing Partition Maintenance

There are three types of partition maintenance activities:

- Activities that rebuild partitions
- Activities that split or merge partitions
- Activities that change ongoing characteristics of partitions

Activities that rebuild partitions must be performed manually. These include rebuilding the indexes on a partition, moving the data in a partition to a different tablespace, and restructuring the data in a partition to reduce the number of extents or change the PCTFREE storage parameter. See the Oracle documentation for instructions on how to carry out these activities.

Oracle Clinical includes the partition mapping form (see "[Maintain Partition Mapping Tables Window](#)" on page 9-7) and a utility script generator that support SPLIT and MERGE operations and changes to ongoing storage characteristics.

Note that all SQL activities are carried out while connected to the RXC account.

Rebuild Partitions Periodically, at weekly or monthly intervals depending on growth rate, review the current partition growth by querying the USER_SEGMENTS view:

```
SQL> select segment_name, partition_name, extents
SQL> from user_segments
SQL> where extents > 20
SQL> and segment_name like 'RESPONSE%';
```

This shows you any partitions that might need to be rebuilt.

In addition, you might want to initiate a manual process for identifying studies that are about to enter periods of intense reporting. The partitions for these studies could then be rebuilt, both to coalesce index space by rebuilding the indexes and, perhaps, to decrease the PCTFREE storage parameter if data is no longer changing.

See [Example 9-6](#) for instructions on rebuilding partition indexes.

Managing New Studies Unless there is a study that will grow extremely rapidly, for instance, due to batch loading, there is no need to anticipate the creation of studies and preallocate their partitions. Since new studies are created with incrementally higher `clinical_study_ids`, they are automatically added to the maximum partition. As long as this partition has a storage clause with large enough space allocations, these studies can start there without significant performance impact. At planned intervals you should review this partition to determine how these studies should be partitioned and use the partition maintenance script ("[Instructions for Partition Maintenance](#)" on page 9-16) to split out the new partitions.

Use the script `list_study_resp_cnt_part.sql` to obtain a count by study of studies in a particular partition:

```
list_study_resp_cnt_part.sql partition_name spool_file_name
```

The following example lists the studies in the last partition, that is, the new ones:

```
SQL>@list_study_resp_cnt_part.sql RESP_CSID_LE_999999998 new_studies.lis
```

Reviewing for Partitions that Need Splitting or Merging As with new studies, existing partitions that contain multiple studies should be periodically reviewed and split as needed.

You may also want to merge partitions for studies that become inactive or that did not grow as planned. In particular, you might want to use the approach of using read-only tablespaces for inactive studies discussed in "[Using Read-Only Partitions to Minimize Backup](#)" on page 9-17.

Maintenance of Cost-Based Statistics Whenever a partition is merged or split, or when the data volume in a partition has changed significantly, the cost-based statistics for that partition need to be refreshed. The command to refresh the statistics for a partition is:

```
ANALYZE TABLE Responses PARTITION (partition_name) COMPUTE STATISTICS;
```

If the partition is large, you can use the statistics estimation with a small sample size. However, since you do not need to analyze the whole table, but just partitions with changes, this may no longer be necessary:

```
SQL> analyze table responses partition (partition_name)
SQL> estimate statistics sample 5 percent;
```

One approach to maintaining the statistics is to use a table to hold the partition statistics from the previous partition maintenance and then drive the creation of the analyze statements from that table and the current statistics. The code fragment in [Example 9-4](#) illustrates this approach. It triggers the ANALYZE when the data volume in a partition increases by more than 50%.

Example 9-4 Using a Table to Compute Statistics

```
CREATE TABLE resp_part AS
  SELECT partition_name, bytes
  FROM user_segments
  WHERE segment_name = 'RESPONSES';

spool analyze_responses.sql

SELECT 'ANALYZE TABLE RESPONSES PARTITION ('||
      u.partition_name||') COMPUTE STATISTICS'
  FROM resp_part r, user_segments u
  WHERE u.segment_name = 'RESPONSES'
  AND u.partition_name = r.partition_name
```

```
        AND u.bytes/1.5 > r.bytes
    UNION ALL
    SELECT 'ANALYZE TABLE RESPONSES PARTITION ('||
    u.partition_name||') COMPUTE STATISTICS'
    FROM user_segments u
    WHERE u.segment_name = 'RESPONSES'
    AND not exists (select null from resp_part r
        where r.partition_name = u.partition_name)
```

Instructions for Partition Maintenance

When you determine that you need to merge or split partitions, first use the Maintain Partition Mapping form (see [Figure 9-2](#) on page 9-7). Insert records for partitions that are to be split or delete records for partitions that are to be merged. You can also alter the storage clauses for partitions, although this affects only new storage allocations — it does not rebuild the existing partition space.

You then use the utility script `gen_alter_partition.sql` to generate the SQL partition maintenance commands.

`gen_alter_partition output_file.sql`

For example:

```
SQL> @gen_alter_partition.sql alter.sql
```

The generation script compares the partition definition in the Oracle Clinical Partition Mapping table with the actual partition structure in the database. It then generates the SQL DDL statements to merge or split the partitions and to alter the storage clauses (see [Example 9-5](#)).

You should review the generated script and make any necessary modifications before you run it.

Example 9-5 Sample Output from the Partition Maintenance Script

```
REM Split case 4: Split RESP_CSID_LE_10002201 into RESP_CSID_LE_10001901 at 10001902
ALTER TABLE responses SPLIT PARTITION RESP_CSID_LE_10002201 AT (10001902) INTO
(PARTITION RESP_CSID_LE_10001901 , PARTITION RESP_CSID_LE_10002201
STORAGE (INITIAL 4M NEXT 4M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
);
ALTER INDEX RESPONSE_PK_IDX MODIFY PARTITION RESP_CSID_LE_10001901
STORAGE (NEXT 2M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
;
ALTER INDEX RESPONSE_RDCM_NFK_IDX MODIFY PARTITION RESP_CSID_LE_10001901
STORAGE (NEXT 4M MINEXTENTS 1 MAXEXTENTS 99 PCTINCREASE 0)
;
REM Merge case 2: Merge RESP_CSID_LE_10001102 into RESP_CSID_LE_10001202
ALTER TABLE responses MERGE PARTITIONS RESP_CSID_LE_10001102,
RESP_CSID_LE_10001202 INTO PARTITION
RESP_CSID_LE_10001202;
REM Merge case 2: Merge RESP_CSID_LE_10001101 into RESP_CSID_LE_10001202
ALTER TABLE responses MERGE PARTITIONS RESP_CSID_LE_10001101,
RESP_CSID_LE_10001202 INTO PARTITION
RESP_CSID_LE_10001202;
```

Rebuild Indexes after Partition Maintenance

After you run the partition maintenance script (see [Example 9-5](#)), some of the associated index partitions may be unusable. Use the SQL code shown in [Example 9-6](#) to detect the affected partitions. It generates a script (rebuild.sql) that you run to rebuild the index partitions.

Example 9-6 SQL Code for Rebuilding Index Partitions

```
set pagesize 1000
set verify off
set feedback off
set heading off
spool rebuild.sql
select distinct 'ALTER TABLE RESPONSES MODIFY PARTITION '|| partition_name||'
REBUILD UNUSABLE LOCAL INDEXES
/'
from all_ind_partitions
where index_name in ('RESPONSE_PK_IDX', 'RESPONSE_RDCM_NFK_IDX')
and status = 'UNUSABLE'
/
spool off
set verify on
set feedback on
set heading on
```

Using Read-Only Partitions to Minimize Backup

Oracle enables you to designate tablespaces as read-only. If a tablespace is designated read-only, any attempt to modify data in that tablespace causes an Oracle error. Since the tablespace can not be modified, it can be created using data files on a separate physical device that only needs to be backed-up after maintenance activity during which the tablespace is modifiable. Over time, a significant portion of the Responses table data volume could be migrated to such read-only tablespaces, dramatically reducing the data volume that needs to be backed up by nightly backups.

To implement this strategy, you would set up the tablespace using data files on a separate physical device. A manual process of identifying studies that will no longer have modifications must be implemented. At periodic intervals, quarterly or semi-annually, you would perform partition maintenance to rebuild the partitions for those studies. During the maintenance, you alter the tablespace to make it writable. You move the data by exporting the partition, dropping the partition, and recreating the partition using the new tablespace. Once all studies have been moved, you alter the tablespace to be read-only once again and perform a backup of the device.

Upgrading Indexes

Oracle Clinical has been retuned to require only two indexes on the Responses table:

- RESPONSE_PK_IDX – primary key index on RESPONSE_ID and RESPONSE_ENTRY_TS
- RESPONSE_RDCM_NFK_IDX – an expanded, concatenated index on RECEIVED_DCM_ID

The following indexes are no longer required:

- RESPONSE_CS_NFK_IDX – on CLINICAL_STUDY_ID
- RESPONSE_DCMQG_NFK_IDX – on DCM_QUESTION_GROUP_ID

- RESPONSE_UK_IDX – on DCM_QUESTION_ID

This, combined with the use of Oracle database leading key compression, results in up to 50% savings in space allocated to the Responses table and its indexes, and a significant reduction in runtime overhead to maintain the indexes. These savings occur whether you partition or not.

Index Upgrade Process

To upgrade the indexes you must modify and execute the script `rebuild_resp_index_non_part.sql` in the install directory while connected to the RXC account. You should modify the script to provide storage parameters appropriate for the size of your Responses table. The foreign key index is approximately 70% the size of the Responses table when created and the primary key index is approximately 40%. In addition, if you are dropping the obsolete indexes, you should un-comment the drop index statements and move them to before the index creation statements to ensure that their space is freed before the new indexes are created.

```
SQL> @rebuild_resp_index_non_part.sql
```

Resizing the Storage Clause for Indexes

If you upgraded without resizing (redefining) the storage clause of indexes using `ocl46indexchg.sql`, you can do it at any time by manually running the script. Modifying these indexes improves performance in queries executed from the RDC application.

To run `ocl46indexchg.sql` in UNIX, from the command line, enter:

```
opa_setup database 46
cd $RXC_INSTALL
sqlplus /nolog @ocl46indexchg.sql
```

To run `ocl46indexchg.sql` in Windows, from the command line, enter:

```
set p1=database
set p2=46
opa_setup
cd %RXC_INSTALL%
sqlplus /nolog @ocl46indexchg.sql
```

Note: Resizing the storage clause and running the script is an optional step in every upgrade path, including from 4.5.2 to 4.5.3, so you may not have done it yet.

Response Index Upgrade

If you have other applications that directly access the Responses table, these may need to be retuned before you perform the index upgrade (due to the new leading CLINICAL_STUDY_ID key on the RESPONSE_RDCM_NFK_IDX) or before you drop the optional indexes (see "[Query Tuning Guidelines](#)" on page 9-20). If you are not partitioning you can retain one or more of these indexes until your other applications are retuned.

Note: If you are partitioning, the new index structure is automatically created as part of the partitioning upgrade, so you should not do the upgrade described in this section.

If you are partitioning and want to retain one or more of the old indexes, you have to manually recreate them as non-partitioned global indexes after the partitioning upgrade.

Before upgrading the indexes, you must analyze your disk space requirements if you are preserving the existing indexes. Due to leading key compression the new, concatenated RESPONSE_RDCM_NFK_IDX index is significantly smaller than the version 3.1 concatenated RESPONSE_DCMQG_NFK_IDX it functionally replaces. However, if you are preserving all pre-existing indexes, there is a small (20-30%) net increase in the size of the pre-existing RESPONSE_RDCM_NFK_IDX. Dropping any of the pre-existing indexes, including the largely superfluous RESPONSE_CS_NFK_IDX, releases at least that amount of space.

Even if you are not preserving existing indexes, since you will be dropping and recreating all of the indexes, the index upgrade is a good time to replan the use of physical storage for the Response table indexes. Placing the indexes on a tablespace on a separate physical device from the Responses table is a good practice.

Regenerate Procedures and Data Extract Views

Once the Response table indexes are rebuilt, you must regenerate all procedures and data extract views for active studies. If you have disabled the generation of Version 4-style procedure and view optimization (see "[Enforcing Pre-Version 4.0 Optimization](#)" on page 9-3), you must enable it before regenerating procedures and views.

To regenerate procedures and views, follow the instructions for using the procedure and view regeneration utilities documented in [Chapter 10, "Utilities"](#). For procedure regeneration you should select the parameters FULL, GENERATE and ALL.

ResponsesT (Test Database) Index Upgrade

A script, rebuild_respt_index.sql in the install directory, rebuilds the indexes on the ResponsesT, or test database Responses table. This script should be run whether or not you are partitioning the Responses table. The upgrade for ResponsesT should be done at the same time as either partitioning or the Responses table index upgrade.

RECEIVED_DCI and RECEIVED_DCM Index Upgrades

To take advantage of the Oracle index compression feature, you can optionally rebuild selected indexes on the RECEIVED_DCMs and RECEIVED_DCIs tables. Since these can be large tables, this script is not automatically run as part of the upgrade to Oracle Clinical V4. The upgrade of the RECEIVED_DCMs and RECEIVED_DCIs indexes can be done at any time that is convenient, independently of either partitioning or Responses table index upgrade. This change reduces the size of these indexes and, therefore, improves performance due to fewer disk accesses.

To rebuild the indexes on the RECEIVED_DCMs and RECEIVED_DCIs tables, execute the script oclupg32to40opt5.sql in the install directory:

```
SQL> @oclupg32to40opt5.sql
```

Query Tuning Guidelines

For both partitioning and index upgrade, Oracle Clinical has been retuned to use only the primary key index `RESPONSES_PK_IDX` with the Response ID leading key or the concatenated `RESPONSES_RDCM_NFK_IDX` with the `clinical_study_id` and `RECEIVED_DCM_ID` leading keys. You should review any applications that directly access the Responses table to ensure that they are correctly optimized for the new index structure.

The basic guidelines for re-optimization are:

1. Include `clinical_study_id` in all access to the Responses table.

There are two reasons for this. Primarily, because Responses are in a partition based on `clinical_study_id`, the query optimizer can restrict its search to the proper partition if the query contains `clinical_study_id`. This is called 'Partition Pruning'. In order of preference this reference to `clinical_study_id` can be a constant, a bind variable in an equi-join, or a join from another table.

Secondly, the concatenated index is prefixed with `clinical_study_id` in order to force Responses from different studies in the same partition to be physically grouped together and to optimize certain partition accesses.

2. Redirect all previous queries on `DCM_QUESTION_ID` or `DCM_QUESTION_GROUP_ID` to use a join through `RECEIVED_DCMs` so that they can use the concatenated index.

Since there are no longer indexes with `DCM_QUESTION_ID` or `DCM_QUESTION_GROUP_ID` as leading keys, these are no longer efficient access paths. Much of the access involving these keys is already done in the context of a `RECEIVED_DCM`, so the query tuning is usually minimal. In some cases, it might be necessary to add joins to `DCM_QUESTIONS` or `DCM_QUESTION_GROUPS`, then through `RECEIVED_DCMs` via `DCM_ID`. For instance, the query shown in Examples 9-7 and 9-8 selects responses to a particular Question where the patient position is owned locally.

Example 9-7 Query Before Redirection

```
SELECT response_id, to_char(response_entry_ts, 'DD-MON-YYYY HH24:MI:SS'),
       received_dcm_id
FROM responses r
WHERE r.dcm_question_id = :dcm_question_id
      AND EXISTS
      (SELECT NULL FROM received_dcms rd, patient_positions papo
       WHERE rd.patient_position_id = papo.patient_position_id
            AND papo.owning_location = :current_location
            AND rd.received_dcm_id = r.received_dcm_id)
```

Example 9-8 Query After Redirection

```
SELECT response_id, to_char(response_entry_ts, 'DD-MON-YYYY HH24:MI:SS'),
       received_dcm_id
FROM responses r
WHERE r.dcm_question_id = :dcm_question_id
      AND
      (clinical_study_id, received_dcm_id, dcm_question_group_id) IN
      (SELECT rd.clinical_study_id, rd.received_dcm_id, dq.dcm_question_group_id
       FROM received_dcms rd, patient_positions papo, dcm_questions dq
       WHERE dq.dcm_question_id = :dcm_question_id
            AND dq.dcm_que_dcm_subset_sn = 1
            AND dq.dcm_que_dcm_layout_sn = 1)
```

```
AND rd.dcm_id = dq.dcm_id  
AND rd.patient_position_id = papo.patient_position_id  
AND papo.owning_location = :current_location)
```


Oracle Clinical provides a set of utilities for performing tasks that are easier to accomplish from a command line or that cannot be done from within the application. These utilities are described in this section. The activities covered by these utilities include:

- [Computing the Validation Status of All Responses](#) on page 10-1
- [Generating Validation Procedures](#) on page 10-2
- [Deleting Inactive Procedures](#) on page 10-4

Information on using data extract within the Oracle Clinical application is available in the *Oracle Clinical Creating a Study* and *Oracle Clinical Conducting a Study* manuals. Information on Procedures is also in *Oracle Clinical Creating a Study*.

Computing the Validation Status of All Responses

Use the `cnvstatus` utility to compute a validation status for all responses. The utility populates a column in the `RESPONSES` table that contains the validation status of each stored response. Before populating the response field `VALIDATION_STATUS`, you might want to add Discrepancy Resolution subtypes to distinguish various types of resolutions. You do this by entering values in the Long Value field of the reference codelist `DISCREPANCY RESOLU TYPE CODE`. This is an installation codelist you access from within Oracle Clinical which maintains user-defined discrepancy statuses.

You must select the values from the following list: `NULL`, `CONFIRMED`, `IRRESOLVABLE`, `SUPERSEDED`, or `NOT DISCREPANT`. The last two values are used only for manual discrepancies; they indicate that the discrepancy applied to a previous version of the response, or that the discrepancy was never really a problem with the data, but just a comment.

When the process is complete, examine the log, `$RXC_LOG/cnvstatus.log`, for errors.

Running `cnvstatus` on UNIX Platforms

To run `cnvstatus` on a UNIX platform:

1. Log on to the server in your user account and change the directory to `$RXC_TOOLS`.
2. Set the environment:

Shell	Command Sequence
C Shell	<code>opa_setup db_name code_env</code>

Shell	Command Sequence
Bourne	<pre>p1 = db_name p2 = code_env . opa_setup</pre>

where *db_name* is a database instance name and *code_env* is a code environment designation.

3. Set the output directory:

Shell	Command Sequence
C Shell	<pre>setenv RXC_LOG usr_log_dir</pre>
Bourne	<pre>RXC_LOG=usr_log_dir export code_env</pre>

4. Run the script. For example:

```
% cnvstatus ALL | Study Name
```

Where "ALL" is all studies in the database and *Study Name* is the name of one study.

Running cnvstatus on Windows

To run *cnvstatus* on Windows:

1. Log on to the server using your local account.
2. Open a DOS window, change directory to %RXC_TOOLS, and set the server environment:

```
set p1=db_name
set p2=code_env
opa_setup
```

3. Set the output directory:

```
set rxc_log=user_log_folder
```

4. Run the command file. For example:

```
cnvstatus ALL | Study Name
```

Where "ALL" is all studies in the database and *Study Name* is the name of one study.

Generating Validation Procedures

With the *gen_procs* utility you can convert existing Validation Procedures to 3.1-style, and regenerate them, on a per-study basis. Its use is not required, or necessarily recommended, for upgrades or new installations of Oracle Clinical.

This utility has the following syntax:

```
gen_procs { ALL | study_name } { FULL | INC } { CONVERT | GENERATE | PARSE } { 31 | 30 | ALL }
```

Choose one option from each set of qualifiers:

ALL | *study_name* — specifies the study you want to apply to. Enter either an individual study name or ALL to include all studies. This qualifier is not case-sensitive.

FULL | INC — specifies whether to perform full or incremental replication. You select FULL when running from the command line. INC is used when replication runs this command. This qualifier is case-sensitive.

CONVERT | GENERATE | PARSE — specifies the action you want to take. CONVERT works only for pre-3.1 Procedures; it converts the Procedure to 3.1-style, as well as generating and parsing as part of processing. PARSE works only with 3.1-style Procedures; it parses and recreates the package. GENERATE works for 3.0, 3.1, or ALL procedures; it also parses each package. PARSE and GENERATE are used primarily when the utility is called for replication.

31 | 30 | ALL — specifies the version of the Procedures to process.

The system creates a file named ora_errors.err in the user's RXC_LOG directory.

Running gen_procs on UNIX Systems

To run gen_procs on a UNIX platform, follow these steps:

1. Log on to the server as the opapps user or a user who has write permission.
2. Set the environment:

```
opa_setup db_name code_env
```

where *db_name* is a database instance name and *code_env* is a code environment designation.

3. Change the directory to \$RXC_TOOLS.
4. Set the output directory:

```
setenv RXC_LOG usr_log_dir
```

5. Run the script. For example:

```
gen_procs ALL FULL GENERATE ALL > gen_procs.log
```

Oracle Clinical creates gen_procs.log in \$RXC_TOOLS. Files ora_errors.err and genprocs.log are created in the RXC_LOG directory.

Running gen_procs on Windows Systems

To run gen_procs on Windows, follow these steps:

1. Log on to the server using your local account.
2. Open a DOS window and set the server environment. Enter:

```
set p1=db_name
```

```
set p2=code_env
```

```
opa_setup
```

```
cd /d %RXC_BIN%
```

3. Set the output directory:

```
set RXC_LOG=user_log_folder
```

4. Run the command file. For example:

```
gen_procs ALL FULL GENERATE ALL > gen_procs.log
```

Oracle Clinical creates genprocs.log in the current directory (%RXC_BIN%). Files ora_errors.err and genprocs.log are created in the RXC_LOG directory.

Deleting Inactive Procedures

Oracle Clinical lets you delete unneeded Procedures from within the application. However, this does not actually delete the database packages that contain the Procedures, which may cause unwanted Procedures to accumulate. To delete them, go to the RXC_TOOLS directory, log in as RXC_PD, and execute the SQL script rxcdelproc.

Setting Up File Viewing

You need to set up file viewing in Oracle Clinical so that users can:

- View report outputs and log files
- View log files from Parameterized Submission (PSUB) batch jobs
- View HTML previews of DCI Forms Layout definitions

This section contains the following topics:

- [File Viewing Setup Overview](#) on page 11-1
- [Editing formsweb.cfg to Change File Viewing Protocol](#) on page 11-2
- [Setting Directory Mappings](#) on page 11-2
- [Setting Up Image Viewing for DCI and DCM Form Layouts HTML Preview Feature](#) on page 11-3

File Viewing Setup Overview

To set up file viewing:

1. Install the Oracle RDBMS and specify the file viewing protocol you want to use: FTP, HTTP, HTTPS, or UNC; instructions are in the *Oracle Clinical Installation Guide*.
 - If your system uses a UNIX Database Server, we recommend that you choose FTP file viewing protocol. However, if your administration policies do not permit FTP use in your system, we recommend you choose HTTP.
 - If your system uses a Windows Database Server, we recommend that you choose the UNC file viewing protocol.
2. Complete the server setup required for the protocol you use:
 - For UNC, set up a shared directory on the database server that is accessible from your WAN.
 - For FTP, set up an FTP server on your database server.
 - For HTTP, setup an HTTP server on the database server.
3. Install the Oracle Clinical Reports Server and create a Reports Server root directory; instructions are in the *Oracle Clinical Installation Guide*.
4. Create one or more log directories for report outputs; see "[Setting Up a Report Server Log Directory](#)" on page 1-2.

5. Create one or more log directories for batch job (PSUB) outputs; see "[Creating a PSUB Log Directory](#)" on page 1-3.
For the UNC or HTTP file viewing protocol, setup the correct permissions. Refer to "[Creating a PSUB Log Directory](#)" on page 1-3.
6. Specify directory mappings in the "[Setting Directory Mappings](#)" section on page 11-2.
7. If you use a different file viewing protocol than the default for the operating system, modify the `formsweb.cfg` file to match the type of file viewing protocol you use. See "[Editing formsweb.cfg to Change File Viewing Protocol](#)" on page 11-2 for information.

Editing formsweb.cfg to Change File Viewing Protocol

If you use a different file viewing protocol than the default for the operating system, modify the `formsweb.cfg` file to match the type of file viewing protocol you use.

This file is located in the `ORACLE_AS10GR2MT_HOME\forms\server\` directory.

For example, to change configure the application server for a change from FTP to HTTP file viewing protocol, modify the `opa_file_viewing` parameter in `formsweb.cfg` from:

```
opa_file_viewing=PSUBMAP=FTP RSMAP=UNC
```

to:

```
opa_file_viewing=PSUBMAP=HTTP RSMAP=UNC
```

Note: The `RSMAP` setting does not affect file viewing.

Setting Directory Mappings

Use this form to map the PSUB log directory specified for each user to a format that can be used to enable the user to view PSUB output files on the database server. This task is required only if you are using HTTP or HTTPS. It is not necessary if you are using UNC or FTP.

To map file viewing specifications:

1. Navigate to **Admin**, then **Directory Mappings**, then **Directory Mappings**. The system opens the Maintain Directory Mappings window.
2. Execute Query (F8), to see all records.
3. In the **Mapping Code** field select the file viewing protocol you are using on the database server.

(You can add or remove values for this list of values in the [MAPPING_TYPE](#) installation reference codelist.)
4. In the **Original Directory** field, enter the root directory portion of the log directory for PSUB or the Reports Server, using the appropriate syntax for the operating system. See [Table 11-1, "UNIX Directory Mapping Example"](#) and [Table 11-2, "Windows Directory Mapping Example"](#).

5. In the **Mapped Directory** field, enter the UNC or the URL for the PSUB root directory. See [Table 11–1, "UNIX Directory Mapping Example"](#) and [Table 11–2, "Windows Directory Mapping Example"](#)

Table 11–1 UNIX Directory Mapping Example

Mapping Code	Original Directory	Mapped Directory	Where...
HTTP	user01/home/logs	http://www.pharma.com/oc_output	shared directory named oc_output

Table 11–2 Windows Directory Mapping Example

Mapping Code	Original Directory	Mapped Directory	Where...
HTTP	E:\opa\users	http://www.pharma.com/oc_output	shared directory name oc_output

Setting Up Image Viewing for DCI and DCM Form Layouts HTML Preview Feature

If your CRFs contain a company logo or other images and you want to be able to view the images using the HTML Preview feature of the Oracle Clinical DCI Forms Layout Editor, configure the J2EE application used in file viewing as follows:

1. Open the Windows Explorer on middle tier and navigate to *ORACLE_AS10GR2MT_HOME\j2ee\opa\application-deployments\ocrdclassic\ocrdclassic*
2. Take a backup of the file *orion-web.xml*.
3. Open the original version in WordPad or a text editor.
4. Insert the following lines.

```
<virtual-directory virtual-path="/crfimages" real-path="/Drive:/<image folder path>" />
```

For example, if your images folder is at *C:\opapps46\html\rdc\dcif_images*, the file would look like:

```
<?xml version="1.0"?>
<!DOCTYPE orion-web-app PUBLIC "-//ORACLE//DTD OC4J Web Application 9.04//EN"
"http://xmlns.oracle.com/ias/dtds/orion-web-9_04.dtd">

<orion-web-app deployment-version="10.1.2.3.0"
                jsp-cache-directory="./persistence"
                jsp-cache-tlds="on"
                temporary-directory="./temp">
    <!-- Uncomment this element to control web application class loader
behavior.
    <web-app-class-loader search-local-classes-first="true"
include-war-manifest-class-path="true" />
-->
    <virtual-directory virtual-path="/crfimages"
real-path="/C:\opapps46\html\rdc\dcif_images"/>
    <web-app></web-app>
</orion-web-app>
```

Note: *real-path* can be a network location. If it is, make sure that the Oracle Process Manager Service on the middle tier is started up as a user with access to the specified network location; see ["Setting Up a Network User to Run the Oracle Process Manager Service"](#) on page 12-2.

If you have configured your Oracle Clinical and RDC installations to use a single repository for all images (see ["Setting Up a Central Image Repository"](#) on page 12-1), make sure that the path is to that location.

5. Save and close the file.
6. Log in as the network account you set up to start the Oracle Process Manager Service.
7. Restart the RDC OC4J instance.

Enabling Image Viewing

This section contains the following topics:

- [Setting Up a Central Image Repository](#) on page 12-1—applies to RDC data entry and to Oracle Clinical DCI and DCM layout HTML previews
- [Copying Image Files to All Installations](#) on page 12-3—applies to RDC data entry only

To enable image viewing on CRFs during RDC data entry, you can choose either to set up a central repository or to copy images to all RDC Onsite installations.

Setting Up a Central Image Repository

You can configure your OC and RDC installations to use a single repository for all images. After the initial setup, this approach is more efficient because edited and added images do not need to be copied to all installations.

There are also disadvantages:

- If the share location goes down for any reason, none of the links to the shared directory will work. The applications should continue to run, but the images will not appear on the data entry CRF or in the layout editor HTML preview.
- If there is considerable network latency between the Oracle Clinical and RDC installations and the share location, performance may suffer.

To set up a single repository:

1. Create a shared directory on a computer that is accessible from all Oracle Clinical and RDC Onsite installations, and put the image files in the shared directory.
2. To use the central image repository in Oracle Clinical, add a line to orion-web.xml at each Oracle Clinical installation for virtual folder mapping to the central repository. See "[Setting Up Image Viewing for DCI and DCM Form Layouts HTML Preview Feature](#)" on page 11-3.
3. To use the central image repository in RDC Onsite during data entry, add a line to orion-web.xml at each RDC Onsite installation for virtual folder mapping to the central repository. See "[Setting Up Image Viewing During Data Entry](#)" on page 12-2.
4. Repeat Step 2 on every Oracle Clinical installation and repeat Step 3 on every RDC Onsite installation.

Setting Up a Network User to Run the Oracle Process Manager Service

On each Oracle Clinical and RDC installation, the Oracle Process Manager Service must be started up as a network user to allow access to shared image files on a network location.

1. Open Windows Service Manager.
2. Select **Oracle AS Process Manager**.
3. Right-click and select **Properties**.
4. Go to the **Log On** tab.
5. Select **This Account**.
6. Enter username/password of the network account and click **OK**.
7. Reboot the computer.

Setting Up Image Viewing During Data Entry

If your CRFs contain a company logo or other images and you want users to be able to see during data entry in RDC, configure the J2EE application used in file viewing as follows:

1. Open the Windows Explorer on middle tier and navigate to *ORACLE_AS10GR2MT_HOME\j2ee\rdc\application-deployments\olsardc\rdconsite\orion-web.xml*
2. Take a backup of the file *orion-web.xml*.
3. Open the original version in WordPad or a text editor.
4. Insert the following lines.

```
<virtual-directory virtual-path="/de/crffimages" real-path="<shared folder path>"/>
```

For example, if your images folder is at `\\sharemachine\images`, the file would look like:

```
<orion-web-app deployment-version="10.1.2.3.0"
    jsp-cache-directory="./persistence"
    jsp-cache-tlds="on"
    temporary-directory="./temp">
  <virtual-directory virtual-path="/de/crffimages"
real-path="\\sharemachine\images" />
  <!-- Uncomment this element to control web application class loader
behavior.
    <web-app-class-loader search-local-classes-first="true"
include-war-manifest-class-path="true" />
  -->
  <web-app></web-app>
</orion-web-app>
```

5. Save and close the file.
6. Log in as the network account you set up to start the Oracle Process Manager Service.
7. Restart the RDC OC4J instance.

Copying Image Files to All Installations

You can create an images directory at every RDC installation and copy all image files to each installation. If the images are updated or if new ones are added, you must copy them to all installations.

Create an images directory at the following location at each installation:

`ORACLE_AS10GR2MT_HOME\j2ee\rdc\applications\olsardc\rdconsite\de\crfimages`

Note: If you choose to copy files to all RDC installations, do not edit RDC Onsite's orion-web.xml file.

Part III

Appendixes

This section includes reference information.

- [Appendix A, "Environment Variables and Registry Settings"](#)
- [Appendix B, "SAS_VIEW Directory Tree"](#)
- [Appendix C, "Troubleshooting"](#)
- [Appendix D, "Oracle Clinical Tablespaces"](#)
- [Appendix E, "Routine Server Administration"](#)

Environment Variables and Registry Settings

This appendix describes the environment variables and registry settings that Oracle Clinical uses to condition the environment on compute servers, and to condition a user's interactive environment to point at a particular database and code environment. These variables are created as part of the Oracle Clinical installation process; most are also set to a default value. Information is provided here so that you can set them up and modify them, if necessary.

This section discusses and describes the following topics:

- [Summary of the Oracle Clinical Setup](#) on page A-1
- [Windows Registry Settings](#) on page A-10

Summary of the Oracle Clinical Setup

The Oracle Clinical server environment definition and setup system, known as opa_setup, consists of a set of scripts (on UNIX systems) or command files (on Windows systems).

The four types of setup files are:

- **Definition** – Edit this file, if necessary, to set or change values on a system-wide or database-specific level.
 - opa_settings – UNIX
 - opa_settings.bat – Windows
- **Initialization (login)** – This file is optional, edit it to set or change values for an individual user.
 - .profile – UNIX platforms, Bourne/Korn shells
 - .cshrc – UNIX platforms, C shell
 - .login – UNIX platforms, C shell
 - login.bat – Windows
- **Selection** – Run this file to choose a configuration from among those defined in the settings file.
 - opa_setup – UNIX platforms, Bourne/Korn shells
 - copa_setup – UNIX platforms, C shell
 - opa_setup.bat – Windows
- **Supplemental** – For compatibility with previous versions of Oracle Clinical; belongs in the user's home directory on the PSUB server machine.

- .oclr – UNIX platforms
- oclrc.bat – Windows

You can edit and maintain the Definition scripts for your installations. However, do not modify the Selection scripts, which call the definition script. The selection script is used in the following contexts:

- When you start or stop the PSUB process for a database, you log in to the operating system as RXCPROD. The selection script is called to set the environment to that database.
- Each time a PSUB job is requested, PSUB executes the setup script to condition its environment to the correct version of the Oracle Clinical code, running against the correct database.
- You may execute the selection script at the command line to define server environments for various purposes, such as connecting to a particular database or running SQL scripts under RXC_TOOLS.

Administrators are not required to create or modify users' installation scripts to enable users to submit back end jobs through the client interface. However, you *must* add entries to the initialization scripts of users who need to run opa_setup, SAS, or SQL*Plus from the back end command line. See "[Setting Up Power Users](#)" on page 1-17 for details.

Editing opa_settings.bat

During installation of the server code, the Installer creates the file opa_settings.bat, located in the *opapps\bin* directory. File opa_settings.bat contains the commands to set environment variables at startup and execution of the PSUB process. Edit this file, and change the following assignments (in bold type), if necessary:

set NLS_DATE_FORMAT=DD-MON-RRRR

NLS_DATE_FORMAT determines the format in which client applications running on the Windows server transfer date information to and from the database. The format must specify the year as RRRR in order to be Year 2000 compliant.

set NLS_LANG=american_america.utf8

NLS_LANG determines which language settings Oracle uses when it reads and writes values into the database. The NLS_LANG entry in your registry for your iSuites Oracle Home must be consistent with the NLS_LANG setting in the Oracle Home and your databases.

opa_settings must have the following setting for PSUB to work correctly for a UTF8 character set database. (If you install more than one Oracle Health Sciences product, you should review information on choosing a character set for combined Oracle Health Sciences products in the *Oracle Clinical Installation Guide*.)

If you don't have a UTF8 character set database, you can use these character sets:

american_america.us7ascii

american_america.we8iso8859p1

Note: Do not create new databases with the default character set (AL32UTF8) by the Assistant.

Setting Up UNIX Environments

On UNIX systems, you run the selection script, which checks the arguments you provide to define a configuration against the settings file. If the arguments are valid, the script applies the appropriate values to the corresponding environment variables in the current shell. The syntax for calling the selection script depends on whether you use the C shell or Bourne/Korn shells. For all shells, the selection script accepts at least one argument and an optional second:

Argument	Description
<i>database</i>	Indicates the database to be used. This can be: <ul style="list-style-type: none"> ■ the Oracle SID of a database on the PSUB server ■ connect string of a database instance on a machine other than the PSUB server ■ - (minus sign). The script sets the code environment, but preserves the existing database context, if any.
<i>code_env</i>	Optional. An Oracle Clinical code environment designator that must refer to a code environment defined in the <i>opa_settings</i> file on the PSUB server.

Note that using a - (minus) for the first argument neither updates nor creates a database context.

Arguments specified	Resulting behavior
<i>database</i>	With no <i>code_env</i> specified, the script sets only Oracle-level environment variables needed for applications to access <i>database</i> .
- (minus) <i>code_env</i>	With no <i>database</i> specified, the script sets only environment variables needed for jobs to run. That is, it sets PATH to include RXC_PSUB and RXC_BIN, and defines the RXC_* environment variables.
<i>database</i> <i>code_env</i>	With both <i>database</i> and <i>code_env</i> specified, the script executes both sets of commands.

- In Bourne and Korn shells:

```
p1=database
p2=code_env
.opa_setup
```

For example:

```
$ p1=test
$ p2=400
$ . opa_setup
```

- In C shell:

```
copa_setup database code_env
```

For example:

```
%copa_setup test 46
```

Changing Configuration Settings on UNIX Database Servers

The configurations are defined in the `opa_settings` file. The Oracle Universal Installer creates all necessary entries in this file during installation of software and creation or upgrade of databases. The most common reason to modify the `opa_settings` file is to customize the values set for various environment variables during execution of back end jobs. You may also need to modify the file to delete databases that are no longer available and enable the use of additional code environments against a database.

Each line in the file defines a particular type of environment information:

```
record_type_key:field_1[:field_2]. . .
```

Starting with an identifier of the type of information (record), the line also contains a colon (:) separator, followed by fields that contain the information for that record, each separated by colons. [Table A-1](#) lists and describes each record type.

Table A-1 List and Description of the Records in the `opa_settings` File

Record Type Key	Description	Example
<code>oratab_filespec</code>	Location of the file <code>oratab</code> on the server Field 1: Fully specified path to the OPA directory	<code>oratab_filespec:/etc/oratab</code>
<code>tnsnames_filespec</code>	Location of the file <code>tnsnames.ora</code> on this server. Ensure that this file has an entry for each connect string (that is, a reference to a remote database) that is required for OPA applications. The record provides information about accessing the database over the network. Field 1: Fully specified path to the file <code>tnsnames.ora</code>	<code>tnsnames_filespec:/etc/tnsnames.ora</code>
<code>opa_home</code>	Location of Oracle Health Sciences (formerly known as Oracle Pharmaceutical Applications) products on the server. Field 1: Fully specified path to the OPA directory.	<code>opa_home:/pharm/home/opapps</code>
<code>remote_db_home</code>	Location of an available remote database, to which <code>ORACLE_HOME</code> should be set. Field 1: Net8 connect string of the remote database. Field 2: <code>ORACLE_HOME</code> value that is used while accessing the current database	<code>remote_db_home:hpx1:/u01/app/oracle/product/9.2.0</code>

Table A-1 (Cont.) List and Description of the Records in the opa_settings File

Record Type Key	Description	Example
code_environment	<p>Location of the code for a version of an OPA application.</p> <p>Field 1: A code environment designator, for example, OC46 for the Oracle Clinical 4.6 code</p> <p>Field 2: The fully specified path to the root directory for the version of the application software</p>	<pre>code_env: oc46: /pharm/home/opapps/46</pre>
db_code_pair	<p>Indicates that a particular code environment can be used with a particular database.</p> <p>Field 1: The system identifier (SID) of a local database instance, or the connect string of a remote database instance.</p> <p>Field 2: A code environment designator</p>	<pre>db_code_pair:prod:oc46</pre>
db_env_setting	<p>Provides either a default or database-specific setting for an environment variable. The following environment variables must have at least default settings:</p> <p>NLS_DATE_FORMAT NLS_LANG RXC_BATCH_QUEUE RXC_NOW_STRING SASORA</p> <p>These settings are assigned default values at install time.</p> <p>Field 1: The database SID, or connect string, if this is a database-specific setting for the environment variable; or <code>_DEFAULT_</code>, if this is a default setting across databases for this environment variable.</p> <p>Field 2: Name of an environment variable</p> <p>Field 3: Value to be assigned to the environment variable</p>	<pre>db_env_setting:_DEFAULT_:SASORA:V7 db_env_setting:TEST:SASORA:V8</pre>

Defaulting, Adding, and Customizing Values

Use `db_env_setting` entries to define the value you want environment variables to assume during execution of back end jobs. You can add an entry for any environment variable you want to define; the definition will be in effect for any database if you set field 1 to `_DEFAULT_`. If you want to limit the environment variable setting so that it affects only those jobs associated with a particular database, use the database's SID as the value for field 1.

The environment variable settings in `opa_settings` affect all users. If you want to set a value for an environment variable for just one user, place a statement in that user's `.oclr` script—for example, `RXC_DEBUG=TRUE; export RXC_DEBUG`.

If you want an environment variable setting to affect all jobs that run against a particular database, add or modify a database-specific entry in `opa_settings`—for example, `db_env_setting:test:SQL_TRACE:TRUE`.

Finally, if you want the setting to affect all jobs run against any database, add or modify a `_DEFAULT_` entry for that environment variable—for example, `db_env_setting:_DEFAULT_:RXC_SAS_BATCH_QUEUE:b`

The last example in [Table A-1](#) shows how to override a system-wide default setting with a database-specific setting. The environment variable SASORA is defaulted to V7 for all databases with the exception of the TEST database, where it is defaulted to V8.

Note: The default settings for all databases or the specific settings for a particular database, such as NLS_LANG, must be correct in the opa_settings file.

Constraints on the opa_settings File

Oracle recommends that you use the defaults where possible, and add overrides only as needed. In addition, note the following constraints if you edit this file.

- In the opa_settings file, there should be exactly one each of these record types:
 - opa_home
 - oratab_filespec
 - tnsnames_filespec
- For each database instance appearing in a db_code_pair record, a value must be defined for each of the database environment settings (record type key db_env_setting). The setting may be made either through a generic _DEFAULT_ record, or through a database-specific record.

Checking for Errors in the opa_settings File

If you modify the opa_settings file, run the script `~opapps/bin/check_opa_settings.sh` to check the settings file for errors. The syntax is:

check_opa_settings.sh [-nowarn] *settings-file-name*

The script generates an error message if it finds any duplicate record_type key values. These would cause an error if present when opa_setup is run. (In fact, opa_setup calls check_opa_settings.sh to preclude this. However, opa_setup does not check for warnings. See below).

Unless the -nowarn argument is provided, check_opa_settings.sh will also generate a warning for multiple db_code_pair entries for a single database. While multiple db_code_pair entries are not invalid, they may represent a condition you do not want to allow. For instance, if you upgrade database 'x' from 4.5 to 4.6, opa_settings would include:

```
db_code_pair:x:45
db_code_pair:x:46
```

In this case, check_opa_settings.sh warns you. Remove the line enabling the 3.2 code environment against the 4.0 database, so you don't mistakenly start up a PSUB process in that configuration.

You might also want to disregard other warnings. For example, if you had a code tree for testing patches, as well as a production code tree. Then opa_settings might have:

```
db_code_pair:x:46
db_code_pair:x:46patchtest
```

You would disregard the warning check_opa_settings.sh would give, since both pairs are valid.

Changing Environment Variables on Windows

On Windows, the values to which you want environment variables to be set during back end job execution are maintained in opa_setup.bat. Below is a list of the Oracle Clinical environment variables that must be defined in opa_settings.bat.

- [NLS_DATE_FORMAT](#)
- [NLS_LANG](#)
- [RXC_MAA_TAB_SPACE](#)
- [RXC_SAS_VIEW](#)
- [SASORA](#)

To change or add environment variable settings active during back end job execution, edit the opa_settings.bat file with a text editor. Each line must be in the following format:

```
set variable_name=value
```

Settings that Affect Back-End Job Execution

This section lists environment variables that affect execution of jobs on back end servers. You can define values for the environment variables that apply to all back end jobs by defining their settings in opa_settings (UNIX) or in opa_settings.bat (Windows). On UNIX you can limit the scope of the environment variable setting to a single instance or to a single user. See "[Defaulting, Adding, and Customizing Values](#)", above, for details.

- [NLS_DATE_FORMAT](#) – National Language Support
- [NLS_LANG](#) – National Language Support
- [RXC_BATCH_QUEUE](#) – Batch queue for non-blocking PSUB jobs (UNIX only)
- [RXC_BDL_DIR](#) – Spool directory for batch data load
- [RXC_DEBUG_BUFFER_SIZE](#) – Output buffer size for executing procedures
- [RXC_IMMED_QUEUE](#) – Batch queue for blocking PSUB job (UNIX only)
- [RXC_LOG](#) – Location for log files
- [RXC_MAA_TAB_SPACE](#) – Data extract temporary tablespace
- [RXC_NOW_STRING](#) – Time when PSUB job is executed (UNIX only)
- [RXC_PRINTER](#) – Default printer for Oracle Clinical
- [RXC_SAS_BATCH_QUEUE](#) – Default PSUB batch queue for SAS jobs (UNIX only)
- [RXC_SAS_CONNECT](#) – SAS connect string (UNIX only)
- [RXC_USER](#) – Root directory for creating data extract files
- [SASORA](#) – Version of Oracle compatible with SAS
- [TEMP](#) – Default location for FTP
- [USER_BV_JOB](#) – Script run after batch validation (back end server)

NLS_DATE_FORMAT

This variable specifies the format used for displaying dates and converting characters to dates. This is a Windows registry setting that the Installer sets.

The default value is "DD-MON-RRRR".

You can modify this variable using `db_env_setting` records in the `opa_settings` file.

NLS_LANG

This variable specifies the language setting used by Oracle RDBMS to read from and write to the database. Set `NLS_LANG` to the appropriate language and character set.

The default value for this variable is:

```
db_env_setting: _DEFAULT_:NLS_LANG:american_america.utf8
```

You can modify this variable using `db_env_setting` records in the `opa_settings` file.

Note: The default settings for all databases or the specific settings for a particular database, such as `NLS_LANG`, must be correct in the `opa_settings` file.

RXC_BATCH_QUEUE

This is the batch queue for nonblocking `PSUB` jobs, on UNIX only.

If you want `PSUB` to use a batch queue other than the default for running user requests, redefine the setting for `rx_batch_queue`. You can define it globally for all users, or individually by placing the command in the user's login script.

Default is a.

RXC_BDL_DIR

This is the spool directory for batch data load.

When a user requests **Prepare to Completion** for a given data file group, and does not specify otherwise in the submission form, any resulting reloadable data files are written to the directory specified by `RXC_BDL_DIR`. If there are no reloadable files, the completed files are placed in `RXC_LOG`.

RXC_DEBUG_BUFFER_SIZE

This sets the output buffer size for executing procedures.

`RXC_DEBUG_BUFFER_SIZE` controls the size of the buffer space used for running a Validation or Derivation Procedure in debug mode. The installed default value is 200000; you may want to increase it to 1000000.

RXC_IMMED_QUEUE

Batch queue for blocking `PSUB` jobs, on UNIX only

If you want `PSUB` to use a batch queue other than the default to process user requests for blocking jobs (such as default layout and generate procedure), redefine the setting for `RXC_IMMED_QUEUE`. It may be necessary to send blocking jobs to another batch queue so that they are not held up by other system activity, such as long-running reports.

Set this variable through `db_env_setting` records in the `opa_settings` file.

RXC_LOG

The directory where the system saves the log files of various processes.

RXC_MAA_TAB_SPACE

Oracle Clinical's Data Extract functionality requires a privileged Oracle user so that Oracle schemas can be created to hold Data Extract Views. The Oracle account for this purpose is RXC_MAA (Maintain Access Accounts).

RXC_MAA_TAB_SPACE specifies the name of the Oracle tablespace defined by RXC_MAA as the temporary tablespace when these schemas are created. During installation RXC_MAA_TAB_SPACE is set to TEMP1 with a size of 10Mb.

Set through `db_env_setting` records in the `opa_settings` file.

RXC_NOW_STRING

Defines the string for "now" that is used by the `at` command in the local language environment. This is effective only for 3GL and PL/SQL jobs submitted in immediate mode to run on UNIX back end servers. Default value is "now". To see your current "now" string, enter:

```
% echo $LANG
```

If LANG is undefined or is equal to "C", you have finished. The RXC_NOW_STRING is simply "now". Otherwise, do this:

```
% cd /usr/lib/nls/$LANG
dumpmsg at.cat
```

The string for "now" is the third item in the third set of output.

Set through `db_env_setting` records in the `opa_settings` file.

RXC_PRINTER

This is the environment variable to which PSUB refers when the user chooses RXC_PRINTER from the list of values for printing a PSUB job. It refers to the default printer for Oracle Clinical.

RXC_SAS_BATCH_QUEUE

This references to the default PSUB batch queue for SAS job, on UNIX only.

If you want PSUB to use a batch queue other than the default for running users' SAS requests, redefine the setting for RXC_SAS_BATCH_QUEUE, globally for all users, or individually by placing the command in the user's initialization file.

RXC_SAS_CONNECT

RXC_SAS_CONNECT defines the Oracle connect string to connect SAS to an Oracle database. The following examples assume an environment pre-set for a particular database.

For more information on connect strings, see your operating system-specific installation manual for SQL*Net.

The example below assumes SAS connects through the pipe driver. This is only possible when SAS and Oracle are installed on the same computer.

Sites using TCP/IP to connect from SAS to Oracle would replace the `@p` with an `@t`.

Bourne shell

```
RXC_SAS_CONNECT='oracle(path='''@p:'''')'; \
export RXC_SAS_CONNECT
```

C shell

```
setenv RXC_SAS_CONNECT 'oracle(path='''@p:'''')
```

Note: On UNIX, if SAS (and SQL*Plus and PSUB) reside on the same computer as the Oracle Clinical database, and [RXC_SAS_CONNECT](#) is not defined, then you can set `remote_os_authent` to false. On Windows, `remote_os_authent` must be set to false.

Refer to the "[Troubleshooting PSUB Based on the Batch Job's Execution Status](#)" on page C-11 for additional information.

RXC_USER

This is the root directory for creating SAS files during data extract. For example, if `RXC_USER` is defined as `/u01/oc`, and `ORACLE_SID` is `prod`, then the data extract files go in `/u01/oc/prod/...`

Note: It is possible to set a different value for `RXC_USER` for each database, if you wish, overriding this default.

SASORA

This environment variable must be defined when you run SAS Access against an Oracle database. The default value shipped in `opa_settings` is `V7`, which is appropriate for SAS 6.12 running against either an Oracle 7.3 or 8i database. The appropriate value for SAS 8.2 running against either an Oracle 8i or 9i database is `V8`.

TEMP

This is the default temporary directory for FTP processes.

USER_BV_JOB

This environment variable specifies the name and location of a user-defined script to be executed as the last step of batch validation.

For example:

UNIX (in .oclr):

```
USER_BV_JOB=/dir1/dir2/dir3/filename
export USER_BV_JOB
```

The full pathname of the file must be specified.

At batch validation run time, the environment variable is evaluated and the corresponding script is submitted for execution via PSUB. The script is called with two arguments: *clinical_study_id* and *clinical_study_version_id*.

Windows Registry Settings

This section lists the Windows registry settings used by Oracle Clinical. It describes the settings for the each of the following:

- [OPA Front End](#) on page A-11
- [Online Help](#) on page A-11
- [Oracle Clinical Front End](#) on page A-12

- [RDC Front End](#) on page A-12
- [OCN Front End](#) on page A-13
- [Report Server](#) on page A-14

OPA Front End

These registry variables apply across products and are located on the SOFTWARE\ORACLE branch of the registry. Each value is set by the Installer.

Table A-2 OPA Front End Registry Variables and Example Values

Registry variable	Example Value	Description
FORMS_PATH	c:\opapps46\opa	The path that is searched to find forms.
FORMS_TIMEOUT	10	The Forms time-out period
OPA_CONFIG	opa46	The OPA configuration name
OPA_RQM_URL	http://server.domain/dev60cgi/rwcgi60.exe	The URL for the Reports Queue Manager
OPA_HOME	c:\opapps46	The top-level OPA products directory
OPA_HOME_DIR	c:\opapps46\opa	The Oracle Health Sciences product directory
OPA_SERVER	<i>server.domain</i>	The full server name
OPA_PORT		This should be set to NULL, that is, "blank", to facilitate either HTTP or HTTPS operations.
NLS_DATE_FORMAT	DD-MON-YYYY	The default NLS date format
NLS_LANG	AMERICAN_AMERICA.W	The NLS language
OPA_JARS	f60all_jinit.jar, opaicons.jar	The names of the OPA jar files to be downloaded to the client. This is used by the OUI to coordinate between product changes to the opa46 config section in the formsweb.cfg file.
OPA_PHYSICAL_MAP	c:\opapps46\html\repout	The physical mapping to the repout directory
OPA_VIRTUAL_MAP	/OPA_REPOUT/	The virtual mapping to the repout directory
OPA_DEV_VERSION	60	The version of Developer

Online Help

These registry variables are located on the SOFTWARE\ORACLE branch of the registry. Each value is set by the Installer.

Table A-3 Xhelp Registry Variables and Example Values

Registry variable	Example Value	Description
opa_doc_dir	http://server.domain/opa46	The URL for standard online help and documentation location
opa_custom_doc_dir	http://server.domain/opa46	The URL for custom online help and documentation
opa_xhelp_dir	c:\opapps\html\xhelp	The location of the online help directories

Oracle Clinical Front End

These registry variables are located on the SOFTWARE\ORACLE branch of the registry. Each value is set by the Installer.

Table A-4 Oracle Clinical Front End Registry Variables and Example Values

Registry variable	Example Value	Description
FORMS_PATH	c:\opapps46\oc	The Forms60 path that is searched to find forms
forms60_repformat	HTML	
forms60_userexits	c:\opapps46\oc\f60xtb.dll; c:\oc\rcde1.dll	User Exits referenced from Oracle Clinical/RDC
forms60_defaultfont	MS Sans Serif 1.0	Oracle Clinical default font
oc_home_dir	c:\opapps46\oc	The Oracle Clinical top level directory
OC_DE_TEXTFONT	Arial.8	The default font for data entry field prompts and boilerplate text
OC_DE_FIELDFONT	Arial.8	The default font for response fields in data entry
OPA_JARS	f60all_jinit.jar, opaicons.jar, ocicons.jar, pharmaocjle.jar, pharmaocgle.jar, xmlcomp.jar, xmlparserv2.jar, jle2-0-3.jar	The names of the OPA JAR files
OPA_XMLTEMP_HTTP	http://server.domain/opa46/rdc/temp	The URL to access the xmltemp directory
OPA_XMLTEMP_UNC	Either: \\appserver\rdc\temp or c:\opapps46\html\rdc\temp	The value that is passed to the report server that informs it how to access xmltemp. If the forms and reports servers are on the same computer, the value is a directory. If the forms and reports servers are on different computers, the value will be a UNC

RDC Front End

These registry variables are located on the SOFTWARE\ORACLE branch of the registry on the middle-tier computer where RDC is installed.

Table A-5 RDC Front End Registry Variables and Example Values

Registry variable	Example Value	Description
FORMS_PATH	c:\opapps46\rdc	The path that is searched to find forms
RDC_HOME_DIR	c:\opapps46\rdc	The location of the RDC directory
RDC_DCIF_IMAGES	\\appserver\rdc\dcif_images or c:\opapps46\html\rdc\dcif_images	The location of the RDC directory images
OPA_LOCALHOST	oclw2k16.us.oracle.com	If the RDC installation is used by client computers other than the application server, use the fully qualified application server name. If you plan to run the client locally on the application server computer, you can use the machine name e.g., oclw2k16.

Table A-5 (Cont.) RDC Front End Registry Variables and Example Values

Registry variable	Example Value	Description
OPA_XML_LOC	OPA_HOME/temp e.g.: c:\opapps46\temp	This is a folder where temporary files are created at runtime and deleted at the end. This can be anywhere. During installation, this is set to its default value: OPA_HOME/temp.
OPA_PJC_LISTENER_DEBUG_LEVEL	1	Sets the debug level for the Pluggable Java Component (PJC). There are three options for the value: <ol style="list-style-type: none"> 1. 0: no debug 2. 1: Low debug level 3. 2: High debug level By default, it is set to "1" during installation.
OPA_PJC_PORT_STARTNUMBER	5567	The port number at which the PJC communicates with the PDF Data Entry Form. This is typically set to a random value of "5567".
OPA_PJC_PORT_NUMATTEMPTS	10	The number of attempt the PJC will make to open a listener port. With each attempt, the PJC increases the port number by one and continues until it has attempted to open the port a number equal to this value.
OPA_PDF_FILE_SOURCE	SERVER	The setting that specifies whether the PDF files will be served from the application server computer or from the cache location on the client computer. The valid values are 'CLIENT' or 'SERVER'. The default value will be 'SERVER'. You change this value to allow users to cache PDF files locally.

OCN Front End

These registry variables are located on the SOFTWARE\ORACLE branch of the registry. Each value is set by the Installer.

Table A-6 OCN Front End Registry Variables and Example Values

Registry variable	Example Value	Description
FORMS_PATH	c:\opapps46\oc	The path that is searched to find forms
OCN_HOME_DIR	c:\opapps46\oc	The OCN Home directory

Report Server

These registry variables are located on the SOFTWARE\ORACLE\<<HOME> branch of the registry for the Reports Server installation. Each value is set by the Installer.

Table A-7 Report Server Registry Variables and Example Values

Registry variable	Example Value	Description
REPORTS_PATH	c:\opapps46\opa, c:\opapps46\oc, c:\winnt\fonts	The path the system searches to find reports
REPORTS_CLASSPATH	c:\opapps46\lib\pdfappend.jar, c:\opapps46\lib\pdrgenerator.jar	The path Reports uses to find classes
NLS_DATE_FORMAT	DD-MON-RRRR	The date format when running reports for Oracle Clinical/RDC with the NLS option
OC_RSERVER_DIR	c:\opapps46\oc	The Reports Server directory
NLS_LANG	american_america.utf8	The NLS language that is used when running Reports; supported values are: UTF8, US7ASCII, WE8ISO8859P1, or any single byte character set
OC_PDF_REPORTS_TEMP_OC	c:\opapps46\temp	The temporary directory that the system uses when you run reports.
OC_RPT_GRIDWIDTH	8	The default gridwidth for the report
OPA_HOME	c:\opapps46\	The top level Oracle Health Sciences products directory. This is written to both the default and the specific branches of the registry.
OC_DE_FIELDFONT	Arial.8	The default font for response fields in data entry
OC_DE_TEXTFONT	Arial.8	The default font for data entry field prompts and boilerplate text
OC_RPT_FIELDFONT		The font for response field data in reports. If not specified, the system uses the value for OC_DE_FIELDFONT .
OC_RPT_TEXTFONT		The font for CRF header field prompts, question prompts, and boilerplate text in reports. If not specified, the system uses the value for OC_DE_TEXTFONT .
RDC_DCIF_IMAGES	c:\opapps46\rdc\dcif_images	The location of images that are used for DCI Forms and PDR generation.
RDC_PDF_PRINT_TOOL	"C:\Program Files\Adobe\Acrobat 5.0\Acrobat\Acrobat.exe" /t	The path to the Adobe Acrobat or Reader application on the Report Server. Path must be in double-quotation marks and the "/t" must be included in the value.

Registry Keys

This section provides details about individual registry keys. Use this information if it becomes necessary to modify the value of a registry key due to configuration or hardware changes.

In general, the values assigned to the keys are set by the Oracle Universal Installer (OUI), during the installation of various Oracle Health Sciences (formerly known as Oracle Pharmaceutical Application—OPA) components, based on answers you provide during the information-collection phase of the installation.

The following registry keys are described in the following sections:

- [FORMS_PATH](#)
- [OPA_JARS](#)
- [OPA_XMLTEMP_UNC](#)
- [OPA_XMLTEMP_HTTP](#)
- [RDC_DCIF_IMAGES](#)
- [OC_DE_FIELDFONT](#)
- [OC_DE_TEXTFONT](#)

FORMS_PATH

The value that is assigned to this key is based on the Oracle Health Sciences products that are installed on the computer. As each component is installed, the OUI appends product-specific values to the existing value. For example, if the Thesaurus Management System (TMS) is installed on a system where Oracle Clinical and RDC are installed, the FORMS_PATH value would be:

```
c:\opapps46\opa;c:\opapps46\oc;c:\opapps46\rdc;c:\opapps46\tms
```

The path string that each component contributes to the FORMS_PATH key value is listed in [Table A-8, "Product-Specific Registry Values for the FORMS_PATH Key"](#)

Table A-8 Product-Specific Registry Values for the FORMS_PATH Key

Product	Addition to the FORMS60_PATH value
OPA Front End	c:\opapps46\opa
Oracle Clinical Front End	c:\opapps46\oc
RDC Front End	c:\opapps46\rdc
TMS Front End	c:\opapps46\tms
AERS Front End	c:\opapps46\aers

OPA_JARS

The value that is assigned to this key is based on the OPA products that are installed on the computer. As each component is installed, the OUI appends product-specific values to the existing value.

OPA_XMLTEMP_UNC

The value that is assigned to this key is the directory on the application server that Oracle Clinical uses to write temporary files during the DCI form generation process. When the Oracle Clinical client is installed, the OUI sets this value to:

```
<drive>:\opapps46\html\rdc
```

The Oracle Reports server also writes files to this directory during DCI form generation. If any reports server used for this task is located on a different computer than the application server, the directory must be shared, with read/write privileges, to the <domain>/account on the report server; see the *Oracle Clinical Installation Guide*. Also, the path specified in the value must use the Microsoft Universal Naming Convention (UNC) format.

For example, if, during initial installation, you reply to the OUI that there is a standalone report server, the Installer sets this the value of this key to:

```
\\<appserver\rdc\temp
```

and requires that you share <drive>:\opapps46\html\rdc with the share name "rdc".

If the only report server that you use to generate DCI forms co-exists on the same computer with the application server, there is no need to share the xmltemp directory and the path specification can be a simple local directory name, such as, c:\opapps46\html\rdc\temp.

OPA_XMLTEMP_HTTP

The value that is assigned to this key must be a valid [URL](#) that points to the forms server directory to which Oracle Clinical writes temporary files during DCI form generation. When the Oracle Clinical client is installed, the OUI sets this value to:

```
<drive>:\opapps46\html\rdc\temp
```

This is the same directory specified by the [OPA_XMLTEMP_UNC](#) key.

In order for the system to use this directory, it must be supported by an http virtual directory that can serve files from it.

For example, if the temp directory is c:\opapps46\html\rdc\temp on myOCServer, then a virtual directory must be associated with c:\opapps46\html:

```
alias /opa46/ "c:\opapps46\html\"
```

This allows a URL of http://myOCServer/opa46/rdc/temp/MYFILE.pdf to resolve and serve the file, c:\opapps46\html\rdc\temp\MYFILE.pdf.

RDC_DCIF_IMAGES

The value that is assigned to this key must be the path specification of the directory in which image files that are referenced in DCI forms are found; see "[Setting Up Image Viewing for DCI and DCM Form Layouts HTML Preview Feature](#)" on page 11-3. However, the Patient Data Report generation subsystem uses its own registry variable to locate the path to the directory.

When the Oracle Clinical client is installed, the Installer sets this value to:

```
<drive>:\opapps46\html\rdc\dcif_images
```

In a manner similar to [OPA_XMLTEMP_UNC](#), the dcif_images directory specification must be one that can be resolved by any reports server that generates DCI forms.

If the only report server that you use to generate DCI forms co-exists on the same computer with the forms server, there is no need to share the images directory and the path specification can be a simple local directory name, such as, c:\opapps46\html\rdc\dcif_images.

If any reports server used for DCI forms generation is located on a different computer than the forms server, then:

- The path specification used for the value of RDC_DCIF_IMAGES must use the UNC format.
- The forms server images directory must be shared, so it can be accessed from other computers.

- The `<domain>/<account used to set up the Reports Server>` must have read/write privileges on the shared forms server directory.

For example, if, during initial installation, you reply to the Installer that there is a standalone report server, the Installer sets this the value of this key to:

```
\\<appserver>\rdc\dcif_images
```

and requires that you share `<drive>:\opapps46\html\rdc` with the share name "rdc".

Note: If the Patient Data Report generation process cannot locate the path to the `dcif_images` directory, each CRF that contains an image in its layout is not printed in the report.

OC_DE_FIELDFONT

The value assigned to this key regulates the font size of response value that are typed in response fields and displayed in the data entry windows and the Patient Data Reports (PDRs). This registry key is present in:

- the `SOFTWARE\ORACLE\` branch, where it is set as part of the Oracle Clinical Front End installation
- the `SOFTWARE\ORACLE\<9iDS>` branch, where it is set as part of the Oracle Clinical Report Server installation

The default value in both locations is "Arial.8".

If you want Patient Data Reports (PDRs) to look the same as the CRFs that are displayed in data entry windows, the value for both keys must be identical.

OC_DE_TEXTFONT

The value assigned to this key regulates the font size of the question prompts and boilerplate text in the data entry windows and the Patient Data Reports (PDR). This registry key is present in:

- the `SOFTWARE\ORACLE\` branch, where it is set as part of the Oracle Clinical Front End installation
- the `SOFTWARE\ORACLE\<9iDS>` branch, where it is set as part of the Oracle Clinical Report Server installation

The default value in both locations is "Arial.8".

If you want PDRs to look the same as the CRFs that are displayed in data entry windows, the value for both keys must be identical.

RDC_PDF_PRINT_TOOL

The value assigned to this key determines the location of the Adobe Acrobat or Reader executable, which allows users to run PDF patient data reports with "PRINTER" specified as the output type. This value must be in the form:

```
"<acrobat-reader_path>" /t
```

Note that the double-quotation marks around the path and the "/t" switch are required. A typical example of a value is:

```
"C:\Program Files\Adobe\Acrobat 6.0\Acrobat\Acrobat.exe" /t
```

In addition to setting this key correctly, ensure that the Adobe Acrobat or Reader application is running on the Reports Server prior to users initiating this type of report job, that is, a job that specifies the output type as "PRINTER".

SAS_VIEW Directory Tree

All Oracle Clinical data not stored in the database, such as SAS Views created with the Data Extract facility, is stored in the SAS_VIEW directory on the Back end server computer. The access restrictions enforced in the database must also be enforced at the file-system level. The structure of the SAS_VIEW directory tree is shown below, together with the associated permissions. Owner is not relevant; in fact, the owner is the user who created the file or directory through the use of the application.

The top-level directory, opapps, is set by the installer. Entries are indented to show the relative subdirectory nesting level.

Directory	File Protections	
	UNIX	Windows
opapps	(0775)	
sas_view	(2775, oclsascr)	(oclsascr, FULL Control)
db_name	(2775, oclsascr)	(oclsascr, FULL Control)
study	(0775, oclsascr)	(oclsascr, FULL Control)
account_type	(0775, oclsascr)	(oclsascr, FULL Control)
*.sas	(0664, oclsascr)	
*.log	(0664, oclsascr)	
*.com	(0775, oclsascr)	

Where *db_name* is the name of the database instance, *study* is the study code in Oracle Clinical, and *account_type*

is the data extract view account type (TEST, CURRENT, STABLE or SNAPSHOT*n*).

For example:

UNIX: /pharm/home/opapps/sas_view

Windows: \\opa-db1\sas_view

To change the location of the SAS_VIEW storage, change the appropriate environment settings for your platform, as shown below:

UNIX: db_env_setting:_DEFAULT_:RXC_USER:/u01/home/opapps
db_env_setting:_DEFAULT_:RXC_SAS_ROOT:/u01/home/opapps/sas_view

Windows: set RXC_SAS_ROOT=%oui_sas_root%\%database%

To set the protections on your directory structure, run the appropriate script:

UNIX: `$RXC_TOOLS/set_rxc_user.sh`

Windows: `%RXC_TOOLS%\set_rxc_user.bat`

(These scripts are run automatically by the Installer.)

On UNIX Systems Only:

The path to the SAS_VIEW directory must not contain uppercase characters (PSUB changes all path specifications to lowercase for UNIX). If your standard naming conventions require uppercase characters in the path, you can provide lowercase and uppercase versions of paths with symbolic links as needed. For example, if the standard path to the SAS_VIEW directory is

```
/usr1/home/Clinical/opapps/sas_view
```

you could create this link:

```
% cd /usr1/home
% ln -s Clinical clinical
```

References to

```
/usr1/home/clinical/opapps/sas_view
```

would also work.

Troubleshooting

This section offers solutions to known Oracle Clinical issues in the following categories:

- [Managing High Sequence Numbers](#) on page C-1
- [Error Messages](#) on page C-5
- [System Malfunction: GPF Occurs During Data Entry](#) on page C-6
- [PSUB Jobs](#) on page C-7
- [Database Trace](#) on page C-15

Managing High Sequence Numbers

If you upgraded to Oracle Clinical 4.6 from either release 4.5.1, 4.5.2, or 4.5.3, it is important to ensure that the internal identifier for each of the following does not exceed 2,147,483,647 (that is, $(2^{31}-1)$):

- Received DCMs (RDCMs)
- Received DCIs (RDCIs)
- Discrepancies

When the internal identifier for these tables exceeds 2,147,483,647, the system incorrectly processes the identifiers in other tables, such as the Responses table. You can still view and update the responses, however batch validation, data extract, replication, and procedure execution operations fail or run incorrectly.

In Oracle Clinical 4.5.1 and after, there is code to prevent sequence numbers from exceeding 2,147,483,647. The [OCL_DE_CONFIG](#) reference codelist includes a short value entry, "SEQUENCEBUFFER", which is assigned an initial long value of 1,000,000. At this setting, when a sequence number is within 1,000,000 of 2,147,483,647, the system displays a warning message when a user attempts to use a relevant subsystem and the system exits the current screen.

Assessing Sequence Sizes

Perform this test to determine if your database is nearing the point where this situation may occur. If the results of this test for the number of Received DCMs, Received DCIs, and discrepancies is well below 2,147,483,647, you do not have to perform the other tasks described in this section.

Assess the Number of RDCMs

To determine the sequence number for RDCMs in your system:

1. Connect to your database through SQL*Plus as RXC.
2. Issue this command to assess the number of Received DCMs:

```
SELECT received_dcm_seq.nextval FROM dual;
```

The system returns a number.

3. Compare the number returned to 2,147,483,647:
 - If the internal identifier number is approaching 2,147,483,647, you should reseed the received_dcm_seq sequence after you complete this task.
 - If the number exceeds 2147483647, reseed received_dcm_seq, identify data errors, and repair data errors according to the instructions in the following sections.
 - If neither of the above conditions apply, run this command from SQL connected as RXC:

```
alter sequence received_dcm_seq maxvalue 2147483646;
```

Assess the Number of RDCIs

To determine the sequence number for RDCIs in your system:

1. Connect to your database through SQL*Plus as RXC.
2. Issue this command to assess the number of Received DCMs:

```
SELECT received_dci_seq.nextval FROM dual;
```

The system returns a number.

3. Compare the number returned to 2,147,483,647:
 - If the internal identifier number is approaching 2,147,483,647, you should reseed the received_dci_seq sequence after you complete this task.
 - If the number exceeds 2147483647, reseed received_dci_seq, using the instructions in the following sections. If you use RDC or DCAPI, contact Oracle Support.
 - If neither of the above conditions apply, run this command from SQL connected as RXC:

```
alter sequence received_dci_seq maxvalue 2147483646;
```

Assess the Number of Discrepancies

To determine the sequence number for discrepancies in your system:

1. Connect to your database through SQL*Plus as RXC.
2. Issue this command to assess the number of Received DCMs:

```
SELECT discrepancy_entry_seq.nextval FROM dual;
```

The system returns a number.

3. Compare the number returned to 2,147,483,647:
 - If the internal identifier number is approaching 2147483647, you should reseed the discrepancy_entry_seq sequence after you complete this task.
 - If the number exceeds 2147483647, reseed the discrepancy_entry_seq sequence after you complete this task.
 - If neither of the above conditions apply, run this command from SQL connected as RXC:

```
alter sequence discrepancy_entry_seq maxvalue 2147483646;
```

Reseeding Sequences

If any of your response numbers are approaching or exceed 2,147,483,647, you should reseed them.

Reseed RDCM Sequence Numbers

To reseed the Received DCM sequence:

1. Stop all Oracle Clinical activity on the database until this procedure completes.
2. Connect to the database through SQL*Plus as RXC.
3. To determine which seed numbers are in use, issue this command.

```
SELECT distinct mod(received_dcm_id,100)
FROM received_dcms;
```

Note: If this is a replicated environment, run this command in all replicated instances.

4. Choose a new starting seed number value between 0 and 99 (inclusive) that is not in the list returned by the above step.
5. Issue this command to drop the received_dcm_seq sequence:

```
DROP sequence received_dcm_seq ;
```

6. Issue this command to recreate the Received DCM sequence with this value as the new starting value (for example, SEQ_START_NO):

```
CREATE SEQUENCE received_dcm_seq
INCREMENT BY 100
START WITH &SEQ_START_NO
MAXVALUE 2147483646
MINVALUE 1
NOCYCLE
CACHE 20
NOORDER;
```

7. Issue this command to grant access:

```
GRANT SELECT on received_dcm_seq to RXCLIN_MOD;
```

Reseed RDCI Sequence Numbers

To reseed the Received DCI sequence:

1. Stop all Oracle Clinical activity on the database until this procedure completes.
2. Connect to the database through SQL*Plus as RXC.
3. To determine which seed numbers are in use, issue this command.

```
SELECT distinct mod(received_dci_id,100)
FROM received_dcis;
```

Note: If this is a replicated environment, run this command in all replicated instances.

4. Choose a new starting seed number value between 0 and 99 (inclusive) that is not in the list returned by the above step.
5. Issue this command to drop the received_dci_seq sequence:

```
DROP sequence received_dci_seq ;
```

6. Issue this command to recreate the Received DCI sequence with this value as the new starting value (for example, SEQ_START_NO):

```
CREATE SEQUENCE received_dci_seq
INCREMENT BY 100
START WITH &SEQ_START_NO
MAXVALUE 2147483646
MINVALUE 1
NOCYCLE
CACHE 20
NOORDER;
```

7. Issue this command to grant access:

```
GRANT SELECT on received_dci_seq to RXCLIN_MOD;
```

Reseed Discrepancies Sequence Numbers

To reseed the discrepancies sequence:

1. Stop all Oracle Clinical activity on the database until this procedure completes.
2. Connect to the database through SQL*Plus as RXC.
3. To determine which seed numbers are in use, issue this command.

```
SELECT distinct mod(discrepancy_entry_id,100)
FROM discrepancy_entries;
```

Note: If this is a replicated environment, run this command in all replicated instances.

4. Choose a new starting seed number value between 0 and 99 (inclusive) that is not in the list returned by the above step.

5. Issue this command to drop the discrepancy_entry_seq sequence:

```
DROP sequence discrepancy_entry_seq ;
```

6. Issue this command to recreate the Discrepancy sequence with this value as the new starting value (for example, SEQ_START_NO):

```
CREATE SEQUENCE discrepancy_entry_seq
INCREMENT BY 100
START WITH &SEQ_START_NO
MAXVALUE 2147483646
MINVALUE 1
NOCYCLE
CACHE 20
NOORDER;
```

7. Issue this command to grant access:

```
GRANT SELECT on discrepancy_entry_seq to RXCLIN_MOD;
```

Error Messages

This section offers fixes or workarounds for certain error messages that users may encounter. It includes the following topics:

- [Message: ORA-12223](#) on page C-5
- [Message: ORA-04020](#) on page C-5
- [Message: Unable to Change Mode](#) on page C-6

Message: ORA-12223

Full message text:

ORA-12223 TNS: internal limit restriction exceeded

This message may appear in the .log file.

Cause: This error can occur when you submit a job to the server while running the process invoked by selecting **Conduct**, then **Data Extract**, and **Maintain Views**.

Action: Increase the swap space on the PSUB server.

Message: ORA-04020

Full message text:

ORA-04020: Deadlock detected while trying to lock.

Cause: This message may appear when batch validation is running and the user who submitted it switches between production and test modes.

Action: Create a separate test account for each user who needs to switch modes frequently. See [Chapter 2, "Oracle Clinical Menu-Based Security"](#), for instructions on modifying menu roles.

Message: Unable to Change Mode

323600 Unable to change to test mode, another session may be connected.

323700 Unable to change to production mode, another session may be connected.

325700 Unable to change to test mode (\0), synonyms not created.

325800 Unable to change to production mode (\0), synonyms could not be dropped.

For each of the above error messages, Oracle Clinical users should check with the administrator. This problem could be due to an RXCSYN package error, missing grants to RXC, or synonym conflicts with your schema objects.

These messages may appear if you switch between production and test modes while having another session open under the same userid. It may also appear if a user submitted a reports job before switching modes, and the reports engine is still associated with that user. The system considers this to be another session by the same user.

To check if you are logged on to more than one session, from SQL, you can enter the command:

```
select username from v$session;
```

If you do not have access to v\$session, consult with a DBA.

In the case of reports jobs, you can prevent future problems by changing the MAXIDLE time of the Reports Server, which controls the length of time a user/engine session is kept open.

Follow these steps:

1. Open up the report queue manager and select the report queue of concern.
2. Select **Options**, then **Privileges**, and **Administrator** and log on as administrator.
3. Choose **Queue**, then **Properties** and change the maximum idle time to one minute or some reasonable smaller number (depending on the number of reports, users, and so forth on that queue).

In the case of a user switching modes, you can create a separate test account as described under [ORA-04020](#), above.

System Malfunction: GPF Occurs During Data Entry

When a general protection fault (GPF) occurs during data entry, the system creates file rxcdecde.dbg, which contains a description of the cause of the GPF. The file resides in the RXC_ROOT directory.

Situation: \$ulimit unlimited

On HP-UX and Compaq Tru64 UNIX, if the operating system parameter ulimit is set to unlimited, you get the following error when you run opa_setup or oraenv:

```
sh: unlimited: The specified number is not valid for this command
```

The workaround is to edit the oraenv shell script, adding a test for the word "unlimited." To modify this script, follow these steps:

1. Change your location to the bin directory:

```
% cd $ORACLE_HOME/bin
```


2. Make a backup copy of oraenv named oraenv.O
3. Use a text editor to add the two lines shown below in **bold** to the file oraenv.


```

if [ $? = 0 -a "$ULIMIT" != "unlimited" ]; then # added line
if [ $? = 0 -a "$ULIMIT" -lt 2113674 ] ; then
    if [ -f $ORACLE_HOME/bin/osh ] ; then
        exec $ORACLE_HOME/bin/osh
    else
        for D in `echo $PATH | tr : " "`
    do
        if [ -f $D/osh ] ; then
            exec $D/osh
        fi
    done
    fi
fi                                     #added line
...

```
4. Save and exit the file oraenv

PSUB Jobs

This section describes steps you should take, in order, when you troubleshoot PSUB problems. To troubleshoot a PSUB job:

1. ["Check the Failure Text in the Submitted Batch Jobs Window"](#) on page C-7
2. ["Check the PSUB Log Files"](#) on page C-8
3. ["If Batch Jobs Hang and the Batch Queue Is Full"](#) on page C-9
4. ["Determining if PSUB is Running for a Database"](#) on page C-10
5. ["Handling PSUB Failures that Return "Fatal two-task communication protocol" Error"](#) on page C-14
6. ["Tracking Previous PSUB Process Connections"](#) on page C-15

Check the Failure Text in the Submitted Batch Jobs Window

If a problem arises while you are running PSUB, you should first review the Failure Text field of the Submitted Batch Jobs window.

To check this field for your batch job:

1. Open the Submitted Batch Jobs window: select Admin, then PSUB/Reports Jobs, and then Batch Jobs.
2. Locate the relevant Batch Job ID number.
3. Check the Execution Status of the job. If there is an entry in the Failure Text field, make a note of its contents

If the failure text does not help you to resolve the problem, refer to the ["Check the PSUB Log Files"](#) section on page C-8. If your batch job is hanging because the batch queue is full, refer to the ["If Batch Jobs Hang and the Batch Queue Is Full"](#) section on page C-9.

Check the PSUB Log Files

The PSUB process log files are cumulative, text-based descriptions of PSUB activity. These files are very helpful when you are troubleshooting problems with PSUB. Process log files can include time stamped entries for:

- error messages returned by the PSUB process
- all jobs submitted by the user; the entry may include each job's:
 - message id
 - batch_job_id
 - user name.

Naming Convention

On both UNIX and Windows systems, PSUB process log file names are in the form:

```
rxcpsd_product_instance_code_environment_1.log
```

On UNIX systems, there is a second process log file. Whenever you examine the "*_1.log" process log file on UNIX systems, you should also check this second file to see if it contains relevant entries. Its name is identical to the first log file, except that it has an "_2" suffix, rather than "_1". So the second UNIX process log file name is in the form:

```
rxcpsd_product_instance_code_environment_2.log
```

The "*_2.log" process log files contain error and warning messages that are generated by certain UNIX commands that the PSUB daemon executes (e.g., non-background commands). These commands are not present in the PSUB service on Windows. Therefore, Windows systems only generate "*_1.log" process files.

Verbose vs. Nonverbose Mode

The [verbose | nonverbose] argument must be included when the PSUB startup command, `rxcpsdps`, is executed. We recommend that you start PSUB in verbose mode because the process logs that are generated:

- contribute to efficient troubleshooting, and
- do not pose significant disk space concerns.

On UNIX systems, `rxcpsdps` is 'wrapped' in the OPA script `start_psub`. By default, the `start_psub` script executes `rxcpsdps` in verbose mode.

On Windows systems, the PSUB service requires that you explicitly provide the [verbose | nonverbose] argument. Refer to the ["Managing the PSUB Process"](#) section on page 8-3.

If you cannot check the Failure text or the .out and .log files because the batch queue is hung, refer to the ["If Batch Jobs Hang and the Batch Queue Is Full"](#) section on page C-9.

Verify that the process log files for the relevant Batch Job ID exist.

Review the .out and .log files. The following table summarizes these files. Make a note of any error messages.

Name	Description	Directory
lbatch_job_id.log	Log file of a specific job	RXC_LOG
obatch_job_id.out	Output file of a specific job	RXC_LOG
*.log	Log file of the PSUB process (see "Viewing Log and Output Files on the Screen" on page 8-10 for naming convention)	RXC_CENTRAL_LOG

Check the job-specific log and output files first, then the central log file. In the central log file, search for the batch job ID number to find the relevant entry. See if the database and code environment settings are correct.

If Batch Jobs Hang and the Batch Queue Is Full

If all PSUB jobs hang (that is, they do not reach a completed execution status), and the batch queue is full, attempt to clear the queue and submit a single job to PSUB. If a problem then occurs with a single job, it may be clearer which area is causing the problem. The method for clearing the queue is either: stop all of the hung batch jobs (on UNIX systems) or stop the PSUB service (on Windows systems).

The queue may become full and PSUB jobs may hang under the following circumstances:

- PSUB is waiting, either for an operating system resource, or a database resource
- the operating system is overloaded, for example, a built-in limitation, such as maximum number of processes, is exceeded.

Stopping Batch Jobs on UNIX Systems

This section describes how to stop batch jobs on UNIX systems. See also ["Starting and Stopping PSUB Manually in UNIX"](#) on page 8-4.

Stopping an Individual Job Follow these steps to stop an individual batch job:

1. Navigate to **Admin, PSUB/Reports Jobs, and Batch Jobs**.
2. Locate and select the row associated with the relevant Batch Job ID.
3. Click the **Stop** button.

Stopping all Jobs On UNIX servers, a series of hanging jobs can cause the batch queue to become full. When the queue fills and is backlogged with hanging jobs, all jobs are eventually given an execution status of SUBMIT_FAILED or SUBMITTED. If this type of problem occurs frequently, it may be advantageous to fine-tune the existing queues or add more queues.

Administrator-level Troubleshooting If, after trying all relevant solutions, you are unable to stop the jobs on a UNIX server, contact your Administrator so that she may use the solutions described here.

Only Administrator-level personnel should attempt to stop PSUB jobs using these solutions. Use these strategies, in the order they are listed, to stop PSUB jobs.

1. Use the stop_psub utility. Refer to the Stopping PSUB on a UNIX system question.

2. Identify and then stop the processes that are hanging:

- a. To identify the process that is hanging, use either:

```
ps -ef|grep rxcprod
```

or

```
ps -ef|grep userid
```

- b. To stop all of the hanging processes that you identified in Step 2a, use this command:

```
kill -9 pid
```

3. Log in as rxcprod and, at a command prompt, enter:

```
at -l [-q]
```

This command lists all of the jobs that are currently in all of the queues. Each job has a unique ID number. (Refer to the at man pages for additional information.)

If there are jobs pending in the queue, the following command, which uses the unique ID number to remove specific jobs from the queue, may be of use:

```
at -r id
```

1. If you are able to stop all PSUB jobs, stop and then restart the PSUB daemon and submit one job. If it hangs, try to isolate whether one particular module is the cause or if any PSUB job hangs, regardless of module.
2. If you are unable to determine a module that is causing the problem and jobs are still hanging, the only recourse is to reboot the computer.

Stopping Batch Jobs on Windows

On Windows systems, we recommend that you:

1. Stop the PSUB service.
2. Shut down any databases, if any, that are on the computer.
3. Reboot the computer.
4. Start the PSUB service.

See "[Starting and Stopping PSUB Manually in Windows](#)" on page 8-6.

Determining if PSUB is Running for a Database

To find out if a PSUB process is listening to a particular database, and if it is, what code environment it is running in, enter this query:

```
SQL> select host, code_environment, stop_ts
2  from psub_process_log
3  where start_ts = (
4  select max (start_ts) from psub_process_log;
```

This query returns the:

- computer on which PSUB was last started against the database
- code environment

- state of the process:
 - if stop_ts is null, the PSUB process is currently active
 - if stop_ts is not null, the PSUB process is stopped.

Note: As an alternative, to find out on which computer PSUB is set up, query either the:

- OCL_STATE local reference codelist, or
- RXC.PSUB_PROCESS_LOG table

Use this information, in conjunction with the operating system-specific instructions, below, to determine if PSUB is running on a given computer.

What PSUB Processes are Running on a Given UNIX Server?

Use this command to find out if PSUB is running on particular UNIX server:

```
% ps -ef | grep -i rxcpsdps
```

The process search command, `ps`, returns descriptions of the PSUB daemons that are currently running. Each row that is returned represents one PSUB process running on the server. Each process has a unique `product_instance` and `code_environment` pair. The format of the response to the process search command listed above is:

```
rxcpsdps [verbose|nonverbose]product_instance code_environment
```

Example C-1 Using the ps Command

Two examples of `ps` command usage:

```
rxcprod 15685 1 0 Apr 04 ? 0:00 rxcpsdps verbose sun3x8 ssuneja_oc40_sun
rxcprod 4143 1 0 Apr 02 ? 0:00 rxcpsdps verbose sun1x40 40102_8163
```

Is PSUB Running on a Given Windows Server?

Use this procedure to find out if the PSUB service is running on a given Windows server.

1. Open the Control Panel.
2. Double-click the Services icon.
3. In the Services window, note the status of the PSUB service with the relevant database name. The status will be "Started" if the service is running.

Troubleshooting PSUB Based on the Batch Job's Execution Status

Execution status as reported in the Submitted Batch Jobs form is shown below. You can take various actions depending on execution status.

Value	Meaning
ENTERED	The user has requested a job submission.
SUBMITTED	The process submitted the job to the batch queue; it may be pending.
SUBMIT_FAILED	The process attempted to submit the job to the batch queue but failed.
STARTED	The job is executing on the batch queue.

Value	Meaning
SUCCESS	The job completed with SUCCESS status.
FAILURE	The job completed with FAILURE status. Look at the Failure Text in the Submitted Batch Jobs window for possible reasons.

Examine the Submitted Batch Jobs window, look for the Execution Status and Failure Text for your Batch Job ID, and take one of the following actions, depending on the circumstances.

ENTERED

If the Execution Status of your batch job remains at ENTERED, perhaps:

- The PSUB process is not running on the server, or it is not receiving the request from the client.
- The corresponding Oracle user's operating system account does not exist.

SUBMITTED

If the Execution Status of your batch job remains at SUBMITTED, perhaps:

- The user is not connected through an OPS\$USER Oracle account.
- The job is pending in the batch queue, or the batch queue is stopped.
- The PSUB process does not have Write permission for the user's RXC_LOG directory on the PSUB server.
- A log file exists with the same number as the one for the submitted job. This is a rare situation. Delete the old log file and resubmit the job.
- In the case of a PSUB job that stays in SUBMITTED status even though the PSUB daemon is up and running, if your .log file says:

```
ERROR:Error while connecting:
      ORA-01017: invalid username/password; logon denied
```

```
Exiting...
```

Edit the file sqlnet.ora by commenting out the following line, and save it.

```
SQLNET.AUTHENTICATION_SERVICES = (NTS)
```

If the PSUB daemon is still running you are all set to resubmit the PSUB jobs. Otherwise, stop, and then start the PSUB daemon.

PSUB does not start after installing or upgrading

1. Locate the file, sqlnet.ora.
2. Locate and comment out the line (i.e., place '#' at the beginning of the line):

```
sqlnet.authentication_service=(NTS)
```

3. Start PSUB.

If PSUB fails to start:

1. Locate and uncomment the line in sqlnet.ora:

```
sqlnet.authentication_service=(NTS)
```

2. Locate and ensure that these lines in init.ora are **not** commented out:

```
remote_os_authent=true
os_authent_prefix="OPS$"
```

Note: On UNIX, if SAS (and SQL*Plus and PSUB) reside on the same computer as the Oracle Clinical database, and **RXC_SAS_CONNECT** is not defined, then you can set remote_os_authent to false. On Windows, remote_os_authent must be set to false.

3. Shutdown any databases on the Windows machine.
4. Start the databases.
5. Locate and comment out the line in sqlnet.ora.

```
sqlnet.authentication_service=(NTS)
```

SUBMIT_FAILED

If the Execution Status of your batch job is SUBMIT_FAILED, examine the Failure Text. If this action gives no possible cause, perhaps:

- The command rsh (remsh on HP-UX) cannot be executed by the RXCPROD user. Check that the host name in the /etc/hosts.equiv file is the official name of the host as specified in /etc/hosts.
- The user's password is not correct.
- The batch queue does not exist. Check the Long Value of the BATCH QUEUE NAME local reference codelist.
- The batch queue is in a stopped state.

STARTED

If the Execution Status of your batch job remains at STARTED, perhaps:

- The job is executing and waiting for some resource.
- The job is hung.

FAILED

If the Execution Status is FAILED, examine the Failure Text. If this action gives no possible cause, perhaps:

- The report or command exited with error status.
- The report or executable file does not exist.
- The print command exited with failure status, because, for example, the specified print queue does not exist.

Other Items to Check

Make sure the Long Value of the entry SERVER_OS in the local reference codelist OCL_STATE is correct for your operating system – that is, set to Windows or UNIX. SERVER_NAME in OCL_STATE should be set to the database/PSUB server.

Note: On UNIX systems, the Long Value of the SERVER_NAME entry (also in OCL_STATE) must be in lowercase letters.

Check that your RXC_LOG is correctly defined or modify the user's log directory via the menu path **Admin**, then **Users**, and **Oracle Accounts**.

Note: You may get an error message on the Windows server about the Kernel32.DLL initialization because of too many jobs running at the same time. Stop the unwanted processes, including cmd.exe and pslaunch.exe, using the Task Manager. If the error happens frequently, stop the PSUB service, reboot the Windows server, and restart the PSUB service. This should fix the problem.

Handling PSUB Failures that Return "Fatal two-task communication protocol" Error

If you submit a PSUB job that fails and returns a "Fatal two-task communication protocol" error (this failure is sometimes followed by the "End-of-communication-channel" in the core dump information on your console), you might have the environment variable NLS_LANG set inconsistently with the settings in the database.

To verify that the environment variable NLS_LANG matches the actual database settings:

1. Execute the following query:

```
SQL> select parameter, value from V$NLS_PARAMETERS
       where parameter in ('NLS_LANGUAGE', 'NLS_TERRITORY', 'NLS_CHARACTERSET');
```

2. Open opa_settings and search for the following string:

```
db_env_setting:database_name:NLS_LANG
```

- a. If you do not find this string, add a line with the following syntax:

```
db_env_setting:database_name:NLS_LANG:NLS_LANGUAGE_NLS_TERRITORY.NLS_
CHARACTERSET
```

Where *NLS_LANGUAGE_NLS_TERRITORY.NLS_CHARACTERSET* are the values returned in step 1.

- b. If you find the string, correct the values to match the values in step one in the following syntax:

```
db_env_setting:database_name:NLS_LANG:NLS_LANGUAGE_NLS_TERRITORY.NLS_
CHARACTERSET
```

Where *NLS_LANGUAGE_NLS_TERRITORY.NLS_CHARACTERSET* are the values returned in step 1.

Handling PSUB Failure that Returns "Illegal use of PSLAUNCH..." Error

In a UNIX environment, you may see the following error when you submit a PSUB job (3GL or PLSQL):

```
Illegal use of PSLAUNCH by user. Job Id=batch_job_id. Exiting...
```

This error generally does not occur each time you run a job.

Workaround

If above problem happens frequently in your environment the workaround is to modify `$RXC_PSUB/launchps.sh` as follows:

1. Logon to the UNIX computer on which the PSUB daemon is running, as owner of the file `launchps.sh` (this is usually OPAPPS).
2. Run `opa_setup` as appropriate for your shell environment.
3. Change to the `$RXC_PSUB` directory.
4. Edit `launchps.sh` by adding the following line just before the 'pslaunch' command:

```
sleep 2
pslaunch $4 $5 $6 $7 $3 $8
```

This introduces a 2-second delay before the system calls `pslaunch`. You may increase the delay if you still have a problem.

Tracking Previous PSUB Process Connections

To find out specific information about PSUB connections to a given database, query the table `RXC.PSUB_PROCESS_LOG`. This will return the:

- instance
- environment
- time a PSUB process started
- time a PSUB process stopped.

Example C-2 Host and Code Environment

This query will return the host and code environment for the last time PSUB was started against the database.

```
SQL> SELECT start_ts, host, code_environment, server_os
  2  from psub_process_log
  3  where start_ts= (select max(start_ts) from psub_process_log);
```

Example C-3 Start and Stop Timestamps

This example lists, in chronological order, all start and stop timestamps of PSUB processes.

```
SQL> SELECT start_ts, stop_ts, host, code_environment
  2  from psub_process_log order by 1;
```

Database Trace

You can trace a session connected to the Oracle Clinical Database and generate a log file. The following example, explains how to run a trace while in the Maintain DCM form.

1. Start a SQL*Plus session as SYS, or another user with the `DBMS_SYSTEM` role.
2. Find the session id and serial number of the Clinical user working in the Maintain DCM form:

```
SQL> select sid, serial# FROM v$session where username =
'OPS$userid';
```

3. Assume that 8 and 12 are returned for sid and serial#, enable SQL trace for the user as follows:

```
SQL> exec dbms_system.set_sql_trace_in_session(8,12,TRUE)
```

4. Have user perform the operation that causes the error. After the error is returned disable SQL trace:

```
SQL> exec dbms_system.set_sql_trace_in_session(8,12,FALSE)
```

5. Find the trace file out in your USER_DUMP_DEST directory. For example,

```
SQL> select value from v$parameter where name = 'user_dump_dest';
```

where value is the path, something like, /ind/oraclelogs/ maria/db/udump. The trace file is placed in this directory.

Oracle Clinical Tablespaces

This appendix lists the tablespaces in an Oracle Clinical database. Names preceded by "d-" are created when the database is created. The remainder are created when the Installer is run to install Oracle Clinical in the database.

Name	Oracle Clinical Use
DISC_REP_DATA	Disconnected Replication tables
RBS	To hold rollback segments
RXA_DES_DATA	Design tables
RXA_DES_IDX	Indexes for Design tables
RXA_LR_DATA	Lab Ranges tables
RXA_LR_IDX	Indexes for Lab Ranges tables
RXC_APP_IDX_TSPA	Indexes for Application Definition tables
RXC_APP_TSPA	Application Definition tables
RXC_DCD_IDX_TSPA	Indexes for Data Collection Definition tables
RXC_DCD_TSPA	Data Collection Definition tables
RXC_DCMQ_IDX_TSPA	Indexes for Data Management tables
RXC_DCMQ_TSPA	Data Management tables
RXC_DEF_IDX_TSPA	Indexes for Definition tables
RXC_DEF_TSPA	Definition tables
RXC_DISC_IDX_TSPA	Indexes for Discrepancy Management tables
RXC_DISC_TSPA	Discrepancy Management tables
RXC_GLIB_IDX_TSPA	Indexes for Global Library tables
RXC_GLIB_TSPA	Global Library tables
RXC_LI_IDX_TSPA	Indexes for Log-In tables
RXC_LI_TSPA	Log-In tables
RXC_RESP_IDX_TSPA	Indexes for Responses table
RXC_RESP_TSPA	Responses table
RXC_VRV_IDX_TSPA	Indexes for Validation Reported Values table
RXC_VRV_TSPA	Validation Reported Values table
d-SYSTEM	Standard Oracle tables

Name	Oracle Clinical Use
d-TEMP	Standard Oracle tables
TEMP1	Temporary Data Extract tables
TEST_DATA	Test tables
TEST_INDEX	Indexes for Test tables
d-TOOLS	Standard Oracle tables
d-USERS	Standard Oracle tables

In addition, the Oracle Thesaurus Management System creates these tablespaces:

Name	Oracle Thesaurus Management System Use
TMS_DATA	Data tables
TMS_IDX	Index tables

Routine Server Administration

This appendix covers system administration tasks that arise from changes to the system hardware or software.

Recreating Symbolic Links—UNIX Only

The symbolic links to the Oracle Clinical executables are lost when you, for example, copy the installation directory to a new drive (see also ["Relocating Oracle Clinical"](#) on page E-2).

To recreate the symbolic links, use the `relink_rxc.sh` script as follows:

```
% ksh
$ $RXC_TOOLS/relink_rxc.sh symbolic_links > $RXC_ROOT/relink_rxc.log 2>&1
exit%
```

The parameter `link` tells the script to re-establish symbolic links to the current Oracle Clinical executables, not to be confused with relinking the server code (see the next section).

Relinking Server Code—UNIX Only

With UNIX servers, you need to relink Oracle Clinical code files after either of the following events:

- a patch or upgrade to your operating system
- a patch to your Oracle RDBMS

Use the `opapps` userid to link all the server code from the supplied object files and set the file protections.

1. Enter the following commands:

```
% ksh
$ $RXC_TOOLS/relink_rxc.sh > $RXC_ROOT/relink_rxc.log 2>&1
$ exit
```

2. Check for errors in the log file, `relink_rxc.log`, using the following command:

```
% grep -i error $RXC_ROOT/relink_rxc.log
```

Or, to find out whether a relink has been successful by using a utility, enter:

```
% ksh $RXC_TOOLS/rxcchkobj.sh progs relink.mk
```

If all executables are created successfully, the output shows a set of empty directory paths. Any executable that is not created is listed in the `rxchkobj` output. For example:

```
Expected progs in =====> /u01/home/oppaps/bin/46/build/tools
gen_views: No such file or directory
cnvstatus: No such file or directory
```

This indicates that two executables, `gen_views` and `cnvstatus`, were expected but not created.

You should investigate the cause of the listed executables not being created.

Relocating Oracle Clinical

Should you decide to move the Oracle Clinical installation, you will have to edit the location references in one or more files, according to your server platform.

UNIX

In the file `oc/46/psub/launchps.sh`, modify the directory reference in this section:

```
p1=$1; export p1;
p2=$2; export p2;
. /pharm/home/opapps/oc/46/bin/opa_setup
USERNAME=$5; export USERNAME;
```

In the file `bin/opa_setup`, modify the directory reference in this section:

```
if [ ${OPA_BIN:-0} = 0 ]
then
  OPA_BIN=/pharm/home/opapps/oc/46/inst/bin
fi
```

Windows

Edit the file `oc/46/psub/launchps.bat`.

Updating Oracle Clinical Seed Data

If you run the Installer to create or upgrade an Oracle Clinical database, the Installer places the correct seed data in that database. If, however, you upgrade an existing Oracle Clinical database manually, you must also upgrade the seed data manually.

To upgrade Oracle Clinical seed data manually:

1. Set the environment variables as follows (for details, see [Appendix A](#)):

```
opa_setup database code_environment
```

Variable	Description
ORACLE_SID	set to the name of the database
ORACLE_HOME	set to your desired Oracle home directory
PATH	make sure <code>oracle_home/bin</code> is in your PATH variable

2. Collect the passwords for OPA and RXC.
3. From the install directory, run the script `loadseed.sql`:

```
SQLPLUS RXC/password@database
loadseed.sql
```

4. Enter responses for the loadseed.sql prompts:

Enter the password for OPA: **opa_password**
 Enter the password for RXC: **rxr_password**
 Enter product code (OC or TMS): OC

Collecting Statistics for Optimization

Oracle Clinical provides SQL scripts that you can use to collect computed statistics on the data distribution and storage characteristics of certain tables, indexes, and partitions. These statistics are used by the Cost-based optimizer.

Note: See the *Oracle® Database Performance Tuning Guide* for information on optimization.

[Table E-1](#) lists the schema for which each script gathers statistics. If you want computed statistics for customer-created tables, such as Thesaurus Management System tables, you must collect them yourself. The Oracle Clinical scripts are located in the RXC_INSTALL directory.

Table E-1 *Scripts for Optimization Statistics*

Schema	Collection script
RXA_DES	anadestab.sql
RXA_LR	analrtab.sql
RXC	anarxctab.sql
OPA	anaopatab.sql
RXA_DES, RXA_LR, RXC, OPA	ananlstab.sql

You must gather statistics on a regular basis to provide the optimizer with information about schema objects. How often you run these scripts depends on how quickly the data volumes in your Oracle Clinical tables increase.

During the initial use of Oracle Clinical you should run these scripts frequently since the data distribution changes rapidly. Once the database is populated, you should run statistics whenever the data volume changes by more than 20% or when some event, such as using a new feature, causes the data distribution to change measurably.

[Table E-2, "Suggested Frequency for Analysis Scripts"](#) gives a rough estimate on the frequency of running the analysis scripts.

Table E-2 *Suggested Frequency for Analysis Scripts*

Number of Studies	Frequency
Less than 10	For each new study
10 to 20	For every other study
20 to 100	For every 5 studies
More than 100	For every 20 studies

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 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.

active mode

In PDF [data entry mode](#), a status assigned to a CRF that allows the user (with appropriate privilege) to modify the CRF. Although multiple CRFs may be open in Only one CRF may be an instance that can be updated by users with appropriate privileges.

See also: [browse mode](#), [privilege](#), update

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, 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, an approval is equivalent to an electronic signature.

audit history

The set of all audit records for a given data point.

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 data point
- the previous value of the data point
- the user name that changed the data point
- the timestamp the data update occurred
- the change reason
- an optional comment

automatic progression

A feature of RDC 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 **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 RDC Classic 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 DE window and may also be present in the CRF Section, especially in multi-section CRFs.

book

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

Boolean expression

In RDC, a statement that uses a **Boolean operator** to construct a search string by combining two or more search strings. For example, the Data Subsearch window, which is subcomponent of the RDC Search window, uses a Boolean operator to join two search phrases.

Boolean operator

A key word that is used to logically join two search strings in a **Boolean expression**. RDC 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 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.

browse mode

In PDF **data entry mode**, a status that allows the user to work with the **CRF** as read-only; that is, data entry or update is not permitted. More than one browse mode CRF can open simultaneously.

Two data entry window components allow you to quickly identify a CRF that is browse mode:

- the **watermark** that is visible along the left-hand margin of the CRF
- the CRF button bar, which differs significantly from the active mode version; in browse mode it contains three buttons:
 1. Close button
 2. Make Active
 3. Help.

See also: **active mode**

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

See **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. RDC, CRFs are depicted electronically, either through the classic data entry window or the PDF 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 user name of the person who made the change are recorded. In RDC, 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 data point changed. The change reason can be supplied either automatically (system-provided) or manually (user-provided).

Classic mode

In RDC, one of two [data entry modes](#) that are available which enable users with appropriate privileges to create and update patient data. In classic mode, the CRF is presented as an Oracle Form in a window that overlays the Main Application window, with the header displayed at the top of the form and each [section](#) presented as its own tab within the form window.

see also: [data entry mode](#), [PDF mode](#)

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, 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](#).

created

An RDC 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 DE staff.

CRF

See [case report form](#)

criterion

In reference to the RDC 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

A component of a CRF as it is displayed in the Classic data entry window. It consists of one or more **header fields**, in which you collect information that uniquely describes and defines the current CRF.

RDC will not save a CRF to the study database until all required CRF header and CRF section header fields are collected.

CRF information

A field in a PDF mode CRF in which you collect information that uniquely describes and defines the current CRF. Based on the type of information it collects, the field may be required or optional. It correlates directly with a CRF header field.

RDC will not save a CRF to the study database until all required CRF information and CRF section information fields are collected.

CRF section

In RDC, 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. 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 for an RDC [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 mode

In RDC, a designation that describes the method that is used to enter data into a CRF and save it to the study database. There are two modes that are available:

1. [Classic mode](#)
2. [PDF mode](#)

data entry status

A designation that describes the current state of data entry for a CRF. In RDC, 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 update

In RDC, 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](#)

DCAPI

An acronym for the Data Capture API system.

DCM

An acronym for [data collection module \(DCM\)](#).

default study

The preferred study associated with your user name. RDC 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 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 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 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, 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**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, that track the progression of a CRF from no data entered ("Created") through entry complete, to approved.

See also: [blank](#), [created](#), [entry started](#), [entry complete](#)

event page

The Spreadsheet view that is associated with a given [spreadsheet view tab](#). An event page may represent a study, phase, or visit event and includes all of the patient rows and visit-page columns that are in the currently retrieved data set.

F

focus

In RDC, 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 is either 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 only.

I

indicator question

A question used with certain **question groups** 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 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 provides visual cues to alert the user to the presence of an investigator comment associated with a data point:

- 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.

Values that are defined for a **discrete value group** are displayed in a list of values.

See also: **list of values**, **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: PDR, status, browse mode, update mode, lock, unlock

lock status

A designation that describes the current state of a CRF, with regard to whether or not it may be updated. In RDC, there are two lock statuses:

- **locked**
- **unlocked**

list of values

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.

Note that when RDC is in PDF-enabled mode, you may leave a mandatory field uncollected and save the CRF in the "Save Incomplete" status to avoid the initiation of a discrepancy.

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, 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 commands.

Refer to the "Main Application window" and the "Menu bar" topics in the *RDC User's Guide* for further information.

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 utilize 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 and, the sites to which you have access. When you click a Site node, all patients assigned to the site that you have access to 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 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 user name, there may be more than one Site node displayed under the Study node, and generally many Patient nodes listed under each Site node.

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:

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

The data that represents a participant in a clinical study. This includes demographic information and clinical results.

patient data report

In Oracle Clinical or RDC, a patient data report (PDR) is a generated compilation of data that is presented in a **PDF** document.

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**.

PDF mode

In RDC, one of two **data entry modes**, PDF data entry enable users to create, view, and update a CRF that is presented as a PDF electronic document.

See also: **Classic mode, data entry mode**

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 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 user to perform a certain task. Privileges are granted to users in the RDC 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 users:

1. **browse**
2. Browse batch loaded data
3. Update data
4. Update batch data
5. Update discrepancies
6. Verify CRFs
7. Approve CRFs (on a site basis only)
8. Lock
9. Unlock (on a site basis only)

progression sequence

The order that RDC uses to navigate to and open CRFs. There are three different modes available in RDC:

1. By patient
2. By patient, within Spreadsheet view (Classic only)
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. In Classic mode, the system uses the progression sequence when other progression settings are selected. In PDF mode, the browse sequence is invoked when you use the Previous and Next buttons.

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

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 CRFs](#).

See also: [CRF](#), [optional CRF](#).

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 data point. This term usually refers to fields in the Question area of a CRF.

See also: [CRF](#), [data point](#)

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 [Classic mode](#) RDC, 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.

In [PDF mode](#) RDC, all save actions are explicit, initiated by the user clicking the Save button or choosing to save pending changes through the Save Edits? window.

save complete

In [PDF mode](#), a save action that causes RDC to assign the CRF to the [entry complete](#) data entry status.

save incomplete

In [PDF mode](#), a save action that causes RDC to assign the CRF to the [entry started](#) data entry status.

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 tasks that are associated with its scope are listed in the [Task pane](#). Because only one study can be active in RDC 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 [settings](#) 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 that allows a user to define directly the **search criteria** that is displayed in the RDC 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, 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 utilized in more than one view. Refer to the "Summary task tab" topic in the *RDC User's Guide* 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.

In **PDF mode**, the system displays a section discrepancy bar along the right-hand side of the CRF. The bar is colored according the highest discrepancy that is associated with the section and it is present along the extent of the CRF section.

In **Classic mode**, the system displays "<Oper>" as an indication of the presence of a section discrepancy in the title bar of the classic 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 and ends when you exit RDC. This is also referred to as an **RDC session**. It is constricted by limitations that are imposed by the following conditions:

- 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 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 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 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.

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 RDC 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

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.

spreadsheet view tab

In the RDC 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 retrieves

the data necessary to complete the task from the study database and displays it in the RDC Spreadsheet.

See also: [node](#), [scope](#), [Navigation pane](#)

test mode

A method of using RDC during study design, prior to the initiation of the protocol. Under normal circumstances, RDC 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 data point 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.

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

A set of users that are assigned to the same [user role](#). (RDC)

user role

A database role that is granted to a user or [user group](#).

In RDC, 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 allows privileges to be assigned independently of user role assignment.

The roles that RDC 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 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 data points, or edit checks, in the case of a single data point, that analyze collected data and return an query, or discrepancy, for each data point 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 data points 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, 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, a visit consists of one or more CRFs. By default, the system displays Spreadsheet Visit view in the RDC Workspace, which displays, for the current patient list, all of the CRFs collected for a single visit.

W**watermark**

A visible feature that overlays a **browse mode** CRF in the PDF DEW. It displays the timestamp of the last modification and the words "BROWSE ONLY". The browse mode watermark is visible along the left-hand margin of each CRF page.

workset

The collection of patient data that is currently displayed in the RDC 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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