Oracle Clinical

Administrator's Guide

Release 5.2.2
F50696-01
February 2022

Oracle Clinical Administrator's Guide, Release 5.2.2

F50696-01

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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 sections:

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.

Related resources

All documentation and other supporting materials are available on the Oracle Help Center.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface of Oracle Health Sciences Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

Part I
Configuration Tasks

This section includes tasks required after you install Oracle Clinical.

> **Note:**
>
> Some tasks also affect Remote Data Capture (RDC) Onsite. The Oracle Clinical Remote Data Capture Onsite Administrator's Guide has additional information.

For more information, see:

- Setting Up User Accounts
- Oracle Clinical Menu-Based Security
- Configuring Discrepancy Management
- Configuring the Mass Changes Utility
- Configuring Data Entry and User Preferences
- Configuring Data Extract
- Reference Codelists

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Setting Up User Accounts

In this section:

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 .
2. Add one of the following database roles; see Granting Additional Database Roles to User Accounts. By default, these roles provide the following menu access:
   - 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 PSUB Administrator Users and Setting Up Power Users.

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.

The Add User script prompts you for directories that users may need. You can set these directories up before or after you enter their names in the script. See Setting Up Batch Job File Viewing.

Who Needs PSUB?

The script prompts you to for a response as to whether the user needs PSUB privileges. 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

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

For more information, see:

- Granting Users Access to the ocpsub Account
- About the Add User Script
- Running the Add User Script
- Required Parameters
- Optional Parameters

Granting Users Access to the ocpsub Account

Users who need to submit PSUB jobs must have the ocpsub account as a proxy database account for PSUB jobs. To give this access, enter the appropriate information in the ocl_add_user.sql script; see Running the Add User Script .

If you have user accounts you created in Oracle Clinical releases prior to 5.0, you can migrate them to the new PSUB setup by running the migration script oclupg50migrateusers.sql. PSUB users no longer need their own operating system account, and they no longer need an account name beginning with OPS$; see Running the Migrate Users Script.

You can use ocl_grant_revoke_OCPSUB.sql to add or revoke access to ocpsub at any time; see Adding or Revoking OCPSUB Access.

Users with access to ocpsub have the PSUB User? field checked in the Oracle Accounts window. The field is read-only.

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
- Creates the setting you specify for PSUB privileges

> **Note:**
>
> You can copy and customize this script, or create different versions of it for different types of users.
>
> `For the 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 Setting Up Data Extract Users). You may want to add a role or profile to enforce password requirements; see Setting Password Requirements for User Accounts.
>
> 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.

Running the Add User Script

1. Log on to the operating system.
2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Change to the RXC_TOOLS directory:

   ```
   cd $RXC_TOOLS
   ```

4. Connect to SQL*Plus as `system`:

   ```
   sqlplus system
   ```

5. Run the Add User script:

   ```
   start ocl_add_user.sql
   ```

   See Table 1-1 and Table 1-2 for a description of the prompts output by the Add User script, valid entries, and examples.

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/Account Name	Defines the login name for the user. Names are not case sensitive.	`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.	`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`
Will this user submit PSUB jobs?/PSUB User?	Y: Account is granted access to ocpsub to submit PSUB jobs. N: No action	`Y`
Does this user need access to all users' jobs?	Y: Account is granted role RXC_VWJOBS. Only administrator users should have this role. See Setting Up PSUB Administrator Users N: No action	`N`

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

Prompt/Equivalent in Oracle Accounts Window	Description	Rules and Examples
`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, in the section "Set Up (Each) Reports Server for Access and File Viewing" of the *Oracle Clinical Installation Guide*.	String length cannot exceed 35 characters. `C:\oc_srvr\users\bsmith`
`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.	**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 following table describes the optional parameters for the Add User script. In addition, you can use the Maintain Oracle Accounts form to manage these optional parameters; see Maintaining Oracle User and Group User Accounts.

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.	-

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

Prompt/Equivalent in Oracle Accounts Window	Description	Rules and Examples
`Printer for PSUB` /Default PSUB Printer	The printer to which PSUB print jobs are routed, in uppercase. This response must match the Short Value of an active entry in the PRINT QUEUE NAME Local 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 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 Codelist. Must be entered in uppercase. 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 Codelist.)
`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 Codelist . Must be entered in uppercase.	`RXC_PRINTER` (This is the default value for the database shipped in the OCL_JOB_PREF Local Codelist.)
`Report Server` /Default Report Server	Specify a value 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 Codelist .	*`REPORT_SERVER`* (This is the default value for the database shipped in the OCL_JOB_PREF Local 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 Codelist . Required for RDC users only if they run Validate Study or Validate Site.	*`REPORT_SERVER`* (This is the default value for the database shipped in the OCL_JOB_PREF Local 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 Codelist . Required for RDC users only if they run Validate Study or Validate Site.	*`REPORT_SERVER`* (This is the default value for the database shipped in the OCL_JOB_PREF Local Codelist.)

Running the Migrate Users Script

If you have user accounts with PSUB privileges created in Oracle Clinical before Release 5.0, you must migrate them to enable them to continue running PSUB jobs in the current release. Instead of their own operating system account, they now need access to the ocpsub operating system account.

A prefix of OPS$ is no longer required, but the migration script does not remove the OPS$ from existing account names so that the user's audit history is not interrupted.

You can run this script on all OPS$ user accounts or on specified user accounts.

To run the migration script oclupg50migrateusers.sql:

1. Log on to the operating system.
2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Change to the RXC_TOOLS directory:

   ```
   cd %RXC_TOOLS%
   ```

4. Connect to SQL*Plus as `system`:

   ```
   sqlplus system
   ```

5. Run the user migration script:

   ```
   oclupg50migrateusers.sql
   ```

The script has one parameter, accounts. Its possible values are:

- `%` runs the script on all existing accounts that begin with the string OP$
- *`%name%`* runs the script on all accounts matching the pattern name, regardless of whether or not there is an OP$ prefix. (You can also use the wildcard % only at the beginning or end of the string: *`%name`* or *`name%`*.)
- *`specific_account_name`* runs the script on a single account

Adding or Revoking OCPSUB Access

You can grant or revoke a single user's access to the ocpsub proxy database account at any time by running the ocl_grant_revoke_OCPSUB.sql script.

To run the script ocl_grant_revoke_ocpsub.sql:

1. Log on to the operating system.
2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Change to the RXC_INSTALL directory:

   ```
   cd %RXC_INSTALL%
   ```

4. Connect to SQL*Plus as `system`:

   ```
   sqlplus system
   ```

5. Run the script:

   ```
   ocl_grant_revoke_ocpsub.sql
   ```

The script prompts for:

- the exact username
- an indication of whether you want to grant the privilege to the user (enter `1`) or revoke it (enter `0`).

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 for users who should have access to the same set of studies, programs, or projects in order to assign data access to all the users at the same time1. A user can belong to multiple group user accounts.
- View and modify settings for individual user accounts

> **Note:**
>
> 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; 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; 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.

PSUB User? - A checkbox column indicating whether or not a user is able to submit PSUB jobs. The user cannot edit the checkbox. The value is set by ocl_add_user.sql.

Report Server Directory- Location for log and output files from Oracle Clinical report jobs. You create the directory as part of setting up the Report Server during Oracle Clinical installation. See the section "Set Up (Each) Reports Server for Access and File Viewing" in the *Oracle Clinical Installation Guide*.

> **Note:**
>
> The location designation for any report server log directory 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 uppercase. 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 uppercase.

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 uppercase.

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 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.

For more information, see:

- Adding a User to a Group User Account

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. 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.

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
- Granting Data Access to a Study
- Superuser and Study Access Interaction
- Revoking User Access

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 select **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.

   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. 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 select **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

In this section:

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 more 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 more 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 also "Configuring Discrepancy Management in *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

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 (Data Collection Instruments, which become CRFs). You can change the default access for any role to RESTRICTED, then further define which DCIs (within the user's study/site access) can be accessed by that user's role.

- 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 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** 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 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 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

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. If you want a user to have read-only access, grant them RXC_ANY only.

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`

For more information, see:

- Additional Database Roles for RDC Users
- Additional Database Roles for Oracle Clinical Users

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 the following table, 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.

These database roles are mapped to user roles in the USER_GROUP_ROLES installation reference codelist. Those user roles are used to define security privileges and to customize various aspects of the user interface. See Configuring Discrepancy Management for more 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 Oracle Clinical Menu-Based Security for more information.

The roles in the following table 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 need a table in their individual user's schema that provides a location to save the SQL code the user creates using data extract functions.

Oracle provides a script, crusrq.sql, that creates a table called USER_QUERIES in an individual user's schema. 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
@rxc_install:crusrq.sql
```

Setting Up PSUB Administrator Users

You can give a user the role RXC_VWJOBS to allow them to:

- View all users' jobs
- View the output from those jobs.
- Stop any job.

You can use either of the following scripts to grant this role to a user:

- ocl_add_user
- ocl_grant_revoke_rxc_vwjobs.sql (This script can also be used to revoke the role.)

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 (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 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).

For more information, see:

- UNIX
- Windows

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. To run opa_setup, ensure that opapps_home/bin is in the PATH environment variable.

Changing Passwords

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

> **Note:**
>
> Passwords can contain only these special characters: ~ # ^ - _ + :
>
> Passwords cannot contain these special characters: & ( ) ' % @ { } | ; , $. * " < > ? ` ! [/ \ ] =

For more information, see:

- Changing the Password for a User
- Changing the Password for a Schema or Role Using the SET_PWD Utility
- Synchronizing Passwords in the WebLogic Admin Server
- Auditing Passwords
- Changing the Password for the OCPSUB or RXC_DISC_REP Account

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*;

Changing the Password for a Schema or Role Using the SET_PWD Utility

The following table lists the Oracle Clinical database objects that are protected by encrypted passwords stored in two locations:

- An Oracle dictionary table
- An Oracle Clinical passwords table

Use the SET_PWD utility to change the passwords for these accounts, encrypt the new password and store it in both locations:

Log in to the database server and, from the windows command prompt or UNIX command line, enter:

```
opa_setup
set_pwd account/account_pwd
```

where *account* is the name of the schema or role from Table 1-4.

> **Note:**
>
> The Oracle Database DEFAULT profile, which applies to all users by default, including these internal roles and schemas, enforces password requirements including an expiration period. **You must proactively change their passwords before they expire, or parts of the system will stop working.**

In rare cases you may want to change the password of the Wallet itself. See the *Oracle Fusion Middleware Administrator's Guide*. You must then change the passwords for the accounts.

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.

Synchronizing Passwords in the WebLogic Admin Server

The passwords for the following application middle tier accounts:

- RDC_MIDTIER_PROXY
- BC4J_INTERNAL
- OPS$TMSBROWSER (if you have TMS integrated with Oracle Clinical)

must be changed to the same value in two places:

- in Oracle Clinical or TMS using set_pwd (see Changing the Password for a Schema or Role Using the SET_PWD Utility)
- in the WebLogic Admin Server Connection Pool Manager

Auditing Passwords

Oracle recommends that you turn on the auditing system for roles. For information on the AUDIT command, see 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
```

Changing the Password for the OCPSUB or RXC_DISC_REP Account

The passwords for OCPSUB and RXC_DISC_REP are stored in Oracle Wallets on the database. You cannot use the set_pwd utility to change these passwords. Instead, do the following:

1. Log on as opapps.

2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Open an MS-DOS window.
4. Set the server environment; see Setting Environment Variables on the Command Line
5. Enter the following command, where *wallet_location* is the full path to the wallet:

```
mkstore -wrl wallet_location - modifyCredential tns_names_entry
OCPSUB_or_RXC_DISC_REP  new_password
```

6. The system prompts you for the wallet password.

Setting Password Requirements for User Accounts

Oracle Database software includes profiles through which you can enforce password requirements, including the DEFAULT profile that applies to all users by default.

> **Note:**
>
> Passwords can contain only these special characters: ~ # ^ - _ + :
>
> Passwords cannot contain these special characters: & ( ) ' % @ { } | ; , $. * " < > ? ` ! [/ \ ] =

For more information, see:

- Default Behavior
- Creating a Profile
- Assigning a Profile to Users
- Getting More Information

Default Behavior

The DEFAULT profile, which applies to all users by default in an Oracle Database installation, includes the following password-related requirements in Release 11gR2:

- Password life time = 180 days
- Password grace time = 7 days
- Password reuse time and password reuse max = Unlimited
- Failed login attempts = 10

> **Note:**
>
> In RDC, the default Failed Login Attempts setting of 10 in fact only allows for 5 failed login attempts before locking the account due to an incorrect password. This is because RDC uses proxy connections and tries to connect twice for each login attempt.
>
> In Oracle Clinical, this is not the case; a setting of 10 gives users 10 attempts.

- Password lock time = 1 day

If these settings are acceptable, you can do nothing and they will apply to all accounts. However, be sure to update internal account passwords; see Synchronizing Passwords in the WebLogic Admin Server.

Creating a Profile

To change the default settings, you can create a new profile for this purpose and assign it to all users. Use the CREATE PROFILE command to define a profile to specify your password policy.

Example 1-1 shows the SQL statements that create the OCL_USER_PROF profile and define the following password policies:

- Password life time — Sets the number of days the same password can be used for authentication to 60 days.
- Password grace time — Sets the time between expiration and lockout to 10 days.
- Password reuse time and password reuse max — Indicates that the user can never reuse a password.
- Failed login attempts

> **Note:**
>
> Set the number of failed login attempts to **two times** the number of failed attempts that you really want to allow. This is because Oracle Clinical uses proxy connections and tries the internal connection two times for each user attempt before locking the account due to an incorrect password.
>
> So in this example, FAILED_LOGIN_ATTEMPTS is set to 6, but this effectively results in 3 failed user attempts resulting in locking the account.

- Password lock time — Locks the account for 2 days if there are 3 failed login attempts.
- Allowed characters — Oracle Clinical and RDC do not support the use of special characters in passwords, which may cause errors. Use password profiles to prevent the use of special characters. Also see Changing Passwords.

For additional information, see the *Oracle Database 2 Day + Security Guide 11g Release 2 (11.2)* at `http://docs.oracle.com/cd/B19306_01/network.102/b14266/policies.htm#i1006575`

Example 1-1 Creating a Profile for Password Management

```
CREATE PROFILE OCL_USER_PROF LIMIT
PASSWORD_LIFE_TIME 60
PASSWORD_GRACE_TIME 10
PASSWORD_REUSE_TIME 1200
PASSWORD_REUSE_MAX UNLIMITED
FAILED_LOGIN_ATTEMPTS 6
PASSWORD_LOCK_TIME 2
```

Assigning a Profile to Users

Assign the profile to users:

- For new users, you can add a line in the ocl_add_user.sql to assign the password enforcing profile as you create each user account.
- For existing PSUB users, you can add the same line to oclupg50migrateusers.sql to give all of them the profile at the same time that you migrate their account to the new PSUB requirements.
- For other existing PSUB users, assign the profile individually or work with Oracle Support to develop a script to migrate them to the new profile.

The SQL statement required to assign a profile to a user is:

```
alter user user_name profile profile_name;
```

Example 1-2 Assigning a Role to Users

```
alter user jjsmith profile ocl_user_prof;
```

Getting More Information

For more information about how to use password management and protection, see the *Oracle® Database Security Guide* 11g Release 2 (11.2).

2
Oracle Clinical Menu-Based Security

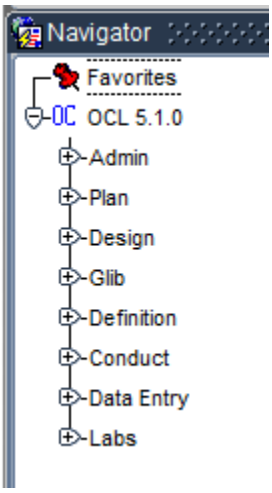
You control which users have access to which menu items in the Oracle Clinical Navigator (see Figure 2-1) by assigning database roles to users.

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.

For information about predefined database roles, see Creating an Administrator User Account, About the Add User Script, and Granting Additional Database Roles to User Accounts.

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.

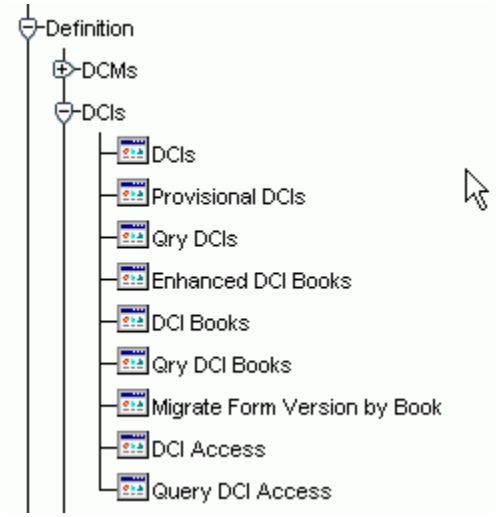
For information about the tasks in each menu, see the following Oracle Clinical user documentation:

- The *Oracle Clinical Administrator's Guide* has information on the Admin menu.
- *Oracle Clinical Creating a Study* has information on the Plan, Design, Global Library, Definition, and Labs 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



For more information, see:

- Predefined Database Roles
- Creating and Modifying Database Roles
- Adding Menu Items to Oracle Clinical

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.

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.

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.

For more information, see:

- Viewing Menu-Role Associations
- Modifying Menu-Role Associations
- Creating Custom Database Roles
- Associating Roles with Menus
- Adding a Custom Role to OPA_MENU_ROLES
- Granting a Custom Role Access to a Custom Module

Viewing Menu-Role Associations

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.

For more information, see:

- Organization of the Menu Module Tree

- Navigating the Menu Modules

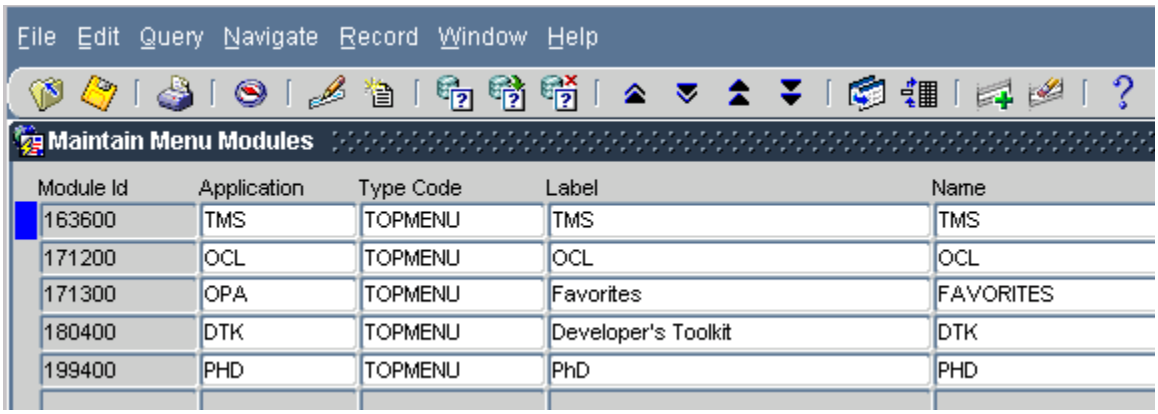
Organization of the Menu Module Tree

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



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.

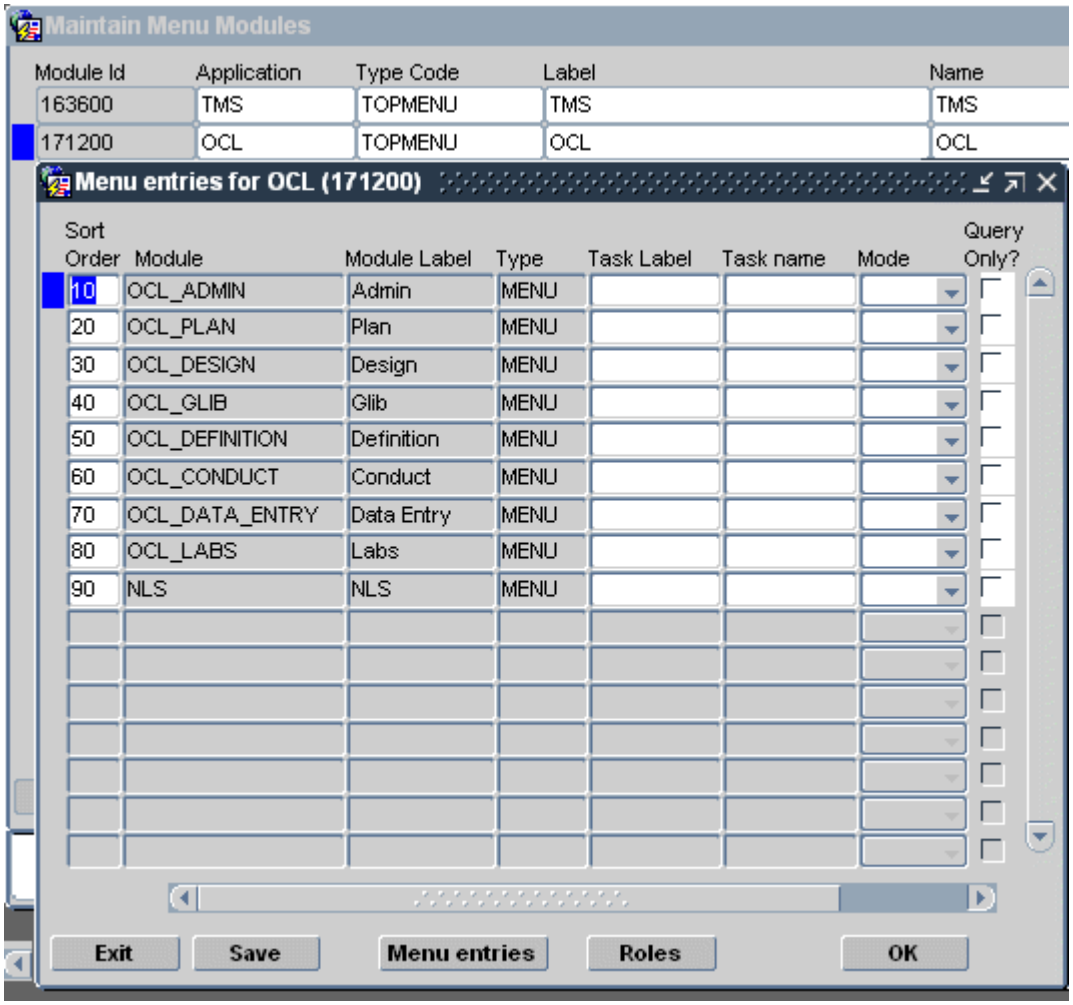
The concatenation of nodes, starting at OPA, ending at the leaf node, and including the task and the query mode, is the internal analog of the Navigator menu path to the activity. For instance, the menu path **OC**, then **Data Entry**, and **Initial Log-In**, plus **Entry** corresponds to the series of nodes OPA:OCL:OCL_DATA_ENTRY:RXCDEMLI, 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. Therefore, 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



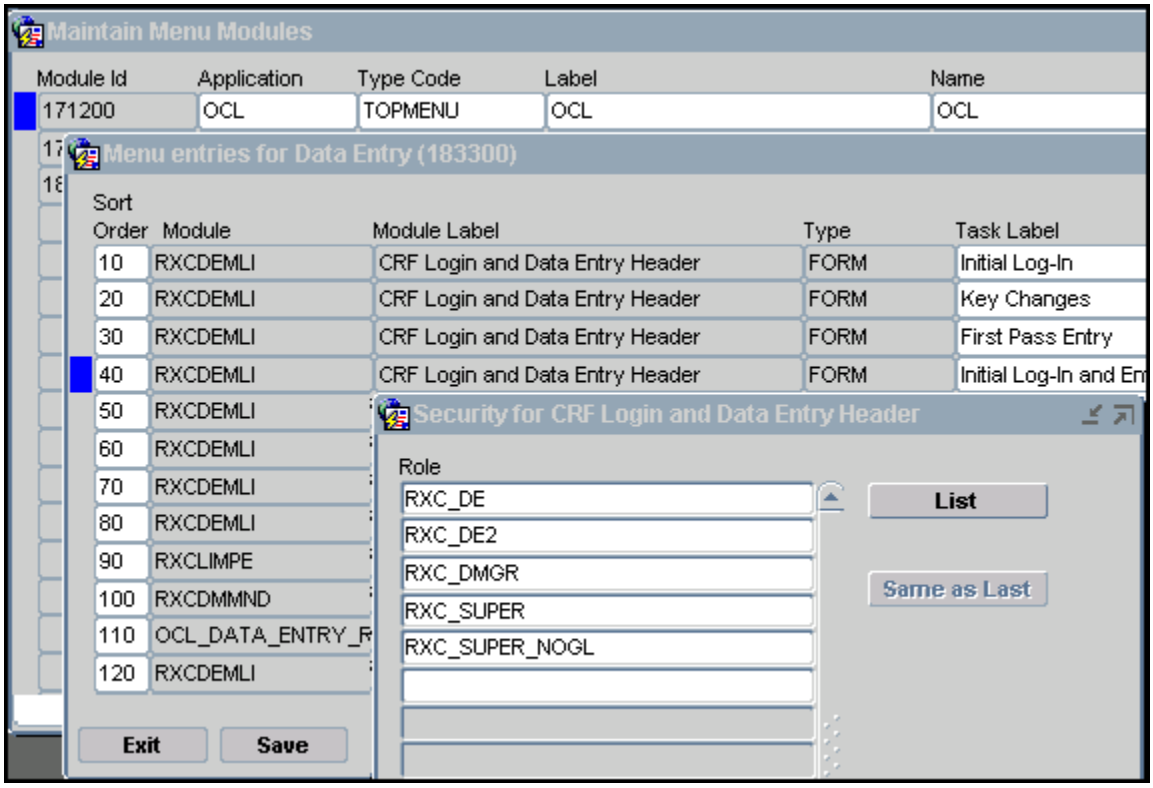
Navigating the Menu Modules

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, 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

Figure 2-5 Security for Task Dialog Box



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.

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 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) and add it to a reference codelist (see Adding a Custom Role to OPA_MENU_ROLES).

Menu and module access role names must start with the three-letter designator of the application to which they will apply **and must not exceed 11 characters total**. The following table list the valid prefixes for the available applications.

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, and 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 Stable Interface Technical Reference Manual*.

In this section:

- Creating Custom Roles for Restricting DCI Access

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. 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. 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. 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) 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. 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 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:**
>
> To assign a new role to a standard Oracle Clinical module, see Modifying Menu-Role Associations.

Adding Menu Items to Oracle Clinical

You can add your own menu items (Developer modules) to the Admin menu, thus extending the functionality of Oracle Clinical. You can preserve changes across releases of Oracle Clinical. See the *Oracle Clinical 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**.

3
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.

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

For more information, see:

- Mapping Database Roles to User Roles
- Customizing Layout Definitions
- Customizing Profiles
- Customizing Flexfields
- Defining Reason Codes for Discrepancies
- Defining the Possible Review Statuses for Discrepancies
- Defining Resolution Reasons for Discrepancies
- Setting Values in the OCL_STATE Local Reference Codelist
- Configuring Role-Specific Discrepancy Management for RDC
- Configuring Study and Site Security for Oracle Clinical Discrepancy Management
- Setting Up Data Clarification Forms (DCFs)
- Creating Reusable Standard Text for Discrepancies and DCFs

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 .
- You can customize profiles for different roles; see Customizing Profiles.

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.

The following table 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 Configuring Discrepancy Management

For more information, see:

- Specifying User Roles for the Oracle Clinical Discrepancy Database
- Assigning Function Privileges and Layouts

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.

For more information, see:

- Assigning and Removing Function Privileges
- Assigning Custom 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.
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 , 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

Customizing profiles 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.

For information about user roles, see Mapping Database Roles to User Roles.

In this section:

Toggling Between View Modes in the Profile Administration Window

To open the Profile Administration window:

1. Navigate to **Admin, Discrepancy Mgmt Admin,** and then select **Profile Administration.**

   The Profile Administration window has two viewing modes: multi-view and single-view. The window opens in multi-view mode by default.

   In multi-view mode, you can view all the profiles currently defined. In single-view mode, you view one profile at a time. In either mode, you can create new profiles and specify the criteria for each profile.

2. Click the **View Mode** button in the upper right corner of the form to toggle between multi-view and single-view mode.

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-view mode 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.)

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 shows a region of the Profile Administration form in multi-view mode. (Many of the intervening criteria fields have been scrolled out of view 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 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

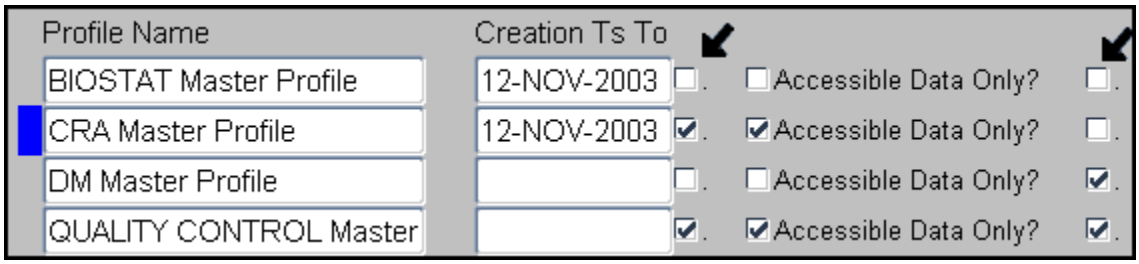


Table 3-4 Legend for Figure 3-1

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 shows 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 Statuses for Discrepancies.) 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.

The following table 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.)

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.

For more information, see:

- Adding Update Privileges by Review Status Code
- Setting Update Privileges by Discrepancy Field
- Setting Review Status Updating Privileges

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.)

> **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. The following table 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. 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

Table 3-6 (Cont.) Field Status Values

Field Status Value	Field in the Maintain Discrepancy Database Form or Description
ASSOCIATED ID	Associate a discrepancy for passive review field
CRF PAGE NUMBER	CRF Page Number
FLEXFIELD1	User-definable field (See Customizing Flexfields.)
FLEXFIELD2	User-definable field (See Customizing Flexfields.)

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 local 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';
```

For more information, see:

DISC_FLEX1 and DISC_FLEX2

Use these local reference codelists to customize the label for Flexfield1 or Flexfield2, to enable the field, to 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	*text*	Enter freeform text as the long value. This text becomes the field 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.)

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 list of values for the flexfield.
Short Value	Is the stored value when the user selects the row from the list of values.
Long Value	Can duplicate the short value; is not displayed in the list of values.
Active box	Select the **Active** check box to have the entry appear in the list of values.
Default	Identifies which value is the default value.
Description	Provides additional information about the value; the information displays 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	Selected	-	Flexfield1 Displayed
2	REQUIRED	N	Selected	-	Flexfield1 Required
3	PROMPT	*Finished?*	Selected	-	Flexfield1 Prompt
4	LOV_VALIDATE	*Y*	Selected	-	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*	*Yes*	Selected	-	-
2	*N*	*No*	Selected	-	-
3	*U*	*Undetermined*	Selected	Selected	-

Defining Reason Codes for 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.

For more information, see:

- Reason Codes and Descriptions for Manual Discrepancies
- Reason Codes and Descriptions for Univariate Discrepancies
- Reason Codes and Descriptions for Multivariate Discrepancies

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.

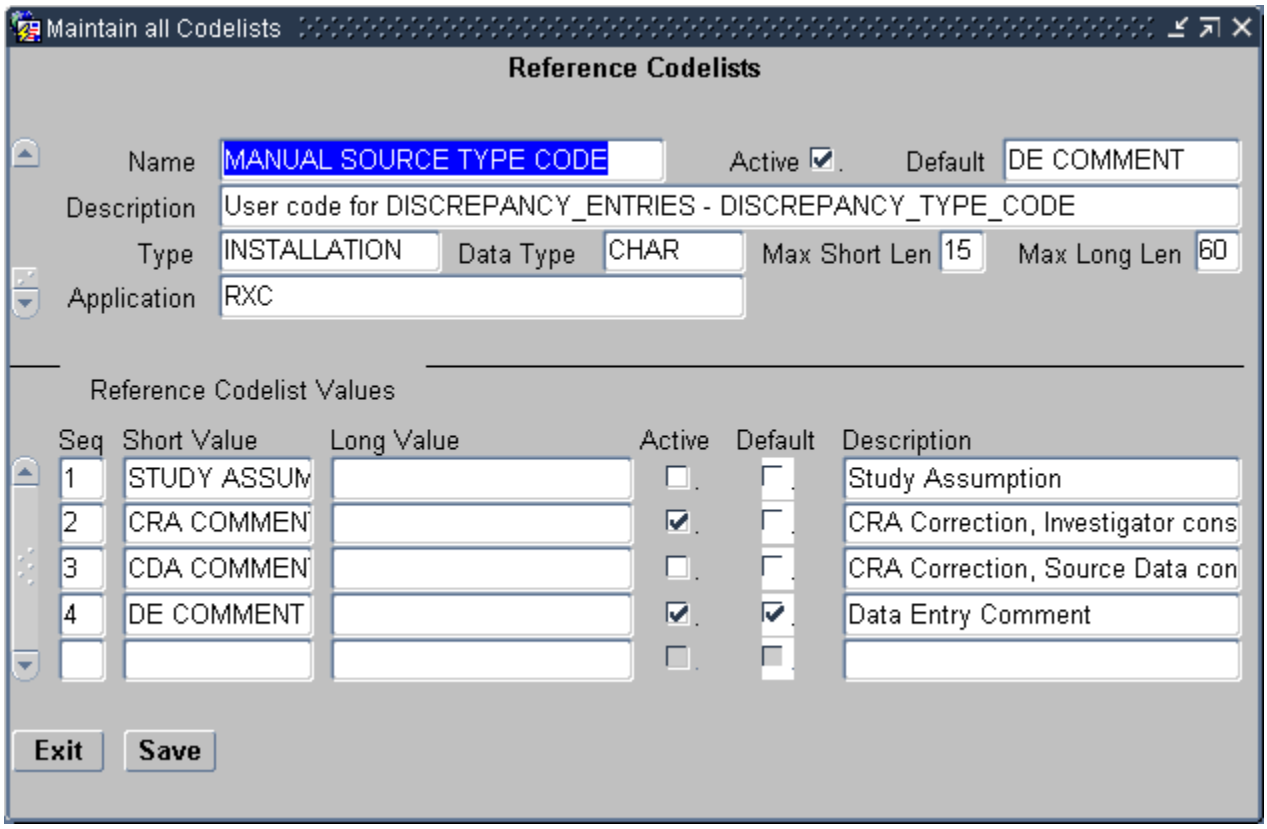
- Set one reason to Default. The first time the user creates a manual discrepancy during a login session, the system inserts the default reason. The user can select a different reason. For subsequent manual discrepancies, RDC Onsite displays the last entered reason. The user can always select a different 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.

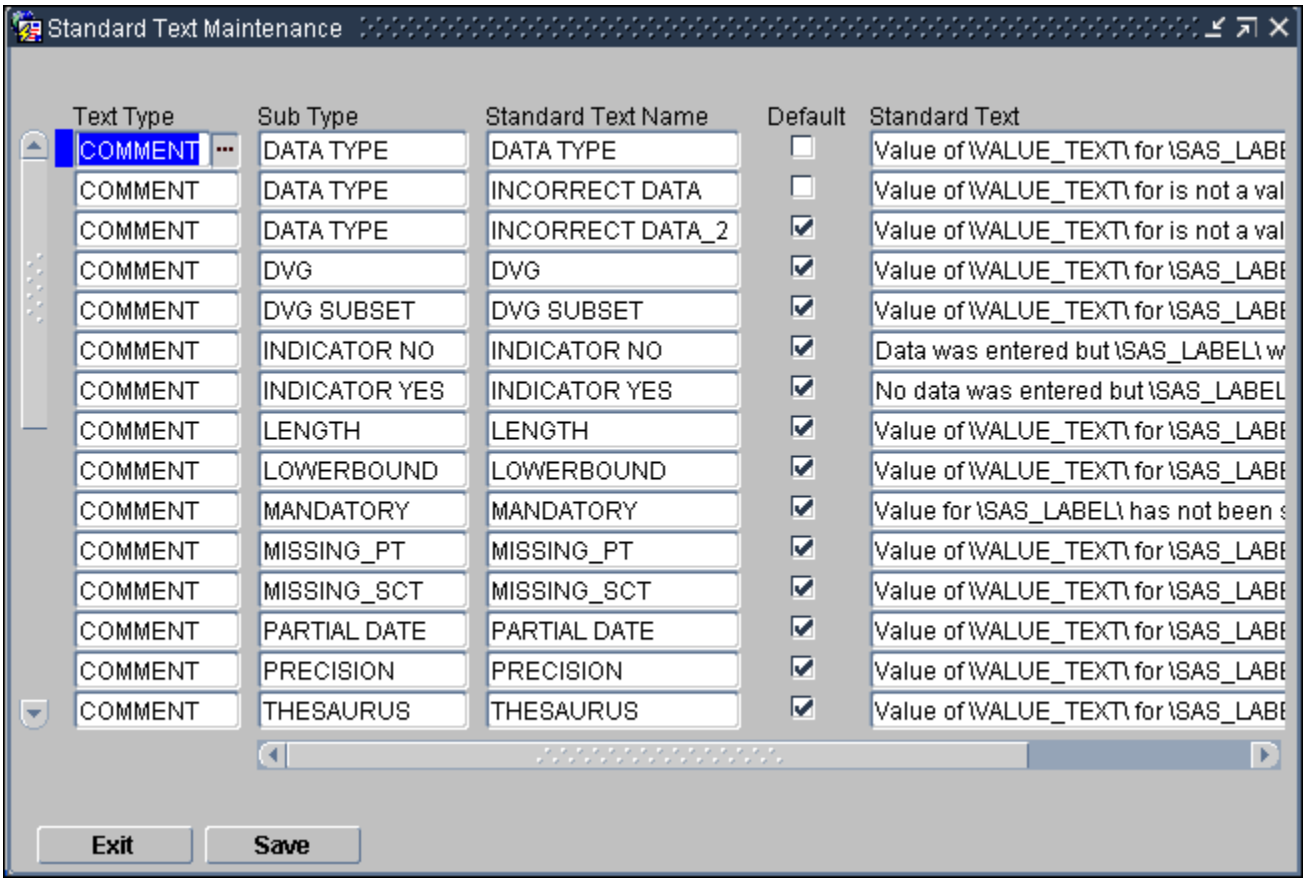
You use the fields in the Standard Text Maintenance form to define descriptions for each type of univariate discrepancy as follows:

- **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, 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.
- In **RDC**, add the new status' short value to each DISCREPANCY STATUS *ROLE* codelist. If the short value is IRRESOLVABLE in the DISCREPANCY REV STATUS CODE reference codelist, it must have a long value of CLOSED in the DISCREPANCY STATUS *ROLE* codelists.
  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 andConfiguring the Actions Allowed on Discrepancies .

In this section:

Default Entries for the DISCREPANCY REV STATUS CODE Codelist

The following table 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
CLOSED	CLOSED	The system sets a discrepancy's status to Closed when it is resolved by either updating the data to a nondiscrepant value or changing the validation procedure or question attribute in such a way that the existing data is no longer discrepant. The discrepancy's system status changes to Obsolete and the discrepancy is removed from its DCF (if any) and no longer appears as current in discrepancy reports.
CRA REVIEW	Null	Under CRA Review
INV REVIEW	Null	Under Investigator Review
RESOLVED	IRRESOLVABLE	Not assigned to any person or process. Setting a discrepancy's status to RESOLVED does not cause the system to close the discrepancy. That happens only when the data is no longer discrepant, either because the data has been updated to a nondiscrepant value or because the validation procedure or question attribute that flagged the value as discrepant has been changed in such a way that the existing value is no longer considered discrepant.
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

Table 3-12 (Cont.) Default Entries for the DISCREPANCY REV STATUS CODE Codelist

Short Value	Long Value	Description
INT CRA REV	Null	Internal - Under CRA Review

CLOSED: The system sets a discrepancy's status to Closed when it is resolved by either updating the data to a nondiscrepant value or changing the validation procedure or question attribute in such a way that the existing data is no longer discrepant. The discrepancy's system status changes to Obsolete and the discrepancy is removed from its DCF (if any) and no longer appears as current in discrepancy reports.

There are additional statuses that are not included in the reference codelist:

OBSOLETE: When the data is no longer discrepant—either because the data is updated or because the validation procedure or question attribute that flagged the data as discrepant is changed in such a way that the data is no longer discrepant—the system automatically updates the system status to OBSOLETE.

PASSIVE REVIEW is a status that allows you to reduce the number of discrepancy queries and the number of discrepancies on a DCF by associating one or more discrepancies with a primary discrepancy. You can then include all the discrepancies in a single query. When you create the DCF, do not include discrepancies marked as Passive Review in the printed DCF.

For example, if you have a page with three lab results and all three lab results are missing, you would have three discrepancies such as:

- AST lab units missing, please provide.
- ALT lab units missing, please provide.
- RBC lab units missing, please provide.

You could send three queries, but to save time, money, and paper you could choose to send only one query such as: Page 7 all lab units are missing, please provide.

To do this, mark the second two discrepancies for passive review associated with the first discrepancy as the primary discrepancy. Then create a DCF, include all three discrepancies in the DCF, but mark the primary discrepancy's status as For Distribution and the other discrepancies' status as Not For Distribution. When you print the DCF, only the primary discrepancy appears, but all three are included in the electronic DCF. When the answer to the query returns, you can update the data for all three discrepancies.

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 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 check box 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.

The following table 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.

Table 3-13 (Cont.) Values for the DISCREPANCY RESOLU TYPE CODE

Short Value	Long Value	Description
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 more 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 discepancies. 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 OCL_STATE local reference codelist 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 Settings in the OCL_STATE Codelist 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_HDFT	Y or N	The system does not use this setting.
DISC_AUTOR_CRFPG	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

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 Reference Codelists for general information on setting reference codelist values.

For more information, see:

- Configuring Discrepancy Display by User Role
- Configuring the Actions Allowed on Discrepancies
- Preventing Update to OTHER Discrepancies
- Adding Reference Codelists for Custom Roles

Configuring Discrepancy Display by User Role

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. You can create a DISCREPANCY STATUS reference codelist for additional roles; see Adding Reference Codelists for Custom Roles.

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.

- **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 check box 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.

For more information, see:

- How RDC Indicates Discrepancies in the User Interface
- Rules for the DISCREPANCY STATUS role Codelists
- Comparison of the Default Values for the DISCREPANCY STATUS role Codelists
- DISCREPANCY STATUS CRA
- DISCREPANCY STATUS DM
- DISCREPANCY STATUS INV
- DISCREPANCY STATUS SITE

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: • 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:**
>
> RDC Onsite uses these reference codelist values.

- 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 check box 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

The following table 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	Long Value – RDC Onsite Display DM	Long Value – RDC Onsite Display INV	Long Value – RDC Onsite Display 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

Table 3-19 (Cont.) Values for the DISCREPANCY STATUS INV Reference Codelist

Seq	Short Value	Long Value	Active Check Box
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
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.

Only RDC uses the set of DISCREPANCY ACTIONS *role* codelists. You can create a DISCREPANCY ACTIONS reference codelist for additional roles; see Adding Reference Codelists for Custom Roles.

> **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 check box 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.

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

- Rules for the DISCREPANCY ACTIONS role Codelists
- DISCREPANCY ACTIONS CRA
- DISCREPANCY ACTIONS DM
- DISCREPANCY ACTIONS INV

- DISCREPANCY ACTIONS SITE

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.

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.

Adding Reference Codelists for Custom Roles

Oracle Clinical ships with Discrepancy Actions and Discrepancy Status reference codelists for these roles: DM, CRA, INV, and SITE. If you have defined additional roles, you can create additional Discrepancy Actions and Discrepancy Status reference codelists for these roles.

> **Note:**
>
> To create a custom role, create a new database role and map it to a User Group Role; see Creating and Modifying Database Roles and USER GROUP ROLES Installation Codelist .

Log in to SQL*Plus as RXC and run a script that includes the following statements to create a new Discrepancy Actions and a new Discrepancy Status reference codelist for your custom role:

```
exec opa_install.insertrc('DISCREPANCY ACTIONS custom_user_group_role',
'Y','60','15','INSTALLATION','CHAR','Discrepancy actions for
custom_user_group_role','','','RXC');

exec opa_install.insertrc('DISCREPANCY STATUS custom_user_group_role',
'Y','6','15','INSTALLATION','CHAR','Discrepancy status groupings for
custom_user_group_role','','','RXC');
```

The new reference codelists then appear in the Oracle Clinical user interface and you can add appropriate values.

Configuring Study and Site Security for Oracle Clinical Discrepancy Management

Study and Site privileges are primarily defined for use in RDC, but the BROWSE, UPDATE and UPD_DISCREP privileges in particular also define Oracle Clinical Discrepancy Management access at the study and site level.

Privileges granted at the site level take precedence over privileges granted at the study to which the site belongs. This hierarchy gives you the flexibility to grant a user privileges that are more extensive at one site and still let that user access data at other sites within the same study.

For more information on using Study and Site security in RDC refer to the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

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.

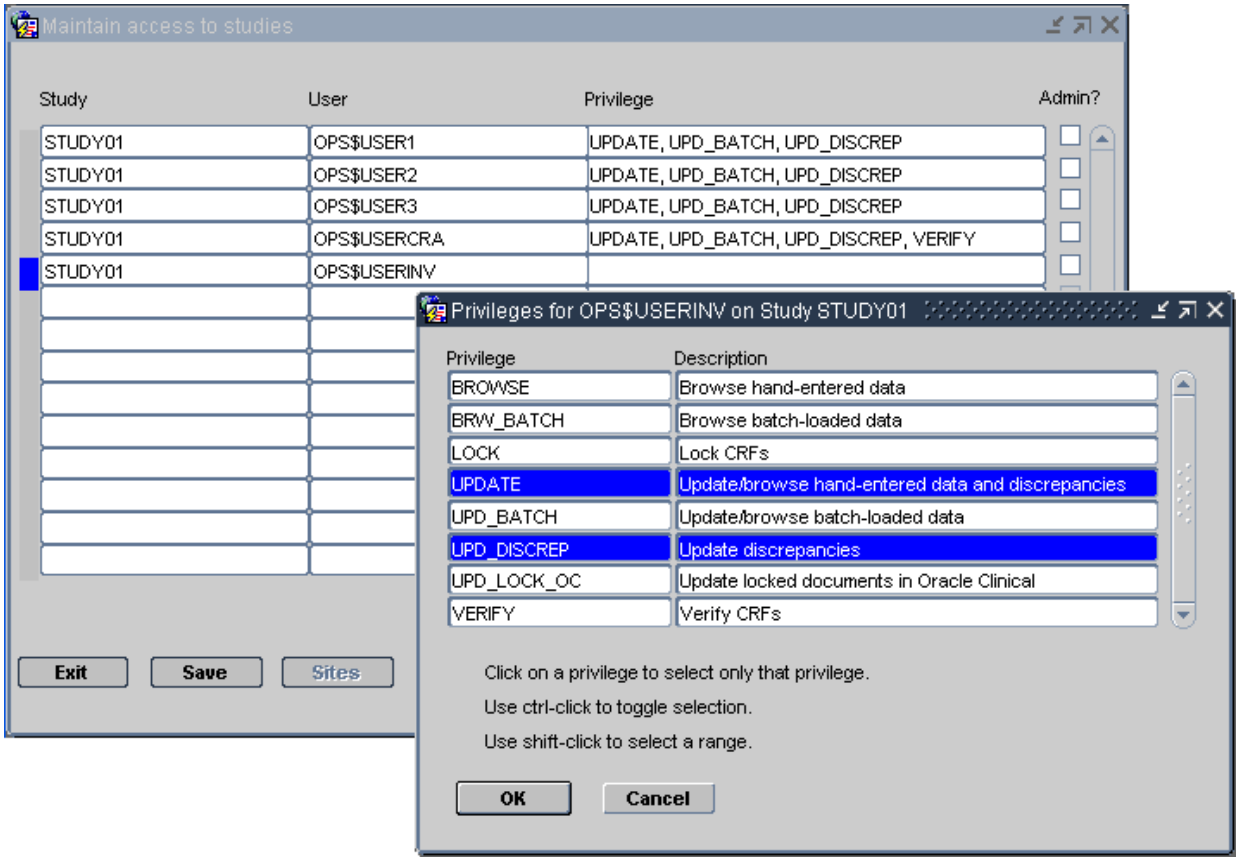
To add or modify the privileges for a user:

1. 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.

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



For more information, see:

- Updating a Discrepancy
- Navigating to Data Entry

Updating a Discrepancy

The study and site level UPDATE and UPD_DISCREP privileges work in conjunction with function profile privileges to allow a user to update discrepancies, as indicated in Figure 3-5.

To grant a user the ability to update discrepancies, make sure the user is configured at the study and site level in one of the following ways:

- The user has no specific privileges at the study level or for the site. In this case, the user is assumed to have the UPD_DISCREP privilege for any study where generic access is defined. See Granting Data Access to a Study
- The user is assigned UPDATE or UPD_DISCREP privileges at the study level. If no privileges are assigned at the site level, then the study level privileges are inherited and allow the user to update discrepancies.
- The user is assigned UPDATE or UPD_DISCREP privileges at the study site level. Since site privileges take precedence over study privileges, if ANY privilege is assigned to the user at the site level, you must also assign the UPDATE or UPD_DISCREP privilege for the site.

See Configuring Study and Site Security Privileges

Navigating to Data Entry

The Discrepancy Management system allows a user to navigate to data entry and browse or update data with the right combination of function privilege(s) and site-level BROWSE or UPDATE privileges, as described below.

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

- To allow a user to update data:

  To allow a user to update the data while in the Data Entry subsystem in Oracle Clinical, grant the UPD DATA ENTRY function profile privilege. It enables the Update Patient Data menu item under the Special menu in the Discrepancy database form. A user can update the data, irrespective of whether or not the user has the UPDATE privilege at the study-level or site-level.

  OR

  To allow a user to update data from RDC at the study-level or site-level, grant the UPDATE privilege in addition to the UPD DATA ENTRY function profile privilege.

  For details on study-level and site-level privilege interaction, see Updating a Discrepancy.

- To allow a user to browse all data:

  To allow a user to browse the data in the Data Entry subsystem in Oracle Clinical, grant the BRWS DATA ENTRY function profile privilege. It enables the Browse Patient Data menu under the Special menu in the Discrepancy database form.

  OR

  To allow a user to update data from RDC for a particular site or study, grant the UPDATE privilege at the study-level or site-level in addition to the BRWS DATA ENTRY function profile privilege.

Table 3-23 Available Function Profile Privileges for Discrepancy Management

Name	Functional Impact and Method of Use
UPD DATA ENTRY	Enables the Update Patient Data menu item under the Special menu, and it allows the user to update while in the Data Entry subsystem irrespective of whether or not the user is assigned the UPDATE privilege at the study-level or site-level.
BRWS DATA ENTRY	Shows the **Browse Patient Data** menu item under the **Special** menu for read-only access to patient data.
MANUAL	Shows the **Add Manual** button in the Maintain Discrepancy Database window, which allows the user to create manual discrepancies and manual header discrepancies.
DCF PRINT DRAFT	Shows the **Draft** option in the DCF Print Options window, which allows the user to print a draft version of a Data Clarification Form (DCF) report.
DCF PRINT COPY	Shows the **Copy** option in the DCF Print Options window, which allows the user to print a copy of a DCF.
DCF PRINT FINISH	Shows the **Final** option in the DCF Print Options window, which allows the user to print a final version of a DCF report.
DCF REPRINT	Shows the **Reprint** option in the DCF Print Options window, which allows 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.

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.

For more information, see:

- Defining DCF Statuses and their Behavior
- Laying Out the DCF
- Replacing the Placeholder DCF Logo Graphic
- Customizing and Upgrading DCF Reports

Defining DCF Statuses and their Behavior

There are several Installation Reference Codelists that affect DCF Statuses. You can modify them to for your organization's needs. See the following:

- DCF STATUS CODES
- DCF OPTIONAL STATUS CODES
- DCF LOCK CONDITIONS

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. Oracle recommends 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

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.

For laying out the DCF's contents and arranging its fields, and view a geographic representation of the DCF's default values and their placements, see:

- Replacing the DCF Placeholder Graphic
- Modifying Codelist DCF REPORT LABELS
- Modifying the DCF Views
- Defining DCF Headers and Footers
- Default DCF Layout Diagram

Replacing the DCF Placeholder Graphic

Oracle Clinical includes a placeholder graphic file located, typically, in your installation's `..\OPA`*`release_number`*`\oc` directory, and named `rxcdcf.bmp`. You can replace `rxcdcf.bmp` with your own graphic file, but you must name it `rxcdcf.bmp`. Oracle recommends 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 Short Value	Default Field Label from DCF_REPORT_LABELS Long Value	Default Data Value from DCF_RPT_MASTER and DCF_RPT_DETAIL Table.Column	Default Data Value from DCF_RPT_MASTER and DCF_RPT_DETAIL 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

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

Default Field Label from DCF_REPORT_LABELS Short Value	Default Field Label from DCF_REPORT_LABELS Long Value	Default Data Value from DCF_RPT_MASTER and DCF_RPT_DETAIL Table.Column	Default Data Value from DCF_RPT_MASTER and DCF_RPT_DETAIL Description
q_field1	Form Name/Visit Name:	dcms.description	Mapped to view value qline1_1
q_field2	Page #:	discrepancy_entries.crf_page_number	CRF page numberMapped to view value qline1_2
q_field3	Date:	discrepancy_entries.creation_ts	Discrepancy time stamp date: mm/dd/yyyyMapped 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

The following tables describe all of the parameters in the two DCF report views. The view scripts for the DCF are in file rxcviews.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.)

> **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.

Table 3-25 (Cont.) View DCF_RPT_MASTER Parameters

Parameter	Default Data Value (Table.Column)	Comments
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 *and* .lastname	DCF creator's account name
line2_left	ocl_investigators.first_name *(and)* .lastname	Investigator's first and last name.
line1_right	patient_positions.patient	Patient position
line2_right	patient_positions.reported_first_name *(and)* 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.
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	-

The following table 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). 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 > Default field label short value> **To:** line1_left ocl_sites.name *<=Default data value for the field*

rxcdcf.bmp

status_dnc dcf_discrepancies.status		**title1 clinical_studies.short_title**			
		title2			
To: line1_left	ocl_sites.name		**Patient#:** line1_right	patient_positions.patien	
Investigator: line2_left	ocl_investigators.first_name (and) .lastname		**Patient Initials:** line2_right	patient_positions.reported_first_name (and) .reported_last_name	
Date: line3_left	sysdate		**Reviewer:** line3_right	oracle_accounts.firstname (and) .lastname	
header_text					
Form Name/ Visit Name q_field1	**Page #** q_field2	**Questions/Comments** q_field4	**Resolution** q_field5		
	Date q_field3				
dcf_id_dnc data_clarification_forms.dcf_id	q_line1_2 discrepancy_entries.crf_page_number	q_line1_4 dcf_discrepancies.comment_text	q_line1_5 dcf_discrepancies.resolution_text		
q_line1_1 dcms.description	q_line1_3 received_dcms.dcm_date				
	Closed:	status_dnc dcf_discrepancies.status			
Disc ID:	discrepancy_entry_id_dnc discrepancy_entries.discrepancy_entries				

status_dnc dcf_discrepancies.status		**title1 clinical_studies.short_title**		
Type:	disc_type discrepancy_entries.de_sub_type_code			
footer_text				
Page *x* of *x*	**DCF ID:** discrepancy_entry_id_dnc	discrepancy_entries.discrepancy_entries	**Revision #:**	(0 for DRAFT and FINAL, and incremented for each reprint by the system)

Replacing the Placeholder DCF Logo Graphic

The Oracle Clinical Data Clarification Form (DCF) report includes a bitmap image on the cover page.

You can replace the default image with your own graphic or logo, or you can use a graphics application to redraw the image.

The source file for the bitmap image is at the following location on Oracle Clinical Reports Server installations:

OPA_HOME/oc/rxcdcf.bmp

You can edit the image locally and then copy it to your server.

Customizing and Upgrading DCF Reports

For DCF Reports, you can customize the following files:

- rxcdrptl.rdf
- rxcdrptp.rdf

These source files are located on the Forms Server in the following directory:

OPA_HOME/oc/admin

Creating Reusable Standard Text for Discrepancies and DCFs

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.

  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 .

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 .

For more information, see:

- Creating New Standard Text
- Inserting Replacement Parameters
- Customizing Default Standard Text Entries

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 more information, see the introduction in Creating Reusable Standard Text for Discrepancies and DCFs.

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. 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 more information, see Inserting Replacement Parameters and, for examples of how the system replaces variables with actual values, Table 3-29.

Inserting Replacement Parameters

Standard text definitions can contain standard *replacement parameters,* or variables. You can insert one of the replacement parameters shown in the following table 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. The following table 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

Table 3-27 (Cont.) Replacement Parameters

Parameter Name	Description	Source
date_time_format	Precision for date and time	dcm_questions.date_time_type_code
dcm_name	DCM Name for the discrepancy	discrepancy_management.name
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. The following table lists the default standard text definitions for Oracle Clinical.

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`

Table 3-28 (Cont.) Default Univariate Discrepancy Messages

Discrepancy Type	Default Text
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.

4

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
- Customizing Mass Changes Local Codelists
- Customizing the Field Display on the Candidate Data Set Form

Creating and Assigning Mass Changes Roles

Oracle Clinical supplies two default database roles for the Mass Changes Utility:

- RXC_MC
- 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

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

Name	Description	Affected Tablename.Columnname
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
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.
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	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: `F:promptlabel` or `S:promptlabel` Where: `F:` locates the field in the left-side, non-scrolling section of the Candidate Data Set form. `S:` locates the field on the scrolling, right-side section of the Candidate Data Set form. *`promptlabel`* The field label on the Candidate Data Set form. If all fields are non-scrolling, you must still use the `F:promptlabel` syntax. For Response data and data comment fields, the prompt is the default prompt for the DCM question concatenated with *`promptlabel`*.

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. Table 4-4 lists all possible column values. You can add, remove, modify, or rearrange the display fields. Footnotes follow that table.

The following table is a legend for the values in Table 4-4.

Table 4-3 Legend for Table 4-4

Symbol	Description
~	A tilde (~) indicates that the value does not qualify for any of the change types. 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, *Column value* refers to the base table field and *short name* refers to the display field. The `clin_plan_eve_name_new` 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.

Table 4-3 (Cont.) Legend for Table 4-4

Symbol	Description
‡	An list of values is present for `exception_value_text` 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 `value_text` 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 `full_value_text` if any discrete value group exists for the DCM question, and values from these groups appear in the list of values.

Table 4-4 Candidate Data Set Form Codelist Values with Display Settings by Mass Changes Utility Change Type

Column Value	Short Name	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	~	~	~
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

Table 4-4 (Cont.) Candidate Data Set Form Codelist Values with Display Settings by Mass Changes Utility Change Type

Column Value	Short Name	Recommended	Set by Default	Can be Set	List of Values	Updateable
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	~	~	~
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	~

Table 4-4 (Cont.) Candidate Data Set Form Codelist Values with Display Settings by Mass Changes Utility Change Type

Column Value	Short Name	Recom-mended	Set by Default	Can be Set	List of Values	Update-able
full_value_text2	f_val_txt2	R†	R†	~	R	~
full_value_text2_new2	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.

5

Configuring Data Entry and User Preferences

In this section:

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.

For more information, see:

- Define Data Entry Configuration Settings
- Configuring Additional Data Entry User Preferences
- Configuring Privileged Update

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
- **Study Level** through the Maintain Study Configuration window (via Maintain Clinical Study States window); see Configure Study-Level Data Entry Settings
- **User Level** through the Maintain Oracle Accounts window; see Configure User-Level Data Entry Settings

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:**
>
> Study-level settings of configuration parameters are not replicated during study replication. Each local database defines its own configuration settings.

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. See Table 5-1 for a complete list of settings.

For more information , see:

- Configure Database-Level Data Entry Settings
- Configure Study-Level Data Entry Settings
- Configure User-Level Data Entry 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.

To change the local settings:

1. Navigate to **Admin, DE Admin**, and then select **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.	Enabled/ Disabled	Enabled
Privileged Update	(Oracle Clinical and RDC) Whether the data entry operator can perform the following while in update mode: • 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 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) 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
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

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

Configuration Parameter	Description	Values	Default setting
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. See Table 5-1 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, Security,** and then select **Clinical Study States**. The Maintain Study States window opens.
2. Query for the study you want to update.
3. Open the **Special** menu and select **DE Configs.** The Maintain Study Configuration window opens.
4. Make the necessary changes to the configuration settings that you want to modify.
5. 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. See 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 has a complete list of settings.

> **Note:**
>
> The **DCI and DCM Date Required** setting is inactive at the user-level (see the table in Configure Database-Level Data Entry Settings for more details).

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**, **Users**, and then select **Oracle Accounts**. The Maintain Oracle Accounts multi-view window displays.
2. Query the user record you want to modify.
3. Open the **Special** menu and select **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.
4. Change any setting, as needed.
5. 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**, **DE Admin**, and then select **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 check boxes or as a list of values.
3. Click **Save as Default** to save the changes, and 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

Table 5-2 (Cont.) Local Data Entry User Preference Settings

User Preference	Description	Values	Default Setting
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). **NOTE**: Although user-level settings generally override database-level settings, when a data type discrepancy is raised for a date field, the resulting warning message displays the discrepant date in the format specified at the database level. Therefore, Oracle recommends that you always specify STANDARD (DD-MON-YYYY) as the Data Entry Display Format at the database level. The other possible values can be misconstrued: US (MM-DD-YYYY), European (DD-MM-YYYY), and Swedish (YYYY-MM-DD).	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

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.

For more information , see:

- Set Privileged Update Using Configuration Settings
- Set Privileged Update Using Study/Site Security

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, see Configure User-Level Data Entry Settings.

- To set privileged update at the study level, see Configure Study-Level Data Entry Settings.
- To set privileged update at the local database level, see 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.

For more information, see:

- Using the Log-in Layout Editor
- Modifying 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 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*).

The log-in layout editor can modify the following windows:

- Received DCI (RDCI) window
- Received DCM (RDCM) window
- 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.

Modifying 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, selecting the Move button and entering new values for the X and Y co-ordinates. The field follows the prompt. If you click on field itself, select the Move button and enter new values for the X and Y co-ordinates, 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 certain fields by clicking either the prompt or the field and then selecting the Hide button. This moves the prompt and field to the Items Not Displayed section of the form. This field is not visible to the data entry operator during normal data entry functioning. The following fields must be displayed: Patient, DCI Short Name, DCI Date, DCI Time, Event, Subevent number.

To make a field displayed again, select either the prompt or the field in the Items Not Displayed section of the form, select the Display button and enter values for the new X and Y co-ordinates of the prompt or field depending on which was selected. This moves both the prompt and the field

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**. 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.

For Smart RDCM window fields other than the Qualifying Value, you can change only the field prompt.

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.

Scheduling a Job to Manage Patient Updates

If any studies or study sites are using partial source data verification with a Patient SDV Plan specifying an autoselection rate and/or a number of initial patients, you must set up a recurring job to check for newly eligible patients available for patient SDV automatic selection. The job runs on all studies that use partial source data verification for patients that have become newly eligible.

To set up the schedule, select **Admin**, then select **DE Admin**, then select **Schedule Pending Patient Updates Job**.Depending on how often new patients become eligible for partial source data verification and the refresh rate needed by your monitors, you can program job execution frequency for an interval between every 15 minutes and daily.

The job also manages locking situations that can arise due to simultaneous requests to update the Patient Positions table. These can have the following effects:

- When a user makes updates in the Maintain Patient Positions window, he or she may receive an error message saying that updates are pending for one or more patients in the study and to try again later. Running this job commits the updates and makes it possible to work in the Maintain Patient Positions window again.
- When the OCL_UTILS package attempts to update a locked patient record, the update is written to the patient_positions_deferred table to be processed the next time the Pending Patient Updates job is executed.

Users can run the same job at any time from the Conduct, Security menu.

> **Note:**
>
> Even if you are not using patient autoselection for source data verification, you should schedule this job on a less frequent basis if you are using any ocl_utils procedure to update the patient positions table on an ongoing basis.

Setting DCI Form Default Values for RDC Data Entry and Patient Data Reports

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.

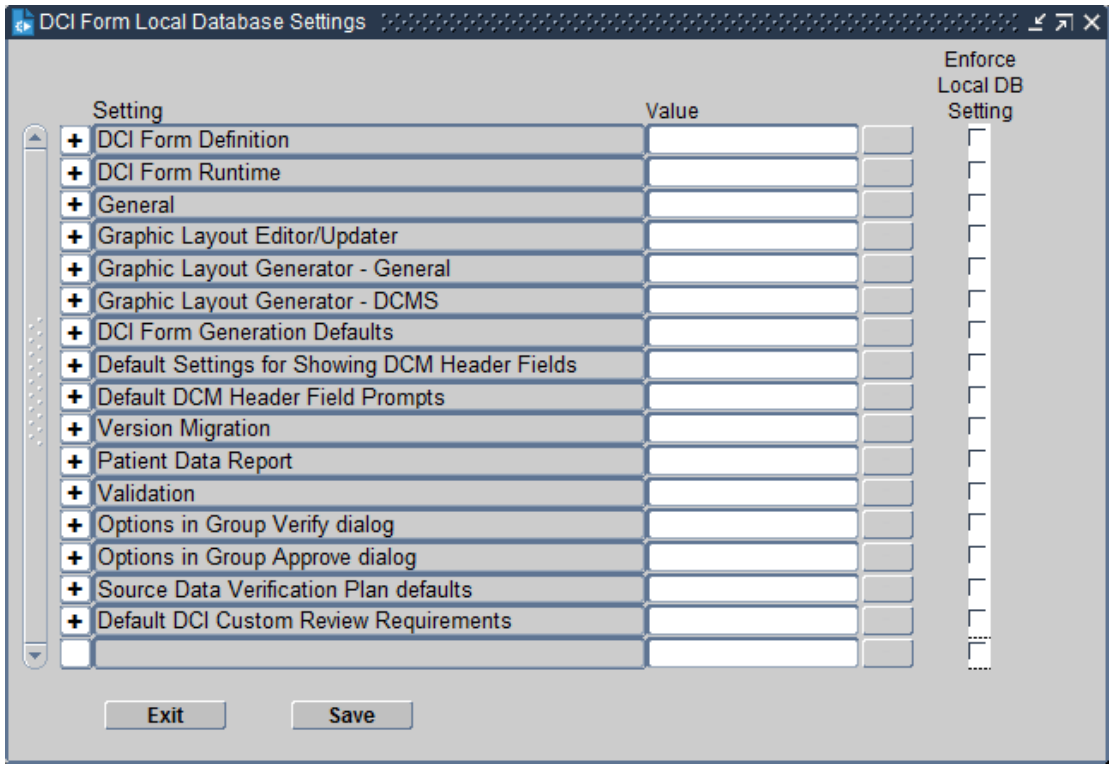
For each setting, you can choose to enforce the value across all studies or allow modification on the study level in the DCI Form Local Study Settings window (under **Design**).

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



For more information, see:

- Setting and Enforcing Values
- Settings

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 more information about the DCI Form Local Study Settings window, see the *Oracle Clinical Creating a Study* manual.

Settings

In this section:

- 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
- Options in Group Verify dialog
- Options in Group Approve dialog
- Source Data Verification Plan
- Default DCI Custom Review Requirements

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:

- **`Disable Delete CRF Icon`** Select **Y** to disable the Delete CRF icon in the RDC Onsite Data Entry window. Select **N** to enable it. When the icon is enabled, users can click it to delete the CRF and its data.
- **`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 *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for more 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; see *Oracle Clinical Creating a Study* for more information.
- **`Represent Disabled Blocks as`** This setting applies to studies using conditional inform 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 or Batch Data Load—and the CRF has not been migrated to a DCI Form version.

> **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 *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* for more 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.

  See 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 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 check boxes. 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 check box shape. The options are: **Circle** and **Square**.
- **`Default Checkbox Size`** Select the default point size for check boxes. The options are: **10**, **12**, **15**, **20**.

> **Note:**
>
> You can change the set of options by modifying the DCIF CHECKBOX SIZE Installation 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 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. The 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 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:**
>
> See also the **Enforce Length as Field Size** setting here, Graphic Layout Editor/Updater.

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 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 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 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.

- **`(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 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 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 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 setting:

`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.

A new setting, Execute TMS validation during site/patient validation, is available in OC under Admin->DCI Form Local Database Settings under the Validation category. This setting can be overwritten on a per study basis by going to Design->DCI Form Local Study settings.

If set to **Y,** TMS processing will continue to happen as part of Validate Site or Validate Patient.

If set to **N,** TMS will not be invoked and TMS derived questions will not be populated until the next batch validation. (Note that Validate Study in RDC invokes batch validation.) The TMS derived responses will then be created as the person running batch validation instead of the RDC user.

In RDC Onsite, you can only validate one or more patients.

Options in Group Verify dialog

The LOV of each of following settings consists of the four possible combinations of CHECKED vs. UNCHECKED and UPDATEABLE vs ENFORCE:

- CHECKED, ENFORCED: Check box is checked and user cannot change it
- CHECKED, UPDATEABLE: Check box is checked but user can change it
- UNCHECKED, ENFORCED: Check box is unchecked and user cannot change it
- UNCHECKED, UPDATEABLE: Check box is unchecked but user can change it

Exclude batch-loaded CRFs

Batch-loaded CRFs are not included in the Verify action.

Exclude CRFs with discrepancies

CRFs with one or more discrepancies are not included in the Verify action.

Exclude non-migrated CRFs

Non-migrated CRFs are not included in the Verify action.

Include CRFs for this visit only

This setting applies only if the action is invoked from the multi-patient casebook page and it applies to both the Verify and the Undo Verification dialogs.

Options in Group Approve dialog

The LOV of each of following settings consists of the four possible combinations of CHECKED vs. UNCHECKED and UPDATEABLE vs ENFORCE:

- CHECKED, ENFORCED: Check box is checked and user cannot change it
- CHECKED, UPDATEABLE: Check box is checked but user can change it
- UNCHECKED, ENFORCED: Check box is unchecked and user cannot change it
- UNCHECKED, UPDATEABLE: Check box is unchecked but user can change it

Exclude batch-loaded CRFs

Batch-loaded CRFs are not included in the Approve action.

Exclude CRFs with discrepancies

CRFs with one or more discrepancies are not included in the Approve action.

Exclude non-migrated CRFs

Non-migrated CRFs are not included in the Approve action.

Include CRFs for this visit only

This setting applies only if the action is invoked from the multi-patient casebook page and it applies to both the Verify and the Undo Verification dialogs.

Include verified CRFs only

Only verified CRFs are included in the Approve action.

> **Note:**
>
> Users are prevented from seeing any evidence of CRF verification status unless they are explicitly granted the BROWSE_VERIFY or other verify privilege. In order to maintain investigator ignorance of verification status, you should configure **Include verified CRFs** only to the UNCHECKED, ENFORCE setting. If you want investigators to see CRF verification status, grant them the BROWSE_VERIFY privilege and use the **Include verified CRFs only** setting as desired.

Source Data Verification Plan

Use these settings to create a Source Data Verification plan for the current study. These settings can be overridden at the study site level in the SDV Site Planning tab in Remote Data Capture by a user with the necessary privileges.

`Exclude batch-loaded CRFs?`

When checked, indicates that even if a patient is identified as requiring 100% SDV, batch-loaded CRFs for that patient should not be presented in RDC as requiring SDV. The default is UNCHECKED.

`Exclude non-migrated CRFs?`

When checked, indicates that even if a patient is identified as requiring 100% SDV, CRFs for that patient that were entered via RDC Classic or Oracle Clinical and that have not been migrated to a DCI Form Version should not be presented in RDC as requiring SDV.

`Initial Patients for 100%SDV`

The number of initial patients to be 100% verified against original source data. Use a number between 0 and 999.

`Patient auto-select rate for 100%SDV`

The rate at which newly SDV-eligible patients should be tagged for SDV. For example, if the rate is 20%, every fifth patient is selected.

For more information, please refer to "Setting Up Partial Source Data Verification" in *Oracle Clinical Creating a Study*.

Default DCI Custom Review Requirements

The settings in this category are:

Allow CRF status change to RN when review is required?

A value of **Y** allows reviewers to change the CRF review status to Review not Required even when the installation setting is set to require custom reviews.

Custom Reviews are Required

A value of **Y** requires that all custom review types be performed for all CRFs in a Study.

Configuring Custom Review Types

To define custom review types and the privileges required to perform custom reviews in RDC, use the Installation Reference Codelist CUSTOM REVIEW TYPES.

- For the Short Value, define the name of the privilege you will assign to users who will perform this type of review, like SAFEREV or DMREV. The short name should have 8 characters at most.
- For the Long Value, define the name of a review type, like Safety Review or DM Review. The long value appears with review metrics in RDC summary reports and elsewhere in the RDC user interface, including the Search pane and the Assign Review Status dialog. For more information, see "Add Custom Review Types" in the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

After you activate and save these codelist values, you can assign the privileges to individual users from the Users and Roles menu under Study Security and Site Security. In RDC, users who are assigned a custom review privilege will be able to update the CRF status for the corresponding review type.

> **Note:**
>
> The privilege BROWSE_REVIEW allows an RDC user to view the CRF status for all review types. For more information on privileges, see "Configuring Study and Site Security Privileges" in the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

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 and investigator ID, that let you 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. See *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.

For more information, see:

- How Flex Fields Work
- Flex Field Components

How Flex Fields Work

Each flex field is customized through the use of a function in the package `rdcpb_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. See 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.

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

Parameter	Description
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
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'). See FLEX_FIELD1 and FLEX_FIELD2 in `rdcpb_clent.sql` for examples of this parameter's usage.

For more information , see:

- Shipped Functions

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, Oracle recommends 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 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.

For more information, see:

- Modifying Calls to Online Help Topic Files
- Copying Online Help Topic Files
- Placing Custom Help Files

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, users click Help and then Custom.

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 placing your cursor in the block and 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 OC 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.
- **OC Document 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 Document 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.

> **Note:**
>
> You must leave the `context` and `topic` values the same as in the corresponding OC Document Name value.

- **Product**: The value can be AERS, RXA, RXC, RDC, or TMS.

> **Note:**
>
> RDC Onsite has a consistent Task Name value of RDC_HTML as well as a Product value of RDC to differentiate it from the defunct PDF version of RDC Onsite, which had a Task Name value of RDC ONSITE.

To modify a call to the online help topic files:

1. Navigate to **Admin** and select **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** check boxes 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 Online Help Topic Files

If you copy the shipped help files 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.

Placing Custom Help Files

The Oracle Clinical help 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 upgrades. Oracle suggests 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.

Viewing Online Help Without Oracle Clinical

In your browser, place a bookmark, or set as a favorite, the following URL:

http://*computer_name.domain*/*code_environment*/xhelp/oc/index.html

where code_environment is a string like `opa52`, with the last two digits corresponding to the Oracle Clinical release number.

The wwhelp.htm file provides links to all the help topics for Oracle Clinical. If you cannot find this file, contact your system administrator. Once you locate help, you can create a shortcut to the home page — or any other topic — for convenience.

> **Note:**
>
> If you do not have Oracle web cache set up in your environment, specify port number 7777 in the above URL.

6

Configuring Data Extract

Oracle Clinical supports extracting Oracle and SAS views of clinical patient data. SAS is optional and must be purchased separately. The first four topics in this section apply only to SAS data extract. The remaining topics apply to both Oracle and SAS data extract.

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*.

For more information, see:

Adding the opapps User to the OCLSASCR User Group

Add the opapps 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. See the *Oracle Clinical Installation Guide* for instructions on creating the OCLSASCR group.

Individual users do not need to be members of the OCLSASCR group.

For more information , see:

UNIX

To add opapps to the OCLSASCR user group in UNIX:

- Use the `usermod` command, or

- Edit 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.

Windows

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

1. From the Start menu, navigate to Administrative Tools, then Computer Management, then Local Users and Groups, then Groups.
2. Right-click **oclsascr** and select **Add to Group**.
3. Click **Add**. The Select Users window opens.
4. Enter the the username and click **OK**.

Authenticating the SAS Connection

When you run a SAS Data Extract job, you actually run two jobs—in the first job Oracle Clinical creates a SAS file, and in the second job SAS creates a SAS view from the file created in first job.

> **Note:**
>
> For command line execution of the SAS file, the user must log in as opapps.

In the first job, Oracle Clinical generates a connect string based on the specified authentication method to be used when the SAS file is executed.

There are two authentication methods and at any point in time, all DX jobs and SAS files must use the same option. You must enter the SAS_CONNECTION value in the OCL_STATE local reference code list: either ORACLE_WALLET or SAS_ENCRYPTION. The default value is ORACLE_WALLET.

> **Note:**
>
> Plan to continue to use a single option consistently. Each time you change from one to the other you must regenerate all files generated using the other option so users can view them. Also, at any point in time, all SAS jobs must use the same option.

For more information , see:

- Using Oracle Wallet for SAS Authentication
- Using SAS Encryption for SAS Authentication

Using Oracle Wallet for SAS Authentication

This is the default option. The connect string generated for Oracle Wallet is:

```
connect to oracle(user='oc_end_user 'password=''path='dbname');
```

Although the individual user ID is specified in the file, the connection is actually made with this account's grant to the ocpsub proxy account, which is stored in the Wallet.

- If your SAS server is the same as the database server, and you set ORACLE_WALLET as the authentication method, the SAS connection is set up automatically—opapps retrieves the OCPSUB database password from the opapps wallet
- If your SAS server is on a different machine from the database and you want to use ORACLE_WALLET, you must first set up the Oracle Wallet on the SAS server, as described in the *Oracle Clinical Installation Guide*.

Using SAS Encryption for SAS Authentication

The connect string for the SAS encryption method is:

```
connect to oracle(user='SAS_PROXY_USER oc_end_user 'pw="&dbpass" path='dbname');
```

To set up a SAS connection using SAS encryption, see the SAS chapter in the *Oracle Clinical Installation Guide*.

Regenerating SAS Views Created in Pre-5.0 Oracle Clinical Releases

SAS views generated in earlier releases are not usable in Oracle Clinical Release 5.0 and later, because 5.0 and later require a different connection string to be embedded in the SAS files. You must re-run all jobs to create new *.sas files. Use the utility gen_views for this purpose; see Generating Data Extract Views.

Creating SAS Output File Directories

You must create a root directory in which to store output files for the jobs SAS Datasets and Proc Print, and enter the path as the value for SAS_OUTPUT_ROOT in the OCL_STATE local reference codelist.

You must also decide whether or not you want to have a subdirectory for each user who submits these jobs, and enter either Y or N as the value for SAS_USERDIRS in the OCL_STATE local reference codelist. The system enforces the choice you make.

If you have very few users who submit SAS Datasets and Proc Print jobs, and if they all have access to the same studies, you may choose not to have user-specific subdirectories. Otherwise, having user-specific directories is the more secure choice because users can see only output files of jobs they have submitted.

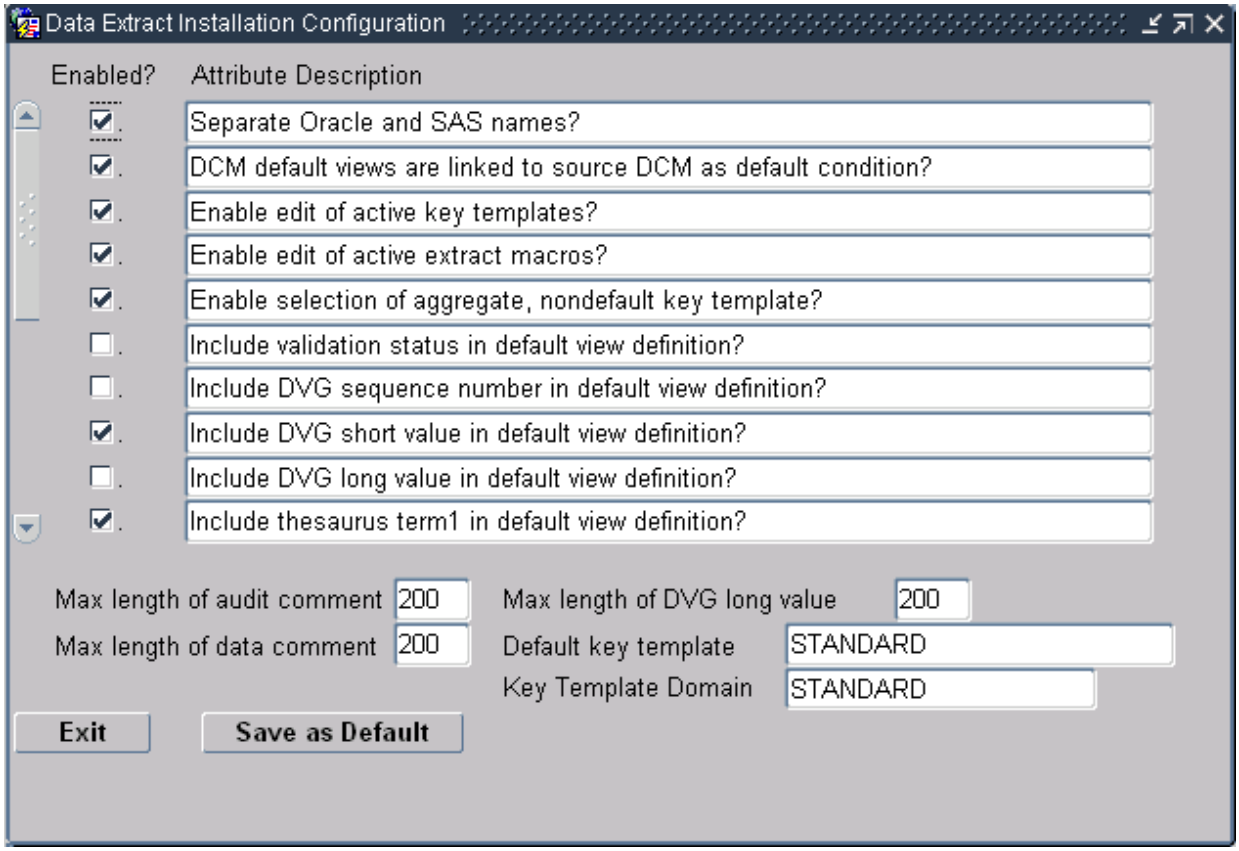
If you choose to have user-specific subdirectories, you must create the subdirectories.

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



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?
- DCM Default Views Are Linked to Source DCM as Default Condition?
- Enable Templates?
- Enable Selection of Aggregate, Nondefault Key Template?
- Include View Definition?
- Enable Update of SAS and Oracle Column Names?
- Enable View Builder as Default in New Studies?
- Use DCM Question-Specific DVG Subset for DVG Attributes?
- Use DCM SAS Label as Seed for Attributes in Default View Definition?

- Max Length of Audit Comment
- Max length of Data Comment
- Max Length of DVG Long Value
- Default Key Template
- Key Template Domain
- Build Fast Views?

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 Templates?

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 to be able to choose alternative Key Templates for different view definitions within a study.

Include View Definition?

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 select 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?

Fast views are created with a different structure from other data extract views. While functionally equivalent, the fast view structure provides better performance when querying the views, especially for queries against response values. If set to Y, the system builds fast views

when possible but builds regular views if the view structure is incompatible with the fast view approach. This is the case with cross-DCM views and with views based on key templates that aggregate across key columns such as patient, visit or received DCM. The system handles cross-DCM views automatically, but for aggregate views you must enter the text "AGGREGATE" in the Status Comment field of the key template. The system then successfully builds a regular view structure.

If you are encountering performance issues--queries are running for several minutes--when querying large data extract views, you should consider using fast views.

Setting Values in Data Extract-Related Reference Codelists

Check the settings of the following reference codelists, described in Reference Codelists:

- DX_CONFIG Installation Codelist
- DX_EXTENDED_ATTRIBUTES Installation Codelist
- DX_INDEX_TABLESPACE Installation Codelist
- DX_KEY_NAME Installation Codelist
- DX_ROLES Installation Codelist
- DX_VIEW_TABLESPACE Installation Codelist

Creating Tablespaces for Data Extract Tables and Indexes

In this section:

- Creating Tablespaces
- Entering Tablespace Names in Reference Codelists
- Creating Data Extract Access Accounts Using Local Tablespaces

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

Entering Tablespace Names in Reference Codelists

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 Installation Codelist
- DX_VIEW_TABLESPACE Installation Codelist

> **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 Installation Codelist and DX_VIEW_TABLESPACE Installation Codelist 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, follow these instructions to make the investigator's last name available to an extract macro:

1. Back up the scripts in the directory $RXC_INSTALL that are used to customize data extract views:
   - pop_vb_static_views.sql
   - rxcptdxvb.sql
2. Bring up pop_vb_static_views.sql in a text editor.
3. Make the changes marked in **bold** so that the updated code is as shown below:

```
…
REM
REM ORACLE TEXT FOR NEW STYLE RDCMS_VIEW
REM
DECLARE
  LTEXT long;
BEGIN
/* SPR24128 JRees 9/24/98 Adding hints to security checks */
LTEXT :=
'create view \0.rdcms_view as
select /*+ ORDERED USE_MERGE(css)
           INDEX(rdcm RECEIVED_DCM_DCM_CS_NFK_IDX\4)
           INDEX(css CLINICAL_STUDY_STATE_IDX) <- Remove '*/' from the end
of this line.
/* to add additional tables, add index hint for joining  */
/* for example, for RDCIs add:                           */
/*         (note that \4 adds the T for test mode)       */
/*           INDEX(RDCI RECEIVED_DCI_PK_IDX\4)           */
/* for example, for OCL_Investigators, add:              */
       INDEX(INV OCL_INVESTIGATOR\4_PK_IDX)    */ <- Remove '/*' from the
start of this line.
       rdcm.received_dcm_id,
       rdcm.dcm_id,
       rdcm.dcm_subset_sn,
       rdcm.dcm_layout_sn,
       rdcm.actual_event_id,
       rdcm.dci_id,
       rdcm.received_dci_id,
       rdcm.received_dcm_entry_ts,
       rdcm.end_ts,
       rdcm.entered_by,
       rdcm.dcm_date,
       rdcm.dcm_time,
       rdcm.received_dcm_status_code,
       rdcm.qualifying_value,
       rdcm.accessible_ts,
```

```
        rdcm.log_in_ts,
        rdcm.last_data_change_ts,
        rdcm.data_lock_flag,
        rdcm.sn,
        rdcm.document_number,
        rdcm.modification_ts,
        rdcm.modified_by,
        rdcm.subevent_number,
        rdcm.investigator_id,
        rdcm.investigator,
        inv.last_name,          <- Add this line. Remember the comma.
        rdcm.clin_plan_eve_id,
        rdcm.clin_plan_eve_name,
        rdcm.visit_number,
        rdcm.site_id,
        rdcm.site,
        rdcm.lab_id,
        rdcm.lab,
        rdcm.lab_range_subset_num,
        rdcm.LAB_ASSIGNMENT_TYPE_CODE,
        rdcm.patient_position_id,
        rdcm.patient,
        rdcm.clinical_study_id
/*  to add additional columns, add here,              */
/*  for example, for Received_DCIs, add:              */
/*       , RDCI.FIRST_BOOK_PAGE                       */
/*  for example, for OCL_Investigators, add:          */
/*       , INV.COUNTRY                                */
\5
/* to customize, extend from list.                    */
/* for example, to add RDCIs add:                     */
/*   note: the \4 adds the T for test account         */
/*   , RECEIVED_DCIS\4 RDCI                           */
/* for example, to add OCL_Investigators add:         */
  , OCL_INVESTIGATORS\4 INV   <- Remove '/*' and '*/' from this line.
WHERE
\1
/* use \6 to access as_of_ts for account-specific     */
/* time restriction,                                  */
/* for example, to join RDCIS, add:                   */
/*  AND RDCM.RECEIVED_DCI_ID = RDCI.RECEIVED_DCI_ID   */
/*  AND RDCI.END_TS > \6                              */
/*  AND RDCI.RECEIVED_DCI_ENTRY_TS <= \6              */
/* for example, to join OCL_Investigators, add:       */
AND RDCM.INVESTIGATOR_ID = INV.INVESTIGATOR_ID   <- Remove '/*' and '*/' from this
line.
  and  (exists
    /* account is super-user  */
          (select /*+ index(oa ORACLE_ACCOUNT_PK_IDX) */
…
```

4. Save the changes made to the pop_vb_static_views.sql file.
5. To add the column as an Extract Key, bring up rxcptdxvb.sql in a text editor.
6. Make the changes marked in **bold**:

```
delete from extract_keys
where OC_INTERNAL_NAME in (
  '/STUDY',
  'DCMS.SUBSET_NAME',
  'DCMS.SUBSET_NAME',
  'DCMS.DCM_SUBSET_SN',
```

```
'RDCM.DOCUMENT_NUMBER',
'RDCM.SITE',
'RDCM.INVESTIGATOR',
'RDCM.LAST_NAME',     <- Add this line.
'RDCM.PATIENT',
'RDCM.ACCESSIBLE_TS',
'RDCM.LOG_IN_TS',
'RDCM.LAST_DATA_CHANGE_TS',
'RDCM.DATA_LOCK_FLAG',
'RDCM.CLIN_PLAN_EVE_NAME',
'RDCM.DCM_DATE',
'RDCM.DCM_TIME',
'R.REPEAT_SN',
…
```

> **Note:**
>
> The new key is added as RDCM.LAST_NAME and not INV.LAST_NAME. In this context RDCM is the alias for the RDCMS_VIEW view to which we added the new column by modifying pop_vb_static_view.sql.
>
> The rxcptdxvb.sql file already contains the required modifications for adding FIRST_BOOK_PAGE from RECEIVED_DCIS and COUNTRY from OCL_INVESTIGATORS. No further modification of this file is therefore required for these columns if you have added them to pop_vb_static_view.sql.

7. Find the `insert into extract_keys` statement for RDCM.DCM_DATE and duplicate it to create an insert statement for the RDCI.INVESTIGATOR.
8. Save the changes made to the rxcptdxvb.sql file.
9. To populate the data extract tables with the customized definitions, log in to SQL*Plus as RXC and run both scripts:

```
SQL> start pop_vb_static_views.sql
SQL> start rxcptdxvb.sql
```

> **Note:**
>
> Note: If when running rxcptdxvb.sql you get `ORA-0001: Unique constraint (RXC.EXTRACT_KEYS_ORA_UK_ID) violated` then perform the following as RXC to clean up:
>
> ```
> SQL> delete extract_keys;
> SQL> commit;
> ```
>
> Re-execute rxcptdxvb.sql and continue with the next step.

10. To confirm that the INVNAME extract key and macro are now available for use, Log into Oracle Clinical and navigate to **Glib**, then **Data Extract View Builder**, then **Extract Macros** and press F8 to query. INVNAME should now be included.
11. To add the extract key and extract macro for the new column to a Key Template, . Query for the template to which

a. Navigate to **Glib**, then **Data Extract View Builder**, then **Key Templates**.

b. Query for the template to which you want to add the macro.

c. Click on **Key Columns**.

d. In an empty field, press F9 to see the list of values.

e. Select INVNAME from the list.

f. Save.

The investigator's last name will appear as column INVNAME in all data extract views created with this Key Template.

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
- Running gen_views on Windows

Running gen_views on UNIX Platforms

To run gen_views on a UNIX platform:

1. Log on to the server in your user account.
2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Change directories to $RXC_TOOLS.
4. Set the output directory:
   - C Shell command: `setenv RXC_LOG usr_log_dir`
   - Bourne Shell command:

```
RXC_LOG = usr_log_dir

export = code_env
```

5. Run the script:

   ```
   gen_views study UNIX view_creation_mode
   ```

   For example:

   ```
   gen_views ALL UNIX DATA_ONLY
   ```

   The script prompts for:

   - Database name
   - Username for user who can submit the DX job
   - Password for the user

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.

   ```
   gen_views study NULL view_creation_mode
   ```

   For example:

   ```
   gen_views ALL NULL DATA_ONLY
   ```

   The script prompts for:

   - Database name
   - Username for user who can submit the DX job
   - Password for the user

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.

For more information , see:

- Converting Views

- Enabling the View Builder in a 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.
2. Add these roles to the DX_ROLES Installation 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.

7

Reference Codelists

In this section:

Overview of Reference Codelists

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 presents 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. See Running the Reference Codelists Report for instructions.

Editing installation reference codelists requires one of the roles RXC_SUPER, RXC_ADMIN, or RXC_GL_FULL.

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.

For more information , see:

- Accessing and Modifying Reference Codelists
- Viewing Original Reference Codelist Settings
- Working in the Maintain or Query Reference Codelists Windows
- Adding a Value to a Reference Codelist
- Modifying a Value in a Reference Codelist
- Running the Reference Codelists Report

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.

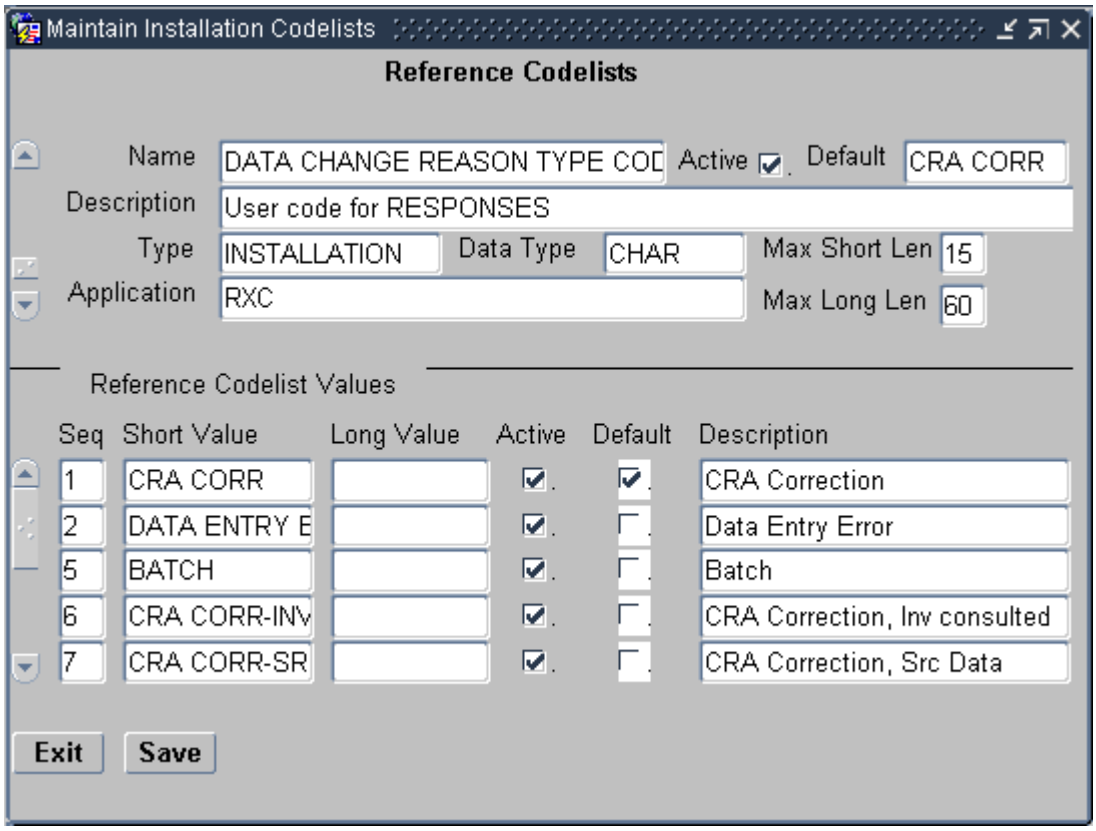
Viewing Original Reference Codelist Settings

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 codelist. You can access all types of codelists through this window, including local, installation, design, and system codelists.

Working in the Maintain or Query Reference Codelists Windows

When you query or maintain a codelist, the system displays the Reference Codelists window. Figure 7-1 depicts a typical "maintain" reference codelist window, which allows you to modify the values in a codelist.

Figure 7-1 Maintain Reference Codelists Window



For more information , see:

- Access
- Components
- Usage

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 following table describes the components that comprise the upper section of the window.

Table 7-1 Components of the Reference Codelist Section

Component	Type	Description
Name	Field	Displays the name of the current reference codelist. In addition, you can use this field to query for a specific codelist.
Active	Check box	Specifies if the codelist is active. You cannot update this component.
Default	Field	Lists the default value, which is the value for which the **Default** check box in the Values section is selected (the Values section is explained in the table below).
Description	Field	Displays 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	Displays the maximum number of characters allowed for the Short Value of each reference codelist value.
Max Long Len	Field	Displays 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 following table describes the components in the lower portion of the window.

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

Table 7-2 (Cont.) Components of the Reference Codelist Values Section

Component	Type	Description
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.

Adding a Value to a Reference Codelist

To add values to an existing local, installation, or design installation codelist:

1. Select **Admin**, and 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. 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 check box 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 **Save.** The system adds the new value to the codelist.

Modifying a Value in a Reference Codelist

You cannot delete a value from a reference codelist. However, you can deactivate a value by clearing its Active check box. If a value if not active, Oracle Clinical does not display the value in a list of values, and does not include the value as an acceptable value during validation.

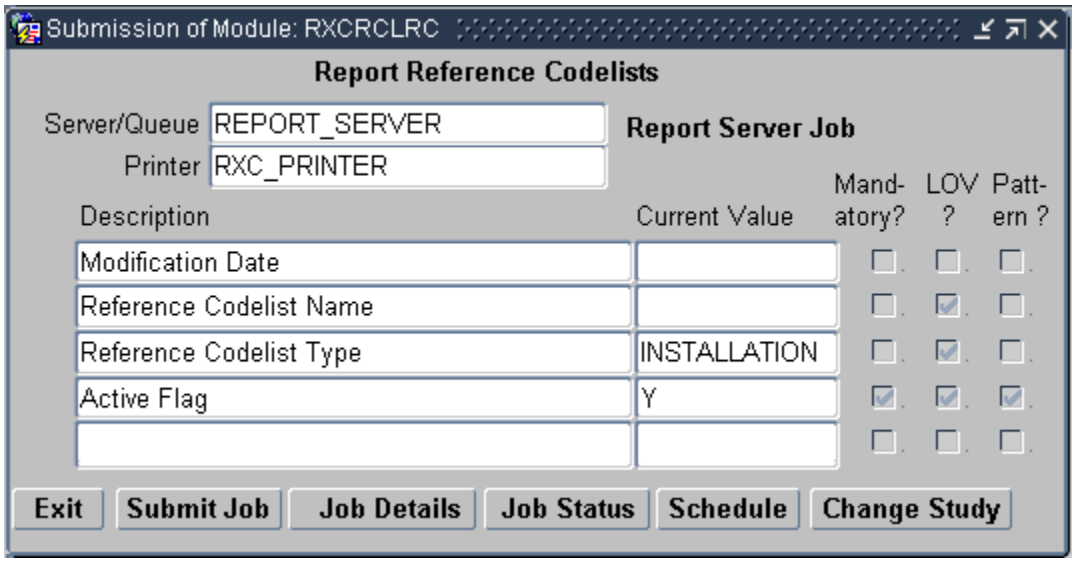
To modify an existing value in a reference codelist:

1. Perform Steps 1 through 3 in Adding a Value to a Reference Codelist to select a reference codelist.
2. Place focus in the value record you want to change.
3. Make your changes. You cannot change the Short Value field. Changing the Active check box activates or deactivates the value. Only active values appear in the list of values for the relevant field and are used in field validation.
4. Click **Save.** Oracle Clinical modifies the changed codelist records in the database.

Running the Reference Codelists Report

Oracle Clinical includes a large number of reference codelists, many of which you can modify. 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 7-2, to set the values of four parameters and specify the information you want to include in the report.

Figure 7-2 Report Submission Window for Reference Codelist Report



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**.

Local Reference Codelists

Local reference 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.

For more information , see:

- BATCH QUEUE NAME Local Codelist
- DB_LINKS Local Codelist
- DCF COMMENT TEXT Local Codelist
- DCF DEFAULT FOOTERS Local Codelist
- DCF DEFAULT HEADERS Local Codelist
- DCF REPORT LABELS Local Codelist
- DISC COLS Local Codelist
- DISC_FLEX1 and DISC_FLEX2 Local Codelists
- DISC_FLEX1_VALUES and DISC_FLEX2_VALUES Local Codelists
- FLD RXCMCMCD RDCI DELETE Local Codelist
- FLD RXCMCMCD RDCI KEY Local Codelist
- FLD RXCMCMCD RDCM KEY Local Codelist
- FLD RXCMCMCD RESPONSE Local Codelist
- IND DISC COLS Local Codelist
- MAN DISC COLS Local Codelist
- MANHD DISC COLS Local Codelist
- MC CDS SORT ORDER Local Codelist
- MC COLUMNS Local Codelist
- MULTI DISC COLS Local Codelist
- NLS_CONFIG Local Codelist
- OCL_DE_CONFIG Local Codelist
- OCL_DE_PREFS Local Codelist
- OCL_JOB_PREF Local Codelist
- OCL MC PREFS Local Codelist
- OCL_MENU_ACCESS Local Codelist
- OCL_STATE Local Codelist
- PRINT QUEUE NAME Local Codelist
- PUBLIC_DB_LINKS Local Codelist
- RDC CONFIGURATION Role Local Codelists
- REPORT_SERVER Local Codelist
- SAS_QUEUE Local Codelist
- SQL FUNCTIONS Local Codelist
- TMS_DSI Local Codelist
- TMS_OPTIONS Local Codelist
- UNI DISC COLS Local Codelist
- WEB_DOCUMENT_CONFIG Local Codelist
- WEB_DOCUMENT_GROUPS Local Codelist

- PDR_FILE_NAMING Local Codelist

BATCH QUEUE NAME Local Codelist

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 Environment Variables and Registry Settings.

DB_LINKS Local Codelist

This codelist contains the names of database links for standard replication.

Standard 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 Local Codelist

This codelist contains values you can use as the initial text for the DCF comment field.

DCF DEFAULT FOOTERS Local Codelist

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 .

DCF DEFAULT HEADERS Local Codelist

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 .

DCF REPORT LABELS Local Codelist

This codelist contains user-configurable labels for the DCF Report.

DISC COLS Local Codelist

This codelist contains the variables that can be specified for MCU CDS Discrepancy criteria; see Customizing Mass Changes Local Codelists.

DISC_FLEX1 and DISC_FLEX2 Local Codelists

See Customizing Flexfields for information.

DISC_FLEX1_VALUES and DISC_FLEX2_VALUES Local Codelists

See Customizing Flexfields for information.

FLD RXCMCMCD RDCI DELETE Local Codelist

This codelist contains the display and order of RDCI Delete Candidate Data Set fields; see Customizing Mass Changes Local Codelists.

FLD RXCMCMCD RDCI KEY Local Codelist

This codelist contains the display and order of RDCI Key Change Candidate Data Set fields; see Customizing Mass Changes Local Codelists.

FLD RXCMCMCD RDCM KEY Local Codelist

This codelist contains the display and order of RDCM Key Change Candidate Data Set fields; see Customizing Mass Changes Local Codelists.

FLD RXCMCMCD RESPONSE Local Codelist

This codelist contains the display and order of response Candidate Data Set fields; see Customizing Mass Changes Local Codelists.

IND DISC COLS Local Codelist

This codelist contains variables that you can specify for MCU CDS Ind discrepancy criteria; see Customizing Mass Changes Local Codelists.

MAN DISC COLS Local Codelist

This codelist contains variables that you can specify for MCU CDS manual discrepancy criteria; see Customizing Mass Changes Local Codelists.

MANHD DISC COLS Local Codelist

This codelist contains variables that you can specify for MCU CDS manual header discrepancy criteria; see Customizing Mass Changes Local Codelists.

MC CDS SORT ORDER Local Codelist

This codelist contains the sort order of CDS fields; see Customizing Mass Changes Local Codelists for information.

MC COLUMNS Local Codelist

This codelist contains variables that you can specify for MCU CDS criteria; see Customizing Mass Changes Local Codelists.

MULTI DISC COLS Local Codelist

This codelist was used for the NLS option, which is no longer supported.

NLS_CONFIG Local Codelist

This codelist was used for the NLS option, which is no longer supported.

OCL_DE_CONFIG Local Codelist

This codelist controls Data Entry configuration settings. The entries for values are listed and described in the following table.

> **Note:**
>
> The settings with sequence numbers 1-9, 12-14, and 17 are also updatable in the Maintain Installation Configuration window under Admin, DE Admin, DE Config Settings; see Define Data Entry Configuration Settings.

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, in enabled.
7	USE DCI BOOK	N	Determines if the system initiates a data entry session using a DCI book.

Table 7-3 (Cont.) Values for the OCL_DE_CONFIG Reference Codelist

Seq	Short Value	Long Value	Description
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. Applies only to Oracle Clinical.
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. Applies only to Oracle Clinical.
15	P2 ALWAYS ALERT	Y	Determines if the system alerts the user whenever Pass 2 data differs from the corresponding Pass 1 data. Note: The Long Value should be a maximum of 2 characters; longer values cause problems in Oracle Clinical data entry.
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.
17	DCI DATE REQ	Y	Sets the default as to whether the DCI date is required in the Log-in form.
18	DVGSEQOVERALPHA	N	Used only when a question meets the following criteria: • An internal DVG and an alpha DVG are assigned. • An Enter By Sequence is enabled for the internal DVG. • The internal DVG 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 the DVGSEQOVERALPHA value is set to **Y.** • Records the alpha DVG value with the same sequence number if the DVGSEQOVERALPHA value is set to **N.**
19	DVG List of Values STYLE	SEQ	Determines how the system displays the list of values for DVG and Alpha DVG questions. Note: The Long Value should be a maximum of 15 characters; longer values cause problems in Oracle Clinical data entry
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.

Table 7-3 (Cont.) Values for the OCL_DE_CONFIG Reference Codelist

Seq	Short Value	Long Value	Description
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	Defines the sequence buffer used to prevent the sequence from reaching its maximum value. At this setting, when a sequence number is within 1,000,000 of 9,999,999,999, the system displays a warning message when a user attempts to use a relevant subsystem and the system exits the current screen; see Managing High Sequence Numbers.
24	RSTRCT LCKD CRF	N	Determines if some actions are permitted on a locked CRF. Applies to RDC Onsite only.

For more information , see:

- DVG List of Values STYLE
- COMMCHGREAS_REQ
- JUSTENTERP1TIME
- JUSTENTERP2TIME
- RSTRCT LCKD CRF

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 Local Codelist

This codelist enables you to set the default data entry preferences for this instance. The default entries are displayed and described in the following table. 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 Local Codelist

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. The following table 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 Local Codelist
DFLT_PSUB_QUEUE	Default PSUB Queue	BATCH QUEUE NAME Local Codelist
DFLT_REPORT_RS	Default Reports Server	REPORT_SERVER Local Codelist
DFLT_JOBSET_RS	Default Job Set Reports Server	REPORT_SERVER Local Codelist

Table 7-5 (Cont.) Entries in the OCL_JOB_PREF Reference Codelist

Short Value	Description	Refers to Reference Codelist
DFLT_PSUBSCH_RS	Default for PSUB Scheduling, generating DCI Forms, and previewing	REPORT_SERVER Local Codelist
DFLT_RS_PRINTER	Default Reports Server Printer	PRINT QUEUE NAME Local Codelist

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 Local Codelist :

   Short Value – Name of the printer, for example, `boston09`
   Long Value – Printer specification, for example, `\\ocldsn1\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 2.

OCL MC PREFS Local Codelist

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.

OCL_MENU_ACCESS Local Codelist

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	PATTERN	Y

OCL_STATE Local Codelist

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

Short Value	Long Value	Description
BDL_ROOT	—	Path to the batch data load root directory used for input and output files.
BDL_R_SE	—	Specifies the rollback segment for Batch Data Load processes.
BDL_USERDIRS	Y	If Y, there are user-specific directories for Batch Data Load, which you must create. If N, there are not. See Creating Directories for Input and Output Files of Certain Job Types.
BOOK_ASSIGN	N	Assign DCI book to patient on first data entry: Y or N.
BOOK_CHANGE	ALLOW	Change of DCI Book for patient: ALLOW, DISALLOW, or DISALLOW IF DATA.
BOOK_USAGE	IGNORE	(Applies only to Oracle Clinical data entry) 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 sytem 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.
DB_BLOCK_SIZE	—	The database block size from init.ora.
DB_HOST	—	Host name for the database, as entered in tnsnames.ora file.
DB_NAME	*name of service*	If you have a RAC environment, enter the name of the service. If you do not have a RAC installation, this is normally the name of the database.
DB_PORT	—	Port number for the database as entered in tnsnames.ora file.
DB_VERSION	—	The database version, this is used by Data Extract to determine optimization.
DCF_TEXT_SYNC	N	Edits to comment and resolution texts in DCFs propagate to discrepancy management.
DFLT_PAGE_TRACK	Y	Specifies the default value of the "Page Tracking Enabled" study level setting.
DISC_AUTO_CRFPG	Y	Auto Generation of CRF Page Number.
DISC_AUTO_HDFT	Y	Auto Generation of Header/Footer Text.

Table 7-7 (Cont.) Values for the OCL_STATE Reference Codelist

Short Value	Long Value	Description
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).
DISC_REP_WALLET	—	If you use disconnected replication, enter the wallet alias you created for RXC_DISC_REP during installation.
DMGR RDC ACCESS	YES	See Granting Automatic Access in RDC to Studies Granted in Oracle Clinical.
DM_PROMPT	Study Site	Prompt for the DM window.
FILE_VIEWER	Y	Used by PSUB to view the log and output files.
INVOKE_IMAGE	N	Enable imaging interface (Y/N) ?
INVOKE_WORKFLOW	N	Used by the Login form to determine if a workflow system can be used.
LAB_ROOT	—	Path to the root directory for Lab Ranges Batch Data Load files.
LAB_USERDIRS	Y	If Y, there are user-specific directories for Lab Ranges Batch Data Load input and out files, which you must create. If N, there are not. See Creating Directories for Input and Output Files of Certain Job Types.
LANGUAGE	ENGLISH	—
LOCATION_CODE	—	Client name for the current location.
OPA_LESTR_SYNCH	1	This value is not used.
PRINTER_TYPE	PDF	Default type of printer output.
PROC_LAB_ALIAS	LAB	The name of the lab variable for the standard Procedure question group prompt.
PSUB_DEL_FILES	N	Select Y to automatically delete PSUB log and output files from the user-specific subdirectory of the PSUB_LOGS_DIR after the file is written to the database table where it will be stored and viewed from permanently. Select N to keep the files in the user-specific subdirectory as well as the database table.
PSUB_LOGS_DIR	/home/opapps/log	Path to the temporary base log and output file directory for PSUB jobs. You must create the directory. The system automatically creates a subdirectory for each user who runs PSUB jobs.
PSUB_SESSION	—	Internal setting - PSUB session ID
QUERY MENU SEC	Y	If set to Y (default), the data security rules applicable to the non-query (enterable) forms applies to the query only forms also. If set to N, the query form displays all data independent of the data security rules defined for the non-query forms.

Table 7-7 (Cont.) Values for the OCL_STATE Reference Codelist

Short Value	Long Value	Description
RAND_ROOT	—	Path to the root directory for Randomization files.
RAND_USERDIRS	Y	If Y, there are user-specific directories for Randomization input and out files, which you must create. If N, there are not. See Creating Directories for Input and Output Files of Certain Job Types.
REMOTE_SASOUT	—	Leave blank. (Reserved for possible future use where you would specify a value if SAS is installed on a separate computer that is not in your intranet. Files would be transferred via SFTP from SAS_OUTPUT_ROOT to REMOTE_SASOUT.)
REMOTE_SAS_SERV	—	Specify the name of the server if SAS is installed on a separate computer within your intranet. Oracle Clinical does not use the specific value that is specified, it only checks if this field is null or not.
REMOTE_SAS_VIEW	—	Leave blank. (Reserved for possible future use where this value would store the equivalent on the remote SAS server of the directory path stored in the RXC_SAS_VIEW environment variable and files would be transferred via SFTP from RXC_SAS_VIEW to REMOTE_SAS_VIEW for MANUAL execution.)
REPL_ROOT	—	Path to the root directory on the PSUB server where disconnected replication export files are exported to and imported from.
SAS_CONNECTION	ORACLE_WALLET	ORACLE_WALLET or SAS_ENCRYPTION SAS authentication method; see Authenticating the SAS Connection.
SAS_DX_EXEC	AUTOMATIC	AUTOMATIC to execute SAS jobs automatically. MANUAL if SAS is local and Oracle Clinical is hosted. If set to AUTOMATIC or not specified, the second job in a SAS DX execution, which must be run by SAS, is executed automatically; see Authenticating the SAS Connection. If set to MANUAL, the user must execute the second job manually in SAS.
SAS_OUTPUT_ROOT	—	Full path to the root directory for DX SAS Datasets and Proc Print output jobs; see Creating SAS Output File Directories.
SAS_USERDIRS	Y	Y or N. Y indicates user-specific subdirectories in SAS_OUTPUT_ROOT. If Y or null, then the user account name is appended to the value of SAS_OUTPUT_ROOT. Note: Unless all SAS users have access to the same studies, customers should use user directories in order to maintain security; see Creating SAS Output File Directories.

Table 7-7 (Cont.) Values for the OCL_STATE Reference Codelist

Short Value	Long Value	Description
SEC_STORE_DIR	—	The Installer populates this with the path of the secret store directory.
SERVER_NAME	—	PSUB server name. In a RAC configuration, if you start PSUB on a different node, you must update this value to the new PSUB server name.
SERVER_OS	Server operating system	Indicates the operating system that the server is running. Valid entries are **NT** (to represent any supported version of Windows) or **UNIX** (to represent any supported version of UNIX).
TEMP_TABLES	—	Temporary Tablespace for use in new account creation activities.
TMS_FAIL_BV_ACT	FAIL	Determines whether Batch Validation continues when TMS derivation fails during Batch Validation: WARN or FAIL.
UPD_FV_INCREM	Y	Y or N - Y means do only incremental PDR Templates and HTML Forms generation.
USR_SAVE_OSPASS	N	Not used.

For more information , see:

- SAS_CONNECTION
- SERVER_OS
- LOCATION_CODE
- SERVER_NAME
- DB_BLOCK_SIZE
- TEMP_TABLES
- DM_PROMPT
- PROC_LAB_ALIAS
- DISC_DCM_PROMPT
- BOOK_ASSIGN
- TMS_FAIL_BV_ACT
- UPD_FV_INCREM

SAS_CONNECTION

During installation, the Database installer prompts you for the SAS_CONNECTION value and adds it to the OCL_STATE reference code list. The short value is SAS_CONNECTION.

The two long values, indicating the method used to connect the SAS and database servers:

- ORACLE_WALLET

- SAS_ENCRYPTION

SERVER_OS

Make sure the Long Value of the SERVER_OS entry in the OCL_STATE local reference codelist is correct for your operating system. You can enter one of the following values:

- **NT** — Indicates the server is running one of the Windows operating systems currently supported by Oracle Clinical.
- **UNIX** — Indicates the server is running the UNIX or Linux operating system.

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.

SERVER_NAME

Set the SERVER_NAME value in this codelist to the database/PSUB server.

On UNIX systems, the Long Value of the SERVER_NAME entry must be in lowercase letters.

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.

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.

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

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 Local Codelist

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 walprt9 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 Local Codelist

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.

RDC CONFIGURATION *Role* Local Codelists

This set of local codelists let you define the configuration settings for the Remote Data Capture application based on user role, such as CRA or investigator.

For more information about creating a configuration, defining its settings, and assigning the configuration to one or more users, see the *Oracle Clinical Remote Data Capture User's Guide* or the *Oracle Clinical Remote Data Capture Classic Data Entry User's Guide*.

REPORT_SERVER Local Codelist

This codelist defines the list of reports servers from which the user can select when setting up to run a report.

SAS_QUEUE Local Codelist

This codelist specifies the value(s) in the BATCH QUEUE NAME Local Codelist that is required to run SAS.

SQL FUNCTIONS Local Codelist

This codelist provides a list SQL functions that you can then use when building queries.

TMS_DSI Local Codelist

This codelist defines settings specific to the Disconnected System Integration (DSI) feature for Oracle Thesaurus Management System. For details about this codelist, see the *Oracle Thesaurus Management System User's Guide*.

TMS_OPTIONS Local Codelist

This local 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 *Oracle Thesaurus Management System User's Guide*.

UNI DISC COLS Local Codelist

This codelist contains variables that you can specify for Mass Change Utility CDS Univariate Discrepancy criteria.

WEB_DOCUMENT_CONFIG Local Codelist

TMS refers to the settings in this codelist to configure several aspects of the Document Repository searches in the TMS HTML Browser. For details about this codelist, see the *Oracle Thesaurus Management System User's Guide*.

WEB_DOCUMENT_GROUPS Local Codelist

This codelist lets you define categories for the documents you retrieve using Document Repository searches in the HTML Browser. For example, you might want to specify that all documents loaded from your internal servers be categorized as Internal documents. For details about this codelist, see the *Oracle Thesaurus Management System User's Guide*.

PDR_FILE_NAMING Local Codelist

This codelist lets you define the naming conventions used to save Patient Data Reports (PDRs) and Blank Casebook Reports generated from RDC or from the command line. For details, see the section "File Names for Reports" in the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

Installation Reference Codelists

Installation codelists control Oracle Clinical behavior installation-wide; that is, across an installation of multiple Oracle Clinical databases. This section describes the purpose of and the settings in each installation codelist.

For more information , see:

- APPLICATION AREA CODE Installation Codelist
- APPLICATION SYSTEM NAME Installation Codelist
- APPROVE VERIFY RETAIN CODE Installation Codelist
- APPROVE VERIFY REVERSE CODE Installation Codelist
- BLIND TYPE CODE Installation Codelist
- CLINICAL PHASE Installation Codelist
- COUNTRIES Installation Codelist
- CRF PAGE NUMBERING SCHEME Installation Codelist
- CRF PAGE STATUS CODES Installation Codelist
- CRF PAGE STATUS QUERY Installation Codelist
- CUSTOM REVIEW TYPE Installation Codelist
- DATA CHANGE REASON TYPE CODE Installation Codelist
- DATA CHANGE REASON2 TYPE CODE Installation Codelist
- DCF LOCK CONDITIONS Installation Codelist
- DCF OPTIONAL STATUS CODES Installation Codelist
- DCF STATUS CODES Installation Codelist
- DCIF CHECKBOX SIZE Installation Codelist
- DCIF FONT TYPESIZE Installation Codelist
- DCIF PAGE DEFINITION Installation Codelist
- DCM DCI QG TYPE CODE Installation Codelist
- DISCREPANCY ACTIONS ROLE Installation Codelist
- DISCREPANCY MESSAGES Installation Codelist
- DISCREPANCY NO OTHER UPDATE Installation Codelist
- DISCREPANCY RESOLU TYPE CODE Installation Codelist
- DISCREPANCY REV STATUS CODE Installation Codelist
- DISCREPANCY STATUS ROLE Installation Codelists
- DISCRETE VAL GRP TYPE CODE Installation Codelist
- DISC_STDST_VALUES Installation Codelist
- DOSE FORM TYPE CODE Installation Codelist
- DOSE FREQUENCY TYPE CODE Installation Codelist
- DX_CONFIG Installation Codelist
- DX_EXTENDED_ATTRIBUTES Installation Codelist
- DX_INDEX_TABLESPACE Installation Codelist
- DX_KEY_NAME Installation Codelist
- DX_ROLES Installation Codelist
- DX_VIEW_TABLESPACE Installation Codelist
- EXP DESIGN TYPE CODE Installation Codelist

- EXTERNAL_TRANS_TYPE Installation Codelist
- LAB RANGE SUBSET CODE Installation Codelist
- MANUAL SOURCE TYPE CODE Installation Codelist
- MAPPING_TYPE Installation Codelist
- MEDICAL EVAL TYPE CODE Installation Codelist
- OBJECTIVE TYPE CODE Installation Codelist
- OCL_DOMAINS Installation Codelist
- OCL_INSTALLATION Installation Codelist
- OCL_OPTIONS_TYPE_CODE Installation Codelist
- OPA_MENU_ROLES Installation Codelist
- PATIENT STATUS CODE Installation Codelist
- PLAN STUDY INT TYPE CODE Installation Codelist
- PROCEDURE TYPE CODE Installation Codelist
- QUESTION CATEGORY TYPE CODE Installation Codelist
- RDCI CHANGE REASON TYPE CODE Installation Codelist
- RDCI CHANGE REASON2 TYPE CODE Installation Codelist
- REGION TYPE CODE Installation Codelist
- RETIREMENT REASON TYPE CODE Installation Codelist
- ROUTE OF ADMIN TYPE CODE Installation Codelist
- SAS_FORMATS Installation Codelist
- SINGLE DCI TYPES Installation Codelist
- SOURCE LOCATION CODE Installation Codelist
- STANDARDS AFFIL TYPE CODE Installation Codelist
- STUDY STATUS TYPE CODE Installation Codelist
- TMS_CONFIGURATION Installation Codelist
- TMS_LANGUAGES Installation Codelist
- TMS_QUERY_TYPE Installation Codelist
- TMS_SOURCE_MAT_VIEWS Installation Codelist
- TMS_TAL_POOL_CONFIGURATION Installation Codelist
- TMS_X_SEARCH Installation Codelist
- TREAT CHG REASON TYPE CODE Installation Codelist
- UNITS_OF_MEASURE_TYPE_CODE Installation Codelist
- USER GROUP ROLES Installation Codelist
- USER GROUPS Installation Codelist
- VALIDATION FAILURE TYPE CODE Installation Codelist

APPLICATION AREA CODE Installation Codelist

This codelist contains settings for areas on the body where the medication can be given.

APPLICATION SYSTEM NAME Installation Codelist

This codelist contains a list of application systems used by Oracle Clinical.

APPROVE VERIFY RETAIN CODE Installation Codelist

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 Approval?`** 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 (see Version Migration

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. 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 Installation Codelist

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 (see Version Migration for more details).

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. 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 Installation Codelist

This codelist contains a list of types of blinding that are available in a study.

CLINICAL PHASE Installation Codelist

This codelist list the clinical phases that are available in the design of a study.

COUNTRIES Installation Codelist

This codelist contains the list of valid countries.

CRF PAGE NUMBERING SCHEME Installation Codelist

This codelist contains the list of valid page tracking statuses that is used by the CRF Page Tracking feature.

CRF PAGE STATUS CODES Installation Codelist

This codelist contains the list of valid CRF page statuses that is used in Maintain Page Status Tracking form.

CRF PAGE STATUS QUERY Installation Codelist

This codelist contains the list of valid statuses for CRF page types that is used in Log-In Query window.

CUSTOM REVIEW TYPE Installation Codelist

See Configuring Custom Review Types

DATA CHANGE REASON TYPE CODE Installation Codelist

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 Installation Codelist, to DCAPIDE and another to DCAPIINV (comma-separated, if there are other values in the LONG VALUE).

DATA CHANGE REASON2 TYPE CODE Installation Codelist

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 Installation Codelist. 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, and RECONCILIATION.

DCF LOCK CONDITIONS Installation Codelist

This codelist contains statuses that refer to particular actions that should be limited; see DCF LOCK CONDITIONS for information.

DCF OPTIONAL STATUS CODES Installation Codelist

This codelist contains optional status codes for DCFs; see DCF OPTIONAL STATUS CODES.

DCF STATUS CODES Installation Codelist

This codelist contains status codes for DCFs; see DCF STATUS CODES.

DCIF CHECKBOX SIZE Installation Codelist

This codelist controls the allowable sizes for check boxes 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 Patient Data Reports.

The values refer to point sizes. The values are:

10
12
15
20

DCIF FONT TYPESIZE Installation Codelist

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 Patient Data Reports.

The default values refer to point sizes. The values are:

8
9
10
11
12
14

DCIF PAGE DEFINITION Installation Codelist

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 Patient Data Reports. 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 Installation Codelist

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* Installation Codelist

See Configuring the Actions Allowed on Discrepancies for information.

DISCREPANCY MESSAGES Installation Codelist

The function of this codelist has been replaced by the Standard Text Maintenance form under Admin, Discrepancy Mgmt Maintenance. See Reason Codes and Descriptions for Univariate Discrepancies for information.

DISCREPANCY NO OTHER UPDATE Installation Codelist

See Preventing Update to OTHER Discrepancies for information.

DISCREPANCY RESOLU TYPE CODE Installation Codelist

SeeDefining Resolution Reasons for Discrepancies for information.

DISCREPANCY REV STATUS CODE Installation Codelist

See Defining the Possible Review Statuses for Discrepancies for information.

DISCREPANCY STATUS *ROLE* Installation Codelists

See Configuring Discrepancy Display by User Role for information.

DISCRETE VAL GRP TYPE CODE Installation Codelist

This codelist lists the severity codes for DVGs.

DISC_STDST_VALUES Installation Codelist

This codelist contains discrepancy Study Site Values.

DOSE FORM TYPE CODE Installation Codelist

This codelist contains Dosage Form Types.

DOSE FREQUENCY TYPE CODE Installation Codelist

This codelist contains frequencies of dose administration.

DX_CONFIG Installation Codelist

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.

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?
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?

Table 7-9 (Cont.) Values for DX_CONFIG Reference Codelist

Seq	Short Value	Long Value	Description
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 Installation Codelist

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 this reference codelist is populated. Attributes whose long value is set to Y here can be used as extended attributes in data extract.

If you change the settings in this reference codelist, run the script vb_def_que_attr.sql again.

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 Installation Codelist

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 for more information.

DX_KEY_NAME Installation Codelist

This codelist contains the column alias for a data extract view keys

DX_ROLES Installation Codelist

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 for more information.

DX_VIEW_TABLESPACE Installation Codelist

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 for more information.

EXP DESIGN TYPE CODE Installation Codelist

This codelist contains experimental design types for studies.

EXTERNAL_TRANS_TYPE Installation Codelist

This codelist provides transaction types for the Data Capture API function SetExternalContext.

LAB RANGE SUBSET CODE Installation Codelist

This codelist contains the set of Lab Range Subset Codes.

MANUAL SOURCE TYPE CODE Installation Codelist

See Reason Codes and Descriptions for Manual Discrepancies for information.

MAPPING_TYPE Installation Codelist

This codelist contains the list of possible file transfer protocols that you allow for use in your Oracle Clinical installation. These values appear in the list of values for the Mapping Code field in the Maintain Directory Mappings window. See Setting Up File and Image Viewing for information on mapping directories.

Table 7-11 Values for MAPPING_TYPE Installation Codelist

Seq	Short Value	Long Value	Description
1	HTTP	HTTP	Hypertext Transfer Protocol
2	FTP	FTP	File Transfer Protocol
3	HTTPS	HTTPS	Secure-socket layer HTTP
4	UNC	UNC	Universal Naming Convention protocol
5	SFTP	SFTP	Secure File Transfer Protocol

MEDICAL EVAL TYPE CODE Installation Codelist

This codelist contains the values you use to categorize Questions. The values appear in the list of values for the Medical Evaluation Type field in the Maintain Questions window.

OBJECTIVE TYPE CODE Installation Codelist

This codelist contains the list of types of Clinical Planned Objective.

OCL_DOMAINS Installation Codelist

This codelist contains the installation-wide list of global library domains. For information, see *Oracle Clinical Creating a Study*.

OCL_INSTALLATION Installation Codelist

This codelist has two values:

1. Verify that the Long Value for the GLIB_LOCATION has the correct name of the Global Library-owning location. In addition, make sure the value is in all uppercase letters. Replication fails if the value is not in uppercase.

   The system requests and stores this value during database creation. Oracle Clinical checks the OCL_STATE Local Codelist 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.

> **Note:**
>
> If you need to change the GLIB_LOCATION value in the OCL_INSTALLATION reference codelist, run the oclstate.sql script located in the Install directory.

2. The Long Value for the ALLOW_DISC_REPL parameter. defines whether to replicate all discrepancies and associated data clarification forms (DCFs). You set this value at the Global Library-owning location only.
   - **Y** — The system copies all discrepancies and all associated data clarification forms (DCFs) during study data replication.
   - **N** — The system does not copy discrepancies and DCFs during study data replication. If you execute the study replication with the **Refresh All** value set to **Y,** any previously replicated discrepancies and DCFs will be removed from the target database.

> **Note:**
>
> If you specify page reference numbers for DCFs, the numbers must be unique in each database instance. Therefore, if you choose to replicate discrepancies and DCFs, you must ensure that the page reference numbers for DCFs are unique across all databases in the replicated installation.

OCL_OPTIONS_TYPE_CODE Installation Codelist

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 is installed; to N if not.
3	VAL_STATUS	Y	Optionally, batch validation determines whether there has been any overall change in the validation status of each response based on discrepancies created or closed for that response. This setting determines whether or not the calculation will be performed and results stored with the response, and whether a change in response validation status will create a versioned response entry (audit) in the database. If set to Y, batch validation calculates validation status for affected responses and if there is a change, versions (audits) the change. If set to NO_AUDIT, Batch Validation calculates validation status for affected responses, but stores changed validation status in the current response record, without versioning (auditing) the change. If set to NONE, Batch Validation does not calculate validation status for affected responses.
4	SR_INSTALLED	Y	Set to Y if Symmetric Replication is installed.

OPA_MENU_ROLES Installation Codelist

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 for information.

PATIENT STATUS CODE Installation Codelist

This codelist describes patient statuses such as enrolled or terminated.

PLAN STUDY INT TYPE CODE Installation Codelist

This codelist describes types of Planned Study Intervals, such as baseline, dosing, and qualifying.

PROCEDURE TYPE CODE Installation Codelist

This codelist contains the list of user code for PROCEDURES.

QUESTION CATEGORY TYPE CODE Installation Codelist

This codelist contains the list of user codes for QUESTION_CATEGORY_RELATIONS.

RDCI CHANGE REASON TYPE CODE Installation Codelist

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. Table 7-13 describes each values in this codelist.

This following subsystems use this installation 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 Installation 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 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

RDCI CHANGE REASON2 TYPE CODE Installation Codelist

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 Installation Codelist

This codelist contains types of region such as state, country, or continents.

RETIREMENT REASON TYPE CODE Installation Codelist

This codelist contains the list of user codes for DCIS, DCMS, DVGS, PROCEDURES, QUES, QUES_GROUPS.

ROUTE OF ADMIN TYPE CODE Installation Codelist

This codelist contains routes of drug administration such as oral, intravenous, and inhalation.

SAS_FORMATS Installation Codelist

This codelist contains a list of optional subsystems.

SINGLE DCI TYPES Installation Codelist

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 following table lists the default values for the SINGLE DCI TYPES codelist.

Table 7-14 Default Values for the SINGLE DCI TYPES Codelist

Seq	Short Value
1	DEMOGRAPHY
2	COMPLETION

SOURCE LOCATION CODE Installation Codelist

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 Installation Codelist

This codelist contains the user code for STANDARDS_AFFILIATIONS.

STUDY STATUS TYPE CODE Installation Codelist

This codelist contains types of Clinical Study Status.

TMS_CONFIGURATION Installation Codelist

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_LANGUAGES Installation Codelist

This codelist populates the Language field in the Define Dictionaries window for Oracle Thesaurus Management System. English is the default dictionary language. See the *Oracle Thesaurus Management System User's Guide* for details

TMS_QUERY_TYPE Installation Codelist

This codelist populates the Query fields in Oracle Thesaurus Management System with default choices for query type. See the *Oracle Thesaurus Management System User's Guide* for details.

TMS_SOURCE_MAT_VIEWS Installation Codelist

This codelist controls whether Oracle Thesaurus Management System uses materialized views or regular views to populate the list of values for each external system value in the Filter window, which launches from Reclassify Verbatim Terms and Approve VTAs. See the *Oracle Thesaurus Management System User's Guide* for details.

TMS_TAL_POOL_CONFIGURATION Installation Codelist

This codelist configures the task allocation for omissions, unapproved VTAs, and unapproved Action assignments specific to Oracle Thesaurus Management System. See the *Oracle Thesaurus Management System User's Guide* for details.

TMS_X_SEARCH Installation Codelist

This codelist populates the list of values for the Search Type field in Oracle Thesaurus Management System. It currently has only one value, Cross Search. See the *Oracle Thesaurus Management System User's Guide* for details.

TREAT CHG REASON TYPE CODE Installation Codelist

This codelist contains the list of valid Treatment Change Reason Type Codes.

UNITS_OF_MEASURE_TYPE_CODE Installation Codelist

This codelist contains units of measure that are available for use in studies in the database.

USER GROUP ROLES Installation Codelist

See Mapping Database Roles to User Roles.

USER GROUPS Installation Codelist

See Specifying User Roles for the Oracle Clinical Discrepancy Database for information on this reference codelist.

VALIDATION FAILURE TYPE CODE Installation Codelist

This codelist contains the user code for DCM_QUESTIONS, PROCEDURE_DETAILS, QUES, and 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 Installation Codelist
- BLIND TYPE CODE Installation Codelist
- CLINICAL PHASE Installation Codelist
- DOSE FORM TYPE CODE Installation Codelist
- DOSE FREQUENCY TYPE CODE Installation Codelist
- EXP DESIGN TYPE CODE Installation Codelist
- OBJECTIVE TYPE CODE Installation Codelist
- PLAN STUDY INT TYPE CODE Installation Codelist
- REGION TYPE CODE Installation Codelist
- ROUTE OF ADMIN TYPE CODE Installation Codelist
- STUDY STATUS TYPE CODE Installation Codelist
- TREAT CHG REASON TYPE CODE Installation Codelist

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. See Running the Reference Codelists Report for instructions.

Part II
Oracle Clinical Administration Tasks

This section includes tasks involved in running Oracle Clinical:

- Managing Batch Jobs
- Partitioning and Indexing
- Utilities
- Setting Up File and Image Viewing
- Setting Up Replication
- Using Replication

8
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).

For troubleshooting information, see PSUB Jobs. See also Setting Up Batch Job File Viewing.

> **Note:**
>
> For information on managing Oracle Reports jobs, see the Oracle Application Server Reports Queue Manager documentation.

For more information , see:

- Account Requirements for Batch Jobs
- How PSUB Handles a Request
- Securing PSUB
- Using PSUB in a RAC Environment
- Starting and Stopping PSUB
- Managing the PSUB Process
- Required Reference Codelist Settings for Batch Jobs

Account Requirements for Batch Jobs

To submit batch job requests, a user must have the following:

- a user database account
- PSUB User? set to Y in the Oracle Accounts table (This value can be set only by the Add User or Migrate User script. It is not updateable in the user interface.) The setting indicates the user has access to the ocpsub account as a proxy user for PSUB jobs.
- a directory for reports output
- an additional directory for certain batch job types; see Creating Directories for Input and Output Files of Certain Job Types.

For instructions on setting up user accounts, see Setting Up User Accounts.

How PSUB Handles a Request

When a user issues a PSUB request to run a job or report, the ocpsub database account acts as a proxy for the user (see Securing PSUB). The system sends a message via Oracle Advanced Queue (AQ) to the PSUB service that includes the batch job ID and the primary key to the RXC.BATCH_JOBS table.

When the process receives the message, it:

- Reads the job information from the RXC.BATCH_JOBS table
- Creates a subdirectory named with the batch job ID under the user-specific subdirectory; see Securing PSUB
- Submits the job on the user's behalf with the PSUB Launcher (PSLAUNCH)
- Places the following files in the batch ID subdirectory, as required, where *nnnn* represents the batch job ID.:
  - l***nnnn***.log: Log file of a user's PSUB job. Note that the initial character is the letter L, not the number one.
  - o***nnnn***.out: Output from a report job.
  - p***nnnn***.log: Log file for a print request from the Submitted Batch Jobs form.
- Copies the files to a database table BATCH_JOBS_LOBS, in a column with the CLOB data type. You can choose to delete the files from the temporary directory or not by setting OCL_STATE reference codelist value PSUB_DEL_FILES.

For more information , see:

- Asynchronous PSUB Requests
- Blocking and Nonblocking Jobs
- Checking a Nonblocking Batch Job

Asynchronous PSUB Requests

The Oracle Advanced Queue (AQ) mechanism is an asynchronous protocol, so messages remain in the queue 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. You may have to resubmit the blocking job if you stop the PSUB process (daemon) while the blocking job is running.

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

Nonblocking jobs include all reports, all jobs launched from the PSUB submission screen, and randomization.

When an application server submits a blocking job, it sends information through an entry in AQ through client_send method then waits on an application server-specific AQ server_recieve method for completion (execution) information, which it receives from PSUB. The pipe is maintained by the application and is named with a unique session name.

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 opapps or system manager account:

```
$ at -l
```

Securing PSUB

In this section:

OCPSUB Proxy Database Account

Users who need to submit PSUB jobs must have access to the login database using a proxy user, the ocpsub database account, to run PSUB jobs. The ocpsub account's credentials are stored in the Oracle Wallet created during the Oracle Clinical Database Server installation; the Oracle Clinical Database Installer prompted for the Wallet's location.

You must change the password for ocpsub before it expires; see Changing the Password for the OCPSUB or RXC_DISC_REP Account and Setting Password Requirements for User Accounts.

File Security for Most PSUB Jobs

You must create a directory to temporarily store PSUB log and output files and enter its path as the long value of the PSUB_LOGS_DIR value in the OCL_STATE local reference codelist. The first time a user runs a PSUB job in Oracle Clinical Release 5.0 or later, the system automatically creates a subdirectory under this directory for the user and places the generated log and output files there before writing them to a database table where they are stored permanently. When the user views or prints the files, the system displays or prints them directly from the database. Users have access only to files for jobs they submitted.

Although users have their own subdirectories, only the opapps account has access to the directories; the system checks the user account name against the user-specific directory

name at runtime to grant access to the files. The system checks only the portion of the username that does not include `OPS$` (if the username includes `OPS$`) because the OPS$ prefix is no longer required.

File Security for PSUB Jobs with Input Files

Each type of batch job that uses input files requires that you set up a directory to contain these files; see Creating Directories for Input and Output Files of Certain Job Types. For these you have the option to manually create user-specific subdirectories or to have users share access to a single directory. Unless you have very few PSUB users and they all have the same data access privileges, you should create individual subdirectories to ensure that users can see only files for jobs they submitted.

If the OCL_STATE reference codelist setting USERDIRS is set to **Y**, indicating that you have user-specific subdirectories, PSUB looks for the input or generates the output file in any directory at or below *JOBTYPE*_ROOT/*user*, where *user* must match the database account ID—minus the `OPS$` string, if any—of the Oracle Clinical user who submitted the job.

Windows Only

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 *Oracle® Database Security Guide 11g Release 2 (11.2)*.

Using PSUB in a RAC Environment

Oracle Clinical is certified on an Oracle Real Application Cluster (RAC) configuration to support multiple nodes with failover capabilities. Oracle recommends installing the Oracle Clinical Database Server, which includes the PSUB Server, on at least two RAC nodes. If PSUB goes down on one node, or if the node itself goes down, you can start PSUB on the other node with little interruption of service.

One and only one PSUB process (service) per database is required and can run on any RAC node where the Oracle Clinical database server is installed. Oracle Clinical cannot detect whether multiple PSUB services are running, so results are unpredictable if this is the case.

If the PSUB service fails, there is no notification of it. You must start PSUB manually for that database on the same or a different server and change the value of the SERVER_NAME setting in the OCL_STATE Local Codelist to the new PSUB server.

> **Tip:**
>
> Create the same directory structure for PSUB files on each computer where PSUB may run. That way you do not have to change the OCL_STATE reference codelist value for the five PSUB directories for jobs that use input files; see Creating Directories for Input and Output Files of Certain Job Types.
>
> If you use NFS to share the files, users will still be able to access files for jobs performed on the other node unless the node itself fails.

In the event of a PSUB failure, current PSUB jobs are affected differently based on their state at the time of PSUB failure:

- SCHEDULED or ENTERED jobs are picked up by the new PSUB service when it is started
- SUBMITTED jobs must be re-submitted
- STARTED jobs continue to run if the server is still running, regardless of PSUB status

If the database instance on the PSUB server goes down, but its server is still active, PSUB continues to process jobs for the other database instances in the RAC environment.

PSUB continues to work when nodes are added or removed except when the node running PSUB is removed. In that case, you can start PSUB manually on a different node.

Starting and Stopping PSUB

In this section:

Starting and Stopping PSUB Manually in UNIX

In this section:

Starting PSUB Manually in UNIX

To start the PSUB service on UNIX:

1. Log in as the opapps user. By default, the opapps uses the C shell.
2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Start the PSUB service:

   ```
   start_psub database_name code_environment wallet_alias
   ```

For example:

```
start_psub prod 52 prod
```

where *prod* is the connect string for the database instance to which the PSUB service connects;

where 52 is the name of the code environment;

where *wallet_alias* is the name of the Wallet specified during installation. By default it is the same as the database name.

4. If there are any errors, check the following log files in the $RXC_CENTRAL_LOG directory:
   - rxcpsd_instance_environment_1.log
   - rxcpsd_instance_environment_2.log

Stopping PSUB Manually in UNIX

The preferred way to stop the PSUB service is with the following utility, from the opapps account, after setting the correct environment. You need to be sure the TNS_ADMIN environment variable is set to the location of the sqlnet.ora file. The Installer puts sqlnet.ora in the opapps Home directory; see Setting TNS_ADMIN on UNIX.

Use the echo command to check the setting, then stop PSUB.

```
echo $TNS_ADMIN
setenv TNS_ADMIN $HOME
stop_psub database_name][environment Wallet_alias
```

Starting and Stopping PSUB Automatically in UNIX

On UNIX systems, you can automate the process of starting and stopping PSUB. See the following:

- Starting PSUB Automatically in UNIX
- Stopping PSUB Automatically in UNIX

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/12.1.0.2
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 - opapps -c start_psub
```

```
;;
'stop')
echo 'Stopping Oracle...'
su - opapps -c stop_psub
su - $ORA_OWNER -c $ORA_HOME/bin/dbshut
;;
esac
# File: start_psub
# Start database 1
start_psub db_name1 code_environment wallet_alias
# Start database 2
start_psub db_name2 code_environment wallet_alias
```

For example:

```
# Start database 1
start_psub venus 52 wallet_alias
# Start database 2
start_psub pluto 52 wallet_alias
```

where the database names are venus and pluto and you have installed Oracle Clinical 5.2.

Stopping PSUB Automatically in UNIX

You can automate the shutdown of the PSUB service on UNIX so that it does not require the entry of a password.

The following example shell scripts for Sun Solaris show how.

```
# File: /etc/init.d/dbora
ORA_HOME=/u01/app/oracle/product/12.1.0.2
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 - opapps -c start_psub
;;
'stop')
echo 'Stopping Oracle...'
su - opapps -c stop_psub
su - $ORA_OWNER -c $ORA_HOME/bin/dbshut
;;
esac
# File: stop_psub
# Stop database 1
set TNS_ADMIN= opapps_home_dir
export TNS_ADMIN
stop_psub venus 52 wallet_alias
# Stop database 2
stop_psub pluto 52 wallet_alias
```

where the database names are venus and pluto and you have installed Oracle Clinical 5.2.

Starting and Stopping PSUB Manually in Windows

In this section:

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 or as a user with administrative privileges.
2. Open a Command Prompt window:
   - If you logged in as Administrator, click **Start**, then **Run**, then enter `cmd`.
   - If you logged in as a different user with administrative privileges, click **Start**, type `cmd` in the **Start** search box, then right-click **cmd** in the list and click **Run as administrator**.
3. 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
```

4. Navigate to Start, then Administrative Tools, then Services.
5. In the Services window, right-click on the PSUB service, then click **Properties**. The PSUB Service Properties window opens.
6. In the General tab, set the **Startup Type** to Manual.
7. In the Log On tab, select **This Account**, then click **Browse**.
8. Enter: `opapps`, then click **Check Names**. The system enters the relative location to opapps.
9. Click **OK**. The system returns to the PSUB Service Properties window.
10. Enter and confirm the opapps password, and click **OK**.
11. Log out from this Administrator session.

Starting PSUB Manually in Windows

To start the PSUB service on Windows:

1. Log in as opapps. (You set up the PSUB service to start as the opapps user, but in Windows you can start the service when logged on as another user.)
2. Set the PSUB service parameters:
   a. In the Start menu, navigate to **Administrative Tools**, then Services.

b. From the list of services in the Services dialog box, double-click the name of the database for this service. It is in this form:

   PSUB Service *database*

c. Enter values for the Log On parameters:

   database code_environment [verbose | noverbose] *value-of-RXC_ROOT wallet_alias*

   For example: `prod 52 verbose c:\\opapps\\oc\\52 <Wallet_name>`

   where *prod* is the connect string for the database instance to which the PSUB service connects;

   where *52* is the name of the code environment;

   where *wallet_alias* is the name of the Wallet specified during installation.

> **Note:**
>
> If your entry requires a backslash (\), you must enter two (\\). Alternatively, you can enter the path using single forward slashes, for example, c:/OPA_HOME/oc/52.

3. Click **Start.**
4. Exit from the Services dialog box.
5. Check the PSUB service log file in <RXC_ROOT>/log for any warning or error messages.

Stopping PSUB Manually in Windows

Do not use Enterprise Manager to stop opapps sessions on Windows; instead, use the Control Panel on the appropriate local machines.

To stop the PSUB service:

1. Log in as the PSUB user; in this case, opapps.
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 the venus database, for example, might appear as:

   ```
   psub service venus
   ```

4. In the Properties window, click Stop.

Starting PSUB Automatically in Windows

You must first install PSUB; see Installing PSUB in Windows.

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 service does not start and an error like the following appears in the PSUB log file (found in the *drive*:\opapps\oc\52\log directory):

```
ERROR:Daemon error while connecting:/@devoc
ORA-1033: ORACLE initialization or shutdown in progress
```

For more information, see:

- Creating a System Environment Variable
- Creating a Batch File
- Scheduling the Batch File and Testing the Setup
- Adding a Shortcut

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 a system environment variable whose name concatenates `PSUBSERVICE` with the database name.

To create a system environment variable in Windows:

1. Navigate from Start to the Control Panel, then click on the **System and Security** link. The System and Security window opens.
2. Click the **System** link. The System window opens.
3. Click the **Advanced System Settings** link at the top left corner. The System Properties window opens.
4. Select the **Advanced** tab, then click **Environment Variables**.
5. Click **New** under System Variables in the lower portion of the window to define the variable.

   For the **variable name**, enter the string `PSUBSERVICE` concatenated with the database name; for example, for the database sun6x2:

   ```
   PSUBSERVICESUN6X2
   ```

   For the **variable value**, use the format: *`database_id code_environment`* `verbose` *`RXC_ROOT wallet_alias`*; for example:

   ```
   pluto 52 verbose t:\\opapps\\oc\\52 wallet_alias
   ```

   where pluto is the database ID and RXC_ROOT is t:\opapps\oc\52.

   Note that if you need a backslash (\) in the text box, you must double it (\\).

Creating a Batch File

Create a batch file called 'psub_start1.bat' in the %RXC_ROOT%/log directory (for example, D:\opapps\oc\52\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. Navigate to Start, then Administrative Tools, then Services. Scroll down and make sure that the **Task Scheduler** service is started.
2. Navigate to Start, then Administrative Tools, then Task Scheduler. The Task Scheduler window opens.
3. Click the **Create Basic Task** link on the right. The Create Basic Task wizard appears.
4. Enter a **Name** and **Description** and click **Next**.
5. In the Task Trigger window, select **When the computer starts** and click **Next**. The Action window appears.
6. In the Action window select **Start a program** and click **Next**. The Start a Program window appears.
7. In the Start a Program window, click **Browse**. The Browse window appears.
8. In the Browse window, browse to the directory where psub_start1.bat is saved and then select **psub_start1.bat**. Leave the other boxes empty and click **Next**.
9. Select **Open the Properties dialog for this task when I click Finish** and click **Finish**. The Properties dialog box opens.
10. In the Properties dialog box, General tab, Security options section, click **Change User or Group** and select **Administrator**.

    To test, shut down the service if necessary (see Stopping PSUB Manually in Windows) 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.
11. In the Services window under Administrative Tools in the Control Panel, right-click the PSUB Service, click **Properties**, and change its Startup Type 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.

Managing the PSUB Process

In this section:

- Viewing Log and Output Files on the Screen
- Using Job Sets to Control Execution Order
- Tracking PSUB Processes

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.

> **Tip:**
>
> 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.

If a particular PSUB process (service) fails, you can start another PSUB service for that database on another server. You do not receive a specific notification if a PSUB service fails.

Oracle Clinical 5.0 and later support one PSUB service per database that can run on any one of the RAC nodes or on a non-RAC server. Since Oracle Clinical cannot detect whether multiple PSUB services are running, such a situation is unpredictable.

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 to the Windows server as Administrator or as a user with administrative privileges.
2. Open a Command Prompt window:
   - If you logged in as Administrator, click **Start**, then **Run**, then enter `cmd`.
   - If you logged in as a different user with administrative privileges, click **Start**, type `cmd` in the **Start** search box, then right-click **cmd** in the list and click **Run as administrator**.
3. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
4. Enter the following commands:

```
cd %RXC_BIN%
rxcpsdps -remove database-connect-string database_instance_name
```

5. Log out from this Administrator session.

Viewing Log and Output Files on the Screen

In this section:

Viewing Logs that Concern Execution of PSUB Processes

The PSUB service 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 service to view the contents of this log file, because it will be locked.

However, the following file can be read while the PSUB service is running:

Operating System	Example Path and File Name for Log File
UNIX	`$RXC_CENTRAL_LOG/rxcpsd_instance_environment_1.log`
Windows	`%RXC_CENTRAL_LOG%\rxcpsd_instance_environment_1.log`

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/user/o12345.out (for UNIX)
- %RXC_LOG%\o12345.out (for Windows)

and a log file name of:

- $RXC_LOG/12345.log (for UNIX)
- %RXC_LOG%\12345.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.

> **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

The steps to use job sets to control execution order are:

- Create a Job Set
- Submit a Job Set

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 service, 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 service was started and the time it was stopped.

Table 8-1 Description of Table RXC.PSUB_PROCESS_LOG

Column Name	Type	Description
PSUB_PROCESS_LOG_ID	NUMBER	ID
HOST	VARCHAR2(64)	Host name
SERVER_OS	VARCHAR2(8)	The type of operating system on the server where PSUB runs
START_TS	DATE	The time stamp when the PSUB service started
CODE_ENVIRONMENT	VARCHAR2(20)	Code environment
VERBOSE	VARCHAR2(1)	Y or N
STOP_TS	DATE	The time stamp when the PSUB service 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;
```

Required Reference Codelist Settings for Batch Jobs

Oracle Clinical manages batch jobs through entries in these reference codelists. See Reference Codelists for additional information:

- BATCH QUEUE NAME Local Codelist
- PRINT QUEUE NAME Local Codelist

- OCL_JOB_PREF Local Codelist
- REPORT_SERVER Local Codelist
- SAS_QUEUE Local Codelist
- OCL_STATE Local Codelist

For more information on the OCL_STATE settings, see Entering Reference Codelist Values.

9
Partitioning and Indexing

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 information on partitioning and on maintaining partitioned tables, see the Oracle database documentation.

For more information, see:

- Introduction
- Planning for Partitioning
- Partitioning the Responses Table
- Partition Maintenance
- Upgrading Indexes
- Query Tuning Guidelines

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.

For more information , see:

- Timing Considerations and Deferral of Index or Partition Upgrade
- 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

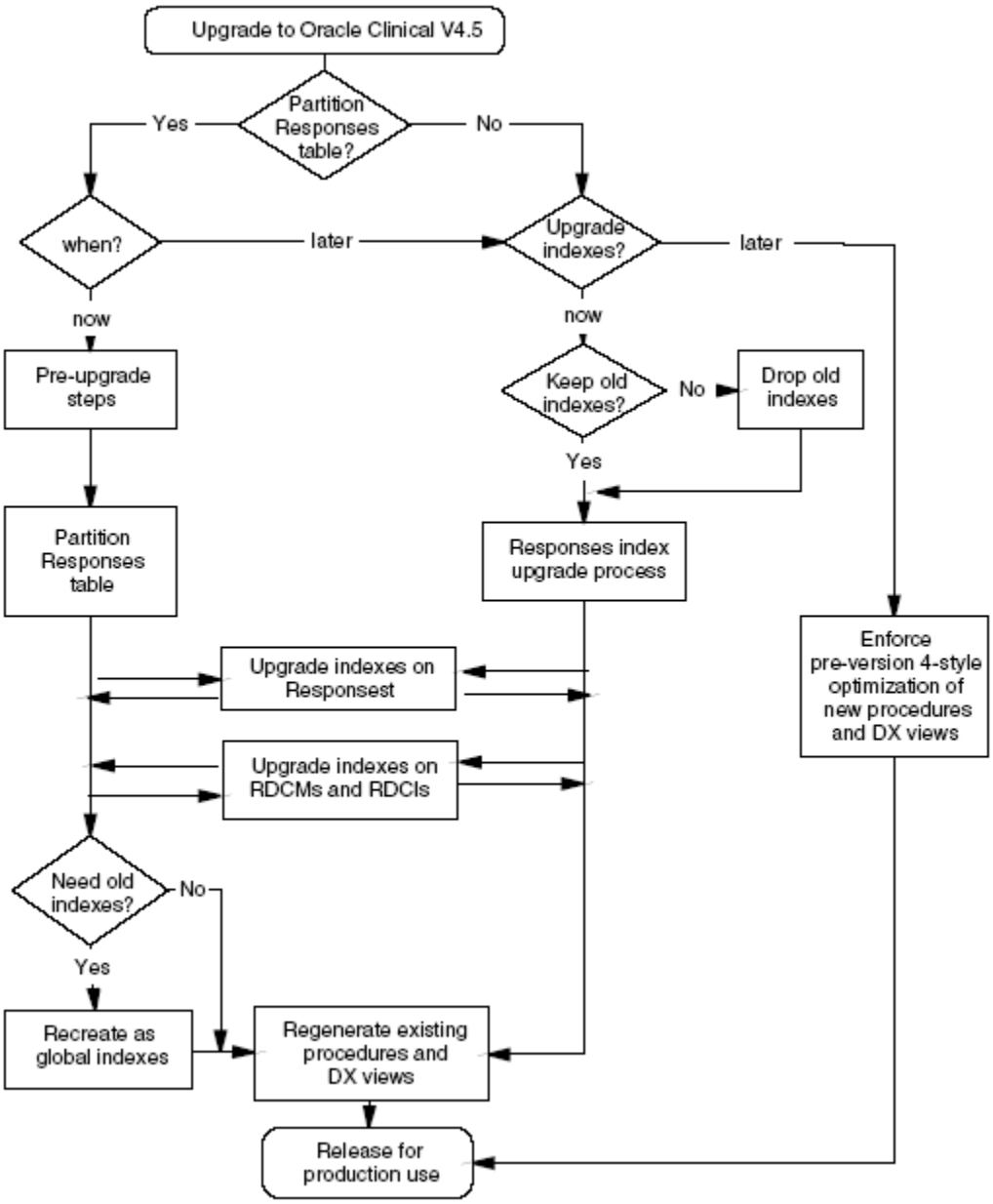
time might reduce the risk and time pressure. The index upgrade is the least time-consuming and is easily performed overnight even on a large database. Partitioning is more time-consuming and, while it can easily be accomplished over a weekend on even the largest Oracle Clinical database, it needs more 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).

The upgrade for Responsest should be done at the same time as either partitioning or the Responses table index upgrade.

See Upgrading Indexes for more information. This upgrade can be done at any time that is convenient.

Figure 9-1 Partitioning and Indexing Decision Paths



For more information , see:

- Enforcing Pre-Version 4.0 Optimization

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 Database documentation.

See the following:

- How Has the Responses Table Been Partitioned?
- Why Partition?

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 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

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

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).

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.

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.

For more information , see:

- Decide Partitions Needed
- Define Partition Structure
- Implement Partition Structure
- Generating Table and Index Creation SQL

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).

   Action: Consolidate as much as possible and locate in read-only tablespace (see Using Read-Only Partitions to Minimize Backup).

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

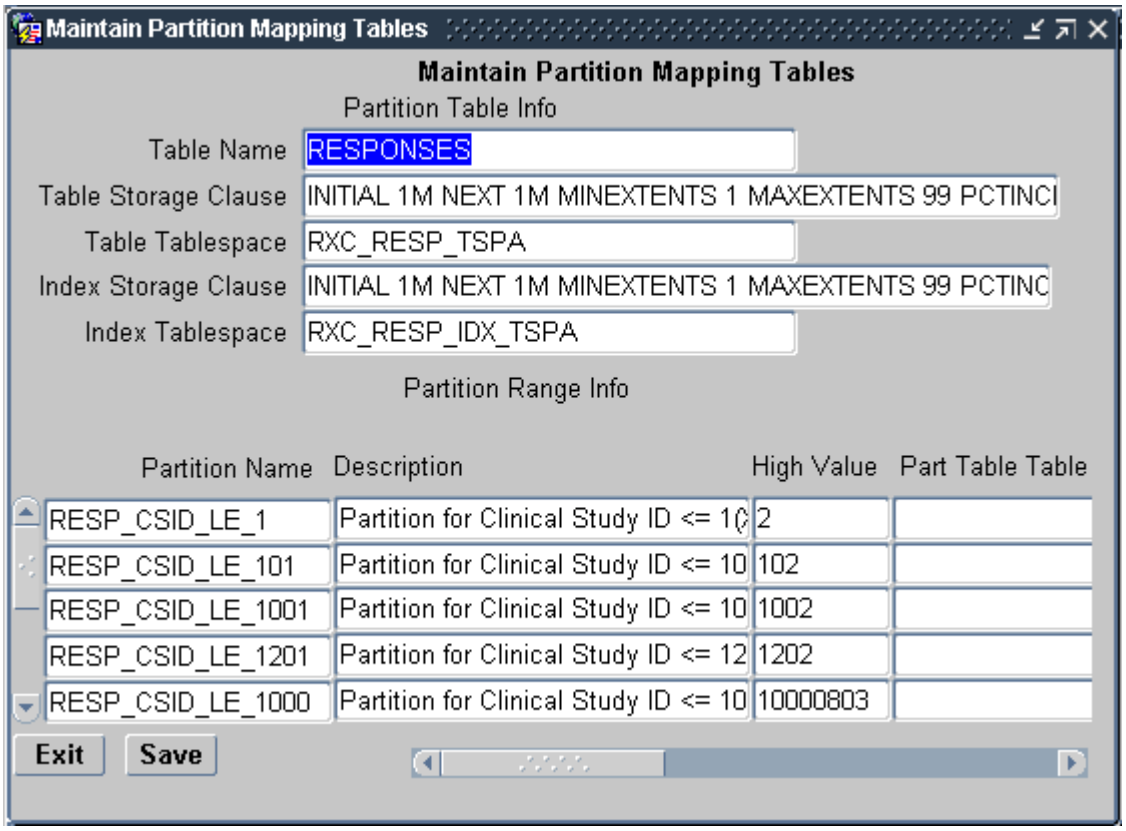
Implement Partition Structure

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 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 Example 9-3), 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_9999999998
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, 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 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 Example 9-2 and Example 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 and Maintenance of Cost-Based Statistics).

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_9999999998
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.

> **Note:**
>
> Conduct all SQL activities while connected to the RXC account, from the tools directory for Oracle Clinical, unless otherwise specified.

The upgrade consists of the following steps:

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.

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.

Perform the following:

- Step 3a Drop Responses Table
- Step 3b Reorganize Tablespaces and System File Space
- Step 3c Create Partitioned Responses Table

Step 3a Drop Responses Table

Drop the existing, unpartitioned Responses table and its indexes:

```
SQL> drop table responses;
```

Step 3b 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.

Step 3c Create Partitioned Responses Table

Create an empty partitioned Responses table by executing the table creation script generated earlier (see Example 9-1). 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 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 Example 9-2 and Example 9-3, above.

Create the indexes by executing the index creation scripts generated and edited earlier (see Generating Table and Index Creation SQL).

```
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 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 `resptrig.sql` in the install directory.

```
SQL> @resptrig.sql
```

Step 8. Back Up the Database (can be deferred to after Step 9)

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), you must enable it before regenerating procedures and views.

To regenerate procedures and views, follow the instructions in 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 (Optional, can be deferred to normal backup schedule)

If you performed Step 8, you can defer this backup to your normal schedule.

If you skipped Step 8, do a full backup now. Remember to re-enable redo log archiving before releasing Oracle Clinical for production use.

Partition Maintenance

In this section:

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.

   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 Figure 9-2) 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.

For more information , see:

- Rebuild Partitions
- Managing New Studies
- Reviewing for Partitions that Need Splitting or Merging
- Maintenance of Cost-Based Statistics

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) 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_9999999998 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.

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). 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 was 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.

For more information , see:

- Index Upgrade Process
- Response Index Upgrade
- ResponsesT (Test Database) Index Upgrade
- RECEIVED_DCI and RECEIVED_DCM Index Upgrades

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
```

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). 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.

For more information , see:

- Regenerate Procedures and Data Extract Views

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), 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 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 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 Example 9-7 and Example 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)
```

10
Utilities

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 the user interface.

Other utilities are covered in other chapters:

- Generating Data Extract Views covers **gen_views**
- Changing the Password for a Schema or Role Using the SET_PWD Utility covers **set_pwd**
- Starting and Stopping PSUB covers **start_psub**
- Starting and Stopping PSUB covers **stop_psub**

This section covers the following:

- Computing the Validation Status of All Responses (cnvstatus)
- Generating Validation Procedures (gen_procs)
- Deleting Inactive Procedures (rxcdelproc)
- Running Reports on Deleted Data and Discrepancies

Computing the Validation Status of All Responses (cnvstatus)

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.

For more information , see:

- Running cnvstatus on UNIX
- Running cnvstatus on Windows

Running cnvstatus on UNIX

To run cnvstatus on UNIX:

1. Log on to the server as opapps and change the directory to $RXC_TOOLS.

2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Set the output directory:
   - C Shell command: `setenv RXC_LOG usr_log_dir`
   - Bourne Shell command:

     `RXC_LOG = usr_log_dir`

     `export = code_env`
4. Run the script. It prompts for the RXC username and its password.

   `cnvstatus study_name` or `ALL`

   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 as opapps.
2. Open a DOS window, change directory to %RXC_TOOLS, and set the server environment; see Setting Environment Variables on the Command Line
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 (gen_procs)

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.

`LAGONLY | ALL` —see the secton on lag variables in the chapter on creating Procedures in *Oracle Clinical Creating a Study*

The system creates a file named ora_errors.err in one of the following locations:

- If you specify a value for RXC_LOG, the system writes the error log to that directory.
- If you do not specify a value for RXC_LOG, the system writes the error log to the user's subdirectory under the directory specified in the PSUB_LOGS_DIRECTORY value in the OCL_STATE local reference codelist.

For more information , see:

- Running gen_procs on UNIX Systems
- Running gen_procs on Windows Systems

Running gen_procs on UNIX Systems

To run gen_procs on a UNIX platform:

1. Log on to the server as opapps.
2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Change the directory to $RXC_BIN.
4. Set the output directory (Optional):
   - C Shell command: `setenv *RXC_LOG usr_log_dir*`
   - Bourne Shell command: `RXC_LOG=*usr_log_dir* export *code_env*`

   If you do not specify a directory, the system places the files ora_errors.err and genprocs.log in the location specified as the value of PSUB_LOGS_DIR in the OCL_STATE local reference codelist.
5. Run the script. For example:

   ```
   gen_procs ALL FULL GENERATE ALL > gen_procs.log
   ```

   The system prompts for the database name and the username and password of any account that can execute a single procedure. You can use the RXC account.

   Oracle Clinical creates gen_procs.log in $RXC_BIN.

Running gen_procs on Windows Systems

To run gen_procs on Windows:

1. Log on to the server as opapps.
2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
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

   The system prompts for the database name and the username and password of any account that can execute a single procedure. You can use the RXC account.

   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 (rxcdelproc)

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.

Running Reports on Deleted Data and Discrepancies

You can run two reports in SQL*Plus to view data and discrepancies that were deleted using the batch job for that purpose if it was running in **Audit** mode:

- List Batch Data Deleted Responses (list_asdd_responses)
- List Batch Data Deleted Discrepancies (list_asdd_discrepancies)

To run either report:

1. Log on to the operating system.
2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Change to the RXC_INSTALL directory:

   ```
   cd $RXC_INSTALL
   ```

4. Connect to SQL*Plus as `rxc`:

   ```
   sqlplus rxc
   ```

5. Run one of the scripts:

   ```
   start list_asdd_responses.sql
   ```

   or

   ```
   start list_asdd_discrepancies.sql
   ```

6. The script prompts for the following parameter values:
   - **Study**: Enter either a single study or use % for wildcard.
   - **Site**: Enter either a single site or use % for wildcard.

- **Patient**: Enter either a single patient name or use % for wildcard.
- **Document Number**: Enter either a single document number or use % for wildcard.
- **User ID who submitted BDD job**: Enter either a single user or use % for wildcard.
- **Batch Job ID**: Enter a particular batch job id or return for all.
- **Job Submitted From**: Enter the BDD job(s) executed from date.
- **Job Submitted To**: Enter the BDD job(s) executed to date.
- **Spool file name**: Enter the file name into which the job should write the output. You can include a relative path if needed.
- **Delimiter**: Enter **~** or another character to simplify import into Excel.

The job writes data to the file specified as the spool file.

> **Note:**
>
> The list_asdd_discrepancies.sql script retrieves discrepancies that have been OBSOLETED because a response was corrected. There will be no corresponding record for the previous discrepant response. On the other hand, a multivariate discrepancy may be listed as CURRENT, even if a response has been updated to resolve that discrepancy. This happens if the discrepancy procedure is only executed when Batch Validation runs (an offline procedure), and Batch Data Delete is executed before Batch Validation has had a chance to OBSOLETE the discrepancy.

11

Setting Up File and Image Viewing

This section includes the following information on the steps required so that users can see the output files for the reports and batch jobs they have submitted:

- Setting Up Batch Job File Viewing
- Setting Up Image Viewing

Setting Up Batch Job File Viewing

In this section:

- Setting Up Directories for PSUB
- Entering Reference Codelist Values

Setting Up Directories for PSUB

Oracle Clinical's Parameterized Submission (PSUB) batch utility runs and schedules most Oracle Clinical jobs.

For more information , see:

- Creating a Directory for Log and Output Files and Registering it in OCL_STATE
- Creating Directories for Input and Output Files of Certain Job Types

Creating a Directory for Log and Output Files and Registering it in OCL_STATE

The logs and output of the PSUB job are stored in the database and retrieved and displayed directly from a database table. Beginning in Release 5.0, FTP is no longer used.

You must create a single directory to temporarily store .log and .out files generated by PSUB before they are stored in the database, and enter the path of this directory in the PSUB_LOGS_DIR entry of the OCL_STATE local reference codelist.

The system automatically creates a subdirectory for each user the first time the user runs a PSUB job, and stores the .log and .out files in the subdirectory.

By default, the system deletes these files from the temporary directory after writing them to the database. If you prefer to keep files in the temporary directory, you can set the PSUB_DEL_FILES entry in OCL_STATE to N.

Creating Directories for Input and Output Files of Certain Job Types

Some PSUB jobs require input files and/or produce output files for which they require an additional directory.

For each job type listed in Table 11-1 below, do the following:

1. **Create a root directory** in the operating system file system for the database for each job type.
2. (Optional but recommended) **Create a user-specific directory for each user who needs to submit jobs of that type**. Oracle recommends having user-specific directories but provides the option in case you have very few users loading files and they have the same security privileges. Not creating user-specific directories may create a security issue, especially if you have multiple studies on the same database. A user could select and view a file from a study other than the one in context in the Oracle Clinical interface.

   You must name the subdirectory exactly the same as the username, minus the `OPS$` string, if any. The system disregards the `OPS$` string when determining whether to give the user access to files in the subdirectory.
3. **Give access to each directory only to the opapps account**. Individual users do not need access and should not have access.

Table 11-1 PSUB Job Types Requiring Special Directories and the Corresponding OCL_STATE Settings

Job Type	Oracle Clinical Menu Path	OCL_STATE Settings
Randomization	From the **Design** menu, select **Randomization**, then **Randomization Batch Load**, then one of the following: • **Download Randomization** • **Validate and Load Randomization** • **Load a Converted Randomization** • **Validate a loaded Randomization**	RAND_ROOT RAND_USERDIRS
Load Patient Enrollment Dates	From the **Design** menu, select **Patient Positions**, then **Load Enrollment Dates**.	BDL_ROOT BDL_USERDIRS
Batch Data Load and Out of Study Load	From the **Conduct** menu, select **Batch Data Load** or **Out of Study Load**, then select **Batch Load Data Files**.	BDL_ROOT BDL_USERDIRS
Load Patient SDV Attributes	From **Design** select **Patient Positions**, and then select **Load Patient SDV Attributes**	BDL_ROOT BDL_USERDIRS
Lab Batch Data Load	From the **Labs** menu, select **Lab Batch Data Load**, then one of the following: • **Lab Ranges Batch Data Load** • **Report Results of the Data Load**	LAB_ROOT LAB_USERDIRS
Disconnected Replication	From the **Admin** menu, select **Replication**, then one of the following: • **Disc Repl Export** • **Disc Repl Load**	REPL_ROOT

> **Note:**
>
> Disconnected Replication does not require or support user-specific subdirectories.

Entering Reference Codelist Values

For each job type listed in Table 11-1, do the following:

- Enter the Root Directory Path in OCL_STATE Local Reference Codelist
- Enter Y or N in the USERDIRS OCL_STATE Setting

Enter the Root Directory Path in OCL_STATE Local Reference Codelist

Enter the directory's path in the matching setting (*JOBTYPE*_ROOT) of OCL_STATE.

Enter Y or N in the USERDIRS OCL_STATE Setting

You can choose to use a subdirectory for each user or not for input and output files for each job type. Each job type (except disconnected replication) has an OCL_STATE setting named *JOBTYPE*_USERDIRS. Enter Y or N.

- If **Y**, the job looks for the input or output file specified by the user in any directory at or below *JOBTYPE*_ROOT/*user*, where *user* must match the database account ID of the Oracle Clinical user who submitted the job.

  If the account ID of the user who submitted the job begins with OPS$, the subdirectory name must match only the user (non-OPS$) portion of the account name.

  Output files, if any, cannot be written unless the user-specific subdirectory has been created by an administrator.
- If **N**,), the job looks for the input or output file in any directory at or below *JOBTYPE*_ROOT.

> **Note:**
>
> Other reference codelist settings control other aspects of PSUB functionality; see Required Reference Codelist Settings for Batch Jobs .

Setting Up Image Viewing

You may need to include your company logo or medical diagrams in Patient Data Reports (PDRs) or CRFs. Beginning in Oracle Clinical 5.0, there is a single directory for images used as follows:

- **Oracle Clinical Reports Server** looks for images for the Patient Data Report and the Layout Editor PDF Preview feature
- **Oracle Clinical Layout Editor** also looks for images used in CRFs in the HTML Preview feature
- **RDC Onsite** looks for images displayed in CRFs during data entry in RDC Onsite

For more information, see:

- Put Images in dcif_images Directory
- Sharing the Images Directory

Put Images in dcif_images Directory

You must place all the images required for image viewing in these three features in the crfimages directory, which is created during installation by the Installer in *OPA_HOME*\html\rdc\dcif_images. By default, *OPA_HOME* is opapps52.

Sharing the Images Directory

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:\opapps52\html\rdc\dcif_images\crfimages`.

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*`:\opapps52\html\rdc` with the share name "rdc".

Automatic Setup During Installation

The Installer automatically does the following:

- Creates the dcif_images directory in *OPA_HOME*\html\rdc
- Enters the dcif_images directory location in the rdcConfig.properties with key as crf_images_path.
- Enters the crfimages alias location as the dcif_images directory's location in the opa52_httpd.conf file found in *Middleware_Home*\Oracle_Home_FR\user_projects\domains\FRdomain\config\fmwconfig\components\OHS\ohs1\moduleconf.
- Places the properties files in the *OPA_HOME*/config directory.
- Populates all registry variable values required for image viewing, including:
  - OPA_CONFIG_FOLDER, which contains the full path of the config directory
  - RDC_DCIF_IMAGES
  - RDC_DCIF_IMAGES_URL

- HTML_DCIF_IMAGES_URL, which must have the same value as RDC_DCIF_IMAGES_URL

Changing the Images Directory Location

Oracle recommends using the default location. You can change it but you must change each thing the Installer does automatically.

> **Note:**
>
> The Patient Data Report template generation process fails if the report server cannot locate the path to the dcif_images directory and the image file for each each CRF that contains an image in its layout.

12

Setting Up Replication

Oracle Clinical supports establishing a study—that is, designing and defining it—in one location, and then copying the study design and definition to other locations.

Each recipient, or sharing location, can conduct the study on its own set of patients. Data collected in sharing locations can be copied back to the location where the study originated, that is, the study-owning location. From there, data can be copied to any other location that has a copy of the study definition.

In this way, each location that participates in a study views an up-to-date set of collected data. Each location can modify only the data collected at its sites; all other data for this study is read-only. This process of distributing a read-only copy of study designs, definitions, and data to other locations in the environment is called **replication**.

> **Note:**
>
> This section discusses the tasks required for a system administrator to prepare Oracle Clinical databases for replication. It does not describe the procedures for actually performing those replications. For those instructions, see Using Replication.

For more information, see:

- Replication Concepts
- Prerequisites to Setting Up Replication
- Setting Up Replication-Related Reference Codelist Values
- Setting Up the Database Links for Standard Replication
- Creating the Study Design Replication Packages
- Setting Up Symmetric Replication

Replication Concepts

The process of distributing a read-only copy of a study design, definition, and data to other locations in the environment is called **replication**.

This section describes the following replication concepts:

- Locations in a Distributed Study Environment Installation
- What Can You Replicate?
- What Methods of Replication Does Oracle Clinical Support?

Locations in a Distributed Study Environment Installation

Replication occurs among multiple database **instances**. Each database instance in your distributed installation must use the same release of Oracle Clinical.

Each included database instance is referred to as a **location**. The locations in an installation share Oracle Clinical data or dictionaries with other databases via Oracle Clinical replication capabilities. A location can refer to a separate database on the same computer or to a database in a different physical location.

This set of locations, which shares the same Global Library and can replicate study designs, definitions, and data, is referred to as an **installation.**

Within a distributed Oracle Clinical installation, you must identify the following locations:

- Global Library-Owning Location
- Study-Owning Location
- Lab-Owning Location

Global Library-Owning Location

The Global Library-owning location, which is also referred to as the global management location, owns and manages all the objects that compose data collection definitions for clinical studies.

These objects include:

- Global Library: questions, question groups, DVGs, standard affiliations, question categories, Global Library procedures, Global Library DCMs, and Global Library DCIs
- Codelists: installation reference codelists
- Global Lab: lab units and related information, lab panels, and textbook ranges

All other locations that are part of the distributed environment get read-only copies of information by replication. Keeping those copies up to date as things change in the Global Library-owning location requires planned follow-up replications.

Study-Owning Location

The study-owning location is the Oracle Clinical location where a particular study is designed and defined. Each study has only one owner. Different locations can be the study-owning locations for different studies.

The study-owning location:

- Creates and modifies the study design and definition.
- Controls the assignments of all patient positions to study-sharing locations.
- Provides a central repository of all collected study data.

  This repository includes data the study-owning location creates and data replicated from other study locations. Once data is centralized at the study-owning location, the data can then replicated to sharing locations.

If the study-owning location is not the Global Library-owning location, then the study-owning location must replicate the Global Library before beginning study definition. While creating and refining the study definition, the study-owning location can then perform Global Library replication at regular intervals to keep the Global Library up to date.

Lab-Owning Location

A lab-owning location maintains information about the attributes and ranges of its lab. Each lab has only one owner. Lab names must be globally unique across the installation. Any location that uses lab data from a lab it does not own must first replicate the lab information from the lab-owning location.

What Can You Replicate?

You can replicate the following Oracle Clinical objects:

- Global Library
- Study design
- Study definition
- Data
- Global Lab information
- Local labs and ranges
- Study randomization

What Methods of Replication Does Oracle Clinical Support?

In your distributed study environment, you can use one method or a combination of methods to replicate data across all the locations in your installation.

Oracle Clinical supports the following methods of replication:

- Standard Replication
- Disconnected Replication
- Symmetric Replication
- Comparison of Standard and Disconnected Replication

Standard Replication

Standard replication is a *retrieving operation,* that is, the location that requires the information must request it from the source location. In addition, standard replication uses a network connection to copy information from one location to another location.

Disconnected Replication

Disconnected replication supports *bi-directional* replication between locations without relying on a network connection. Instead, disconnected replication creates an export file that contains the data from the source location to be transferred to the target location. You choose how to transport the export file to the target location. For example, you can choose disk media, tape media, E-mail, or local area network (LAN). The target location then imports (or loads) the data from the export file.

Symmetric Replication

Symmetric replication copies only the supporting study design information and replication happens automatically. You do not need to select any menu option.

Comparison of Standard and Disconnected Replication

The final result of a standard replication is indistinguishable from a disconnected replication. The following table lists the key differences between the standard replication process and the disconnected replication process.

Table 12-1 Comparison of Standard versus Disconnected Replication

Standard Replication	Disconnected Replication
Requires a network connections to transfer information between locations.	Copies information between locations via file transfer. A network connection is not required.
The location requesting the data accesses the source database and copies the data. The owner of the data is not aware that the data is being copied.	The source location extracts the data to an export file and determines when to transfer the file to target locations. The owner of the data is actively involved in the process.
The study is marked as replicated only after the first replication successfully occurs.	The study is marked as replicated after the extract and export phase at the source location is complete, but before the import and load phase starts at the target locations. Therefore, existing restrictions about what can be done to a study once it has been replicated are imposed after the extract and export phase.
Supports full and incremental replication.	Supports full replication only.

Prerequisites to Setting Up Replication

Each database instance in your distributed installation must use the same release of Oracle Clinical.

In addition, the following replication-specific objects must be in place before you can set up and use replication in your Oracle Clinical installation:

- The Oracle accounts required to set up and perform replication.
- The tables that record each type of replication. The replication types are Global Library, study design, study definition, data, Global Labs, and local labs and ranges.
- The seed number (unique sequence generators).

You already set up these items as part of creating the database.

This section reviews the prerequisites so you can check that your system meets the requirements before you begin the actual replication setup activities.

For more information , see:

- Oracle Accounts for Replication
- Tables that Store Replication Information

- Seed Numbers for Databases Involved in Replication

Oracle Accounts for Replication

When you install Oracle Clinical, the system creates the following accounts for managing and conducting studies in a distributed environment:

See Changing the Password for a Schema or Role Using the SET_PWD Utility

For more information, see:

- RXA_READ Account
- RXC_REP Account
- RXC_DISC_REP Account

RXA_READ Account

Oracle Clinical uses the RXA_READ account for various read-only operations for standard replication. As part of the setup for standard replication, you create a public database link that connects to each of the other database locations as the RXA_READ account.

The RXA_READ account has SELECT privilege on the study design tables and UPDATE privilege on the CLINICAL_STUDY_STATES table.

RXC_REP Account

You use the RXC_REP account to replicate the Global Library, study definitions, study design, data, and labs (Global lab, local labs, and ranges). The RXC_REP account has the following privileges:

- SELECT on all the journal tables; INSERT, UPDATE, and DELETE on some journal tables
- SELECT, INSERT, UPDATE, and DELETE on all replicated tables
- SELECT, INSERT, UPDATE, and DELETE on the following tables:
  - STUDY_REPLICATION_JOBS
  - LAB_REPLICATION_JOBS
- SELECT, INSERT, and UPDATE on the following tables:
  - CLINICAL_STUDY_STATES
  - REPLICATION_TAB

> **Note:**
>
> The password of the RXC_REP account is used when creating database links at other locations. If it is modified, you must recreate the database links at those remote sites.

RXC_DISC_REP Account

Only disconnected replication uses the RXC_DISC_REP account. The RXC_DISC_REP account has the following privileges:

- SELECT on all the journal tables; INSERT, UPDATE, and DELETE on some journal tables
- SELECT, INSERT, and DELETE on all replicated tables
- SELECT, INSERT, UPDATE, and DELETE on the STUDY_REPLICATION_JOBS table
- SELECT, INSERT, and UPDATE on the following tables:
  - DESIGN_REPLICATION_JOBS
  - LAB_REPLICATION_JOBS
  - CLINICAL_STUDY_STATES
- SELECT and INSERT on the REPLICATION_TAB table

Tables that Store Replication Information

The following table lists the tables that Oracle Clinical uses to record information about the execution of each type of replication. The information recorded, which varies from table to table, may include the date and time the replication started, the current status of the replication, and the date and time the replication completed.

Table 12-2 Oracle Clinical Tables that Store Information about Replication

Owner	This Table…	Stores Replication Information About…
RXC	REPLICATION_TAB	Global Library and study definition
RXC	STUDY_REPLICATION_JOBS	Data
RXA_DES	DESIGN_REPLICATION_JOBS	Study design
RXA_LR	LAB_REPLICATION_JOBS	Global labs, labs, and ranges
RXC_DISC_REP	DISCONNECTED_REPL_JOBS	Extracts and loads of the disconnected replication process

Seed Numbers for Databases Involved in Replication

Each database within an installation requires a unique **start with** value that seeds the internal numbers assigned to generated study objects (DCMs, Validation Procedures, and so on) so they are uniquely identified across all locations.

When you install Oracle Clinical, the Oracle Universal Installer prompts you for a unique starting number (from 1 to 99) for each database to be involved in replication. For information on the installation process, see the *Oracle Clinical Installation Guide*.

Setting Up Replication-Related Reference Codelist Values

The following table lists the reference codelists that Oracle Clinical uses to manage each method of replication. For more information, see Reference Codelists.

Table 12-3 Reference Codelists that Manage Replication

Codelist Name	Standard Replication	Symmetric Replication	Disconnected Replication
SOURCE LOCATION CODE Installation Codelist	YES	—	YES
OCL_INSTALLATION Installation Codelist	YES	—	YES
OCL_STATE Local Codelist	YES	—	YES
DB_LINKS Local Codelist	YES	—	—
PUBLIC_DB_LINKS Local Codelist	YES	—	—
OCL_OPTIONS_TYPE_CODE Installation Codelist	—	YES	—

Setting Up the Database Links for Standard Replication

Standard replication is a *retrieving operation*; that is, the database location requesting the data must initiate the action. In addition, standard replication uses a network connection to copy information from one location to another location. As a result, you need to create links between the locations in your installation. (Note that disconnected replication is done by export and load, and does not rely on database links or a network connection.)

For more information , see:

- Configuring the DB_LINKS Codelist for Standard Replication
- Configuring the PUBLIC_DB_LINKS Codelist for Standard Replication
- Creating the Private Database Links for the RXC_REP and RXA_DES Accounts
- Creating the Public Database Link for RXA_READ

Configuring the DB_LINKS Codelist for Standard Replication

Each database location in the installation maintains the DB_LINKS local reference codelist, which has 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 RXC_REP or RXA_DES user.

To configure the DB_LINKS codelist for standard replication:

1. Navigate to **Admin, Reference Codelists,** and then select **Local Codelists.**
2. Query for the DB_LINKS local codelist.
    a. In the **Short Value** field, enter a name for each of the other locations (instances) in the installation. This name should be descriptive, such as "CRO-LONDON" or "HEADQUARTERS" or "PHILA-SITE."

b. In the **Long Value** field, enter the database link name of the *private* link to that database.

Note the name of the private link you specify in the DB_LINKS codelist. You will need this information when you create the private database links for the RXC_REP and RXA_DES accounts later in this section.

Configuring the PUBLIC_DB_LINKS Codelist for Standard Replication

Each database in the installation also maintains the PUBLIC_DB_LINKS local reference codelist, which also has 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.

To configure the PUBLIC_DB_LINKS codelist for standard replication:

1. Navigate to **Admin, Reference Codelists,** and then select **Local Codelists.**
2. Query for the PUBLIC_DB_LINKS local reference codelist:
   a. In the **Short Value** field, enter the name for each of the other locations in the installation.
   b. In the **Long Value** field, enter the database link name of the *public* link to that database.

Note the name of the public link you specify in the PUBLIC_DB_LINKS codelist. You will need this information when you create the public database link for the RXA_READ account later in this section.

Creating the Private Database Links for the RXC_REP and RXA_DES Accounts

After you set up the DB_LINKS and the PUBLIC_DB_LINKS local reference codelists, you need to create the database links to the other locations in your installation

> **Note:**
>
> You use the password for the RXC_REP and RXA_DES accounts when creating database links at other locations. If you modify the password, you must recreate the database links at those other locations.

To create the private database links required for standard replication:

1. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
2. Create the private database link for the RXC_REP account:
   a. Connect to SQL*Plus as `RXC_REP`.
   b. Create a private database link to each of the other database locations:

```
create database link linkname connect to rxc_rep identified by
password using 'connectstring';
```

where:

- *linkname* is the name specified for your private database link in the DB_LINKS reference codelist.
- *password* is the password of the RXC_REP account.
- *connectstring* is the appropriate SQL*Net connect string.

  Make sure the *connectstring* has single quotes around it. Oracle recommends that the *connectstring* be the same as the *linkname* although it is possible for them to be different.

c. Verify that you created the link correctly. The following command should return RXC_REP as the user:

```
SELECT username FROM user_users@linkname;
```

3. Create the private database link for the RXA_DES account:

a. Connect to SQL*Plus as `RXA_DES`.

b. Create a private database link between the RXA_DES accounts in each instance:

```
create database link linkname connect to rxa_des identified by password
using 'connectstring';
```

where:

- *linkname* is the name specified for your private database link in the DB_LINKS reference codelist (and also matches the linkname value used for the same database in the previous step).
- *password* is the password of the RXA_DES account.
- *connectstring* is the SQL*Net alias of the database to which the link connects.

  Make sure the *connectstring* has single quotes around it.

c. Verify that you created the link correctly. The following command should return RXA_DES as the user:

```
SELECT username FROM user_users@linkname;
```

4. Exit from SQL*Plus.

Creating the Public Database Link for RXA_READ

To set up the public database link for standard replication:

1. Connect to SQL*Plus as `SYS`.
2. Create a public database link to each of the other database locations for the RXA_READ account:

```
create public database link linkname connect to rxa_read identified by
password using 'connectstring';
```

where:

- *linkname* is the name specified for your database link in the PUBLIC_DB_LINKS reference codelist.
- *password* is the password of the RXA_READ account.
- *connectstring* is the SQL*Net alias of the database to which the link connects.

Make sure the *connectstring* has single quotes around it. Oracle recommends that the *connectstring* be the same as the *linkname,* although it is possible for them to be different, if Global Naming is not enabled for the database.

3. Verify that you created the link correctly. The following command should return RXA_READ as the user:

```
SELECT username FROM user_users@linkname ;
```

4. Exit from SQL*Plus.

Creating the Study Design Replication Packages

The following table lists the scripts that you must run if you are using:

- Standard replication to replicate study-specific designs
- Symmetric replication to replicate data related to study design, but not specific to a study

These scripts, which are located in the RXC_INSTALL directory, create the study design replication packages required by standard and symmetric replication.

Table 12-4 Scripts Required to Use Standard Replication for Replicating Study Design

Script Name	You Run this Script …
RXASRALL.SQL	At every location/for every location. The RXASRALL.SQL script automatically calls the following scripts: • RXAOCLRP.SQL • RXARELRP.SQL • RXASTMRP.SQL
RXASRAVW_CUSTOM.SQL	At every location/for every location; rename to RXASRAVW.SQL.
RXASVSRA.SQL	At each location.
DYNA_RXAPKIRP.SQL	At each location, for each remote location from which data will be retrieved.

For more information , see:

- Using the rxasrall.sql Script
- Creating the Views and Synonyms Required to Replicate Study Design
- Creating the Package for Replicating Investigators and Sites

Using the rxasrall.sql Script

The rxasrall.sql script is the driver script that automatically calls the following three scripts to create the study design replication packages:

- rxaoclrp.sql
- rxarelrp.sql
- rxastmrp.sql

The rxasrall.sql script accepts the name of the remote (that is, shared) database and the name of the database link to that database, and then passes the information to the other three scripts. The study design replication packages replicate all the study-specific design details for the selected study as well as study design supporting information.

For more information , see:

- About Running the rxasrall.sql Script for Each Location
- Running the rxasrall.sql Script

About Running the rxasrall.sql Script for Each Location

You run the rxasrall.sql script in each location, once for each of the remote (shared) locations in the installation. For example, if you have databases A, B, and C, you need to run the rxasrall.sql script six times:

- First, you run the script on database A passing in the database name and database link for database B, and then you run the script again on database A passing in the database name and database link for database C.
- Next, you run the script on database B passing in the database name and database link for database A, and then you run the script again on database B passing in the database name and database link for database C.
- Finally, you run the script on database C passing in the database name and database link for database A, and then you run the script again on database C passing in the database name and database link for database B.

Running the rxasrall.sql Script

To run the rxasrall.sql script:

1. Change to the RXC_INSTALL directory.
2. Connect to SQL*Plus as `RXA_DES`.
3. Run the rxasrall.sql script in each location, once for each of the shared locations in the installation:

   ```
   start rxasrall
   Name of the Remote Oracle Clinical Database: location_code
   Name of db Link to Remote Oracle Clinical Database Name: db_link
   ```

   where:

   - *location_code* is the identifying code stored for this database in the SOURCE LOCATION CODE reference codelist. If the *location_code* has spaces, replace them with underscores.
   - *db_link* is the database link stored for this database in the PUBLIC_DB_LINKS codelist.
4. Exit from SQL*Plus.

Creating the Views and Synonyms Required to Replicate Study Design

The rxasravw_custom.sql script creates the ALL_*name* views on the design tables, and the AVAILABLE_CLINICAL_STUDIES view. The rxasvsra.sql script creates synonyms to all the views.

You need to run these scripts if you are using:

- Standard replication to replicate study-specific designs
- Symmetric replication to replicate data related to study design, but not specific to a study

To create the views and synonyms required for study design replication:

1. Copy the rxasravw_custom.sql script to the rxasravw.sql script, overwriting the default version. (The default version is for non-replicated installations only.) The custom version creates the views required for design replication.

   The rxasravw.sql script assumes there are *two* locations remote from any given installation (*total* of three locations in your replication installation).

   - If you have three or fewer locations, you can use the script as is. Copy it to each of the other one or two locations and proceed to Step 2.
   - If you have more than three locations edit rxasravw.sql, adding a clause for each remote location. If your installation has *n* locations, your script should contain *n*-1 clauses. Copy your edited script to each location.

   > **Note:**
   >
   > If you have more than one environment in the same code area, save more than one copy of rxasravw.sql with a name that indicates the environment to which it applies. For example, rxasravw_prod for your production database.

2. Connect to SQL*Plus as `RXA_DES`.
3. Run the rxasravw.sql script at each location. For example:

   ```
   Name of the Current Oracle Clinical Database: example_mexico
   Name of Remote Oracle Clinical Database 1: example1_jersey
   Name of db Link to Remote Oracle Clinical Database 1: to_example1
   Name of Remote Oracle Clinical Database 2: example2_york
   Name of db Link to Remote Oracle Clinical Database 2: to_example2
   ```

   You do not need to replace spaces in the location codes with underscores.

4. Run the rxasvsra.sql script at each location. This script creates synonyms to all the views created by the rxasravw.sql script.

Creating the Package for Replicating Investigators and Sites

The dyna_rxapkirp.sql script creates the REPLINVSITE_*remote_location* package, which replicates the investigators and sites used in a study from the specified source location.

Only standard replication uses the REPLINVSITE_*remote_location* package. Therefore, you run the dyna_rxapkirp.sql script *only if* you are using standard replication.

As RXC_REP, you need to run the dyna_rxapkirp.sql script at each location, for each remote location from which data will be retrieved.

To run the dyna_rxapkirp.sql script:

1. Change to the RXC_INSTALL directory.
2. Connect to SQL*Plus as `RXC_REP`.
3. Run the dyna_rxapkirp.sql script at each location, once for each of the source locations in the installation:

   ```
   start dyna_rxapkirp.sql
   ```

   The script prompts for the following information:

   `Enter value for source_location:` *`location_code`* `Enter value for link:` *`database_link`*

   where:

   - *location_code* is the code for the remote location from which data will be retrieved to the current database. The value you specify should match the identifying code stored for this database in the SOURCE LOCATION CODE reference codelist. Be sure to replace any spaces in the location_code with underscores.
   - *database_link* is the name of the database link to the source database. The value you specify should match a record in the DB_LINKS reference codelist.
4. Exit from SQL*Plus.

Setting Up Symmetric Replication

With standard replication, study design replication copies the supporting design information (not study-specific information) as well as the study-specific design details. You must select a menu option to replicate data for a specific study. Only the data related to that study is replicated.

Symmetric replication copies only the supporting study design information (not study-specific information). In other words, symmetric replication replicates data related to study design, but not data specific to a study. However, with symmetric replication, all data potentially or actually related to study design is replicated automatically. You do not need to select any menu option.

Symmetric replication offers the following advantages:

- Design elements are defined in one location then automatically replicated to other database locations, reducing input time and risk of error.
- After initial replication, changes to design elements are automatically replicated to the other locations.
- The database system checks for changes at regularly scheduled intervals of your choosing.
- Self-referencing information is replicated: information about regions within regions, what strata are part of what combined strata, and what single treatment regimens are part of what combined treatment regimen.

To replicate study design elements between databases, Oracle Clinical requires that the databases share the same Global Library. That is, you must perform a full Global Library replication before you perform the first design replication at a sharing location.

For more information , see:

- Setting Up Symmetric Replication
- Enabling Symmetric Replication

- Reconciling Data
- Troubleshooting Symmetric Replication

Setting Up Symmetric Replication

To successfully complete symmetric replication, you should have a firm understanding of managing multi-master replicated databases. A complete description of this topic is beyond the scope of this documentation. If you choose to perform symmetric replication, see the following Oracle database manual for details about advanced replication and for references to related documentation:

Oracle Database Advanced Replication 11g Release 2 (11.2) Part Number: E10706-05

> **Note:**
>
> If you are using the Oracle Thesaurus Management System (TMS) with Oracle Clinical in a distributed environment, you must set up Oracle Clinical to run symmetric replication. Oracle Clinical handles symmetric replication for both itself and TMS.

For more information , see:

- Installing Symmetric Replication
- Running the Symmetric Replication Scripts Required for Oracle Clinical
- Verifying Data Is Replicating

Installing Symmetric Replication

This section describes the tasks that you must complete before you perform the Oracle Clinical-specific tasks described in the following sections. For detailed information about symmetric replication, see your Oracle documentation.

1. Install the database image with symmetric replication.
2. Check that the init*dbname*.ora file contains the following specifications:
   - JOB_QUEUE_PROCESSES — At least 10.
   - SHARED_POOL_SIZE — See *Oracle Database Reference 11g Release 2 (11.2)* for details on setting this parameter.
   - GLOBAL_NAMES — **TRUE.**
   - DISTRIBUTED_LOCK_TIMEOUT — At least 30.
   - OPEN_LINKS — Number of symmetrically replicated sites.

   See *Oracle Database Reference 11g Release 2 (11.2),* Part Number E17110-05, for more information about these parameters.

Running the Symmetric Replication Scripts Required for Oracle Clinical

The following table lists the scripts that you run to set up Oracle Clinical to use symmetric replication. These scripts complete the appropriate setup activities for each of the locations.

Before you run these scripts, you must have installed symmetric replication. For details, see Installing Symmetric Replication.

Execute the following prepared scripts in the order listed after you have performed the general tasks described in the previous section.

Table 12-5 Scripts to Run to Set Up Symmetric Replication

Script Order	Run from Account	Script Name	Locations to Run	Script Purpose, Parameters, and Notes
1	SYSTEM	CATREP.SQL	Run at each location.	**NOTE:** This script is automatically executed when the Oracle database is created or upgraded. If it was run previously, you do not need to run the script again.
2	SYSTEM	OPASRC01.SQL	Run at each location.	The OPASRC01.SQL script: • Creates REPSYS accounts and grants privileges required for replication. • Registers REPSYS as the replication propagator and receiver. • Schedules a job to purge pushed trans-actions from the deferred transaction queue. This script prompts you to enter the: • Name of the local database (that is, the current location). • Name of the remote database. You can press Enter for this prompt. The OPASRC01.SQL script does not require the name of the remote database instance. • Password for local SYSTEM account. • Password for local REPSYS account. Verify your progress at this point by entering the following SQL command: `SELECT * FROM user_users@dbname .domain` The REPSYS account should be open.

Table 12-5 (Cont.) Scripts to Run to Set Up Symmetric Replication

Script Order	Run from Account	Script Name	Locations to Run	Script Purpose, Parameters, and Notes
3	SYSTEM	OPASRC02.SQL	Run at each location, for each remote location.	The OPASRC02.SQL script: • Creates public and private database links to the remote location. • Connects to remote location and schedules a job to push the deferred transaction queue to the master location. This script prompts you to enter the: • Name of the local database (that is, the current location). • Name of the remote database (that is, the complete connect string for the remote database). • Password for local SYSTEM account. • Password for local REPSYS account. • Password for REPSYS account at *remote* location. **NOTE:** When the script finishes processing, you will receive the error message: `ERROR at line 1: ORA-02011: duplicate database link name` Ignore this message. The public database link was already created when you set up standard replication.
4	RXA_DES	RXASRCPK.SQL	Run at each location.	Creates primary keys in each table. **CAUTION:** If you have existing data, you must reconcile data in all tables symmetrically replicated at all locations *before you go any farther.* See Reconciling Data for details.
5	SYSTEM	COMPILE_ALL_INVALID.SQL	Run at each location.	Compiles objects rendered invalid by the RXASRCPK.SQL script.
6	REPSYS	RXASRC03.SQL	Run at the master definition location.	Creates empty, quiesced master replication group RXA_DES.
7	REPSYS	RXASRC03A.SQL	Run at the master definition location.	Indicates that each object in the Design sub-system is a replicated object in the RXA_DES schema. Makes column groups for conflict resolution.
8	REPSYS	RXASRC04.SQL	Run at the master definition location.	Sets update resolution to latest time-stamp method.
9	REPSYS	RXASRC04A.SQL	Run at the master definition location, for each remote location.	Adds each remote location to the replication environment as another master group. This scripts prompts for the fully qualified database name of the remote location.

Table 12-5 (Cont.) Scripts to Run to Set Up Symmetric Replication

Script Order	Run from Account	Script Name	Locations to Run	Script Purpose, Parameters, and Notes

10	REPSYS	RXASRC05.SQL	Run at the master definition location.	Generates triggers and packages needed to support replication, at all locations.
				Wait while the packages generate at all locations.
				To monitor progress, enter the following SQL command from each location:
				`SELECT * FROM dba_repcatlog WHERE gname = 'RXA_DES';`
				When the generation process is done, the DBA_REPCATLOG has no records. Once the count is zero, enter the following SQL command from each location:
				`SELECT COUNT(*) FROM dba_repobject WHERE sname = 'RXA_DES';`
				The count should be 138.

11	REPSYS	RXASRC06.SQL	Run at the master definition location.	Resumes normal replication activity on RXA_DES (quiesced by the RXASRC03.SQL script).

Verifying Data Is Replicating

To check whether data is replicating correctly:

1. Modify the description of a region at each location.
2. Verify that the change replicates to the other locations.

> **Caution:**
>
> Do not change the description of the same record at two different locations unless the first change is replicated. Otherwise, you may cause a data conflict. See Problems During Installation of Symmetric Replication for more information.

Enabling Symmetric Replication

To activate symmetric replication in each location:

1. Log in at the Global Library-owning location.
2. Navigate to **Admin, Reference Codelists,** and then select **Installation Codelists.**
3. Query for the OCL_OPTIONS_TYPE_CODE installation codelist.
4. Set the Long Value of the SR_INSTALLED parameter to **Y.**
5. Save your changes.

6. Perform Global Library replication.

You cannot change this codelist setting manually at other sites.

Reconciling Data

This section outlines *one approach* for reconciling data at different locations. A description of Oracle Clinical's management of conflict resolution follows.

Execute all scripts from the RXA_DES account at the master definition location, with the current or default directory being the install directory.

> **Note:**
>
> Use the OCL_MENU_ACCESS local reference codelist to specify which types of data can be maintained at each location. You can set this reference codelist at any time.

To reconcile data:

1. Make sure that the database is active, but that no study design entries are being made.
2. Enter the following command from the SYS account of each database:

   ```
   GRANT EXECUTE ON DBMS_RECTIFIER_DIFF TO RXA_DES;
   ```

3. Pick a reconciliation master location.

   Once the reconciliation process is completed, all data will be copied from the master location to the remote location.

4. Set the SQL*Plus environment before running the scripts:

   ```
   SET ARRAYSIZE 1
   ```

5. Make sure the RXA_DES account is assigned a default tablespace in which it has quota.
6. Log in as RXA_DES. Run the diffwsetup.sql script. This script creates the tables that will be populated when you run the diffwgo.sql script.
7. Run the command:

   @diffremote.sql *remote_db_link*

   where *remote_db_link* is the database link to the remote database. For example:

   ```
   @diffremote hp73x1.world
   ```

8. Run the diffwgo.sql script. For each table, this script:
   - Empties DIFF*tablename* and DIFFR*tablename*.
   - Uses the Oracle DBMS_RECTIFIER_DIFF.DIFFERENCES function to compare the *tablename* table with the like table in the remote database and populates the DIFF*tablename* and DIFFR*tablename* tables based on the comparison.

     These tables are used for later steps.

- Inserts any records from the remote location that are missing at the master location into the master location.
- Creates the COMP*tablename* comparison table.

  This table contains two records for each record at the master location that matches a record in the remote location based on primary keys, but differs from the remote location on one or more field values.
- Creates the COMP2 *tablename* comparison table similar to the COMP *tablename* table, but eliminates duplicate master location records when that same record is compared to multiple remote locations.

9. Look at the COMP2*tablename* tables created when you ran the diffwgo.sql script. The following tables will probably show differences:

   COMP2OCL_INVESTIGATORST
   COMP2OCL_SITEST
   COMP2TREATMENT_REGIMENS

   COMP2OCL_INVESTIGATORST and COMP2OCL_SITEST will show differences for the XDUMMY1 investigator and site because of differences in the times these dummy records were created. These records are created at installation.

   COMP2TREATMENT_REGIMENS will show differences for previously replicated treatment regimens because of differences in the PM_ID field. Before V3.1, the PM_ID field was not correctly replicated.

   For values that are different, decide whether the value from the remote location or the master location is more accurate. If the value from the remote location is more accurate, update the table corresponding to that comparison table to have the appropriate value. If the master location is more accurate, no action is necessary. Delete all records from COMP2*tablename* (or only those that have reconciled, if you do not look at all of them).

   > **Caution:**
   >
   > Before executing the diffwpropagate.sql script in the next step, back up your data. The script copies all tables involved in symmetric replication to the remote location. Set the SQL*Plus environment again (Step 4), if necessary.

10. Run the diffwpropagate.sql script.

    This script propagates data involved in symmetric replication from the master location to the remote location. The script automatically uses the remote database link that you specified with the diffremote.sql command (Step 7).

11. Repeat Step 6 through Step 10 for each remote location.
12. Run diffwdrop.sql to drop all tables used for comparison.

For more information , see:

- Conflict Resolution
- Non-study-specific Tables Replicated

Conflict Resolution

Updates to the same record at more than one location before the updates are replicated creates a conflict. For example, if two locations tried to change the code associated with a particular investigator this could cause a conflict when replication is invoked. Handling this type of conflict is one of the management tasks Oracle Clinical performs as part of the replication process. This section describes how Oracle Clinical manages this conflict resolution.

Oracle advanced replication offers several methods for resolving this conflict, while keeping the data synchronized and creating no additional entries in the error queue. Oracle Clinical implements the latest time-stamp method, that is, the update with the most recent time stamp overrides updates at other conflicting locations.

For example, an update to a record in New York has a time stamp of 10:00, Boston updates the same record with a time stamp of 10:02, and the updates are not propagated between the two updates. In this case, the Boston update overrides the New York update.

This does mean that in the case of update conflicts locations in a later (more eastern) time zone will usually prevail, as the latest time-stamp method is not sensitive to differences in time zones. However, these conflicts should occur rarely in Oracle Clinical because the data chosen to be symmetrically replicated is not updated frequently and the replication is scheduled to occur every 2 to 3 minutes.

Without an update conflict resolution method, when update conflicts occur an entry is added to the error queue and neither update is propagated. The error queue can be difficult to manage, so keeping it as clean as possible is important. Additionally, further updates to the same record would automatically create conflicts because symmetric replication requires the pre-update value of all fields exactly match.

Other types of conflicts can occur, such as two locations inserting exactly the same record or a record with the same key values. If some data that is symmetrically replicated is part of clinical study replication (which could occur if the data had not yet been symmetrically replicated), then when symmetric replication occurred, a unique key (insert) conflict would occur. However, having SR_INSTALLED set to Y in the OCL_OPTIONS_TYPE_CODE Installation Codelist avoids this type of conflict. When this option is enabled, symmetrically replicated data is not inserted when a user replicates a clinical study from the menu between symmetric replications.

Non-study-specific Tables Replicated

The following table lists the set of tables containing non-study-specific information that is replicated between all locations when you run the RXASRALL.SQL script.

The OCL_MENU_ACCESS local reference codelist determines which of the non-study-specific tables can be updated at your site. When you set up this access, coordinate the sites. You probably do not want one site responsible for all updating, but if too many sites have update privileges, you risk creating conflicts. Other considerations include how frequently these tables are replicated and time zone differences.

The following is the list of non-study-specific tables that are replicated between all locations when you run the rxasrall.sql script:

- CLINICAL_SUBJECTS

- OCL_PRODUCT_MASTERS
- PATTERNS
- COMBINED_TREATMENT_COMPONENTS
- OCL_PROGRAM_PRODUCT_MASTERS
- REGION_COMPONENTS
- DAILY_DOSES
- OCL_PROGRAMS
- REGIONS
- FACTORS
- OCL_PROJECTS
- STRATA
- OCL_DOSAGE_FORMS
- OCL_SITES
- STRATUM_COMPONENTS
- OCL_INVESTIGATORS
- OCL_SITEST
- TITRATION_STEPS
- OCL_INVESTIGATORST
- OCL_STUDIES
- TREATMENT_REGIMENS
- OCL_ORGANIZATION_UNITS
- OCL_UOM_CONVERSIONS
- TREATMENT_REGIMEN_BY_RANGES

Troubleshooting Symmetric Replication

Symmetric replication provides much desirable capability to sites using it, but it requires monitoring that takes some regular time and education. This section provides some guidelines to stay abreast of issues that affect the monitoring of Oracle Clinical on systems with symmetric replication enabled.

You should be familiar with Oracle Server advanced replication concepts. The most relevant items in the documentation set are the *Replication* and *Replication* API Reference manuals. Significant chapters include:

- Using Multimaster Replication
- Administering a Replicated Environment
- Using Deferred Transactions

This section is not intended to be comprehensive, but offers some guidance in diagnosing symmetric replication problems. The first two sections cover the two stages when most problems arise: while installing Oracle Clinical with symmetric replication, and during routine use. The last section provides some ideas for disaster recovery.

In this section:

Problems During Installation of Symmetric Replication

If problems arise in replication during the installation process, check the parameters listed in this section.

Parameters in the init.ora File

The following table lists the parameters in the init.ora file that:

- Are used in testing Oracle Clinical and required at installation
- Are known to have an impact on performance

Table 12-6 Parameters to Check in the init.ora File for Symmetric Replication

Parameter	Value	There parameters are...
JOB_QUEUE_PROCESSES	1	used in testing Oracle Clinical and required at installation.
JOB_QUEUE_INTERVAL	600	used in testing Oracle Clinical and required at installation.
SHARED_POOL_SIZE	At least 60 MB	used in testing Oracle Clinical and required at installation.
GLOBAL_NAMES	TRUE	used in testing Oracle Clinical and required at installation.
DISTRIBUTED_LOCK_TIMEOUT	30 or greater	known to have an impact on performance.
OPEN_LINKS	Number of symmetrically replicated sites	known to have an impact on performance.

Advanced Replication Option Is Installed

```
SELECT * FROM v$option;
```

The value of the Advanced replication parameter should be TRUE.

Invalid Replication Objects

```
SELECT sname,oname FROM dba_repobject WHERE status != 'VALID'
```

DBA_REPCATLOG Is Empty

```
SELECT timestamp, sname, oname, message FROM dba_repcatlog;
```

Problems During Routine Use of Symmetric Replication

If you encounter problems after you have successfully initiated symmetric replication, checking for the following situations may provide clues or answers.

Broken Jobs

```
SELECT job,broken,interval,what FROM user_jobs;
```

The PSUB job that executes symmetric replication is set to run every few minutes. After 16 consecutive failed attempts to connect to a location, its status becomes BROKEN. Broken job can occur, for example, if a database went down halfway through a replication.

You must stop and restart the broken jobs.

Scheduled Jobs Executing

```
SELECT job,dblink,last_date FROM defschedule;
```

The last date should have a value for the job in question.

Unavailable Queues

If you get an error message that a queue is not available for enqueueing, enter the following statement from the SYSTEM account in the master database:

```
EXECUTE dbms_aqadm.start_queue (    queue_name => 'queue_name_from_message');
```

followed by a commit.

Errors in DEFERROR

```
SELECT * FROM deferror;
```

DEFTRAN queue emptying after sufficient time has elapsed

```
SELECT COUNT(*) FROM deftran;
```

Pending Calls

```
SELECT * FROM defcall;
```

Invalid Objects in RXA_DES, SYS, SYSTEM, and REPSYS

```
SELECT owner,object_name,object_type FROM dba_objects WHERE owner IN
('RXA_DES','SYS','SYSTEM');
```

Incorrect Links

```
SELECT username,global_name FROM user_users@link, global_name@link;
```

- From SYS, the user name should be REPSYS.
- From RXA_DES, the user name should be RXA_DES.
- From RXC_REP, the user name should be RXC_REP.
- From *anyuser*, the user name should be RXA_READ.

Error and Transaction Queues Not Processing Correctly

First, force the transactions to occur.

- From location 1:

```
EXECUTE DBMS_DEFER_SYS.EXECUTE('location 2 link');
```

- From location 2:

```
EXECUTE DMBS_JOB.EXECUTE('location 1 link');
```

Then, check the error queue and transaction queue. If these queues are working, the problem is probably the job scheduling.

Deadlocks or Other Database Errors

Examine the Oracle trace files.

Differences in Data at Different Locations

See Reconciling Data and follow the procedure to see if there are differences in the data at disparate locations. You may want to eliminate the last step that propagates data from one location to another.

Problems after a Failure when Using Symmetric Replication

Oracle Clinical uses several different techniques to replicate data and the underlying database model is very complex. This section is not intended to be the definitive guide to data recovery; it provides some idea of the issues specific to Oracle Clinical replication.

> **Note:**
>
> This section assumes you have already established a backup and recovery plan as described in the *Oracle Backup and Recovery Guide*.

With most failures, standard Oracle recovery methods are sufficient. For example, if there were an instance failure during replication, Oracle Clinical would recover cleanly and resume from where it left off (with the possible exception of "broken" jobs, see above). In the event of a disaster, the primary concern is the Global Library.

Following are some scenarios of possible disasters and how to recover from them. They assume that generic database recovery has been completed but was unable to fully restore the database. Recovering from a real disaster will probably involve several different scenarios.

Damage to the Global Library at a Non-Global Library Location

Once Oracle Clinical is available for normal use, you can recover the Global Library at a non-Global Library location by performing a full replication from the Global Library-owning location.

> **Note:**
>
> The global library is a *logical* collection of data within Oracle Clinical. The actual tables also contain study definitions. Depending upon the cause of the disaster, you may also need to recover study definitions.

Damage to the Global Library at the Global Library-owning Location

To repair damage to the Global Library at the Global Library-owning location:

1. Restore the Global Library-owning location.
   a. Identify the most recent copy of the global library.
   b. Open the OCL_INSTALLATION installation reference codelist.
   c. Set the Long Value of the GLIB_LOCATION parameter to that site.
   d. Perform a full replication at the Global Library-owning location.
   e. Return to the OCL_INSTALLATION codelist and set GLIB_LOCATION back to its original Long Value.
2. Recover the data entered into the Global Library between the time of the original replication and the actual disaster. This orphaned data can exist only at the Global Library-owning location.
   a. Test for Study Questions, Question Groups, DCMs, DCIs, and DVGs where the corresponding library object is missing.
   b. Either delete the orphaned study records or reconstruct the Global Library records. This process requires altering internal IDs from SQL*Plus.

13

Using Replication

This section describes how to use standard replication and disconnected replication in your Oracle Clinical distributed study installation.

The Oracle Clinical replication concepts that apply to standard replication apply to disconnected replication as well. This section assumes you are familiar with the terms and concepts required to conduct a clinical study in a distributed environment or installation. For more information, see Setting Up Replication.

For more information, see:

- Example of an Oracle Clinical Distributed Study
- Operating from the Study-Owning Location
- Operating from a Sharing Location
- Enabling a Study for Replication
- Using Standard Replication
- Using Disconnected Replication
- Changing Study Ownership
- Replicated Tables

Example of an Oracle Clinical Distributed Study

Figure 13-1 illustrates a sample installation configuration for an Oracle Clinical study that is distributed over three physically separate locations.

In this installation:

- One study is being conducted at the investigation sites, that is, Hospital A, Hospital B, Hospital C, and Hospital CA.
- Location A is the Global Library-owning location.
- Location C is the study-owning location.
- Location A and Location B are study-sharing locations.

For more information , see:

- Location A Maintains Global Information
- Location C Replicates the Global Library
- Sharing Locations Replicate Study Design and Definitions
- Local Processing and Lab Replication

Location A Maintains Global Information

As the Global Library-owning location, Location A is responsible for maintaining Global Library objects, and global lab information (lab units and panels).

Location C Replicates the Global Library

Location C, which is the study-owning location, is responsible for designing the study and defining study elements. Before beginning the study design and definitions, Location C must replicate the Global Library from Location A. To complete the study definition, Location C may need the global lab information as well. The heavy black arrow between Location C and Location A represents this replication task.

Sharing Locations Replicate Study Design and Definitions

Once Location C completes the study design and definitions, and makes the study available for replication, then the other locations (Location A and Location B) must replicate these study elements from Location C. The heavy gray arrows from Location C to both Location A and Location B represent this replication task.

Location A and Location B cannot modify any of the study design or definition elements. However, these locations must maintain certain local responsibilities such as assigning sites and investigators.

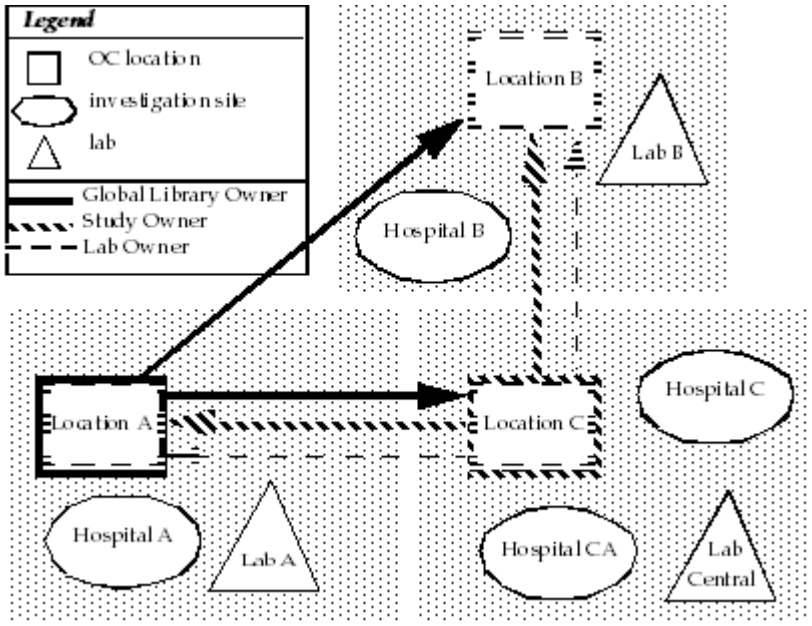
Local Processing and Lab Replication

Each location in the installation deals with local facilities to conduct their part of the study.

Location A conducts investigations at Hospital A and processes results at Lab A. Likewise, Location B conducts investigations at Hospital B and processes results at Lab B. Each of these Oracle Clinical locations is a lab-owning location for its local lab.

Location C has two hospitals serving as investigation sites, but this setup has no ramifications for replication. However, the lab setup at Location C does have an effect on replication. Location C is the lab owner for Lab Central, which services Location C and also processes some tests for the other locations. As part of its lab owning responsibility, Location C maintains the lab ranges for Lab Central. Because the other locations (Location A and Location B) use Lab Central, they must replicate the ranges for Lab Central from Location C. The dotted-line arrows from Location C to both Location A and Location B represent this replication task.

Figure 13-1 Sample Installation with Three Physically Separate Locations



The following table summarizes the roles and responsibilities for each location (Location A, Location B, and Location C) in the sample Oracle Clinical distributed study.

Table 13-1 Roles and Responsibiliities for Locations of Distributed Studies

Location	Roles	Responsibilities
Location A	Global Library Owner	Maintain Global Library objects Maintain global lab informatin--lab units and panels Maintain textbook ranges
Location A	Lab Owner (Lab A)	Maintain lab units Maintain ranges for this lab
Location A	Study-sharing location	Replicate study design Replicate study definition (initial) Replication study definition (periodic)
Location A	Lab user (Central Lab)	Replicate lab range information
Location B	Non-Global Library owner	Replicate Global Library (initial) Replicate Global lab data (initial) Replicate Global Library (periodic) Replicate Global lab data (periodic)
Location B	Lab owner (Lab B)	Maintain lab units Maintain ranges for this lab
Location B	Study-sharing location	Same as Location A

Table 13-1 (Cont.) Roles and Responsibiliities for Locations of Distributed Studies

Location	Roles	Responsibilities
Location B	Lab user (Central Lab)	Same as Location A
Location C	Non-Global Library owner	Same as Location B
Location C	Lab owner (Central Lab)	Maintain lab units Maintain ranges for this lab
Location C	Study-owning location	Replicate Global Library (initial) Replicate Global Library (periodic)

Operating from the Study-Owning Location

A study-owning location has responsibility for the design and definition of a study. For the tasks involved in designing and defining a study, see *Oracle Clinical Creating a Study*.

This section describes the following elements of conducting a study that directly relate to replication:

- Changing Ownership and Replicating Patient Positions
- Maintaining Investigators and Sites
- Constraints at the Study-Owning Location
- Replicating Data at a Study-Owning Location

Changing Ownership and Replicating Patient Positions

Defining patient positions is part of defining a study. In defining patient positions, the study-owning location declares which location owns each patient position. You can change ownership later to a different location, as long as no data has been associated with the patient and no book has been assigned to the patient.

The process of changing the location of patient positions has two parts:

- The owning location must change the ownership.
- The receiving location must replicate, or retrieve, the patient positions.

For more information , see:

- Changing the Ownership of Patient Positions
- Retrieving Patient Positions

Changing the Ownership of Patient Positions

When you create patient positions, you can define the patient positions as screening, normal, or replacement.

To change the ownership of any type of patient position:

1. Navigate to **Design, Patient Positions,** and then select **Change Ownership.**

The system displays a list of all studies. Select the study for which you want to change patient positions.

2. Click **Change Owning Location.**
3. Complete the fields in the Change Patient Position Owner window as follows:
   a. In the **Location to own Patients** field, enter the name of the location that is to receive ownership of the set of patient positions.

      If you are not the study owner, you can only change ownership back to the study-owning location.

   b. In each **Number To Update** field, enter the number of patient positions you want to process for each patient type. Note that you can process one, two, or all three types of patient positions (screening, normal, and replacement) by entering a number into the respective Number To Update field.

   c. In the **Start *patient-position* Patient** fields, enter the patient number to start with when changing the ownership. You can enter a starting number for each type of patient position (screening, normal, and replacement).
4. Click **Change Owning Location** to change the ownership.

After the study design is next replicated, the new owner will have control of these patients. The owner will be able to maintain their details, assign them to study sites, and enter data for them.

Retrieving Patient Positions

In a distributed study, the study-owning location controls the assignments of all patient positions. If a patient position currently owned by a sharing location must change ownership, the study-owning location must reclaim, or retrieve, ownership of the patient position first.

The study-owning location can reclaim ownership of a patient position from any sharing location provided no data has been entered for the patient.

To retrieve patient positions:

1. Navigate to **Design, Patient Positions,** and then select **Retrieve Patients.**
2. Complete the fields in the Replicate a Clinical Study window as follows:
   a. In the **Source Study Code** field, select the study that currently owns the patient positions. The list of values includes only those studies that are available for replication and that are owned by the current location. If only one study is available, the system automatically populates the field for you.

      Once you specify the source study code, the system automatically populates the **Source Study Title** field for you.

   b. In the **Retrieve Patient From** field, select the source location. The available locations are based on the active locations defined in the SOURCE LOCATION CODE installation codelist.
3. Click **Retrieve Patients.**

   Oracle Clinical processes and reclaims ownership of the specified patient positions provided no data has been entered for the patients.

Maintaining Investigators and Sites

Each study-sharing location assigns sites to the study and assigns investigators to those study sites. You cannot collect patient data without a study site and an assigned investigator.

Investigator and site names must be unique across all locations in the installation. Investigator and site information is replicated as part of data replication.

Constraints at the Study-Owning Location

Replication imposes constraints on design activity at the study-owning location. Although a few exceptions exist (see sections below), you cannot delete the following once they have been replicated:

- Patient positions
- Clinical study
- Clinical study versions
- Clinical planned events
- Treatment assignments

For more information , see:

- Exceptions for Patient Positions
- Exceptions for Study Design Activities

Exceptions for Patient Positions

The study-owning location creates patient positions and assigns them to various sharing locations. In general, you cannot alter patient positions after they have been assigned to a sharing location, except in the following circumstances:

- The study-owning location can reclaim ownership of a patient position from any sharing location provided no data has been entered for the patient.
- Sharing locations cannot exchange patient positions with each other directly. However, the study-owning location can retrieve patient positions from one sharing location and then reassign those patients to another sharing location.
- The study-owning location can delete a patient position if it owns the patient position and if no data has been entered for the patient.
- After randomized patient positions have been replicated, you cannot re-randomize them, but you can expand the randomization. After a randomized study has been replicated, you cannot re-randomize the study.

Exceptions for Study Design Activities

The study-owning location can perform all study design activities. Sharing locations can perform only the following study design activities:

- Assign sites and investigators to the study
- Assign patients owned by that sharing location to study sites

- Break the blind for a patient
- Maintain personal details for a patient

These activities are managed by the owning location of the patient position. This location may be a sharing location or the study-owning location, depending on which one owns the patient position.

Replicating Data at a Study-Owning Location

The study-owning location is the only location that can replicate study data directly from all sharing locations. As the study data repository, the study-owning location must schedule replications of data from the sharing locations for the study.

The sharing locations can replicate only from the study-owning location. So, at any point in the conduct of the study, the sharing locations have available to them only the data replicated by the study-owning location from the various sharing locations, plus the data collected at the study-owning location itself.

As a study-owning location, if you receive study data from a lab owned by another location, you must replicate that lab and its ranges into your database.

Operating from a Sharing Location

A sharing location takes its design and definition for the study from the study-owning location. It can conduct a study, but cannot modify the study design or definition. It can replicate, from the study-owning location, copies of data collected at other sharing locations for the study.

For more information , see:

- Study Design at a Sharing Location
- Study Definition at a Sharing Location
- Study Conduct at a Study-Sharing Location
- Data Replication at a Study-Sharing Location
- Replication of Labs and Lab Ranges at a Sharing Location
- Error if Flexible Study Setting Mismatch Between Locations

Study Design at a Sharing Location

Sharing locations receive their study design from the study-owning location. Every replication results in a fresh copy of the study design, including all new patient positions assigned to the sharing location.

A location that shares a study may also own studies itself. Every location can see the creation and maintenance screens in study design, however; a location cannot access studies it does not own via those screens, only via the query screens.

In general, a sharing location cannot modify the study design. However, a few exceptions to modifying the study design exist. At a sharing location, you can alter the study design as follows:

- You can:
  - Assign sites to the study

  - Assign investigators to study sites
  - Assign patients owned by your sharing location to the appropriate study site

  To perform any of these tasks, navigate to **Design, Investigators and Sites,** and then select **Study Sites.**

- You can locally disclose the treatment pattern assigned to a patient and create a blind break.

  To do this, navigate to **Design, Randomization, Randomization Maintenance,** and then select **Disclose Patient Treatment Assignments.**

- You can locally maintain patient details using either of the following options:
  - Navigate to **Design, Patient Positions,** and then select **Patients.**
  - Navigate to **Data Entry,** and then select **Patient Enrollment.**
- You can create and amend site plans for local study sites. To do this, navigate to **Design, Studies,** and then select **Study and Site Plans.**

> **Note:**
>
> When performing any of these study design activities at a sharing location, you see only the patient positions assigned to your location since the last time you replicated the study design.

Study Definition at a Sharing Location

The study-owning location defines all the core elements of a study—DCMs, DCM question groups, DCIs, and so on. A sharing location receives these definitions by replicating the study design and definition from the study-owning location. Study definition replicated from the study-owning location is available to view read-only from the study-sharing locations.

If the study-owning location changes any definitions, a study-sharing location must perform an incremental replication of the study definition. Once the study-sharing location completes the replication, Oracle Clinical ensures that all changes to the study definition are automatically applied to the study data during the next batch validation. The same automatic re-validation and re-derivation that occur at the study-owning location occur at each study-sharing location.

> **Note:**
>
> After the first full replication of a study definition at a study-sharing location, the study-sharing location must insert a record into the CLINICAL_STUDY_STATES table for the study-sharing location.

Study Conduct at a Study-Sharing Location

The study-sharing location can perform all study conduct activities, including:

- Log in documents for those patients that it owns.
- Do pass 1 entry, pass 2 entry, and update for its patients.
- Run Batch Validation against locally collected data.
- Do discrepancy management for locally collected data.

Data Replication at a Study-Sharing Location

At a study-sharing location, you can replicate study data from the study-owning location, but you cannot replicate study data directly from other sharing locations. Therefore, at any point in the conduct of a study, you have available only the data that the study-owning location has replicated from the various study-sharing locations, plus the data that the study-owning location has collected itself.

At a study-sharing location, when you replicate study data, you can elect to replicate the available data from one participating location (either another study-sharing location or the study-owning location) or from all participating locations (all study-sharing locations plus the study-owning location).

Replication of Labs and Lab Ranges at a Sharing Location

The options for replicating labs and lab ranges at a study-sharing location are the same as those at the study-owning location.

Error if Flexible Study Setting Mismatch Between Locations

The value of the **Flex Study Enabled?** setting at the source location must match the value of the **Flex Study Enabled?** setting at the target location. If a mismatch occurs, the replication job fails. Oracle Clinical reports the errors as follows:

- If a mismatch occurs during either a full or an incremental replication of a *single study,* the replication job completes with FAILURE. The output file contains the following error message:

  `Error: Flex Study Enabled flags do not match between source and target for study: study_name`

- When you submit a replication job, you can use the % wildcard character to replicate all studies. If a mismatch occurs during either a full or an incremental replication of *multiple studies* and if the mismatch occurs with more than one study, the replication job completes with SUCCESS. The failure text in the Batch Jobs window displays the following message:

  `COMPLETED WITH WARNING DUE TO FLEXSTUDY FLAG MISMATCH`

  In addition, the output file contains the following warning message:

  ```
  Warning: Flex Study Enabled flags do not match between source and target for
  one or more studies. Please check Clinical Study States form. The Job
  completed with Warnings.
  ```

- If a mismatch occurs during data replication of a study, the replication job completes with FAILURE. The output file contains the following error message:

  `Error: Flex Study Enabled flags do not match between source and target for study: study_name`

To resolve these issues:

1. Log in to Oracle Clinical at the source location.
2. Navigate to **Conduct, Security,** and then select **Clinical Study States.**
3. Verify the value of the **Flex Study Enabled** setting.
4. Update the value at each target location accordingly.
5. Save your changes.

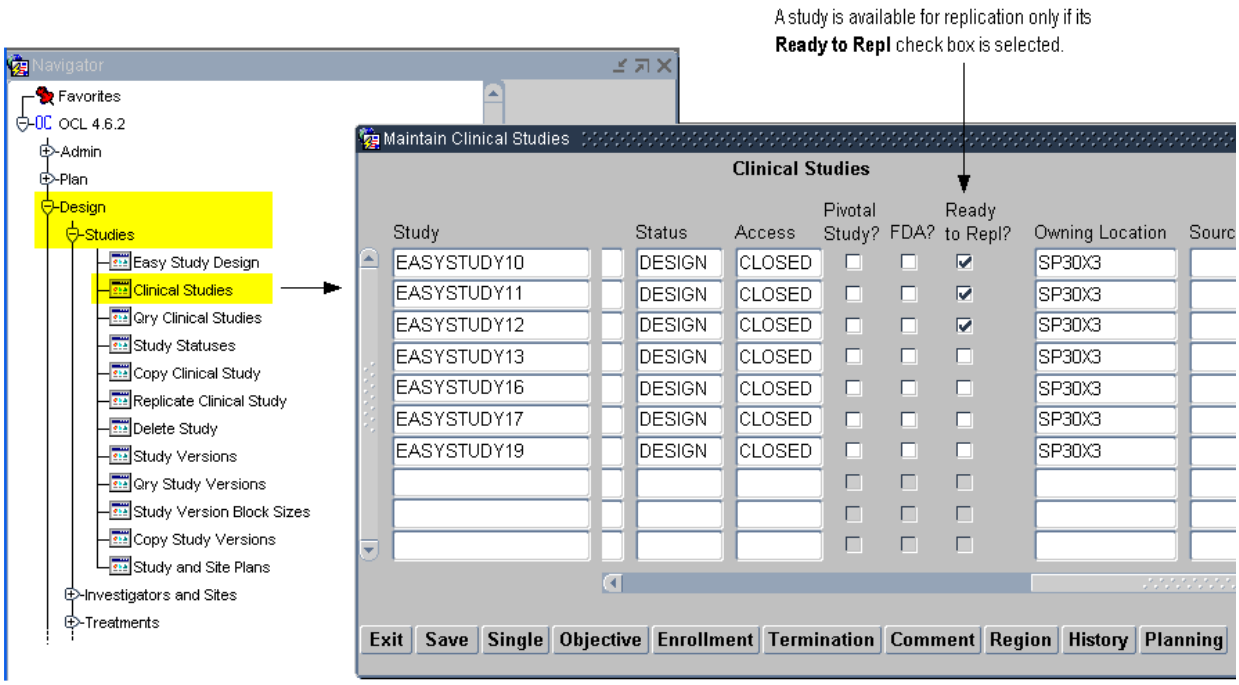
Enabling a Study for Replication

A study is available for replication only if its **Ready to Repl** check box is selected. In addition, only the study-owning location can designate when a study is ready for replication.

To enable a study to be available for replication:

1. Navigate to **Design, Studies,** and then select **Clinical Studies.**
2. Scroll to the right in the window.
3. Select the **Ready to Repl?** check box. See Figure 13-2.
4. Click **Save.**

Figure 13-2 Enabling a Clinical Study for Replication



Using Standard Replication

Standard replication is a *retrieving operation,* that is, the location that requires the information must request it from the study-owning location. In managing replication,

you must make sure that specific replications occur at consistent intervals and that you inform people when particular information is updated.

Standard replication has two options:

- Full replication — A *full* replication replaces the rows of the local tables with the current contents of the source location's table. For study definitions, only the rows for the replicated studies are replaced; for Global Library tables, all rows are replaced.
- Incremental replication — When *incremental* replication occurs, all operations (inserts, updates, and deletes) that have occurred on the source location's tables since the last replication are applied to the local database. Because only new and changed information is transferred, this minimizes the amount of information that must be transferred between locations over a network.

For more information , see:

- Review of Setting Up Standard Replication
- Replicating a Global Library
- Replicating Study Designs
- Replicating a Study Definition
- Replicating Data
- Replicating Lab Information
- Replication and Frequency

Review of Setting Up Standard Replication

To set up standard replication, you must complete the following tasks:

- Configure the SOURCE LOCATION CODE installation reference codelist
- Configure the OCL_INSTALLATION installation reference codelist
- Configure the OCL_STATE local reference codelist
- Create and set up the private and public database links
- Create the study design replication packages

For details about these installation tasks, see Setting Up Replication.

Replicating a Global Library

Standard replication of a Global Library supports both full replication and incremental replication:

- A *full replication* of a global library replaces *all* existing Global Library information at a sharing location with information from the tables at the Global Library-owning location.
- An *incremental replication* of a global library applies to the Global Library-sharing location only those operations (inserts, updates, and deletes) that have occurred at the Global Library-owning location since the last Global Library replication was performed at the Global Library-sharing location.

When using standard replication to replicate a Global Library, Oracle recommends that you execute a full replication initially, and incremental replications thereafter. You need to repeat the full replication of the Global Library only if the target library is corrupted.

To use standard replication to replicate a global library:

1. Select one of the following options:
   - To execute a *full* replication of a global library, navigate to **Admin, Replication,** and then select **Full Library.**
   - To execute an *incremental* replication of a global library, navigate to **Admin, Replication,** and then select **Incremental Library.**

   You do not need to specify any input parameters to replicate the Global Library.
2. Click **Schedule** to open the Schedule Jobs window.
3. Define when you want the replication to occur.
4. Click **OK** to save your changes.
5. Click **Submit Job** to submit the batch job.
6. Click **Exit** to return to the main menu.

Replicating Study Designs

When you use standard replication to replicate a study design, Oracle Clinical performs a *full* replication of the design information for a single study from the study-owning (source) location. Study design replication includes all design information except randomization and blinding information.

Because you might not want to make all study definitions available for replication—perhaps they are incomplete or intended only for local use—you must explicitly enable a study to be available for replication.

For more information , see:

- Replicating the Design of a Clinical Study
- Creating a Local Configuration for the Replicated Study

Replicating the Design of a Clinical Study

To use standard replication to replicate a study design:

1. Navigate to **Design, Studies,** and then select **Replicate Clinical Study.**
2. Complete the following fields in the Replicate a Clinical Study window:
   a. In the **Source Location** field, select a location from which to replicate a study design. The list of values includes only the *active* location codes defined in the SOURCE LOCATION CODE installation codelist.
   b. In the **Source Study Code** field, select from the studies owned by the selected source location that are available for replication. Note that the field lists only those studies that are owned by the location you specified in the Source Location field and that are designated as ready for replication. See Enabling a Study for Replication for details.

      Oracle Clinical automatically populates the Source Study Title field, the Target Study Code field, and the Target Study Title field.
3. Click **Replicate Study.** Oracle Clinical immediately begins the replication process.

Your terminal remains locked until the replication completes, which may take anywhere from a few minutes to several hours, depending on the size of the study design and the traffic on your network.

Creating a Local Configuration for the Replicated Study

Every study, whether replicated or not, requires a record in the CLINICAL_STUDY_STATES table. Study design replication does not automatically create the record. Therefore, after you replicate a study design for the first time at a study-sharing location, you must manually create a record in the CLINICAL_STUDY_STATES table.

In addition, you can configure several study-level settings in the CLINICAL_STUDY_STATES table that control collection at the study-sharing location. When you save your changes, Oracle Clinical automatically creates study access accounts at the study-sharing location that are required to perform data extract.

To create the Clinical Study States record and configure the study-level settings:

1. Navigate to **Conduct, Security,** and then select **Clinical Study States.**
2. Select the study.
3. Select the configuration settings for this study.
4. Save your changes.

Replicating a Study Definition

Once the study-owning location makes a study available for replication, you can replicate the study definition to a sharing location. The study definition includes the DCIs, DCMs, and Procedures, but not the received DCIs, received DCMs, responses, and discrepancies.

When you replicate a study definition, Oracle Clinical automatically replicates the Global Library before replicating the study definition to ensure that all Global Library information is consistent with references from the replicated studies.

Standard replication of the study definitions supports both full replication and incremental replication:

- A *full* replication of a study definition replaces *all* the existing study definitions being replicated with a copy of the information from the study definition tables at the study-owning location.
- An *incremental* replication of a study definition applies all operations (inserts, updates, and deletes) that have been performed on study definition tables at the study-owning location since the last replication.

To use standard replication to replicate a study definition:

1. Select one of the following options:
   - To execute a *full* replication of a study definition, navigate to **Admin, Replication,** and then select **Full Study.**
   - To execute an *incremental* replication of a study definition, navigate to **Admin, Replication,** and then select **Incremental Study.**
2. Complete the **Current Value** field for each parameter as follows:

a. For the **Source Location Code** parameter, select the code for the study-owning location. The list displays the active location codes from the SOURCE LOCATION CODE installation reference codelist.

b. For the **List of Study names to be replicated** parameter, select the study that you want to replicate. The list displays only those studies that are owned by the location you specified for the Source Location Code parameter.

   You can also use the % wildcard to replicate one, several, or all studies owned by the specified source location.

3. Click **Schedule** to open the Schedule Jobs window.
4. Define when you want the replication to occur.
5. Click **OK** to save your changes.
6. Click **Submit Job** to submit the batch job.
7. Click **Exit** to return to the main menu.

Replicating Data

Data replication includes investigators, sites, patient positions, and patient data. Optionally, data replication can include discrepancies and associated data clarification forms (DCFs).

For more information, see:

- What Does Oracle Clinical Include in Data Replication?
- Tracking the Execution of Data Replication
- Invoking Study Data Replication
- Managing Data at Multiple Locations

What Does Oracle Clinical Include in Data Replication?

When you initiate data replication, Oracle Clinical automatically:

- Replicates data for all patients, including all data modifications since the last data replication.

  Oracle Clinical moves, tracks, and commits the data one patient at a time to avoid single large transactions. This includes responses that change because a univariate validation criterion is modified, which causes the value to move from the exception value text to the response value text field.
- Invocates incremental study definition replication, and if necessary, Global Library replication.
- Replicates investigator and site information to ensure that all referenced information is present at the receiving location. This includes investigators, sites, study sites, study site roles, and patient position information.

In addition, data replication includes discrepancies and associated DCFs if the ALLOW_DISC_REPL parameter in the OCL_INSTALLATION codelist is set to **Y.** You set the ALLOW_DISC_REPL parameter at the Global Library-owning location only. See OCL_INSTALLATION Installation Codelist

Tracking the Execution of Data Replication

Oracle Clinical uses the STUDY_REPLICATION_JOBS table to track the execution of a replication, along with information about the timing and completion status of each data replication for a study.

Invoking Study Data Replication

To invoke study data replication:

1. Navigate to **Admin, Replication,** and then select **Data.**
2. Select the study that you want to replicate.
3. Complete the fields in the Replication of all the Study Data window as follows:
   - **Source Location Code** — Enter the name of the location that owns the study definition.
   - **Data Location Code** — Enter a percentage sign (%) to replicate all available data stored at the study-owning location; or enter the name of a single location participating in the study to replicate the data from that location currently available from the study-owning location. This name could be any sharing location or the study-owning location, unless you are replicating from the study-owning location itself.
   - **Refresh all data?** — Enter **Y** to have Oracle Clinical examine and refresh all data. Enter **N** to have Oracle Clinical refresh only data that has changed since the last replication. Selecting **N** results in a large reduction in data volume and consequently, reduces the likelihood of greatly degrading performance.
4. Click **Schedule** to open the Schedule Jobs window.
5. Define when you want replication to occur.
6. Click **OK** to save your changes.
7. Click **Submit Job** to submit the batch job.
8. Click **Exit** to return to the main menu.

Managing Data at Multiple Locations

Only locally owned data can be modified at any given location, and changes to the study definition should be applied uniformly at each location.

Integrity

Oracle Clinical enforces the integrity of distributed data by ensuring that each location can modify data and related information only for patients owned by that location. Oracle Clinical implements this integrity in the following activities:

- Log-In — Only locally assigned patient positions can be entered or accessed.
- Data Entry — Only locally assigned patient positions can be accessed, unless in browse mode.
- Patient Enrollment — Only locally owned patient positions can be accessed.
- Batch Data Load — Only locally owned patient positions can be loaded.

- Discrepancy Management — A location has only its own discrepancies available in the local discrepancy database tables.
- Data Freezing and Locking — A location can freeze and lock only locally assigned patients and their data and locally owned study sites. The study-owning location can freeze the study only after all locations with data stored at the study-owning location have frozen the study at their locations.
- Batch Validation — Procedures and other validation activities are only applied to patients owned by the current location.
- Investigator/Site — Each location maintains its own investigator and site assignments to the study; other locations can only view those assignments.
- Site Plans — Each location creates and maintains its own site plans; the study-owning location maintains the study plan.

Consistency

Data consistency means maintaining the correct relationship between the study definition and the data in the study. For example, data consistency guarantees that:

- You cannot replicate data for a DCM question to a location that does not yet have the definition for that DCM question.
- A modification to a DCM question's range at the study-owning location results in the re-validation of all data collected for that DCM question at all locations.
- Making a Derivation Procedure provisional then active, after removing a derived question and placing its derivation in another Procedure, results in the correct sequence for deleting existing derived information and re-deriving the information at all locations.

To preserve this data consistency, Oracle Clinical:

- Conducts an incremental replication to automatically update the study definition at the target location *before* replicating any data from the study-owning location.
- Tracks and replicates information about changes to Procedures and derived information, and tracks the times of previous replications to ensure detection and application of changed definitions when batch validation is executed.

Consistency and Data Extract

Data Extract poses the following special problems for distributed study data:

- Data extract view maintenance does not correctly detect all changes to DCM definitions when run in incremental mode. Therefore, all sharing locations should run data extract view maintenance in full mode.
- Stable and snapshot data extract views provide a consistent and unchanging view of data. However, when data from multiple locations is present in a study, you must be aware of these limitations:
  - Replication of data entered at a local time prior to a snapshot, or prior to the batch validation run that defines a stable view, causes data to appear in the view. Therefore, a view is truly stable only after all data entered before the time stamp defining the view is moved to the location with the views.
  - Replication of data whose own stable time stamp (Last Batch Run) is later than the local time stamp (which can arise due to time-zone differences) can cause data to be viewed where the derived information is inconsistent with entered information.

You can handle these limitations on a day-to-day basis by timing the replications. As long as you do not invoke replication during the day, stable views remain stable during the course of the day. Snapshot views will be stable as long as you ensure that all locations have been replicated before being used. As long as the local batch validation occurs later than the time stamp of the batch validation at the source location, no inconsistencies occur between entered and derived information in the stable views.

To ensure completely consistent and stable snapshot views—such as for interim analysis—you must ensure that following batch validation at each location serving as a source of data for the snapshot, no data is entered or modified for a time interval greater than or equal to the difference in time zones. A second batch validation run then establishes a second time stamp from which data modification activities can resume.

You can usually satisfy these constraints by scheduling the batch validation to run in the early evening and the replication to run in the middle of the night. You can then establish the second stability point by scheduling a second batch validation to run in the morning, prior to data entry resuming. The second batch validation does little processing because no data or definition changes need to be applied. This caution is necessary only if the data is to be accessed for reporting or other formal purposes through the stable or snapshot views.

During both incremental and full replication, the system preserves local language translations for the Global Library, study design, and study definition.

Replicating Lab Information

Lab information distribution includes the global definition of lab units, lab panels, and related information, as well as the ability to share lab definitions and lab ranges among locations processing tests at the same lab.

The lab range system consists of three sets of information with different relationships in a distributed environment. See the following table for details.

Table 13-2 Lab Information and Management Location

Information Set	Location Relationship
Lab units, lab panels, textbook ranges, and all related information	Maintained centrally at Global Library-owning location; replicated to all Global Library-sharing locations in the Oracle Clinical installation
Labs and lab ranges	Maintained at the location responsible for lab; replicated to any location that has replicated study data referencing the lab
Lab assignment criteria	Maintained separately at each location; not replicated

The globally maintained lab units and panels information is maintained at the same location that maintains the Global Library. At all other locations, you can access only the query versions of the forms.

For more information , see:

- Replicating the Global Lab Information
- Replicating Labs and Lab Ranges

Replicating the Global Lab Information

Global lab replication invokes full replication of the centrally maintained lab system information. No parameters are necessary to submit the replication batch job. Each time you execute global lab replication, Oracle Clinical copies to your location a fresh copy of all the information maintained in those tables from the location that maintains the global lab information.

To use standard replication to replicate global lab information:

1. Navigate to **Admin, Replication,** and then select **Global Lab Info.**

   Note that no parameters are necessary to submit the replication batch job.
2. Click **Schedule** to define when you want the replication to occur.
3. Click **Submit Job** to submit the batch job.
4. Click **Exit** to end the function and return to the main menu.

Replicating Labs and Lab Ranges

Each location maintains its labs and lab ranges. These labs and lab ranges can then be used by studies run locally or at locations that are part of a distributed study. Lab identifiers must be unique across all locations.

If a lab, such as a central lab, is shared by multiple locations, you can maintain the ranges for that lab at one location and replicate to other locations for their use. Alternatively, you can separately identify and maintain the lab at each location. You can only update lab and range information for labs owned by your location.

To use standard replication to replicate labs and lab ranges:

1. Navigate to **Admin, Replication,** and then select **Labs and Ranges.**
2. Select the name of the location that owns the lab, and then click **Submit Job.**

   This process updates the list of labs that are available to you from that location. In addition, for those labs for which you have previously selected the Replicate? check box, this process updates the lab and lab ranges information for the labs owned by the site from which you replicate.
3. Navigate to **Labs, Labs,** and then select **Labs** to open the Maintain Labs window.
4. Query for all the labs owned by the source location.
5. Review the status of the **Replicate?** check box for each lab.

   The **Replicate?** check box indicates whether to replicate its ranges the next time you run lab and ranges replication. Therefore, note that:

   - The first time you replicate labs from a lab-owning location, the **Replicate?** check box is not selected for those labs.
   - For any lab created by the lab-owning location since the last time you ran labs and ranges replication, the **Replicate?** check box is not selected.
6. Process each **Replicate?** check box as follows:

   - If you want the ranges for a lab that did not have the **Replicate?** check box enabled, select the check box and then select **Admin, Replication,** and **Labs and Ranges** again to replicate its lab ranges from the lab-owning location.

- If, for some reason, you no longer want to replicate the ranges for a particular lab, clear the **Replicate?** check box. That lab's ranges will not be replicated again until you re-select the check box.

Note that you can use the information in the Last Replication field in the Maintain Labs window to determine when the lab ranges were replicated.

Replication and Frequency

You will likely want to adjust the frequency of replications according to what activities are occurring. For example, while a study-owning location is creating and modifying the study definition, it must maintain a frequent schedule of replications of the Global Library to consistently have the most recent definitions.

When a study definition is replicated, Oracle Clinical automatically checks to ensure that the Global Library information is up to date. If the information is not up to date, Oracle Clinical automatically invokes incremental replication of the Global Library before proceeding.

In addition, you must consistently schedule data replication to ensure that all locations in the installation have access to all study data. For example, you could schedule the study-owning location to replicate data from each sharing location every evening, and then before work starts at each location the following day, you schedule a time for each sharing location to replicate data from the study-owning location. Because replication is a PSUB job, you can schedule each job to occur at a regularly scheduled time every day.

Using Disconnected Replication

Disconnected replication supports *bi-directional* replication between locations without relying on a network connection. Instead of transferring data real-time via a Wide Area Network (WAN), disconnected replication transfers data between locations via file transfer.

For more information, see:

- Overview of Disconnected Replication
- Extracting Source Data to an Export File
- Defining the Extract Data Parameters
- Loading Data from the Export File into a Target Location

Overview of Disconnected Replication

With disconnected replication, you begin by exporting data to a file. When you export data to a file, you can choose to include the following type of information:

- Global Library
- Global Labs (textbook ranges and conversion tables)
- Labs
- Study designs
- Study definitions
- Patient data
- Study randomizations

You can choose to replicate the Global Library, Global labs, labs, study designs, study definitions, and patient data either separately or as a single unit.

For each of these areas, all the existing functionality of the full replication mode is supported. With each selected type, all data is replicated.

For more information , see:

Users Who Can Run Disconnected Replication

Any user with the following privileges can run disconnected replication:

- RXC_ADMIN
- RXC_SUPER
- RXC_SUPER_NOGL

Disconnected Replication Uses Full Replication Only

Disconnected replication supports full replication only. It does not have an incremental option like standard replication. Instead, each time you initiate another disconnected replication, Oracle Clinical creates a new copy of the source data. When you import and load the new source data to the target location, Oracle Clinical overwrites the existing data at the target location with the new source data.

If your installations are set up for standard replication, you can, however, use disconnected replication in conjunction with standard replication. For example, you can choose to use disconnected replication to initially populate a study, and then use full or incremental standard replication at any time.

Advantages of Disconnected Replication

There are several circumstances where disconnected replication offers a valuable alternative to standard replication. Disconnected replication:

- Enables a Contract Research Organization (CRO) to conduct clinical trials on behalf of an Oracle Clinical sponsor without requiring that the sponsor be able to communicate via a direct network connection.
- Can perform the initial transfer of large studies or of the Global Library in a network environment. You can then use standard replication (full or incremental) to maintain the Global Library and studies over the network.
- Can act as a backup to standard replication when a major network failure occurs.
- Can transfer large volumes of patient data when a study is being consolidated for analysis.

Security Concerns with Disconnected Replication

Because the export file may contain confidential information, you should implement the following security measures:

- Impose strict controls over who can access the file.
- Make read access to the file available only to authorized disconnected replication users.
- Encode the file if you intend to transfer the file over a public network.
- Control and restrict access to backup copies and to all physical media.

The internal schema RXC_DISC_REP stores replicated data in tables ending with $REP. Like all other users, it is assigned to the DEFAULT profile which enforces that its password expires in 180 days. You must proactively change the password before it expires. Its password is stored in a wallet that you set up by following instructions in the *Oracle Clinical Installation Guide*. See Changing the Password for the OCPSUB or RXC_DISC_REP Account

Example of How Disconnected Replication Is Used in Distributed Studies

In practice, a sponsor can use disconnected replication to transfer files to and from a Contract Research Organization (CRO) in the following manner:

- The sponsor uses disconnected replication to export Global Library non-study data and the definition of a study to the CRO.
- The CRO imports the information and begins to collect data to perform a study.
- The CRO uses data replication to export the study data back to the sponsor.
- The sponsor imports the study data from the CRO and refreshes the data in the Oracle Clinical database.

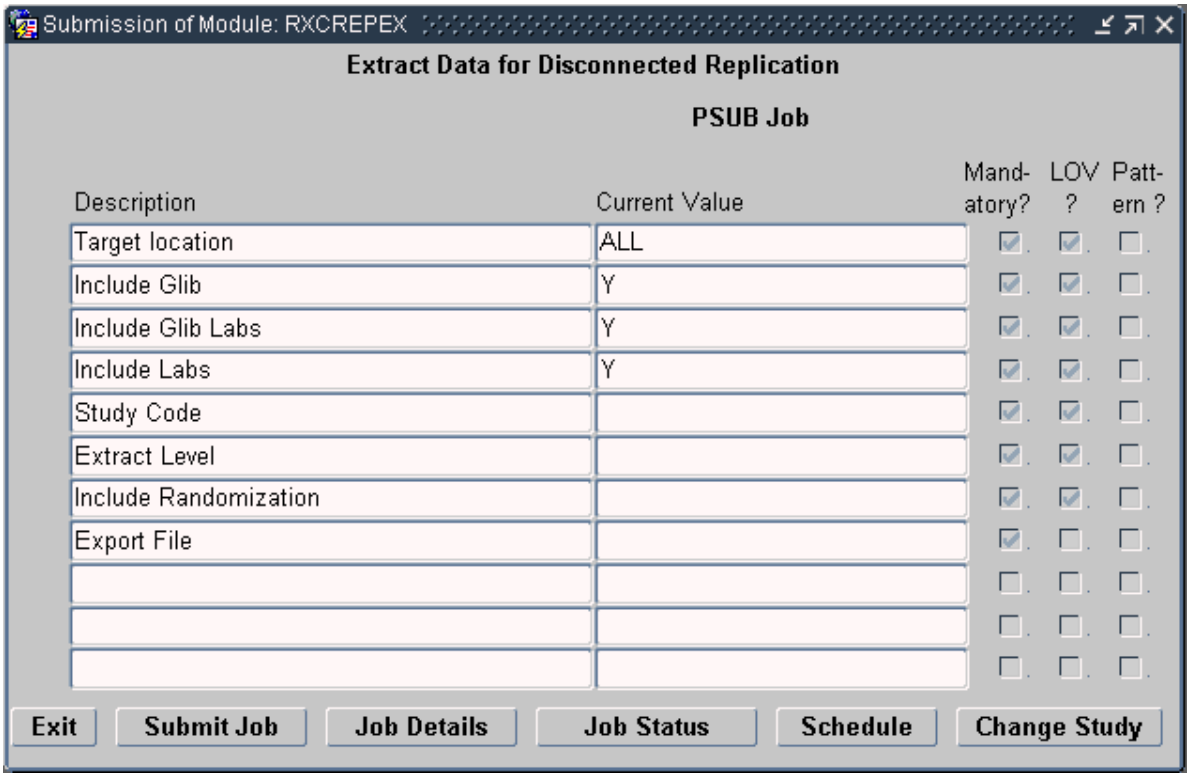
Extracting Source Data to an Export File

To extract source data to an export file:

1. Navigate to **Admin, Replication,** and then select **Disc Repl Export.**
   Oracle Clinical opens an Extract Data for Disconnected Replication window, which varies slightly depending on whether the location owns the Global Library for the selected database.

   Note that the window includes the following parameters only if the location is the Global Library-owning location:

   - Include GLIB
   - Include GLIB Labs



2. Enter values for the parameters displayed in the Extract Data window. See Defining the Extract Data Parameters for details.
3. Click **Submit Job** to send the replication job to the Parameterized Submission (PSUB) utility for processing.
   Alternatively, you can click **Schedule** to schedule the job for a particular date and time.

   For additional information about using the Parameterized Submission (PSUB) utility to submit jobs, see *Oracle Clinical Getting Started*.

Defining the Extract Data Parameters

This section describes the values that you can enter for each parameter displayed in the Extract Data window. For more information, see:

- Target Location
- Include GLIB
- Include GLIB Labs
- Include Labs
- Study Code
- Extract Level
- Include Randomization
- Export File

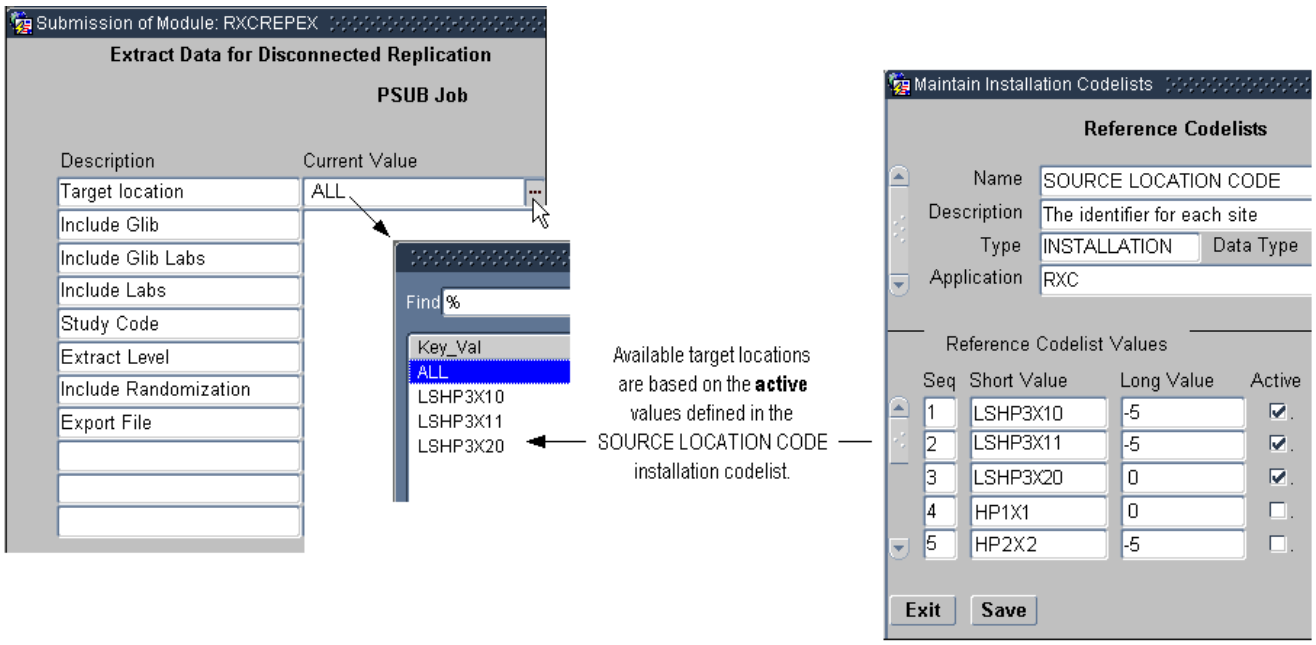
Target Location

Select the name of a specific target location or select **ALL.** Note that the available target locations are based on the **active** values in the SOURCE LOCATION CODE installation reference codelist. See Figure 13-3.

The value you select depends on the type of data you are replicating:

- For Global Library, Global labs (textbook ranges and conversion tables), or lab data, select **ALL** to extract data for replication to multiple sites. Select the name of one target location to extract data for replication to a single site.
- For study design, study definition, or patient data, select the name of one target location to extract data for replication to a single site.

Figure 13-3 Available Target Locations based on SOURCE LOCATION CODE Installation Codelist



Include GLIB

Set to **Y** to include Global Library information in the exported file. Note that the Include GLIB parameter is available only at the Global Library-owning location.

Include GLIB Labs

Set to **Y** to include textbook ranges and conversion tables in the exported file. The replicated data includes the following information:

- Textbook Ranges
- LAB_PANELS
- LAB_PANEL_QUESTIONS

- LAB_TEST_QUESTION_UNITS
- LAB_UNITS
- LAB_UNIT_CONVERSIONS
- PREFERRED_LAB_UNITS
- PREFERRED_LAB_UNIT_GROUPS

Note that the Include GLIB Labs parameter is available only at the Global Library-owning location.

Include Labs

Set to **Y** to include lab information in the exported file.

Study Code

Enter the appropriate value depending on the type of data you are replicating:

- For study design, study definition, or patient data, select the name of a study. When you select a specific study, you can use the exported file only at the one site specified in the Target location field.

  Note that a study is available for replication only if its **Ready to Repl** check box is selected. See Enabling a Study for Replication for details.
- For Global Library data, enter **N/A.**
- Studies previously owned by the current location and now being given to the target location.

Extract Level

Enter the level of data you want to replicate and export to the file. Valid values are:

- **DESIGN** — Study design
- **DEFINITION** — Study design and study definition
- **DATA** — Study design, study definition, and data
- **N/A** — Not applicable

Include Randomization

Set to **Y** to include randomized treatment assignments to patient positions.

Export File

Enter the name of the file to which Oracle Clinical exports the data. The directory path defaults to the path on the PSUB server defined in REPL_ROOT in the OCL_STATE local reference codelist.

Loading Data from the Export File into a Target Location

After you create an export file that contains the data from the source location, you choose how to transport the export file to the target location. For example, you can choose disk media, tape media, E-mail, or local area network (LAN). The export file is

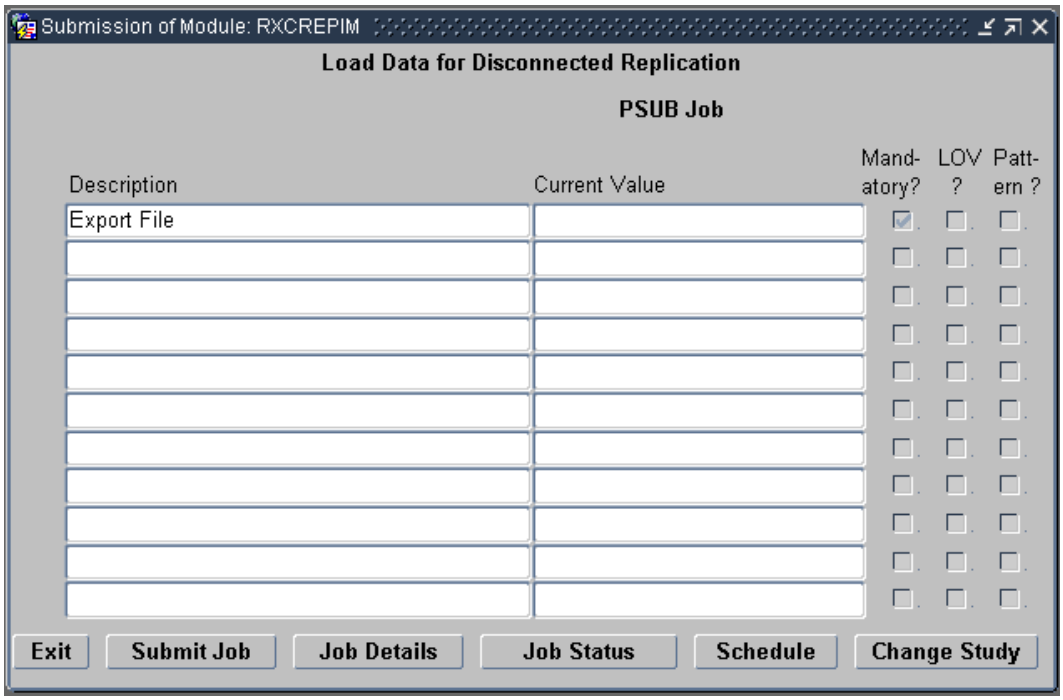
fetched from the location defined in REPL_ROOT under the OCL_STATE local reference codelist.

The target location then imports (or loads) the data from the export file.

Note that you can import study data only if, at the time of data extract, the Global Library at the target location is the same as, or more recent than, the Global Library at the source location.

To receive data from a source location:

1. Navigate to **Admin, Replication,** and then select **Disc Repl Load.** Oracle Clinical displays the Load Data for Disconnected Replication window.



2. Enter the name of the export file to load.
3. Click **Submit Job** to send the job to the Parameterized Submission (PSUB) utility for processing.
   Alternatively, you can click **Schedule** to schedule the job for a particular date and time.

   For additional information about using the Parameterized Submission (PSUB) utility to submit jobs, see *Oracle Clinical Getting Started*.

See the following:

- How Disconnected Replication Commits Data

How Disconnected Replication Commits Data

Disconnected replication commits data to the target location incrementally — completely committing the Global Library, for example, before staging the Global Library labs.

Commits occur in the following order:

- Global Library

- Global Library labs
- Labs
- Study design
- Study definitions
- Patient data, on a per patient basis

Changing Study Ownership

It is possible to change the owner of a clinical study. To do this, the current owner updates the Owning Location field in the Maintain Clinical Studies form. Ownership actually transfers the next time the new owner initiates replication.

If the receiving location does not have an up-to-date copy of the study definition, an error message is issued when the owning location is changed. The new owner can not replicate the study until receiving an updated copy of the study definition.

The replication process that changes ownership also replicates the randomization in the study.

Replicated Tables

The following is the list of tables that are replicated as a part of standard replication and disconnected replication.

> **Note:**
>
> The CLINICAL_STUDY_STATES table is not replicated as part of standard replication. Therefore, with standard replication, you must manually create a record in the CLINICAL_STUDY_STATES table. For more information, see Creating a Local Configuration for the Replicated Study.
> The CLINICAL_STUDY_STATES table is replicated as part of disconnected replication.

ACTUAL_EVENTS
BATCH_DCMQ_CHANGES
BLIND_BREAKS
BLOCK_DEFINITIONS
CLIN_ST_TERMINATION_CRITERIA
CLIN_STUDY_ENROLLMENT_CRITERIA
CLINICAL_PLANNED_EVENTS
CLINICAL_PLANNED_PROCESSES
CLINICAL_PROCEDURES
CLINICAL_STUDIES
CLINICAL_STUDY_HISTORY
CLINICAL_STUDY_OBJECTIVES
CLINICAL_STUDY_STATES
CLINICAL_STUDY_VERSION_SIZES
CLINICAL_STUDY_VERSIONS

CLINICAL_SUBJECTS
COMBINED_TREATMENT_COMPONENTS
COMPLEX_QUESTIONS
COPY_GROUP_DETAILS
COPY_GROUPS
CORRELATION_ITEMS
DAILY_DOSES
DATA_CLARIFICATION_FORMS
DATA_EXTRACT_VIEWS
DCF_DISCREPANCIES
DCF_DISCREPANCIES_HIST
DCF_PAGE_ENTRIES
DCF_PAGES
DCF_PRINT_STATUS
DCF_STATUS_TRACKING
DCI_BK_RULE_TRG_DCIS_TGT_STAT
DCI_BOOK_CPES
DCI_BOOK_DCI_CONSTRAINTS
DCI_BOOK_EXPLODED_RULES
DCI_BOOK_INTERVALS
DCI_BOOK_PAGES
DCI_BOOK_PHYSICAL_PAGES
DCI_BOOK_RULE_TGT_DCIS
DCI_BOOK_RULE_TGT_INTERVALS
DCI_BOOK_RULE_TRG_DCIS_INST
DCI_BOOK_RULE_TRG_DCIS_STAT
DCI_BOOK_RULES
DCI_BOOKS
DCI_FORM_CONDITIONAL_BLOCKS
DCI_FORM_VERSIONS
DCI_HTML_FORM_VERSIONS
DCI_MODULE_PAGES
DCI_MODULES
DCI_USER_ROLE_PRIVS
DCI_USER_ROLE_PRIVS_DCIS
DCIS
DCM_CONDITIONAL_BRANCHES
DCM_LAYOUT_ABS_PAGES
DCM_LAYOUT_GRAPHICS
DCM_LAYOUT_TEXT
DCM_QUES_REPEAT_DEFAULTS
DCM_QUESTION_GROUPS
DCM_QUESTIONS
DCM_SCHEDULES
DCMS
DISCREPANCY_ENTRIES
DISCREPANCY_ENTRY_REVIEW_HIST
DISCRETE_VALUE_GROUPS
DISCRETE_VALUES

ENROLLMENT_PLANS
EXTRACT_MACRO_PARAMETERS
EXTRACT_MACROS
FACTORS
FORM_LAYOUT_TEMPLATES
FORMAT_MASK_COMPONENTS
FORMAT_MASKS
HTML_DCIF_FIELD_VALUES
INTERVAL_TREAT_REGIMEN_ASSIGN
LAB_PANEL_QUESTIONS
LAB_PANELS
LAB_RANGE_SUBSETS
LAB_TEST_QUESTION_UNITS
LAB_UNIT_CONVERSIONS
LAB_UNITS
LABS
OCL_DOSAGE_FORMS
OCL_INVESTIGATORS
OCL_ORGANIZATION_UNITS
OCL_PRODUCT_MASTERS
OCL_PROGRAM_PRODUCT_MASTERS
OCL_PROGRAMS
OCL_PROJECTS
OCL_SITES
OCL_STUDIES
OCL_STUDY_REGIONS
OCL_STUDY_SITE_ROLES
OCL_STUDY_SITES
PATIENT_FLEX_TRACKING
PATIENT_POSITIONS
PATIENT_POSITIONS_HISTORY
PATIENT_STATUSES
PATTERNS
PLANNED_STUDY_INTERVALS
PP_EXPECTED_CPES
PP_EXPECTED_DCIS
PP_EXPECTED_INTERVALS
PREFERRED_LAB_UNIT_GROUPS
PREFERRED_LAB_UNITS
PROC_DET_VAR_USAGE
PROCEDURE_DETAILS
PROCEDURE_QUESTION_GROUPS
PROCEDURE_QUESTIONS
PROCEDURE_TEXTS
PROCEDURE_VARIABLES
PROCEDURES
QUERIES
QUERY_DETAILS
QUERY_KEY_COLS

QUERY_WHERE
QUERY_WHERE_COLS
QUES_MEDICAL_EVAL_QUALIFIERS
QUESTION_ATTRIBUTES
QUESTION_CATEGORY_RELATIONS
QUESTION_GROUP_QUESTIONS
QUESTION_GROUPS
QUESTION_SET_QUESTIONS
QUESTION_SETS
QUESTIONS
RANDOMIZATION_BLOCKS
RANDOMIZATIONS
RANGES
RDCI_HISTORY
RECEIVED_DCIS
RECEIVED_DCMS
RECEIVED_PAGE_HISTORY
RECEIVED_PAGES
REFERENCE_CODELIST_VALUES
REFERENCE_CODELISTS
REGIONS
RESPONSE_LOBS
RESPONSES
S_A_SET_ITEMS
STANDARDS_AFFILIATIONS
STRATA
STRATUM_COMPONENTS
STRATUM_TREATMENT_PATTERNS
STUDY_COMMENTS
STUDY_REPLICATION_JOBS
STUDY_SITE_PATIENT_POSITIONS
STUDY_STRATIFICATION_FACTORS
TEMPLATE_COLUMNS
TEMPLATE_INDEX_COLS
TEMPLATE_INDEXES
TEMPLATES
TITRATION_STEPS
TREAT_PATT_BLOCK_DEFINITIONS
TREATMENT_ASSIGNMENTS
TREATMENT_PATTERN_REGIMENS
TREATMENT_PATTERNS
TREATMENT_REGIMEN_BY_RANGES
TREATMENT_REGIMENS
UNIONS
VALIDATION_REPORTED_VALUES
VIEW_QUESTION_MAPPINGS
VIEW_RESTRICTION_COLS
VIEW_RESTRICTIONS
VIEW_TEMPLATE_QUESTIONS

XMLP_DCIF_FIELD_VALUES

A
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 database 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 using indentation.

```
opapps
   sas_view
      db_service
         study
            account_type
            *.sas
            *.log
            *.com
```

The following table shows the permissions for each folder and file. The 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.

Table A-1 File Protections

Directory or File	UNIX	Windows
opapps	(0775)	~
sas_view	(2775, oclsascr)	(oclsascr, FULL Control)
db_service	(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 location of the SAS_VIEW storage sas_view, change the appropriate environment settings for your platform, as shown below. This may already be set in the setup file for your operating system; see Database Tier Settings.

UNIX:

```
db_env_setting:_DEFAULT_:RXC_USER:/u01/home/opapps

db_env_setting:_DEFAULT_:RXC_SAS_ROOT:root/home/opapps/sas_view/database
```

where *database* is the value of $ORACLE_SID for a local database or $TWO_TASK for a remote database.

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.

B

Environment Variables and Registry Settings

This appendix describes the environment variables and registry settings that Oracle Clinical uses to condition the environment on computer 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.

In this section:

Oracle Clinical Setup Files

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. The Oracle Universal Installer creates the file in *drive*:\opapps\bin.
  - 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.
  - .oclrc – 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 opapps. 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 for details.

Database Tier Settings

This section includes information about opa_settings on UNIX and Windows.

For more information , see:

- OPA Settings
- Changing opa_settings on UNIX
- Setting TNS_ADMIN on UNIX
- Changing opa_settings.bat on Windows

OPA Settings

You can define values for the environment variables 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 for details.

On UNIX some of these settings are in opa_setup (Korn or Bourne shell) and copa_setup (C shell).

Most of these environment variables affect job execution on back end servers.

For more information , see:

- NLS_DATE_FORMAT
- NLS_LANG
- RXC_BATCH_QUEUE
- RXC_BDL_DIR
- RXC_DEBUG_BUFFER_SIZE
- RXC_IMMED_QUEUE
- RXC_LOG

- RXC_MAA_TAB_SPACE
- RXC_NOW_STRING
- RXC_PRINTER
- RXC_SAS_BATCH_QUEUE
- RXC_SAS_ROOT
- RXC_SAS_VIEW
- RXC_USER
- SASORA
- TEMP
- USER_BV_JOB

NLS_DATE_FORMAT

This variable determines the format used for displaying dates and converting characters to dates. The default value is "DD-MON-RRRR". The year must be specified as RRRR.

You can modify this variable using `db_env_setting` records in the opa_settings file.

NLS_LANG

This variable specifies the language and character set settings used by Oracle RDBMS to read from and write to the database.

For Oracle Clinical and RDC Onsite, Oracle strongly recommends that you use the AL32UTF8 character set (the default value set during installation). However, these applications support UTF8, US7ASCII, WE8ISO8859P1, or any single byte character set.

Oracle Clinical and RDC use the NLS_LANG environment variable to control the **language, territory**, and **character set** used for database connections. The NLS_LANG variable concatenates the three components as LANGUAGE_TERRITORY.CHARSET.

- You must set the CHARSET component of the NLS_LANG variable to match the character set of the database.
- You must use the **same character set on the database tier and the application tier**. If you select US7ASCII for the database tier and AL32UTF8 or UTF8 for the application tier, Oracle Clinical stores some special characters incorrectly in the database.
- For PSUB to work correctly for an AL32UTF8 character set database, the opa_settings file must have the following setting:

  `db_env_setting:`*`database`*`:NLS_LANG:american_america.AL32UTF8`

The default value for this variable is:

```
db_env_setting:_DEFAULT_:NLS_LANG:american_america.AL32UTF8
```

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 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 rxc_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_ROOT

Set this variable to the full path of the database subdirectory of the sas_view directory: *OPA_Home*/sas_view/*database_Oracle_SID*. For example:

```
c:/home/opapps/sas_view/example_db
```

RXC_SAS_VIEW

Set this variable to the full path of the database subdirectory of the sas_view directory: *OPA_Home*/sas_view/*database_Oracle_SID*. For example:

```
c:/home/opapps/sas_view/example_db
```

> **Note:**
>
> For historical reasons, two environment variables identify the same directory. Both RXC_SAS_VIEW and RXC_SAS_ROOT identify the root directory for all the input and output files associated with the Data Extract jobs that run in your installation. See SAS_VIEW Directory Tree. (This is true with the exception of the .log and .out files now stored in the database).
>
> The Installer automatically populates these variables in UNIX and Windows, whether the database is local to the machine or remote.

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/… directory.

> **Note:**
>
> It is possible to set a different value for RXC_USER for each database, if you wish, overriding this default.

SASORA

When SAS is installed on a UNIX database, this environment variable must be defined when you run SAS Access against an Oracle database. The default value shipped in opa_settings is V9.

When PSUB and the SAS server are both on Windows, you must comment out the setting of SASORA in opa_settings.bat:

```
rem set SASORA=V9
```

TEMP

This is the default temporary directory for SFTP and 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 .oclrc):

```
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*.

Changing opa_settings on UNIX

This section has information on UNIX settings as mentioned below:

- Setting Up UNIX Environments
- Changing Configuration Settings on UNIX Database Servers
- Defaulting, Adding, and Customizing Values
- Constraints on the opa_settings File
- Checking for Errors in the opa_settings File

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
database	Indicates the database to be used. This can be: • 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.
code_env	Optional. An Oracle Clinical code environment designator that must refer to a code environment defined in the opa_settings 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
database	~	With no *code_env* specified, the script sets only Oracle-level environment variables needed for applications to access *database*.
- (minus)	*code_env*	With no *database* 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.
database	*code_env*	With both *database* and *code_env* 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=52
$ . opa_setup
```

- In C shell:

  `copa_setup` *database code_env*

  For example:

```
%copa_setup test 52
```

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 B-1 lists and describes each record type.

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_. 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. To set a value for an environment variable for just one user, place a statement in that user's .oclrc 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 B-1 shows how to override a system-wide default setting with a database-specific setting.

> **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 5.1 to 5.2, opa_settings would include:

```
db_code_pair:x:51
db_code_pair:x:52
```

In this case, check_opa_settings.sh warns you. Remove the line enabling the 5.1 code environment against the 5.2 database, so you don't mistakenly start up a PSUB process in that configuration.

You might 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:52
db_code_pair:x:52patchtest
```

You would disregard the warning check_opa_settings.sh would give, since both pairs are valid.

Table B-1 List and Description of the Records in the opa_settings File

Record Type Key	Description	Example
oratab_filespec	Location of the file oratab on the server Field 1: Fully specified path to the OPA directory	`oratab_filespec:/etc/oratab`
tnsnames_filespec	Location of the file tnsnames.ora 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 tnsnames.ora	`tnsnames_filespec:/etc/tnsnames.ora`
opa_home	Location of Oracle Health Sciences (formerly known as Oracle Pharmaceutical Applications) products on the server. Field 1: Fully specified path to the OPA directory.	`opa_home:/pharm/home/opapps`
remote_db_home	Location of an available remote database, to which ORACLE_HOME should be set. Field 1: Net8 connect string of the remote database. Field 2: ORACLE_HOME value that is used while accessing the current database	`remote_db_home:hpx1:/u01/app/oracle/product/9.2.0`
code_environment	Location of the code for a version of an OPA application. Field 1: A code environment designator, for example, OC52 for the Oracle Clinical 5.2 code Field 2: The fully specified path to the root directory for the version of the application software	`code_env: oc52:/pharm/home/opapps/52`
db_code_pair	Indicates that a particular code environment can be used with a particular database. Field 1: The system identifier (SID) of a local database instance, or the connect string of a remote database instance. Field 2: A code environment designator	`db_code_pair:prod:oc52`

Table B-1 (Cont.) List and Description of the Records in the opa_settings File

Record Type Key	Description	Example
db_env_setting	Provides either a default or database-specific setting for an environment variable. The following environment variables must have at least default settings: NLS_DATE_FORMAT NLS_LANG RXC_BATCH_QUEUE RXC_NOW_STRING SASORA These settings are assigned default values at install time. Field 1: The database SID, or connect string, if this is a database-specific setting for the environment variable; or _DEFAULT_, if this is a default setting across databases for this environment variable. Field 2: Name of an environment variable Field 3: Value to be assigned to the environment variable	db_env_setting:_DEFAULT_:SASORA:V9 db_env_setting:TEST:SASORA:V9

Setting TNS_ADMIN on UNIX

The TNS_ADMIN environment variable is located in the .cshrc file in the opapps Home directory. It must point to the location where sqlnet.ora exists. The Installer puts sqlnet.ora in the opapps Home directory. slqnet.ora contains the path of the Oracle Wallet that contains the credentials for OCPSUB.

To set the value to the opapps Home:

`.chsrc:`

```
setenv TNS_ADMIN $HOME
```

Changing opa_settings.bat on Windows

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.

Below is a list of the Oracle Clinical environment variables that must be defined in opa_settings.bat.

- NLS_DATE_FORMAT

  ```
  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 to be Year 2000 compliant.

- NLS_LANG

```
set NLS_LANG=american_america.AL32UTF8
```

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 AL32UTF8 character set database. See NLS_LANG for more information.

- RXC_MAA_TAB_SPACE

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*

Application Tier Settings

This section lists the Windows registry settings used by the Oracle Clinical application tier.

It describes the settings for the each of the following:

- OPA Front End
- Oracle Clinical Front End
- RDC Front End
- OCN Front End
- Reports Server
- Registry Keys
- Online Help

OPA Front End

These registry variables apply across products and are located at HKEY_LOCAL_MACHINE\SOFTWARE\ORACLE\KEY* where * is a random number assigned to the Oracle Home. Each value is set by the Installer.

Table B-2 OPA Front End Registry Variables and Example Values

Registry Variable	Example Value	Description
FORMS_PATH	c:\opapps52\opa	The path that is searched to find forms.
FORMS_TIMEOUT	10	The amount of time in elapsed minutes before the Form Services process is terminated when there is no client communication with the Form Services. To prevent the forms session's timing out due to inactivity, set the heartbeat value(defined in the formsweb.cfg file) to less than the forms_timeout value. See article ID 549735.1 'Description List For Parameters Affect Timeout In Webforms' on My Oracle Support.
OPA_CONFIG	opa52	The OPA configuration name.

Table B-2 (Cont.) OPA Front End Registry Variables and Example Values

Registry Variable	Example Value	Description
OPA_RQM_URL	https://*server.domain:port*/reports/rwservlet/showjobs?server=*report_server_name*	The URL for the Reports Queue Manager.
OPA_HOME	c:\opapps52	The top-level OPA products directory.
OPA_HOME_DIR	c:\opapps52\opa	The Oracle Health Sciences product directory.
OPA_SERVER	*server.domain*	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 opa52 config section in the formsweb.cfg file.
OPA_PHYSICAL_MAP	c:\opapps52\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.

Oracle Clinical Front End

These registry variables are located on the SOFTWARE\ORACLE\KEY*number* branch of the registry. Each value is set by the Installer.

Table B-3 Oracle Clinical Front End Registry Variables and Example Values

Registry Variable	Example Value	Description
FORMS_PATH	c:\opapps52\oc	The Forms60 path that is searched to find forms
forms60_repformat	HTML	
forms60_userexits	c:\opapps52\oc\f60xtb.dll; c:\oc\rxcde1.dll	User Exits referenced from Oracle Clinical/RDC
forms60_defaultfont	MS Sans Serif 1.0	Oracle Clinical default font
oc_home_dir	c:\opapps52\oc	The Oracle Clinical top level directory
OC_DE_TEXTFONT	Arial.8	The default font for Oracle Clinical data entry field prompts and boilerplate text
OC_DE_FIELDFONT	Arial.8	The default font for response fields in Oracle Clinical data entry
OPA_JARS	f60all_jinit.jar, opaicons.jar,oclicons.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/opa52/rdc/temp	The URL to access the xmltemp directory

Table B-3 (Cont.) Oracle Clinical Front End Registry Variables and Example Values

Registry Variable	Example Value	Description
OPA_XMLTEMP_UNC	If forms and reports servers are on the same computers, the value should be c:\opapps52\html\rdc\temp If forms and reports servers are on different computers, the value should be t:\html\rdc\temp (where t:\ is mapped to OPA_HOME of the server where reports server is installed)	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\KEY*number* branch of the registry on the application tier server where RDC is installed.

Table B-4 RDC Front End Registry Variables and Example Values

Registry Variable	Example Value	Description
FORMS_PATH	c:\opapps52\rdc	The path that is searched to find forms
RDC_HOME_DIR	c:\opapps52\rdc	The location of the RDC directory
RDC_DCIF_IMAGES	\\appserver\rdc\dcif_images or c:\opapps52\html\rdc\dcif_images	The location of the RDC directory images
OPA_LOCALHOST	oclw2k16.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.
OPA_XML_LOC	OPA_HOME/temp e.g.: c:\opapps52\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: 1. 0: no debug 2. 1: Low debug level 3. 2: High debug level By default, it is set to "1" during installation.

OCN Front End

These registry variables are located on the SOFTWARE\ORACLE\KEY*number* branch of the registry. Each value is set by the Installer.

Table B-5 OCN Front End Registry Variables and Example Values

Registry Variable	Example Value	Description
FORMS_PATH	c:\opapps52\oc	The path that is searched to find forms
OCN_HOME_DIR	c:\opapps52\oc	The OCN Home directory

Reports Server

These registry variables are located on the SOFTWARE\ORACLE\KEY*number* *HOME* branch of the registry for the Reports Server installation. Each value is set by the Installer.

Table B-6 Report Server Registry Variables and Example Values

Registry Variable	Example Value	Description
REPORTS_PATH	c:\opapps52\opa, c:\opapps52\oc, c:\winnt\fonts	The path the system searches to find reports
REPORTS_CLASSPATH	c:\opapps52\lib\pdfappend.jar, c:\opapps52\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:\opapps52\oc	The Reports Server directory
NLS_LANG	american_america.AL32UTF8	The NLS language that is used when running Reports; supported values are: AL32UTF8, US7ASCII, WE8IS08859P1, or any single byte character set
OC_PDF_REPORTS_TEMP_OC	c:\opapps52\temp	The temporary directory that the system uses when you run reports.
OC_RPT_GRIDWIDTH	8	The default grid width for the report
OPA_HOME	c:\opapps52\	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 Oracle Clinical data entry
OC_DE_TEXTFONT	Arial.8	The default font for data entry field prompts and boilerplate text.
OC_RPT_FIELDFONT	Arial.8	The font for response field data in the Patient Data Report. This variable is not created by the Installer. If you need to differentiate the field font used for the PDR from the one used for data entry, add this registry variable and set it. If not specified, the system uses the value for OC_DE_FIELDFONT.

Table B-6 (Cont.) Report Server Registry Variables and Example Values

Registry Variable	Example Value	Description
OC_RPT_TEXTFONT	Arial.8	The font for CRF header field prompts, question prompts, and boilerplate text in the Patient Data Report. This variable is not created by the Installer. If you need to differentiate the text font used for the PDR from the one used for data entry, add this registry variable and set it. If not specified, the system uses the value for OC_DE_TEXTFONT.
RDC_DCIF_IMAGES	c:\opapps52\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_version*\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 some 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.

These 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
- RDC_PDF_PRINT_TOOL

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 5.1 are installed, the FORMS_PATH value would be:

```
c:\opapps52\opa;c:\opapps52\oc;c:\opapps52\rdc;c:\opapps52\tms
```

The following table lists the path string that each component contributes to the FORMS_PATH key value.

Table B-7 Product-Specific Registry Values for the FORMS_PATH Key

Product	Addition to the FORMS60_PATH value
OPA Front End	`c:\opapps52\opa`
Oracle Clinical Front End	`c:\opapps52\oc`
RDC Front End	`c:\opapps52\rdc`
TMS Front End	`c:\opapps52\tms`
AERS Front End	`c:\opapps52\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 Oracle Universal Installer sets this value to:

drive:\opapps52\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 "Configure the Reports Server and Forms Server for DCI Form Generation" section in the *Oracle Clinical Installation Guide*.

For example, if during installation you specify in the Oracle Universal Installer that there is a standalone report server, the Installer sets the value of this key to:

C:*appserver_hostname*\rdc\temp

and requires that you share *drive:**appserver_hostname*\html\rdc with the share name "rdc".

If the only report server that you use to generate DCI forms is installed on the same computer as 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:*appserver_hostname*\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:\appserver_hostnamedomain:port\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:\opapps52\html\rdc\temp on myOCSever, then a virtual directory must be associated with c:\opapps52\html:

```
alias /opa52/ "c:\opapps52\html\"
```

This allows a URL of http://*myOCServer*/opa52/rdc/temp/MYFILE.pdf to resolve and serve the file, c:\opapps52\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. 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:

```
OPA_HOME\html\rdc\dcif_images\crfimages
```

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:\opapps52\html\rdc\dcif_images\crfimages`.

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*`:\opapps52\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 values that are typed in response fields and displayed in data entry windows. This registry key is set as part of the Oracle Clinical Front End installation and the Oracle Clinical Report Server installation in the SOFTWARE\ORACLE\KEY*number* branch.

The default value is **Arial.8**.

OC_DE_TEXTFONT

The value assigned to this key regulates the font size of the question prompts and boilerplate text in data entry windows. This registry key is present in:

- the SOFTWARE\ORACLE\KEY*number* branch, where it is set as part of the Oracle Clinical Front End installation
- the SOFTWARE\ORACLE\KEY*number**DatabaseServer* 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 change the value in one location, change it in the other too.

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".

Online Help

These registry variables are located on the SOFTWARE\ORACLE\KEY*number* branch of the registry. Each value is set by the Installer.

Table B-8 Xhelp Registry Variables and Example Values

Registry Variable	Example Value	Description
opa_doc_dir	http://server.domain/opa52	The URL for standard online help and documentation location
opa_custom_doc_dir	http://server.domain/opa52	The URL for custom online help and documentation
opa_xhelp_dir	c:\opapps\html\xhelp	The location of the online help directories

Setting Environment Variables on the Command Line

Many tasks in this guide require setting environment variables on the command line in UNIX or Windows. The syntax varies by the operating system and shell type, but always includes the database name and code environment.

The code environment value is two digits for the current Oracle Clinical major or minor release, without the point (.). For example, by default the code environment for Oracle Clinical 5.1 is `51` and the code environment for Oracle Clinical 5.2 is `52`.

The syntax is:

- For UNIX servers, C shell:

```
opa_setup database_name code_environment
```

- For UNIX servers, Bourne shell:

```
p1 = database_name
p2 = code_environment
. opa_setup
```

- For Window servers:

```
set p1=database_name
set p2= code_environment
opa_setup
```

C

Troubleshooting

This section offers solutions to known Oracle Clinical issues in the following categories:

See also Troubleshooting Symmetric Replication

For more information, see:

- Restart Application Server After Redeploying RDC Onsite
- Managing High Sequence Numbers
- Error Messages
- System Malfunction: GPF Occurs During Data Entry
- PSUB Jobs
- Database Trace
- Problems in Reports
- Error Accessing Web Services from Client

Restart Application Server After Redeploying RDC Onsite

If you redeploy the RDC Onsite .ear file—for example, to apply a patch—restart the application server, including the WebLogic Admin Server. This helps clear connection pools and any DLLs that may be loaded. If you do not restart the server, the following message is displayed the next time a user opens an RDC Onsite data entry window:

```
java.lang.UnsatisfiedLinkError: Native Library
drive:\opapps52\bin\olsadcapiprocmgr.dll already loaded in another classloader
```

Managing High Sequence Numbers

If you receive the following warning: `ConnectOCL - 970100: The following sequence(s) is approaching its maximum value : DISCREPANCY_ENTRY_SEQ` (or another of the sequences mentioned below), you need to reseed the sequence; see Reseeding Sequences .

In all versions of Oracle Clinical since 4.5.1 the system enforces that the internal identifier for each of the following cannot exceed 9,999,999,999 (that is, 10^10 -1):

- Received DCMs (RDCMs)
- Received DCIs (RDCIs)
- Discrepancies

In addition, Response IDs cannot exceed 1,000,000,000,000,000 (10^15).

This is because in earlier versions, when the internal identifier for these records exceeded 2,147,483,647 the system incorrectly processed the identifiers and batch validation, data extract, replication, and procedure execution operations failed or ran incorrectly.

The OCL_DE_CONFIG Local Codelist includes a value, 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 9,999,999,999, the system displays the warning message above when a user attempts to use a relevant subsystem and the system exits the current screen. If you prefer a larger or smaller buffer, you can change the value in the reference codelist.

For more information , see:

- Assessing Sequence Sizes
- Reseeding Sequences

Assessing Sequence Sizes

Perform this test to proactively determine if your database is nearing the point where this situation may occur. If the result of this test for the number of Received DCMs, Received DCIs, or discrepancies is well below 9,999,999,999—or 1,000,000,000,000,000 for responses—you do not need to reseed the corresponding sequence.

For more information , see:

- Assess the Sequence Numbers of RDCMs, RDCIs, and Discrepancies
- Assess the Sequence Number of Responses

Assess the Sequence Numbers of RDCMs, RDCIs, and Discrepancies

To determine the next sequence number to be generated for an RDCM, RDCI, or discrepancy in your system:

1. Connect to your database through SQL*Plus as RXC.
2. Issue a command to determine the next sequence value to be assigned:
   - For RDCMs:

     ```
     SELECT received_dcm_seq.nextval FROM dual;
     ```

   - For RDCIs:

     ```
     SELECT received_dci_seq.nextval FROM dual;
     ```

   - For discrepancies:

     ```
     SELECT discrepancy_entry_seq.nextval FROM dual;
     ```

   The system returns a number after each command. If any internal identifier number is approaching 9,999,999,999, you should reseed the sequence; see Reseeding Sequences .
3. Use this query to check if the maximum sequence value is correctly set to 9999999999. (Releases prior to 4.5.1 had no maximum limit.)

   ```
   col max_value format 9999999999
   select sequence_name,max_value
   from dba_sequences
   where sequence_name in
   ```

```
('RECEIVED_DCM_SEQ','RECEIVED_DCI_SEQ','DISCREPANCY_ENTRY_SEQ');
```

> **Note:**
>
> If the nextval value retrieved in Step 2 is greater than 2,147,483,647 and the maximum has not been set to 9999999999, see My Oracle Support note ID 277278.1.

4. If the query finds that any of the maximum values is set to anything other than 9999999999, run a command to reset it:
   - For RDCMs:

     ```
     alter sequence received_dcm_seq maxvalue 9999999999;
     ```

   - For RDCIs:

     ```
     alter sequence received_dci_seq maxvalue 9999999999;
     ```

   - For discrepancies:

     ```
     alter sequence discrepancy_entry_seq maxvalue 9999999999;
     ```

Assess the Sequence Number of Responses

To determine the next sequence number to be generated for a response in your system:

1. Connect to your database through SQL*Plus as RXC.
2. Issue this command to determine the next sequence value to be assigned:

   ```
   SELECT response_seq.nextval FROM dual;
   ```

   The system returns a number. If it is approaching 1000000000000000 (10^15), you should reseed the sequence; see Reseeding Sequences .
3. Use this query to check if the maximum sequence value is correctly set to 1000000000000000 (10^15). (Releases prior to 4.5.1 had no maximum limit.)

   ```
   col max_value format 9999999999999999
   select sequence_name,max_value
   from dba_sequences
   where sequence_name in ('RESPONSE_SEQ';
   ```

4. If the query finds that any of the maximum values is set to anything other than 1000000000000000, run a command to reset it:

   ```
   alter sequence response_seq maxvalue 1000000000000000 ;
   ```

Reseeding Sequences

If any of your sequence numbers are approaching or exceed the maximum value, you should reseed them. The system generates sequence numbers in increments of 100, so unused numbers are available.

When you reseed a sequence, the system prompts you to provide a previously unused start value. After reseeding, the system uses the same increment value to generate new values, ensuring that the new generated values are unique.

To reseed any of these sequences:

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 already in use for the sequence(s) you are reseeding, issue a command:
   - For RDCMs:

     ```
     SELECT distinct mod(received_dcm_id,100)
     FROM received_dcms;
     ```

   - For RDCIs:

     ```
     SELECT distinct mod(received_dci_id,100)
     FROM received_dcis;
     ```

   - For discrepancies:

     ```
     SELECT distinct mod(discrepancy_entry_id,100)
     FROM discrepancy_entries;
     ```

   - For responses:

     ```
     SELECT distinct mod(response_id,100)
     FROM responses;
     ```

   > **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 a command to drop the sequence(s) you are reseeding:
   - For RDCMs:

     ```
     DROP sequence received_dcm_seq ;
     ```

   - For RDCIs:

     ```
     DROP sequence received_dci_seq ;
     ```

   - For discrepancies:

     ```
     DROP sequence discrepancy_entry_seq ;
     ```

   - For responses:

     ```
     DROP sequence response_seq ;
     ```

6. Issue a command to recreate the sequence(s) with a new starting value. The system prompts you to enter the new starting value (`START WITH &SEQ_START_NO`).
   - For RDCMs:

```
CREATE SEQUENCE received_dcm_seq
INCREMENT BY 100
START WITH &SEQ_START_NO
MAXVALUE 9999999999
MINVALUE 1
NOCYCLE
CACHE 20
NOORDER;
```

- For RDCIs:

```
CREATE SEQUENCE received_dci_seq
INCREMENT BY 100
START WITH &SEQ_START_NO
MAXVALUE 9999999999
MINVALUE 1
NOCYCLE
CACHE 20
NOORDER;
```

- For discrepancies:

```
CREATE SEQUENCE discrepancy_entry_seq
INCREMENT BY 100
START WITH &SEQ_START_NO
MAXVALUE 9999999999
MINVALUE 1
NOCYCLE
CACHE 20
NOORDER;
```

- For responses:

```
CREATE SEQUENCE response_seq
INCREMENT BY 2000
START WITH &SEQ_START_NO
MAXVALUE 1000000000000000
MINVALUE 1
NOCYCLE
CACHE 20
NOORDER;
```

> **Note:**
>
> In the case of responses, the sequence uses 2000 as the increment and Oracle Clinical manipulates this value by adding 100 to it 20 times before going back to sequence.

7. Issue this command to grant access:
   - For RDCMs:

     ```
     GRANT SELECT on received_dcm_seq to RXCLIN_MOD;
     ```

   - For RDCIs:

     ```
     GRANT SELECT on received_dci_seq to RXCLIN_MOD;
     ```

   - For discrepancies:

     ```
     GRANT SELECT on discrepancy_entry_seq to RXCLIN_MOD;
     ```

   - For responses:

```
GRANT SELECT on response_seq to RXCLIN_MOD;
```

Error Messages

> **Note:**
>
> The *Oracle Clinical Conducting a Study* guide has a list of batch data load error messages with descriptions of the problem.

This section offers fixes or workaround for the following error messages:

- Message: Not Using Named Package
- Message: ORA-12223
- Message: ORA-04020
- Message: Unable to Change Mode
- Message: ConnectOCL - 970100
- Message: PL/SQL Package Body: Looping Synonyms

Message: Not Using Named Package

This message may appear in the `.log` file and is a data replication issue. Oracle Clinical expects to conduct data replication between two locations using named packages rather than synonyms.

Solution: The named packages should have been created during setup for replication by executing the dyna_rxapkirp.sql script. See Creating the Package for Replicating Investigators and Sites.

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 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.

To change the MAXIDLE time of the Reports Server:

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 Message: ORA-04020 , above.

Message: ConnectOCL - 970100

See Managing High Sequence Numbers.

Message: PL/SQL Package Body: Looping Synonyms

If procedure generation fails and the parse error displays: "PL/SQL Package Body: Looping Synonyms" the problem is actually that the account RXC_PD does not have a password set. It may have expired due to Oracle Database security settings. To reset these passwords, log into SQL*Plus and enter:

```
set_pwd rxc rxc_pd
```

The system prompts for the RXC password and the new RXC_PD password.

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.

PSUB Jobs

This section describes steps you should take, in order, when you troubleshoot PSUB problems.

To troubleshoot a PSUB job:

- Check the Failure Text in the Submitted Batch Jobs Window
- Check the PSUB Log Files
- If Batch Jobs Hang and the Batch Queue Is Full
- Determining if PSUB Is Running for a Database
- Troubleshooting PSUB Based on the Batch Job's Execution Status
- Handling PSUB Failures that Return "Fatal two-task communication protocol" Error
- Handling PSUB Failure that Returns "Illegal use of PSLAUNCH…" Error
- Tracking Previous PSUB Process Connections
- PSUB Fails to Start
- PSUB Remains at Entered Status
- Troubleshooting PSUB on a Windows Database

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, see Check the PSUB Log Files. If your batch job is hanging because the batch queue is full, see If Batch Jobs Hang and the Batch Queue Is Full.

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 process 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. Oracle recommends that you start PSUB in verbose mode because the process logs that are generated:

- Contribute to efficient troubleshooting
- 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. See Managing the PSUB Process.

If you cannot check the Failure text or the .out and .log files because the batch queue is hung, see If Batch Jobs Hang and the Batch Queue Is Full.

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
l`batch_job_id`.log	Log file of a specific job	RXC_LOG
o`batch_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 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.

For more information , see:

- Stopping Batch Jobs on UNIX Systems
- Stopping Batch Jobs on Windows

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.

Stopping an Individual Job

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.
2. Identify and then stop the processes that are hanging:
    a. To identify the process that is hanging, use either:

```
ps -ef|grep opapps
```

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 opapps 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.

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 process 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, Oracle recommends 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.

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.

– new code list

> **Note:**
>
> As an alternative, to find out on which computer PSUB is set up, query one of the following:
>
> - OCL_STATE local reference codelist, SERVER_NAME setting
> - 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.

For more information , see:

- What PSUB Processes Are Running on a Given UNIX Server?
- Is PSUB Running on a Given Windows Server?

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 processs 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:

```
opapps 15685 1 0 Apr 04 ? 0:00 rxcpsdps verbose example_db ssuneja_oc40_sun
opapps  4143 1 0 Apr 02 ? 0:00 rxcpsdps verbose example_db 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.
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
- SUBMITTED
- SUBMIT_FAILED
- STARTED
- FAILED
- Other Items to Check

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.
- The Advanced Queue is not started; see PSUB Remains at Entered Status

SUBMITTED

If the Execution Status of your batch job remains at SUBMITTED, perhaps:

- The job is pending in the batch queue, or the batch queue is stopped.
- The opapps account 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 process is up and running, if your .log file says:

```
ERROR:Error while connecting:
      ORA-01017: invalid username/password; logon denied

Exiting...
```

  Edit sqlnet.ora (in *drive*:\app\oracle\product\11.2.0.2.0\NETWORK\ADMIN):

  – **UNIX**: Comment out the following line (add # at the beginning of the line) and save.

```
# SQLNET.AUTHENTICATION_SERVICES = (NTS)
```

– **Windows**: Make sure the same line in sqlnet.ora is **not** commented out (if there is a pound sign (#) at the beginning of the line, remove it and save):

```
SQLNET.AUTHENTICATION_SERVICES = (NTS)
```

If the PSUB process is still running you can now resubmit the PSUB jobs. Otherwise, stop and then start the PSUB process.

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 ssh command cannot be executed by the OPAPPS 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 SERVER_OS entry in the OCL_STATE local reference codelist is correct for your operating system. You can enter one of the following values:

- **NT** — Indicates the server is running one of the Windows operating systems currently supported by Oracle Clinical.
- **UNIX** — Indicates the server is running the UNIX operating system.

Check that the SERVER_NAME in OCL_STATE is 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 1 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...
```

For more information , see:

- Verify PSUB Account Uses C Shell
- Modify launch.ps

Verify PSUB Account Uses C Shell

This error can occur if the PSUB user is not using the C Shell (csh). The default shell gets set up when you create the user account. For example, on Linux, the bash shell is set by default.

Verify that all user accounts that run PSUB jobs are configured to use the C Shell (csh).

Modify launch.ps

If the error continues to occur after you verify that PSUB account uses C Shell, modify `$RXC_PSUB/launchps.sh` as follows:

1. Log on to the UNIX computer on which the PSUB process is running, as owner of the file `launchps.sh`. (The owner is usually OPAPPS.)
2. Set environment variables for the database name and code environment; see Setting Environment Variables on the Command Line
3. Change to the $RXC_PSUB directory.
4. Edit `launchps.sh` by adding the following line immediately before the **pslaunch** command:

   ```
   sleep 2
   pslaunch $4 $5 $6 $7 $3 $8
   ```

   This command introduces a 2-second delay before the system calls `pslaunch`. You may increase the delay if the error continues to occur.

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 Time Stamps

This example lists, in chronological order, all start and stop time stamps of PSUB processes.

```
SQL> SELECT start_ts, stop_ts, host, code_environemnt
  2  from psub_process_log order by 1;
```

PSUB Fails to Start

If PSUB does not start; for example, after installing or upgrading:

1. Check one line in sqlnet.ora (in *drive*:\app\oracle\product\11.2.0.2.0\NETWORK\ADMIN):
   - **UNIX**: Edit sqlnet.ora by commenting out the following line (add # at the beginning of the line) and save it.

     ```
     # SQLNET.AUTHENTICATION_SERVICES = (NTS)
     ```

   - **Windows**: Make sure the same line in sqlnet.ora is **not** commented out (if there is a pound sign (#) at the beginning of the line, remove it and save):

     ```
     SQLNET.AUTHENTICATION_SERVICES = (NTS)
     ```

2. Locate and ensure that these lines in init.ora are **not** commented out and the values are as specified:

   ```
   remote_os_authent=null
   ```

   ```
   os_authent_prefix=""
   ```

   (a null string)
3. Shutdown the database.
4. Start the database.
5. Start PSUB.

PSUB Remains at Entered Status

If PSUB remains at Entered status, you may need to manually restart the AQ process:

1. Stop PSUB, see Starting and Stopping PSUB.
2. Log in as sysdba.
3. Enter:

   ```
   EXEC DBMS_AQADM.START_QUEUE('RXC.PSUB_REPLY_QUEUE',TRUE,TRUE);
   EXEC DBMS_AQADM.START_QUEUE('RXC.PSUB_SEND_QUEUE',TRUE,TRUE);
   ```

4. Restart PSUB.
5. Rerun the job.

Troubleshooting PSUB on a Windows Database

If you have difficulty starting PSUB on a Windows database after upgrading to or installing Oracle Clinical:

1. Open the sqlnet.ora file and confirm that following line is not commented (that is, there is no '#' at the beginning of the line). If there is, uncomment the line (remove the #):

   ```
   sqlnet.authentication_service=(NTS)
   ```

2. Attempt to start PSUB.

If PSUB fails to start:

1. Open the init.ora file. Ensure that the following lines are not commented out and have the values specified. If not, uncomment and/or change the values.

   ```
   remote_os_authen=NULL
   os_authent_prefix="OPS$"
   ```

2. Shut down any databases on the Windows server, then start the databases.

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 Oracle Clinical user working in the Maintain DCM form:

   ```
   select sid, serial# FROM v$session where username = 'userid';
   ```

3. Assume that 8 and 12 are returned for sid and serial#, enable SQL trace for the user as follows:

   ```
   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:

   ```
   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,

   ```
   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.

Problems in Reports

The following problems are related to the Oracle Clinical Report Server:

- Truncated Field Display
- Preview for Form Layout Editor or DCI Form Generation Fails on Standalone Reports Servers

Truncated Field Display

Oracle Clinical reports may:

- display field values that appear truncated
- display dates as ******

To fix this issue, change the display setting on Windows to 150%.

From the Windows Control Panel, navigate to Ease of Access, then Optimize, then Visual Display.

If the Windows 2008 R2 application server is accessed using remote desktop, you may need to apply a Microsoft Windows patch - 2726399 to be able to modify the setting.

Preview for Form Layout Editor or DCI Form Generation Fails on Standalone Reports Servers

This problem can arise if you add separate Reports Servers to an installation with no Forms Servers configured to support them. For separate Reports Servers to work, you must set up registry settings on each separate Reports Server and a Forms Server, and share directories on the Forms Server. See Setting Up Image Viewing and OPA_XMLTEMP_UNC and OPA_XMLTEMP_HTTP for more information.

Unable to Stop a Reports Job

Check if this is a scheduled job. If it is, use the Oracle AS10*g*R2 Enterprise Manager to stop it. Navigate to **Action**, **Report Queue Manager** from any screen, or **Admin**, **PSUB/Report Jobs**, **Enterprise Manager**. The Report Queue Manager window opens. The instructions vary by manager version, so follow the instructions in the window to stop the job.

PDR Fails with "Generating Cover Page" Error

The Patient Data Report fails if the patient code contains a slash (/) and gives an error beginning:

```
Generating Cover Page for patient 770/001
```

where the patient code is 770/001.

Error Accessing Web Services from Client

When invoking webservices from client, you may get the following error:

```
Error invoking
'getServiceProperty':'oracle.fabric.common.xml.xpath.XPathFunctionException:
oracle.apps.aia.core.config.PropertyNotFoundException: Property Not Found
(SystemConfiguration/Default.SystemID)'
```

To resolve the issue:

1. In the PATH environment variable, add the JDK path as `C:\Oracle\Java\jdk\bin;`
2. Add the Managed Server (the server where wsdl .ear is deployed) in the config.xml file:
   a. Take a backup of the config.xml file under $DOMAIN_HOME/config as config.xml_bkp and open config.xml.
   b. Search for the string `oracle.wsm.seedpolicies`.
   c. The current entry has only the AdminServer deployment location. Add the Managed Server separated by a comma as shown below:

```
<library>
   <name>oracle.wsm.seedpolicies#11.1.1@11.1.1</name>
   <target>AdminServer,AIAServer1</target>
   <source-path>C:/Oracle/Middleware/oracle_common/modules/
oracle.wsm.policies_11.1.1/wsm-seed-policies.jar</source-path>
    <security-dd-model>DDOnly</security-dd-model>
   <staging-mode>nostage</staging-mode>
 </library>
```

3. Restart the Managed Server.

D

Routine Server Administration

This appendix covers system administration tasks that arise from changes to the system hardware or software.

For more information, see:

- Recreating Symbolic Links — UNIX Only
- Relinking Server Code — UNIX Only
- Relocating Oracle Clinical
- Updating Oracle Clinical Seed Data
- Collecting Statistics for Optimization
- Using Dynamic Sampling to Improve Batch Data Load Performance

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). 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 rxcchkobj output. For example:

```
Expected progs in =====> /u01/home/oppaps/bin/52/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

If you move your Oracle Clinical installation, you must edit the location references in one or more files, according to your server platform. See Setting Environment Variables on the Command Line

UNIX

In the file oc/*code_environment*/psub/launchps.sh, modify the directory reference in this section:

```
p1=$1; export p1;
p2=$2; export p2;
. /pharm/home/opapps/oc/code_environment/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/code_environment/inst/bin
fi
```

Windows

Edit the file oc/code_environment/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 Environment Variables and Registry Settings):

   ```
   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

Variable	Description
PATH	make sure *oracle_home*/bin 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: rxc_password
Enter product code (OC or TMS): OC
```

Collecting Statistics for Optimization

Two scripts gather statistics required for the Oracle 11g Optimizer to be effective for accounts used internally by Oracle Clinical and RDC Onsite. Each script prompts for the password of the account(s) it processes.

If your database contains large amounts of data, the scripts may take a long time to run. You may want to edit the scripts. For information on the scripts' parameters see documentation on the Oracle DBMS_STATS package that is called by these scripts: http://docs.oracle.com/cd/B19306_01/appdev.102/b14258/d_stats.htm#i1036456.

Failure to execute these scripts can negatively impact performance.

1. Set the database initialization parameter **optimizer_features_enable** to 11.2.0.4.

> **Note:**
>
> Do set the initialization parameter to 11.2.0.4 even though Oracle Clinical is installed with Oracle Database 12*c*.

2. Log into SQL*Plus as **system** and run the scripts:
   - **ocstats.sql** captures new statistics in the RXC, RXA_LR, RXA_DES, RXA_DISC_REP application accounts required for the Oracle 11g optimizer to be effective and result in better performance of Oracle Clinical and RDC Onsite.
   - **opastats.sql** captures new statistics in the OPA application account used by Oracle Clinical, RDC Onsite, and TMS.

Using Dynamic Sampling to Improve Batch Data Load Performance

After collecting DBMS_STATS (see Collecting Statistics for Optimization), delete and lock statistics for the temporary tables used by Batch Data Load in order to optimize performance. When encountering tables with no statistics, Oracle RDBMS dynamically gathers the necessary statistics as part of query optimization. With volatile temporary tables, dynamic sampling contributes to better performance.

1. Set database initialization parameter **optimizer_dynamic_sampling** to 2 or higher. (The default value is 2.)
2. Log into SQL*Plus as **system** and run the following commands to delete statistics for Batch Data Load temporary tables:

```
EXEC DBMS_STATS.DELETE_TABLE_STATS(ownname=>'RXC', TABNAME=>'TEMPORARY_BATCH_DCIS');
EXEC  DBMS_STATS.LOCK_TABLE_STATS(ownname=>'RXC', TABNAME=>'TEMPORARY_BATCH_DCIS');
EXEC DBMS_STATS.DELETE_TABLE_STATS(ownname=>'RXC', TABNAME=>'TEMPORARY_BATCH_DCMS');
```

3. Lock statistics for the Batch Data Load temporary tables to enable dynamic sampling:

```
EXEC  DBMS_STATS.LOCK_TABLE_STATS(ownname=>'RXC',
TABNAME=>'TEMPORARY_BATCH_DCMS');
EXEC DBMS_STATS.DELETE_TABLE_STATS(ownname=>'RXC',
TABNAME=>'temporary_batch_data_items');
EXEC  DBMS_STATS.LOCK_TABLE_STATS(ownname=>'RXC',
TABNAME=>'temporary_batch_data_items');
```

E

Oracle Clinical Tablespaces

This appendix lists the tablespaces in an Oracle Clinical database and their use. Names preceded by "d-" are created when the database is created. The rest are created when the Installer is run to install Oracle Clinical in the database.

- DISC_REP_DATA: Disconnected Replication tables
- RBS: 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
- 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:

- TMS_DATA: Data tables
- TMS_IDX: Index tables

Glossary

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.

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.

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:

- Current value of the data point
- Previous value of the data point
- User name that changed the data point
- Time stamp the data update occurred
- Change reason
- 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 by 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

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.

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.

C

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. In RDC, CRFs are depicted electronically through the data entry window.

See also: **CRF**

change history

A listing of the values that have been assigned to data or information. Each list item includes information that uniquely identifies it. Specifically, a time stamp 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).

clinical planned event

(CPE) 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 data entry staff.

CRF

See case report form

CRF header

A component of a CRF as it is displayed in the 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 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 study 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)

The Oracle Clinical term for a CRF. A DCI is composed of one or more DCMs.

See also: case report form, data collection module (DCM), CRF

data collection module (DCM)

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 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

1) A single piece of clinical data collected during a trial. In most cases, the response to a single question for a patient during a visit.

2) 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

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 Application Programming Interface system.

DCM

An acronym for data collection module (DCM).

default study

In RDC, 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 log in, 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.

discrepancy management

1. 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.

2. A subsystem of Oracle Clinical and RDC that supports managing discrepancies.

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

2) 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

(DVG) 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.

A DVG subset contains a subset of the responses of another DVG.

document

The equivalent of a CRF.

document number

A system-assigned unique identifier for a particular collected CRF.

DVG

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 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

F

focus

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, visit, or study.

G

Graphical User Interface

(GUI) 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 group**s** that allows "branching" during data entry based on the response.

For example, in a Drug Allergy question group, an indicator question could be, "Allergic to any drug?"

- If the response is "Yes", the remaining questions in the question group, such as "Drug Name" and "Type of Reaction", require responses.
- If the response is "No", the rest of the question group is not collected.

initial data entry

The step in the RDC 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.

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: discrete value group

lock

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.

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

M

mandatory response field

A response field in the question area of a 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.

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 the action of a validation procedure on 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

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. In RDC, 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. In Oracle Clinical, the Batch Validation process runs all validation procedures.

See also: discrepancy, discrepancy management, manual discrepancy

N

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 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 group

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 group 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

pass 1 complete

A data entry status that assigned to CRFs that originate in the Oracle Clinical data entry system. It indicates that the first pass is complete.

pass 1 started

A data entry status that assigned to CRFs that originate in the Oracle Clinical data entry system. It indicates that at least one response field has been recorded in the first pass.

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) includes all study data for a single patient in a PDF document.

patient ID

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.

patient list

The set of patients with at least one CRF that satisfies the search criteria.

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 attibute 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.

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.

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 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 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 group

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 group

A question group that is collected more than once in the same CRF section (or Oracle Clinical DCM).

In some cases each data point is preceded by a prompt that distinguishes the response required from the other questions in the group, which are often displayed on subsequent rows. For example, a question group may collect findings for several organs. The prompt in each row is automatically populated to identify one organ, and the data point field collects the finding for that organ. The organ names are defined as Default Repeat Values in Oracle Clinical.

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 resolves the discrepancy and 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

scope

In the RDC Activity List window, a category or classification of a set of tasks: study, site, or 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.

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) (DCM).

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.

See also: discrepancy, CRF section

session

The period that starts when a single user successfully logs in to an application and ends when the user exits the application. In RDC, it is also referred to as an **RDC session**.

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 CRF has multiple sections). Discrepancies are listed 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 time stamp, 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**

T

test mode

A method of using RDC during study design, prior to the initiation of the protocol. Under normal circumstances, RDC runs in Production mode. Test 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.

time stamp

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

univariate discrepancy

A discrepancy that is dependent on the value of a single data point. This type of discrepancy usually occurs when the value recorded for a response does not meet criteria defined by the study sponsor.

See also: discrepancy, discrepancy management, manual discrepancy, multivariate discrepancy

unlock

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 that 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.

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 several 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.

V

validation

An action that entails the initiation and processing of sponsor-defined procedures, or edit checks, on multiple data points, or other checks on a single data point, that returns a discrepancy for each data point that does not meet the defined criteria. 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

In RDC, a designation that describes if a CRF has been verified, including: not verified, verified, awaiting re-verification, 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

1) Check a data point or CRF against the collected source data.

2) 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 in one or more CRFs, which at some point is recorded and saved to the study database.

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