Oracle® Clinical Development Analytics

User and Administrator Guide

Release 2.0.0.2

E18162-03

February 2011

ORACLE®

Oracle Clinical Development Analytics User and Administrator Guide, Release 2.0.0.2

E18162-03

Contents

5 Extract Transform Load Programs

6 Implementing Security

Preface

This guide provides information about how to use Oracle Clinical Development Analytics (OCDA).

This preface contains the following topics:

Audience

The first and second chapters of this guide are intended for the following job classifications:

- Clinical Program/Study Manager, Clinical Data Manager, Clinical Research Associate, Clinical Data Entry Manager, Site Personnel, and Executive Management.

The other chapters in this guide are intended for the following job classifications:

- Data Warehouse Administrators, ETL Developers and Operators
- System Administrator

This guide assumes that you have the following general skills:

- Knowledge of Oracle Life Sciences Data Hub.
- Knowledge of Oracle Business Intelligence Enterprise Edition Plus.
- Knowledge of Informatica PowerCenter.
- Familiarity with Oracle Clinical.
- Familiarity with Oracle's Siebel Clinical.

Documentation Accessibility

Our goal is to make Oracle products, services, and supporting documentation accessible to all users, including users that are disabled. To that end, our documentation includes features that make information available to users of assistive

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

Accessibility of Code Examples in Documentation

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

Accessibility of Links to External Web Sites in Documentation

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

Deaf/Hard of Hearing Access to Oracle Support Services

To reach Oracle Support Services, use a telecommunications relay service (TRS) to call Oracle Support at 1.800.223.1711. An Oracle Support Services engineer will handle technical issues and provide customer support according to the Oracle service request process. Information about TRS is available at http://www.fcc.gov/cgb/consumerfacts/trs.html, and a list of phone numbers is available at http://www.fcc.gov/cgb/dro/trsphonebk.html.

Finding Information and Patches on My Oracle Support

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

Before you install and use an Oracle software release, always visit the My Oracle Support Web site for the latest information, including alerts, release notes, documentation, and patches.

Creating a My Oracle Support Account

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

To register for My Oracle Support:

1. Open a Web browser to http://support.oracle.com.
2. Click the **Register here** link to create a My Oracle Support account. The registration page opens.
3. Follow the instructions on the registration page.

Signing In to My Oracle Support

To sign in to My Oracle Support:

1. Open a Web browser to http://support.oracle.com.
2. Click **Sign In**.
3. Enter your user name and password.

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

Searching for Knowledge Articles by ID Number or Text String

The fastest way to search for product documentation, release notes, and white papers is by the article ID number.

To search by the article ID number:

1. Sign in to My Oracle Support at http://support.oracle.com.
2. Locate the Search box in the upper right corner of the My Oracle Support page.
3. Click the sources icon to the left of the search box, and then select Article ID from the list.
4. Enter the article ID number in the text box.
5. Click the magnifying glass icon to the right of the search box (or press the Enter key) to execute your search.

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

In addition to searching by article ID, you can use the following My Oracle Support tools to browse and search the knowledge base:

- Product Focus — On the Knowledge page, you can drill into a product area through the Browse Knowledge menu on the left side of the page. In the Browse any Product, By Name field, type in part of the product name, and then select the product from the list. Alternatively, you can click the arrow icon to view the complete list of Oracle products and then select your product. This option lets you focus your browsing and searching on a specific product or set of products.
- Refine Search — Once you have results from a search, use the Refine Search options on the right side of the Knowledge page to narrow your search and make the results more relevant.
- Advanced Search — You can specify one or more search criteria, such as source, exact phrase, and related product, to find knowledge articles and documentation.

Finding Patches on My Oracle Support

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

To locate and download a patch:

1. Sign in to My Oracle Support at http://support.oracle.com.
2. Click the **Patches & Updates** tab.

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

   - In the Patch ID or Number is field, enter the primary bug number of the patch you want. This option is useful if you already know the patch number.
   - To find a patch by product name, release, and platform, click the Product or Family link to enter one or more search criteria.
3. Click **Search** to execute your query. The Patch Search Results page opens.
4. Click the patch ID number. The system displays details about the patch. In addition, you can view the Read Me file before downloading the patch.

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

Finding Documentation on Oracle Technology Network

The Oracle Technology Network Web site contains links to all Oracle user and reference documentation. To find user documentation for Oracle products:

1. Go to the Oracle Technology Network at

   `http://www.oracle.com/technetwork/index.html` and log in.

2. Mouse over the Support tab, then click the **Documentation** hyperlink.

   Alternatively, go to Oracle Documentation page at

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

3. Navigate to the product you need and click the link.

   For example, scroll down to the Applications section and click Oracle Health Sciences Applications.

4. Click the link for the documentation you need.

Related Documents

For more information, see the following documents in the *Oracle Clinical Release 4.6* documentation set, the *Oracle Life Sciences Data Hub Release 2.1.3* documentation set, or the *Oracle Business Intelligence Enterprise Edition Release 10.1.3.4* documentation set:

Oracle Life Sciences Data Hub Documentation

The Oracle Life Sciences Data Hub documentation set includes:

- *Oracle Life Sciences Data Hub Implementation Guide* (Part E14368)
- *Oracle Life Sciences Data Hub System Administrator's Guide* (Part E14369)
- *Oracle Life Sciences Data Hub Application Developer's Guide* (Part E14370)
- *Oracle Life Sciences Data Hub User's Guide* (Part E14371)
- *Oracle Life Sciences Data Hub Installation Guide* (Part E14366)

Oracle Business Intelligence Enterprise Edition Documentation

The *Oracle Business Intelligence Suite Enterprise Edition Online Documentation Library* (Part E10415) documentation set includes:

- *Oracle Business Intelligence Presentation Services Administration Guide* (Part B31766)
- *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide* (Part B31767)
- *Oracle Business Intelligence Web Services Guide* (Part B31769)
- *Oracle Business Intelligence Server Administration Guide* (Part B31770)

Oracle Clinical Documentation

The *Oracle Clinical* documentation set includes:

- *Oracle Clinical Administrator's Guide* (A83791)
- *Oracle Clinical Getting Started* (B12308)

- *Interfacing from Oracle Clinical* (A83793)
- *Oracle Clinical Conducting a Study* (A85201)
- *Oracle Clinical Creating a Study* (A85200)
- *Oracle Clinical Installation Guide* (A83779)

Siebel Clinical Documentation

The *Oracle Clinical* documentation set includes:

- *Siebel Data Model Reference for Industry Applications*
- *Siebel Life Sciences Guide*

Conventions

The following text conventions are used in this document:

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

Part I

Using Oracle Clinical Development Analytics

This part of the Oracle Clinical Development Analytics User and Administrator Guide describes how to use OCDA.

Part I contains the following chapters:

1

Getting Started with Oracle Clinical Development Analytics

This chapter contains the following topics:

Overview

Oracle Clinical Development Analytics (OCDA) is an analytical and transactional reporting application based on a predefined set of key performance indicators (KPIs), facts, and dimensions with support for predefined and custom reporting. OCDA also functions as a decision support system to monitor process bottlenecks and compliance deviations.

Clinical Development Organizations require insights into the following key Clinical Data Management and Clinical Trial Operations Management business processes areas that impact clinical trial performance:

- Clinical Data Collection Management: All required data must be collected with no data omitted or wrongly entered using electronic data capture.
- Clinical Data Cleanliness Management: Each discrepancy must be resolved, either by correcting the data that gave rise to it or by changing the rules that define the discrepancy.
- Study Startup and Site Activation: All sites that are selected to recruit subjects and administer the study must be activated. Impediments to site activation must be identified and resolved.
- Subject Recruitment: Study team must monitor if the subjects are enrolling, and the rate at which they are enrolling. If required, additional sites must be identified.
- Site Monitoring Visits: All internal standard operating procedures must be met and all required data relevant to subject visits must be collected properly and on time.

OCDA provides mechanisms to gain operational and clinical insights to and evaluate performance of your clinical trials, and take corrective action to reduce cycle times.

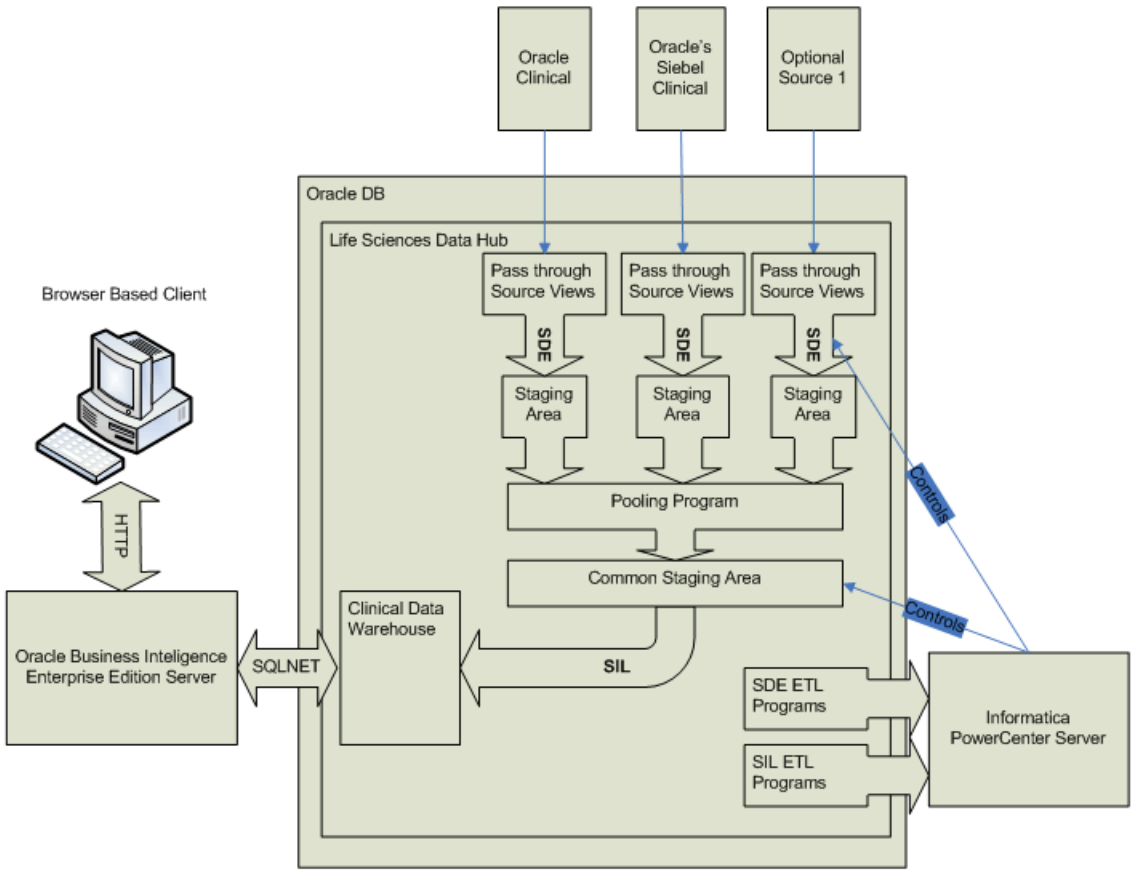
What Can I Do Using Oracle Clinical Development Analytics?

OCDA integrates clinical trial performance data from Oracle Clinical, Oracle's Siebel Clinical, and additional sources where appropriate, into a predefined data warehouse schema and generates both predefined and custom reports of key metrics across the clinical development spectrum. OCDA lets you perform the following functions:

- Extract all necessary clinical trial data from Oracle Clinical and Siebel Clinical into a predefined data warehouse, for viewing through the rich dashboard and report interface of Oracle Business Intelligence Enterprise Edition Plus (OBIEE).
- Extract such data from other database sources as well, subject to the development of separate Extract Transform Load (ETL) programs for each database source.
- View predefined analytical reports delivered with the application.
- Rapidly create new reports using the extensive predefined cycle time, quality and volume based metrics across data management and clinical operations processes.

Architecture

Figure 1–1 The Oracle Clinical Development Analytics Architecture



The OCDA architecture includes the following principal components:

- A predefined Intelligence application, based on Oracle Business Intelligence Enterprise Edition Plus (OBIEE), including Oracle BI Presentation Services, and a predefined set of Oracle BI reports, accessible through prebuilt interactive dashboards.
- A prebuilt clinical data warehouse schema, designed to drive both predefined and custom intelligence reports.
- Informatica PowerCenter based Extract Transform Load (ETL) programs, designed to extract clinical trial transactional data from Oracle Clinical and Siebel Clinical databases into the data warehouse schema.
- A predefined presentation catalog including a unique mix of clinical measures (facts, dimensions), populated by the data warehouse schema.
- Oracle Life Sciences Data Hub (LSH), including the following functions and features:
  - Hosts the data warehouse.
  - Provides security and versioning for changes to programs and data structure used by OCDA, ensuring regulatory compliance.
  - Integrates with Informatica PowerCenter to let you maintain, schedule, and execute the transformations that keep the data warehouse populated with clinical trial transactional data.
  - Integrates with OBIEE to enable the visualization of all data in the data warehouse. The OBIEE repository file (RPD), which contains the transformational metadata for presentation purposes, is version controlled within LSH.

Reporting

OCDA provides reports for the following key functional areas:

- Clinical Data Collection Management: Reports on the data management workload and the rates at which work is progressing to provide insights to help minimize time to data lock.
- Clinical Data Cleanliness Management: Cleanliness reports track the discrepancy-resolution workload, rates of progress, durations in various statuses, and provide drill-down detail.
- Study Startup and Site Activation: Reports on sites that have not been activated and where they are in the process provide insight to help meet the recruitment goals.
- Subject Recruitment: Reports on subject enrollment helps evaluate if additional sites are needed or if protocol amendment is necessary.
- Site Monitoring Visits: Reports analyzing key metrics across the clinical monitoring process helps maintain compliance with internal standard operating procedures.

See Also:

- Chapter 2, Using Oracle Clinical Development Analytics
- Chapter 3, Working with Reports
- Appendix A, Dashboards and Reports

Regulatory Compliance

OCDA is designed as a single data-warehousing platform that facilitates integration of both non-regulated and regulated data. This single platform provides secure access to authorized users. It provides reduced total cost of ownership through reduced data integration costs and infrastructure maintenance costs, compared with multiple warehousing solutions.

The primary regulatory requirements include: (i) data tracking and (ii) Extract Transform Load (ETL) Version Management.

Tracking Data

The origin of any data displayed in a report must be traceable to its source, and all transformations applied to the data must be accessible. Data sourced from Oracle Clinical and Siebel Clinical is traced by the following criteria and rules:

- Load: When the data was loaded from the source database into the staging tables.
- Staging Mapping: The version of ETL mapping used to transform the data from source to staging table, and when it was executed.
- Target Mapping: The version of ETL mapping used to transform the data from the staging table to target tables, and when it was executed.
- Transformations and calculations performed on the data within the OBIEE Repository are versioned and saved permanently in Oracle LSH.
- Calculations can also be performed in reports managed through OBIEE Answers. The OBIEE Answers Administrator is responsible for controlling what calculations are performed, and who can perform them.

Managing ETL Versions

Every time a new version of an ETL mapping is created, the previous version is saved and stored as a historical record of previous transformations. The new version is identified with a version number and creation date, and is executed as the current version. Oracle LSH records each execution of the ETL, and retains version and execution timestamp.

Security

Data within the data warehouse is secure from updates by unauthorized personnel, and can only be updated through controlled execution of ETL mappings.

The ability to modify ETL routines is restricted to a user group or role of ETL developers. Access to execute ETL routines is restricted to a specific privilege, which can be granted to a user group or role.

In addition, access to data is available for authorized personnel only constrained through user groups or roles.

See Also:

Chapter 6, Implementing Security

2

Using Oracle Clinical Development Analytics

This chapter contains the following topics:

> **Note:** The appearance of the user interface that you see in the application may vary from the figures displayed in the subsequent sections.

See Also:

Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide

For ease of reference, the subsequent sections contain excerpts from *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide*, altered to include specific information related to OCDA.

Overview

OCDA includes dashboards, reports, and metrics that let you view relevant, interactive information—current as at the last date the data warehouse was refreshed.

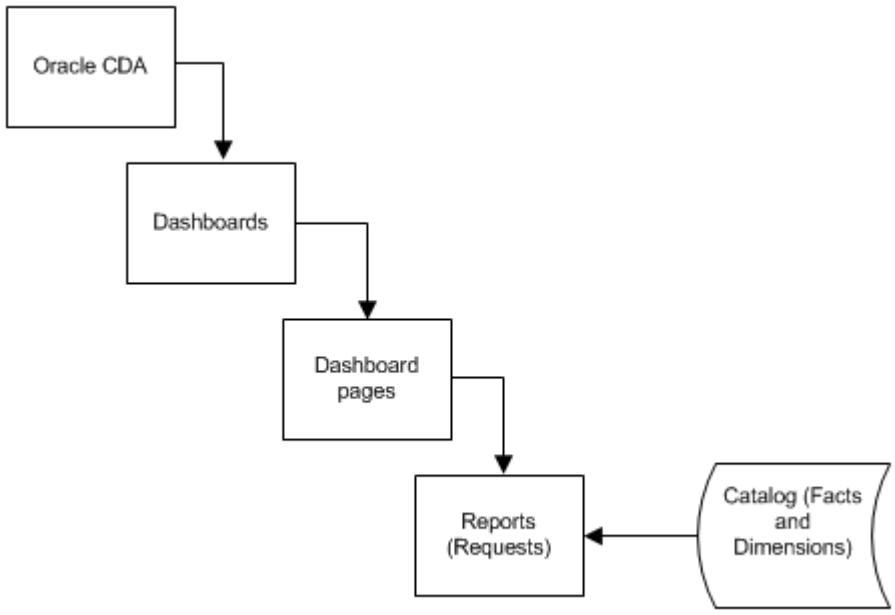
Dashboards are access points for information. Each dashboard is designed for a specific job responsibility. For example, a data manager can access only the DM EDC and DM Paper dashboards.

When you access a dashboard, the information displayed changes based on your security privileges. For example, a Data Manager for Study 101 may (at the discretion of the OCDA Administrator) be restricted to seeing reports only on the status of data processing for Study 101, while Project Managers can see data processing information across all studies in their respective project.

A dashboard contains one or more related dashboard *pages*. A dashboard page contains a series of related *reports* (also called *requests*). A report can contain a tabular report, pivot table, or graph. You can drill down to detailed report by clicking the

linked data. You can also filter the data that you see in reports using a set of *parameters* (called *filters*). Figure 2-1 displays the report hierarchy.

Figure 2–1 The Report Hierarchy



In addition to the dashboards and reports that are packaged with OCDA, you can also create and manage reports or dashboards if you have appropriate permissions. Use Oracle BI Answers to manage reports.

OBIEE includes additional applications that are not directly used by OCDA. These include Oracle BI Delivers and Oracle BI Publisher. These applications extend the usefulness of the information provided by OCDA.

Use Oracle BI Delivers to detect specific analytic results and notify appropriate user or group about the result. Use Oracle BI Publisher to create formatted and printable reports.

See Also:

- Chapter 3, Working with Reports for more information about creating and managing reports.
- Appendix B, Oracle Clinical Development Analytics Presentation Catalog for more information about the columns in OCDA that you can use to create and modify reports.
- *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide*.

Accessing Oracle Clinical Development Analytics

Your security privileges determine what reports you can see and what you can do in OCDA. To log in to OCDA, you must have a browser on your computer and a URL, username, and password provided by your company.

Logging In

1. Open your browser and enter the URL provided by your company.

   Typically, the URL to access the dashboards will be

   `http://<system_name_or_ip_address>:<port_number>/analytics/saw.dll?Dashboard`

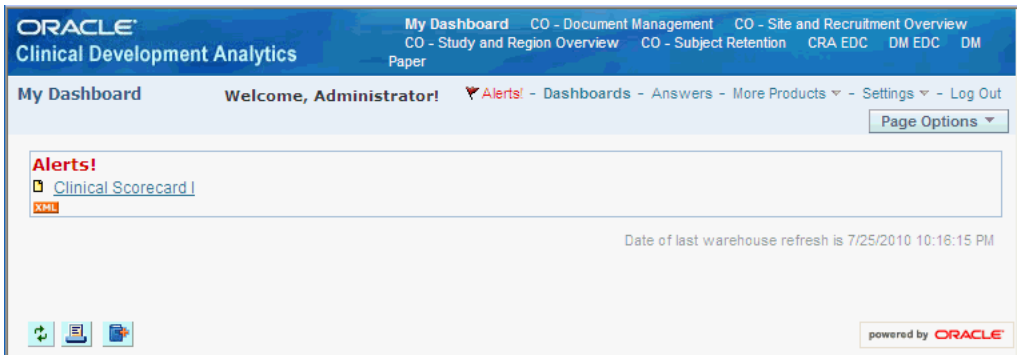
   Figure 2-2 displays the OCDA login page.

Figure 2–2 Oracle Clinical Development Analytics Login Page

2. Enter your user ID and password.
3. Click **Login**.

   After your login credentials are authenticated, your default dashboard page is displayed (as shown in Figure 2-3).

Figure 2–3 Sample Dashboard of an Administrator



Viewing a Dashboard

Perform the following steps to view a dashboard:

1. Log in to OCDA.

2. Select a dashboard.

Using Oracle Business Intelligence

Clinical organizations track and store large amount of clinical trial data. After the data has been organized and analyzed, it can provide an organization with the metrics to measure the state of a clinical trial. Oracle BI helps end users obtain, view, and analyze the data.

Oracle Business Intelligence Presentation Services Components

From an end-user perspective, Oracle BI Presentation Services consists of the following interfaces:

Oracle Business Intelligence Answers

Oracle BI Answers provides answers to business questions. This interface allows users with the appropriate permissions to build and modify reports, also called as *requests*, that let end users explore and interact with information, and present and visualize information using charts, pivot tables, and reports.

The results of an Oracle BI Answers request can be formatted, saved, organized, and shared with others. A report can be configured to refresh results in real-time.

Reports created with Oracle BI Answers can be saved in the Oracle BI Presentation Catalog and integrated into OCDA home page or dashboards. Results can be enhanced through options such as charting, result layout, calculation, and drill down features.

See Also:

Appendix B, Oracle Clinical Development Analytics Presentation Catalog

Oracle Business Intelligence Interactive Dashboards

Interactive Dashboards provide points of access for analytics information. When an end user accesses OCDA, the user's default dashboard is the first page that appears. Dashboards are used to display reports that contain content specific to the needs of individual users or groups. Historical and current data sources can be merged into a single dashboard.

Users with the appropriate permissions can place results from Oracle BI Answers into dashboards for use by end users.

Oracle Business Intelligence Delivers

Oracle BI Delivers is the interface used to create Oracle Business Intelligence Alerts based on analytics results. Specific results can be detected within reports and the appropriate people notified immediately through Web, wireless, and mobile communications channels.

Oracle BI Delivers uses intelligence bots called iBots to detect specific results. iBots are software-based agents, driven by schedules or events that can access, filter, and perform analytics on data based on specified criteria.

Users with the appropriate permissions can use Oracle BI Delivers to set up the conditions to trigger an alert.

Note: OCDA does not directly use Oracle BI Delivers. You can use this feature to extend the usefulness of the information that OCDA provides.

Performing Common Tasks in Oracle Business Intelligence

This section explains how to perform the following common tasks in Oracle BI:

- Exiting from Oracle Business Intelligence
- Viewing Descriptions of Oracle BI Dashboards and Saved Requests
- Using Online Help
- Printing an Oracle BI Dashboard or Saved Request
- Emailing an Oracle BI Dashboard Page or Request
- Downloading Oracle BI Results
- Refreshing an Oracle BI Interactive Dashboard or Oracle BI Request
- Refreshing Information in the Oracle BI Selection Pane

Exiting from Oracle Business Intelligence

Do not close the browser window to exit from Oracle BI. Perform the following step:

1. From any OCDA screen, click the **Log Out** link.

Viewing Descriptions of Oracle BI Dashboards and Saved Requests

Report and dashboard designers can supply a description when saving a dashboard or request in the Oracle BI Presentation Catalog. If no description is supplied, the description defaults to the name of the dashboard or saved request.

To view the description of a saved request:

1. Pause the cursor over the title of the saved request in the selection pane in Oracle BI Answers.

To view the description of a dashboard:

1. Pause the cursor over the name of the dashboard in Oracle BI Interactive Dashboards.

To view the description of a dashboard page:

1. Pause the cursor over the page tab.

Using Online Help

Oracle Business Intelligence includes OCDA-specific online help for both dashboards and reports.

Dashboard pages include hyperlinks to (i) the master OCDA online help page, from which you can navigate throughout the help system, and (ii) topic-specific help pages for the selected dashboard.

Report pages include hyperlinks to topic-specific help for the selected report. Table 2-1 summarizes the available help links:

Table 2–1 Accessing Online Help

Click...	on...	to access...
OCDA Help	each dashboard page	master OCDA online help page.
CO - Document Management Reference	each page within this dashboard	specific help for this dashboard.
CO - Site and Recruitment Overview Reference	each page within this dashboard	specific help for this dashboard.
CO - Study and Region Overview Reference	each page within this dashboard	specific help for this dashboard.
CO - Subject Retention Reference	each page within this dashboard	specific help for this dashboard.
CRA EDC Reference	each page within this dashboard	specific help for this dashboard.
DM EDC Reference	each page within this dashboard	specific help for this dashboard.
DM paper Reference	each page within this dashboard	specific help for this dashboard.
?	each report title bar	specific help for selected report.

Online help opens in a new browser window. You can scroll down the help page or use hyperlinks to navigate to other topics.

Note that you can use the following icon to view the OCDA release version:

About OCDA

Printing an Oracle BI Dashboard or Saved Request

You can display printer-friendly versions of existing dashboards and requests. A printer-friendly version does not contain any extraneous links or other hypertext items.

You can print using HTML or Adobe PDF (Portable Document Format). Adobe PDF is the only print option available for Oracle BI Publisher reports. Adobe Reader 6.0 or greater is required to print using Adobe PDF.

Note: The HTML method of printing relies on the print handling capabilities of your browser. If you do not get the results you want, choose PDF to open, and then print the dashboard or request.

To print a dashboard or a request:

1. Navigate to an existing dashboard or request.
2. To print a request, click the **Print** link, and then choose **HTML** or **PDF**.

   To print a dashboard page, click the following icon at the bottom of the dashboard, and choose HTML or PDF:

   - For HTML, a new window shows the selected item without the extraneous links. Choose **File > Print** on the browser menu.
   - For PDF, use the options available in the Adobe PDF window to save or print the file.

Emailing an Oracle BI Dashboard Page or Request

You can email a dashboard page or a request as an attachment. The format you use depends on your browser, such as Web Archive, Single File (.mht) in Internet Explorer or Mozilla Archive Format (.maf) in Mozilla and Firefox.

Note: The Mozilla Archive Format capability is available as a separately downloaded plug-in.

In any browser, you can also save a dashboard page or request as a collection of HTML files. You can then zip and email the corresponding directory of associated files.

To email a dashboard page or request:

1. Navigate to the dashboard page or request that you want to send.
2. To email a request, click the **Print** link, and then choose **HTML** or **PDF**. To email a dashboard page, locate and click the Print icon at the bottom of the dashboard, and then choose HTML or PDF.

   A new browser window opens that contains the dashboard page or the request.
3. From the browser's toolbar, choose **File > Save As**.
4. Save the file to the desired location, with the appropriate file type for your browser.
5. Send the saved attachment using an email application.

Note: The saved attachments can also be used as a means to archive and restore requests as they exist at a particular point in time.

Downloading Oracle BI Results

Oracle BI provides options for downloading results. These appear in Oracle BI Answers as options for the Download link. The Download link can also appear with a request in a dashboard.

- **Download to Excel**

  This option makes the request results available to Microsoft Excel or Microsoft Excel 2000 in HTML format, including tables or charts that appear with the results. It also includes any other views included in the report. Excel controls the positioning of the HTML.

- **Download Data**

  This option downloads results as a tab-separated list of values. The file will have a .csv extension to facilitate opening it in Excel. After downloading a request in tab-delimited format, you can use a third-party application to display the data.

- **Download Web Page (MHTML)**

  This option downloads results as a Web page. This allows you to download the underlying data for an existing request as a Web page (MHTML) file.

To download results in Microsoft Excel format:

1. Navigate to the request.
2. Click the **Download** link and choose either **Download to Excel** or **Download to Excel 2000**.

   The File Download dialog box appears.
3. Save the file to the desired location, or open it in Excel.
4. If desired, use Excel to refine the formatted results.

   See Also:

   Microsoft Excel documentation for more information.

To download results as a tab-separated list of values:

1. Navigate to the request.
2. Click the **Download** link and choose **Download Data**.
3. Save the file on your hard drive.

To download results as a Web page:

1. Navigate to the request.
2. Click the **Download** link and choose **Download Web Page (MHTML)**.

   The File Download dialog box appears.
3. Save the file on your hard drive.

Refreshing an Oracle BI Interactive Dashboard or Oracle BI Request

When executing an Oracle BI Interactive Dashboard or a request, Oracle BI uses temporary storage areas, called *caches*, to save frequently accessed or recently accessed results. Storing certain results in cache helps to improve Oracle BI performance. You can use the Refresh feature to make sure that your request bypasses saved information in the Oracle BI Presentation Services cache, and is issued to the Oracle Business Intelligence Server for processing.

Note: The Oracle BI Server maintains its own cache. This cache is separate from the Oracle BI Presentation Services cache.

When you select a specific dashboard or request, Oracle BI Presentation Services checks its cache to determine if the identical results have recently been requested. If so, Oracle BI Presentation Services returns the most recent results, thereby avoiding unnecessary processing by the Oracle BI Server and the back-end database. If not, the request is issued to the Oracle BI Server for processing.

If the Oracle BI Server has cached results that can satisfy your request, the results are returned from that cache. If not, Oracle BI Server issues the request to the back-end database. You cannot force your request past the Oracle BI Server's cache.

Oracle BI administrators can configure cache settings for Oracle BI Presentation Services that control what is cached and for how long. For more information, refer to *Oracle Business Intelligence Presentation Services Administration Guide*. For information about the Oracle BI Server cache, refer to *Oracle Business Intelligence Server Administration Guide*.

To refresh a dashboard or request:

1. Navigate to an existing dashboard or request.
2. To refresh a request, click the **Refresh** link. To refresh a dashboard, click **Refresh**.

Refreshing Information in the Oracle BI Selection Pane

The Oracle BI selection pane appears in Oracle BI Answers. When changes have been made to the saved content or to the Oracle BI Server metadata, you can refresh the display to access the most current information.

Note: The information available in the selection pane is determined by your permissions and responsibilities.

To refresh the information in the selection pane:

- To refresh the information for saved requests, filters, briefing books, and dashboard content, click the **Refresh Display** link at the bottom of the selection pane.
- To refresh the view of the Oracle BI Server metadata for subject areas, click the **Reload Server Metadata** link at the bottom of the selection pane.

Navigating in Oracle Business Intelligence

This section explains basic navigation within Oracle BI.

What is Available to You After Accessing Oracle BI?

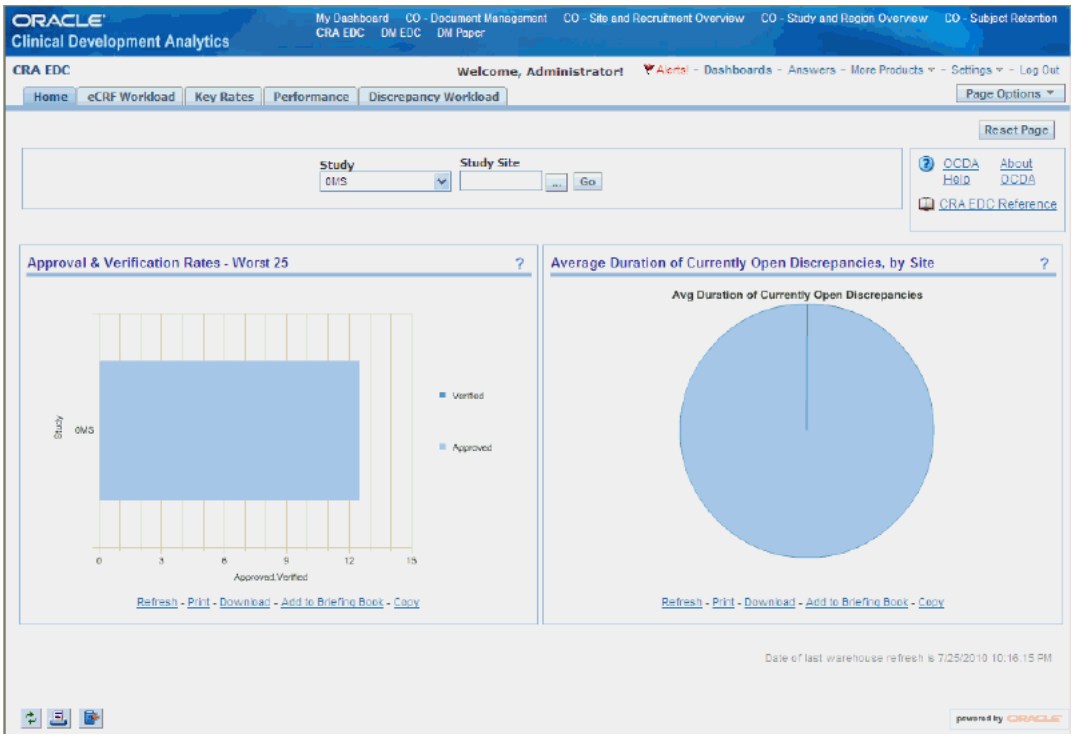
When you access Oracle BI, the first screen that is displayed is your personal dashboard, named My Dashboard, or a dashboard for your job function. Dashboards typically contain reports and other information for your area of responsibility.

See Also:

Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide (Using Oracle BI Interactive Dashboards), for more information about dashboards.

Figure 2-4 shows an example dashboard page. You can change some aspects of the appearance of the dashboard page based on your personal preferences.

Figure 2–4 Sample Dashboard Page



Using Oracle BI Feature Links

The links that provide access to Oracle BI functions are located near the top of the page, if you have permissions to access those links. You can access other links as views, such as Dashboards, Answers, Delivers, Alerts, Administration, and My Account. The views that you can access are determined by your role and responsibilities.

Table 2-1 describes some of the Oracle BI feature links.

Table 2–2 Oracle BI Feature Links

Link	Description
Alerts!	Accesses the Active Alerts page, from which you can view and manage your active alerts. This link appears only if you have active alerts.
Dashboards	Accesses the Interactive Dashboard page, from which you can view the dashboards to which you have access.
Answers	Accesses Oracle BI Answers, from which you can view, create, and manage requests.
More Products	Accesses Oracle BI Publisher, Delivers, Marketing, and Disconnected Analytics.
Settings/MyAccount	The Settings link accesses the Oracle BI Presentation Services Administration page, the Act As page, and the My Account page. The My Account page enables you to view general account information and set your preferences for the Oracle BI application.

Table 2–2 (Cont.) Oracle BI Feature Links

Link	Description
Log Out	Used to log out of Oracle BI. Always use this link to log out of Oracle BI.

Working with Oracle BI Pages

Oracle BI is organized into pages. Pages have two components:

- **Panes:** Oracle BI Answers pages display a left and a right pane. The left pane is the selection pane, used to navigate to, select, and manage saved information. The right pane is used to display and work with the content selected in the left pane.
- **Tabs:** Tabs provide access to other pages related to the current page. The tabs appear in the top part of the page. The list of available tabs depends on which page you select.

Oracle BI feature links are used to access these pages. Each feature link provides access to a specific feature or topic. Pages can contain other organization and navigation elements, such as tabs, areas, and panes. For more information about feature links, refer to Using Oracle BI Feature Links on page 2-10.

Drilling Down in Oracle BI

Many of the results that appear in Oracle BI represent hierarchical data structures. Oracle BI metadata specifies these hierarchies, and this allows you to access the different levels of detail within them. You can drill down to an actual item in the database.

Sorting Columns in Tables in Oracle BI

In a dashboard, the column headers of tables that can be sorted have a slightly raised visual appearance. You can click a column header to sort it.

Using the Oracle BI My Account Page

From the My Account page in Oracle BI, you can perform the following actions:

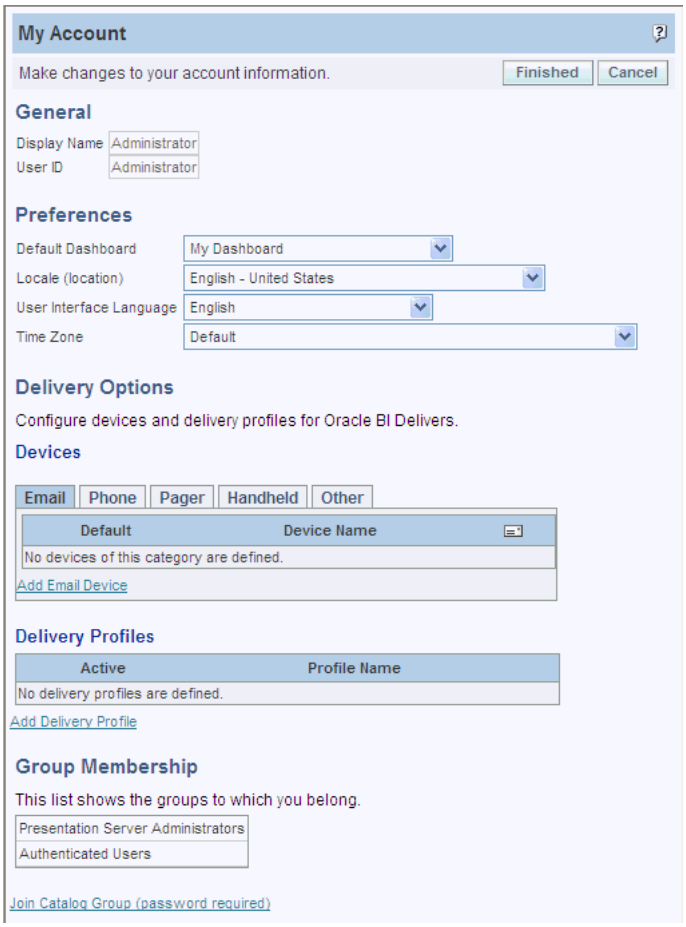
- View general account information, such as your display name and user ID.
- View and modify your preferences.
- Set your time zone.
- View and modify your delivery options for Oracle BI Delivers iBots.
- View a list of users who can access your reports and dashboards. Depending on your privilege settings, not all of these options may be available.

To display your account settings:

1. Log in to OCDA.
2. Click **Settings** (if available), and the **My Account** link. Your My Account page appears.

   Your My Account page appears as displayed in Figure 2-5.

Figure 2–5 Sample My Account Page



Setting Your Oracle BI Preferences

You can access the Preferences section of the My Account page to specify preferences such as a default dashboard, your locale, and a language in which to view the user interface screens.

To change your preferences:

1. Log in to OCDA.
2. Click **Settings** (if available), and the **My Account** link.
3. In the Preferences section, perform one of the following actions:
   - In Default Dashboard, select the dashboard you want to display when you log in to Oracle BI.
   - In Locale, select the locale that you want to use for this session.
   - In User Interface Language, select the language in which you want Oracle BI to appear.

Setting Your Oracle BI Time Zone

You can use the time zone option to choose your Oracle BI account's preferred time zone. This option allows system users who do not reside in the same physical location to override the default time zone that was set by the system administrator. For

example, the Oracle BI server that sends you alerts resides in the US Pacific time zone, but your work location is in the US Central time zone. After you set the Central time zone as your preferred time zone setting, the delivered time on your alerts appears in Central time.

Your account's time zone will automatically apply to any items that you create, modify, run, receive, and print.

The date and time columns included in reports appear according to the report designer's specifications. The report designer can force a specific time zone to appear in the column, or allow the user's default time zone to appear in the column. A clock icon will appear in the column heading, and when you mouse over this icon, the name of the time zone used in the column is displayed.

See Also:

Oracle Business Intelligence Presentation Services Administration Guide, for more information on how the administrator sets the Oracle BI Presentation Server's time zone.

To change your time zone preference:

1. Log in to OCDA.
2. Click **Settings** (if available), and the **My Account** link.
3. In the preference section, select a time zone from Time Zone.
4. Click **Finished**.

3

Working with Reports

Using Oracle BI Answers, you can run or display predefined reports (delivered with OCDA), and you can also create or modify custom reports.

This chapter contains the following topics:

See Also:

Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide

For ease of reference, the subsequent sections contain excerpts from *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide*, altered to include specific information related to OCDA.

Predefined Reports

OCDA is delivered with 50 predefined reports. A subset of these reports is displayed on your dashboard pages based on the user group you are assigned to.

A report can contain data in a tabular format, pivot table, or graph. You can filter the data visible on the report based on certain criteria such as Program, Study, and Study-site. These filters are called *prompts*. Some reports let you drill down to a more detailed report.

Following are some of the report-related tasks that you can perform:

- Create and modify reports.
- Refresh the results.
- Print and Save reports.
- Add reports to the briefing book.
- Copy reports.

See Also:

- Chapter 2, Using Oracle Clinical Development Analytics for more information about report-related tasks.

- Appendix A, Dashboards and Reports for more information about predefined reports.
- *Oracle Clinical Development Analytics Installation Guide* for instruction on installing OCDA.
- *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide*

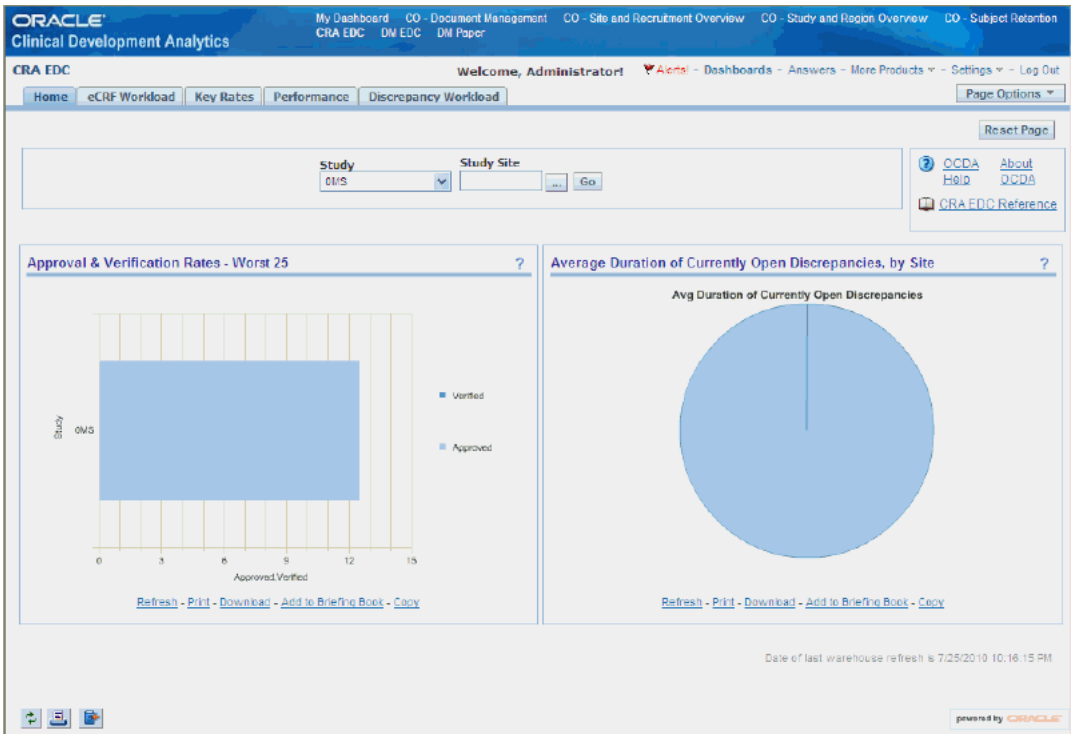
Viewing a Predefined Report

Perform the following steps to view a predefined report:

1. Log in to OCDA.
2. At the top of the dashboard, select the dashboard page that contains the report you want to view.

   Figure 3-1 displays the CRA EDC dashboard of an administrator.

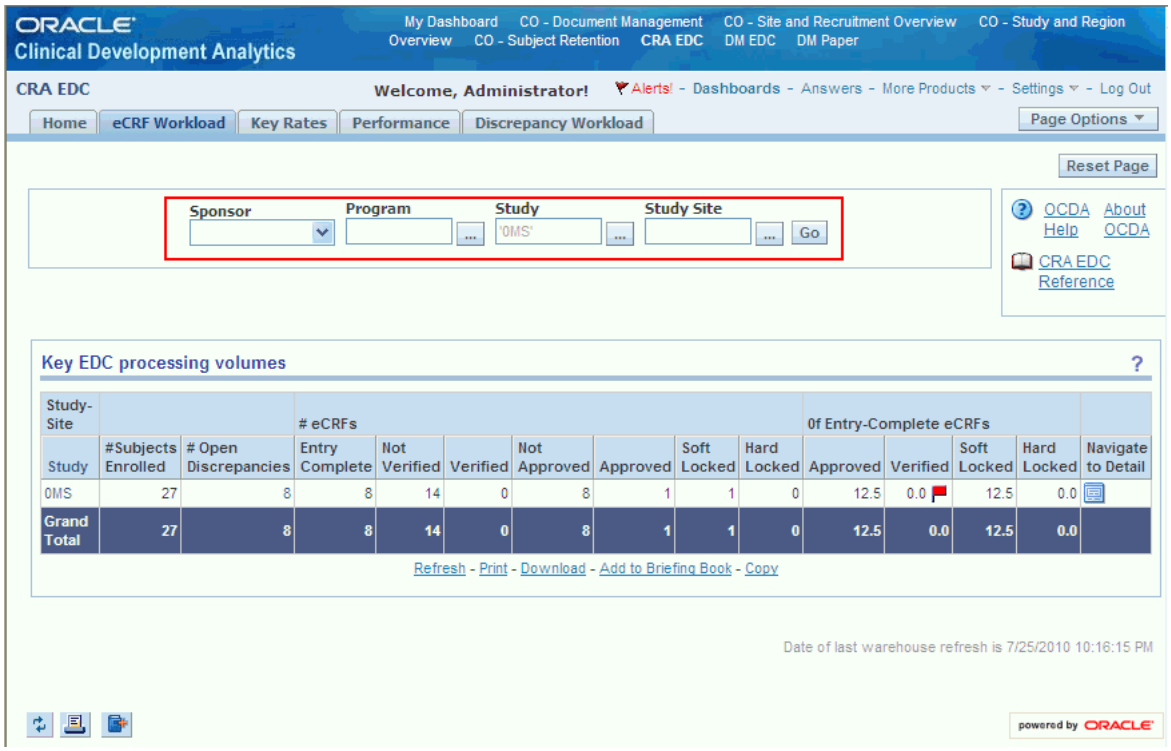
Figure 3–1 The CRA EDC Dashboard



Note: Every predefined dashboard page displays the ETL Refresh Date at the bottom of the page. This date indicates the date when the data warehouse was last refreshed.

Parameters are displayed if you can filter the reports. Figure 3-2 displays the parameters in the eCRF Workload page.

Figure 3–2 Parameters Displayed in the eCRF Workload Page of the CRA EDC Dashboard



3. To filter the report based on selected criteria:
    1. Select the value from the parameters displayed.
    2. Click **Go**.

See Also:

Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide

Custom Reports

You can create a custom report if you have been assigned the required permissions and responsibilities. If you prefer, you can copy a pre-defined report and use it as a template for the new report.

Use the Oracle BI Answers user interface to create your own report. But before you proceed, consider the following points:

- Do not modify a predefined report. If you do, your changes will be overwritten when a new release of OCDA is installed. Alternatively, you can make a copy, and modify the copy.
- Define a Catalog Folder hierarchy that gives each Answers user a unique folder tree. Limit the right to move requests into public folders to members of the OCDA Administrators group.
- Limit the right to place requests onto shared dashboards to members of the OCDA Administrators group.

Action Links

An action link is a link to an action that you can embed in a request that, when clicked, runs an associated action. For more information, refer to *Oracle Business Intelligence Presentation Services Administration Guide*.

You can create action links for the following objects of OCDA 2.0.0.1:

- AD05-19 Investigator Action Link
- AD07-09 Product Action Link
- AD08-06 Site Action Link
- AD09-15 Study Action Link
- AD10-39 Study-Site Action Link
- AD14-08 Team Member Action Link
- AD15-19 Contact Action Link
- AD16-04 Program Action Link
- AD17-04 Region Action Link
- TD01-30 Subject Action Link

Viewing Reports With Your Apple iPhone

You can use Oracle Business Indicators to view both custom and predefined reports on your Apple iPhone. Refer to the *Oracle Business Indicator Configuration and User Guide*, for further information about product licensing, setup, and reporting options.

About Oracle BI Answers

Oracle BI Answers provides answers to business questions. It allows you to explore and interact with information, and present and visualize information using charts, pivot tables, and reports. You can save, organize, and share the results.

Requests that you create with Oracle BI Answers can be saved in the Oracle BI Presentation Catalog and integrated into any Oracle BI home page or dashboard. Results can be enhanced through charting, result layout, calculation, and drill down features.

Definitions and summary information about features in Oracle BI Answers appear on each page. When more information is available that will not fit on the page, a Help icon appears. Click the icon to see more detailed information.

Table 3-1 provides definitions for common terms in Oracle BI Answers.

Table 3–1 Common Terms Used in Oracle BI Answers and Their Definition

Term	Definition
Column	Columns indicate the columns of data that your request will return. Together with filters, they determine what your results will contain. To run a request, you need to specify at least one column to return.
Criteria	Request criteria consists of the columns and filters you specify for a request.

Table 3–1 (Cont.) Common Terms Used in Oracle BI Answers and Their Definition

Term	Definition
Dashboard	A dashboard is made up of sections of information that can contain items such as results from Oracle BI Answers, external Web content, HTML text, graphics, links to other sites, embedded objects such as requests, and so on. Dashboard content is organized into pages. The pages appear as tabs across the top of the screen in Oracle BI Interactive Dashboards.
Dashboard Prompt	A dashboard prompt is a special dashboard filter object that affects all content on a particular dashboard page, and potentially the content on additional dashboard pages. For more information, refer to *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Using Prompts to Simplify Filtering in an Oracle BI Request)*.
Filter	A filter is a mechanism that restricts the result see. Together with columns, filters determine what your results will contain.
Folder	A folder is an organizational construct that holds any kind of content you want to see in your dashboard, including requests created with Oracle BI Answers. A folder is similar to an operating system directory or subdirectory, or a Microsoft Windows folder.
Query	A query is the underlying SQL issued to the Oracle BI Server. You do not have to know a query language to use Oracle BI Answers.
Results	Results are the output returned from the Oracle BI Server for the request criteria you specified. The Oracle BI Presentation Services formats the data for presentation to you.
`SELECT` statement	Oracle BI Answers uses a modified form of the SELECT statement from Structured Query Language (SQL). Oracle BI Answers sends your request criteria in the form of logical SQL to the Analytics Server. The server then generates one or more requests for data, or queries, against one or more data sources. When the server gets the raw data back, it is in the form of tables that contain rows and columns. The server merges the data from multiple sources, and when necessary, applies any additional calculations or filters that pertain to the results. The server then sends the results back to Oracle BI Answers
Subject Area	Oracle BI presents data in subject areas. A subject area contains columns that represent information about the areas of your organization's business, or about groups of users within your organization. Subject areas have names that correspond to the types of information they contain. Columns also have names that indicate the types of information they contain.
Presentation Catalog	The Oracle BI Presentation Catalog stores content created with Oracle BI Answers and Oracle BI Interactive Dashboards. Content can be organized into folders that are either shared or personal. Types of content that can be stored in the Presentation Catalog include requests created with Oracle BI Answers, HTML content, and links to other images, documents, and sites. For more information on the Presentation Catalog delivered with OCDA, refer to Appendix B, Oracle Clinical Development Analytics Presentation Catalog.

Example of an Oracle BI Answers Start Page

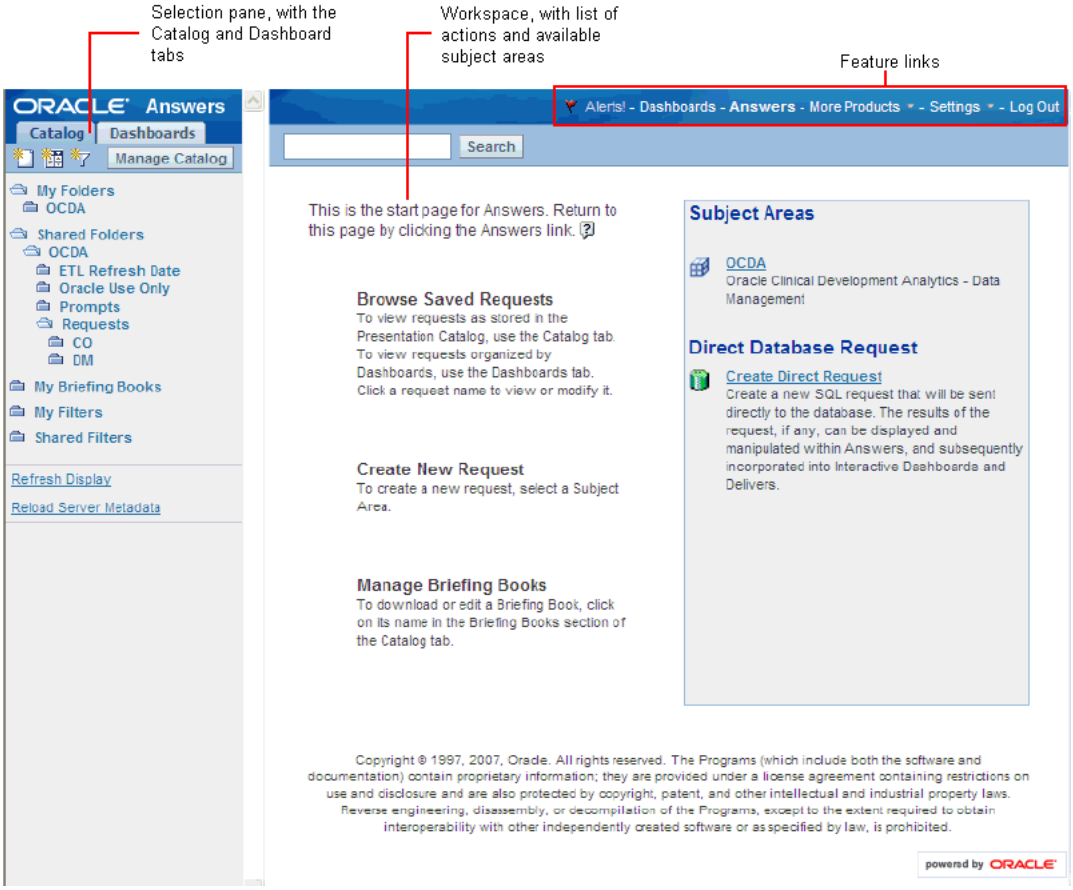
Figure 3-3 shows an example of an Oracle BI Answers start page. This is the first Oracle BI Answers page you see when you click the **Answers** link.

The Oracle BI Answers start page contains two panes. The selection pane on the left contains the Catalog and Dashboard tabs that you use to select items to work with. The workspace on the right contains a list of the actions you can perform and the

subject areas that are available to you. The feature links listed at the top of the workspace provide access to Oracle BI functions.

Note: Files in the *Oracle Use Only* folder are intended for use by Oracle only, during development and testing. Users should not use objects (requests, prompts, or filters) found in this folder as the basis for developing objects of their own.

Figure 3–3 Oracle BI Answers Start Page



See Also:

Appendix B, Oracle Clinical Development Analytics Presentation Catalog

Using Oracle BI Answers to Create, Modify, and Save Requests

This section contains information about working with requests in Oracle BI Answers.

Important: To ensure that the request you create is not overwritten when you install a new release of OCDA, you must save it in a custom directory.

Accessing Subject Areas and Requests Using the Oracle BI Answers Start Page

The Oracle BI Answers start page provides access to subject areas and saved requests.

Note: What you see in Oracle BI Answers depends on the permissions granted to your user ID, so you may not see everything that is described in this section.

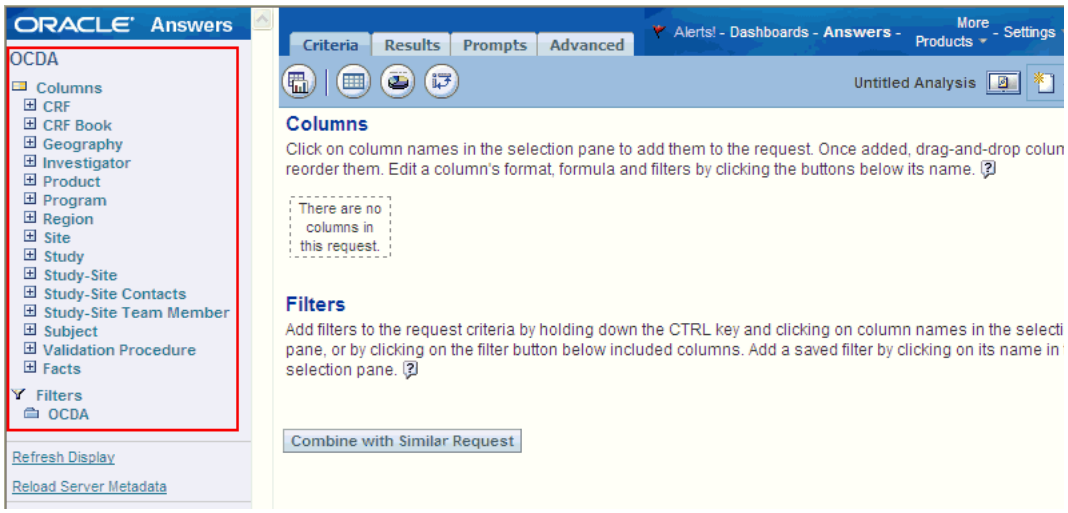
The start page has two main areas:

- **Selection Pane:** The selection pane, located on the left side of the screen, shows content saved in the Presentation Catalog, such as personal and shared requests and filters.
- **Workspace:** The workspace, located to the right of the selection pane, initially shows the subject areas you can work with to create requests.

When you make a selection from the selection pane, such as clicking a saved request, your selection appears in the workspace so you can work with it.

When you click the OCDA subject area in the workspace to create a new request, the selection pane changes to show the columns and filters for that subject area that you can include in a request, and the workspace displays the tabs for working with requests. Figure 3-4 displays the columns and filters in the OCDA subject area.

Figure 3–4 Columns and Filters in the OCDA Subject Area



To view saved requests organized by dashboard:

1. Log in to OCDA and click the Dashboard tab.
2. Click the Dashboard tab in the selection pane.

To view saved requests as stored in the Presentation Catalog:

1. Log in to OCDA and click the **Answers** link.
2. Click the **Catalog** tab in the selection pane.

To search for a saved request:

1. Type all or part of its name into the Search text box, and click **Search**.

   Search results are listed in the workspace.

> **Note:** If you use a backslash character (\) in an iBot name (for example, Na\me), the search string used to find it must contain an additional backslash (called an escape character). For example, an iBot called Na\me would require the search string Na\\me, to retrieve details for that iBot. Without the additional backslash an error message is displayed.

To return to the Oracle BI Answers start page:

1. Click the **Answers** link from anywhere within OCDA.

Accessing the Tabs in the Oracle BI Answers Workspace

The Oracle BI Answers workspace displays the following tabs for working with a request:

- **Criteria:** This tab provides access to the columns selected for the request, and icons to access the most common view types.
- **Results:** This tab allows you to work with the results of the request.
- **Prompts:** This tab allows you to create prompts to filter the request.
- **Advanced:** This tab allows advanced users to work with the XML and logical SQL for the request.

Each tab contains on-screen information and icons to help you create, access, and manage requests. On each tab, you can pause your mouse over each icon for a description of what it does. Table 3-2 provides additional information about each tab.

To access the tabs in the Oracle BI Answers Workspace:

1. Click the **OCDA** subject area to create a new request, or modify a saved request.

   The workspace displays the tabs for working with the request.

Table 3-2 describes the tabs in the Oracle BI Answers workspace.

Table 3–2 Tabs in the Oracle BI Answers Workspace

Tab	Description
Criteria	Use the Criteria tab to view or change the columns and filters for the request. You can specify the order in which the results should be returned, column subtotals, formatting (such as headings and number of decimal places), and column formulas (such as adding a Rank or Percentile function). You can also add or modify column filters. Four common views are available from this tab by clicking the appropriate view icon:  Displays the compound layout view, where you can combine individual views and arrange them for display on a dashboard.  Displays the table view, where you can show results in a table.  Displays the chart view, where you can show results in different kinds of charts.  Displays the pivot table view, where you can take row, column, and section headings and swap them around to obtain different perspectives.
Results	Use the Results tab to work with the results of a request, and create different views of the results such as charts, tickers, and pivot tables. You can add a variety of views, including charts and pivot tables that show the data, plain or formatted text that describes the results, HTML, and more. The default results view is a simple table with a title. Your Oracle BI Presentation Services administrator may have configured a different default results view for your organization. You can combine views and position them anywhere on the page. For example, you can create side-by-side pivot tables that reflect different views of the data, charts that allow you to explore interrelationships in depth, and filters that limit the results. If the request is embedded in a dashboard, the dashboard page can also include links to additional requests of interest, related graphics, news stories, and so on.
Prompts	Use the Prompts tab to create prompts that allow users to select values to filter a request. Prompts allow users to select values that dynamically filter all views within the request.

Table 3–2 (Cont.) Tabs in the Oracle BI Answers Workspace

Tab	Description
Advanced	Use the Advanced tab to work directly with the XML and logical SQL generated for the request. If you know SQL and the structure of your underlying data sources, you can use the Advanced tab to view and work directly with the SQL statements generated for the request. For example, you can change the subject area or add advanced SQL statements. The Advanced tab also provides access to links that you can use to execute saved requests from an external Web page, portal, or application. **NOTE:** The Advanced tab is recommended for use only by developers or experienced users with complex data analysis needs and capabilities. Only users with the appropriate responsibilities are given access to the Advanced tab.

Running a Request from the Oracle BI Answers Start Page

This section explains how to run a request from the Oracle BI Answers start page. You can run a saved request or create a new request.

Your My Folders folder is designed to hold the requests that you run most often. This folder is located at the top of the selection pane on the Catalog tab. The first time you see this folder, it will be empty. You can populate it by saving requests to it. For more information about saving requests, refer to Saving an Oracle BI Request to a Personal or Shared Folder on page 3-14.

To run a saved request:

1. In the selection pane, click a saved request from your My Folders list or from a shared folder.

> **Note:** Selecting a request from a folder causes the request to be executed immediately.

To create a new request:

1. Click the **OCDA** subject area.
2. Select the columns and filters to include in the request.
3. Click the **Results** tab or one of the result view icons.

See Also:

Creating a New Oracle BI Request or Changing the Criteria for an Existing Request on page 3-10

Creating a New Oracle BI Request or Changing the Criteria for an Existing Request

Use the following procedure to select the columns and filters to include in a request. The subject area for the request is listed on the Catalog tab in the selection pane, together with the tables and columns the request contains.

> **Caution:** If you click your browser's Refresh icon before you are done creating a request, be aware that the browser will reload all frames and discard your changes.

To create a new request or change the criteria for an existing request:

1. Perform one of the following actions:

   - To modify an existing request, click the request on Catalog tab in the selection pane. Then, click **Modify**.

     The Criteria tab appears in the workspace.

     Tip: To go directly to the Criteria tab, press and hold down the CTRL key when you click the request.

   - To create a new request, click the **OCDA** subject area at the Oracle BI Answers start page.

     Alternatively, click the following icon to create a new request (located at the top of the Catalog tab in the selection pane, and when you are working with a request, in the upper right corner of the workspace) and choose **OCDA**:

     Creating a new request clears any previous request from the workspace, and allows you to continue working with the OCDA Subject area.

   The subject area for the request appears in the selection pane, together with its columns.

2. Click on columns to add them to the request.

   Tip: In general, the request should contain at least one column from the Facts table in the selection pane. Facts are the key additive measurements of business performance, such as total number of discrepancies, or the number of CRFs that are approved. Running a request without including any facts generally produces reports that are not meaningful, and can cause poor query performance or unexpected results. If you want to build a request without any facts, you should first consult your Oracle BI administrator.

3. Use the column icons to control the use of each column in the request.

   For information about the column icons, refer to Table 3–3 Oracle BI Request Column Icons on page 3-12.

4. To reorder columns in the workspace, drag and drop a column name from its current location to another location.

5. To preview the results, perform any of the following actions:

   - Click one of the result view icons for a table, chart, or pivot table near the top of the workspace.
   - Click the preview icon to see how results will look on the dashboard.

     Note: If the preview icon is not available, your Oracle BI Presentation Services administrator has suppressed its display.

   - Click the **Results** tab and choose a view from the drop-down list.

6. To save the request, perform one of the following actions:

   - Click the **Save Request** icon.

For more information, refer to Saving an Oracle BI Request to a Personal or Shared Folder on page 3-14.

- Click **Save and Schedule** to save the request in Oracle BI Answers, and create an iBot in Oracle BI Delivers for the saved request.

  Note: The Save and Schedule icon is not available if your organization is not using Oracle BI Delivers.

  Oracle BI Delivers displays the Schedule tab for the new iBot. For more information, refer to *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide (Scheduling an Oracle BI Delivers iBot).*

Table 3-3 describes the Oracle BI Request columns icons.

Table 3–3 Oracle BI Request Column Icons

Icon	Description
	**Order By:** The Order By icon specifies the order in which results must be returned, ascending or descending. You can order results by more than one column. If you choose more than one column, the order is shown on the Order By icon. You can click the Order By icon to remove or change the sort order from a column by clicking until the sorting is changed or removed. Different images appear on the icon, depending on the selected sort order. The example icon in this table shows two arrows side by side, one pointing up, the other pointing down. For information about the forms an Order By icon can take, refer to Table 3–4 Sort Orders Available in Oracle BI Answers on page 3-13.
	**Format Column:** The Format Column icon lets you edit various format properties for the column. The icon displays the image of a hand with its index finger pointing to the left and down. For more information, refer to *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Using Column Formatting Functions in Oracle BI Answers).*
	**Edit Formula:** The Edit Formula icon lets you change the column heading and the formula for the column, such as adding a Rank or Percentile function. You can also combine multiple values or ranges of values from a given column into bins. The icon displays the image of lowercase, italic characters fx. For more information, refer to *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Editing the Formula of a Column).*
	**Filter By Column:** The Add Filter icon lets you create or edit a filter for the column. The icon displays the image of a funnel. For more information, see *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Using Column Filters in an Oracle BI Request).*
	**Remove Column:** The Delete icon removes the column from the request. The icon displays the image of an uppercase X.

Specifying the Sort Order for Columns in Oracle BI Requests

In Oracle BI Answers, you can specify the sort order for one or more columns that appear in a request. When you click the Order By icon, it shows a new image to indicate the sort order that the selected column will apply to the results.

To sort a request based on columns in Oracle BI Answers:

1. In Oracle BI Answers, display the request with which you want to work.
2. Click the Order By icon for the column you want to sort by.

   The icon changes to indicate the sort order.
3. Continue clicking the Order By icon until the sort order you want appears.

Table 3-4 describes the available sort orders and the images on the Order By icon that represent them.

Table 3–4 Sort Orders Available in Oracle BI Answers

icon	Description
	The image of two arrows-one pointing up, the other pointing down-indicates that the selected column will not be used to sort the results.
	The image of an up arrow indicates that the results will be sorted in ascending order, using the items in the selected column.
	A number that appears on an Order By icon indicates that the column is not the primary sort column applied to the results. The number corresponds to when the sort order is applied. In this example, which shows an up arrow with the number two, the column is used as the second sort order column. The up arrow indicates that the results are sorted in ascending order, using the items in the selected column.
	The image of a down arrow indicates that the results will be sorted in descending order, using the items in the selected column.
	A number that appears on a Order By icon indicates that the column is not the primary sort column applied to the results. The number that appears corresponds to when the sort order is applied. In this example, which shows a down arrow with the number two, the column is used as the second sort order column. The down arrow indicates that the results are sorted in descending order, using the items in the selected column.

Refreshing Information in the Oracle BI Answers Selection Pane

When changes have been made to saved content or to the Oracle BI Server metadata, you can refresh the display to see the most current information.

To refresh information in the selection pane for saved requests, filters, and dashboard content:

1. Click the **Refresh Display** link at the bottom of the selection pane

To refresh information in the selection pane for the view of the Oracle BI Server metadata for subject areas:

1. Click the **Refresh Server Metadata** link at the bottom of the selection pane

Viewing and Working with Oracle BI Answers Results

The following procedure explains how to view and work with basic Oracle BI Answers results:

1. Click the **Results** tab.

   The results appear in the workspace, in a table.

2. (Optional) Perform one or more of the following actions:

   - To page forward and backward through the results, use the paging icon at the bottom of the page.

     Note: The paging icons appear only when two or more pages of results are present.

   - To edit the criteria used in the request, click the **Criteria** tab or the option to show header toolbars.
   - To add prompts to the request, click the **Prompts** tab.
   - To edit the XML or logical SQL for a request, click the **Advanced** tab.

     Note: The Advanced tab is for advanced users and developers only. Only users with the appropriate responsibilities are given access to the Advanced tab. For more information, refer to *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Examining or Editing the Logical SQL Generated for an Oracle BI Request)*.

   - To add grand totals or column totals to a result, use the table or pivot table view:
     - To add grand totals, click **Grand Totals** at the top of the workspace.
     - To add totals for an individual column, click **Total By** for that column.

     Note: The Total By icon is available only for columns that can be totaled.

Saving an Oracle BI Request to a Personal or Shared Folder

When you save a request in one of your personal folders, only you can access it. When you save it in a shared folder, users with permission to access that folder can access it too.

Your top-level personal folder is called My Folder. Every user with a unique user name has a folder called My Folder. This is designed to hold the requests that you run most often, and other content that you access frequently.

When you click the Refresh Display link at the bottom of the selection pane, the request is listed under the folder in which you saved it.

To save a request to a personal or shared folder:

1. Click **Save Request**.

   The Choose Folder dialog box appears.

2. Choose a personal or shared folder in which to save the request.

To specify a subfolder, perform one of the following actions:

1. Navigate to it.
2. Click **Create Folder** to create a new subfolder.
3. Type the path in the Folder box.

3. Type a descriptive name for the request.

   The name will appear when a user pauses the mouse on the request in the selection pane.

4. (Optional) Type a description for the request.

   Descriptions are displayed when Oracle BI administrators use the Oracle Business Intelligence Catalog Manager.

5. Click **OK**.

Embedding an Oracle BI Request in an Oracle BI Dashboard

Embedding a request in a dashboard causes it to execute automatically and display the results within the dashboard. This provides access to current results.

Depending on how your organization implements caching, Oracle BI Answers uses the most efficient method to obtain results; either from the cache, or by running the request again and caching the results again.

You can embed saved requests by using the Dashboard Editor. For information about the Dashboard Editor, refer to *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Adding Content to an Oracle BI Interactive Dashboard).*

Using Variables to Display Values in Request Results and Dashboards

You can reference a session variable, repository variable (example, `User.displayName`), or a presentation variable, and use its value in request results, dashboards and iBots.

See Also:

Oracle Business Intelligence Server Administration Guide

About Session, Repository, and Presentation Variables

Session and repository variables are predefined values maintained by the server (example, `NQ_SESSION.System.currentTime`). A presentation variable must be declared in a dashboard prompt (using the Set Variable field), and its name and value are determined by the user, either when it is initially declared, or when it is referenced in request results and dashboards.

See Also:

Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Creating a Dashboard Prompt for Filtering Oracle BI Requests)

The following examples suggest how you might reference a session variable or a presentation variable:

- Example 1 - Referencing a session variable

  To enable an author to display the current user's name in a report title view, the author simply adds a reference to the session variable `@{NQ_`

SESSION.User.displayName} to the report title view. This session variable displays the current user name in the title view.

- Example 2 - Referencing a presentation variable

  Where a dashboard report displays a prompt for a single region, the author would like to display the region selected by the user in the title of the dashboard report. To do so, the author simply adds a reference to a presentation variable in the report title for example, @{variables.myFavoriteRegion}. The presentation variable (myFavoriteRegion) needs to have been declared for the dashboard prompt. This presentation variable displays whatever region has been entered by the user in this dashboard prompt.

Referencing Session Variables

You can reference variables in the following areas:

- Title Views
- Narrative Views
- Column Filters
- Column Formulas
- Conditional Formatting conditions (presentation variables only)
- Direct Database Requests
- Dashboard prompts

  Users will be prompted for a variable value which is then set into a request (session) variable and passed to the Oracle BI server.
- Chart scale markers
- Gauge range settings
- Static text
- iBot Headlines and text

Syntax for Referencing Session Variables

The syntax for referencing session variables is as follows:

```
@{NQ_SESSION.variableName} For example, @{NQ_
SESSION.dashboard.description}
```

where,

- NQ_SESSION - indicates that this item references a session variable.
- variableName - a reference to an object available in the current session context. For example: dashboard.description.

Syntax for Referencing Repository and Presentation Variables

The syntax for referencing repository and presentation variables is as follows:

- @{<variableName>}{<value>}[format] - for repository variables.

  For example, @{dashboard.path} - inserts the path to the current dashboard.
- @{variables.<variableName>}{<value>}[format] - for presentation variables

For example, `@{variables.myFavoriteRegion}{Central}` - inserts the value of the presentation variable `myFavoriteRegion`.

- `variables` - prefix that is required when you reference a presentation variable in a request.
- `variableName` - a reference to an object available in the current evaluation context. For example: `@{variables.myFavoriteRegion}`.
- `value` - (optional) - a constant or variable reference indicating a value to be used if the variable referenced by the variableName is not populated (is undefined).
- `format` - (optional) - a format mask dependent on the data type of the variable. For example: #,##0, MM/DD/YY hh:mm:ss, and so on.

Note: If the @ sign is not followed by a {, it will be treated as an @ sign. For more information, refer to *Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Editing the Appearance of Column Contents in Oracle BI Answers).*

Referencing Predefined Variables

Table 3-5 contains a list of predefined variables that can be referenced in request results and dashboards.

Table 3–5 Predefined Variables

Object	Variable	Example
System	productVersion	system.productVersion = 1.0.0.0 (Build 305800.453)
	currentTime	system.currentTime = 2009-5-15 14:1:35
Session	locale	session.locale = en-gb
	language	session.language = en
	rtl	session.rtl = false
	timeZone	session.timeZone = Unknown Time Zone
	loginTime	session.loginTime = 2009-5-15 13:0:3
	logoutTime	session.logoutTime = 2009-5-15 17:0:17
	lastAccessTime	session.lastAccessTime = 2009-5-15 14:01:35
	currentUser	session.currentUser = administrator
User	id	user.id = administrator
	displayName	user.displayName = administrator
	homeDirectory	user.homeDirectory = /users/administrator
Dashboard	currentPage	dashbaord.currentPage = test page name
	xml	dashbaord.xml = the dashboard XML

Part II

Administration

This part of the Guide discusses topics and tasks related to administration of Oracle Clinical Development Analytics.

Part II contains the following chapters:

- Chapter 4, Maintaining the Repository and Warehouse
- Chapter 5, Extract Transform Load Programs
- Chapter 6, Implementing Security

4

Maintaining the Repository and Warehouse

This chapter contains the following topics:

Maintaining the Oracle Clinical Development Analytics Repository

Each release of Oracle Clinical Development Analytics (OCDA) contains a Repository (RPD) file. The Repository is the data store for the Oracle BI Server. It maintains the mapping of the physical tables comprising the data warehouse to the Presentation Layer, which holds the columns and tables available for use in OBIEE Requests. As shipped, the RPD corresponds to the OCDA data warehouse, and can be used without any modification.

However, you might find it desirable to modify the Oracle-supplied OCDA Repository file (RPD), for any of the following reasons:

- You want to add a column or table to the data warehouse, and propagate that addition into the layers of the repository.
- You want to add a calculated column in the Presentation Layer as a function of some set of physical layer columns.
- You want to modify a repository variable value, or add a new repository variable, for use in some Presentation Catalog calculation. For instance, you may want to modify the frequency with which the value of the dynamic repository variable CURRENT_DAY is refreshed. For more information about why OCDA must refresh this variable, refer to the Note in step 13 of the Executing the ETL Programs section.
- You want to modify a group, an account, or a privilege maintained through the repository.

This section describes the procedures you must follow to carry out these types of modifications.

You should be aware that, once you have modified the Oracle-supplied Repository, it is your responsibility to merge these modifications into Repositories supplied by Oracle in patches and releases of OCDA. Details on how to re-apply your modifications are provided below.

Caution: Changes to the Repository should be made with care.

Privileges to make changes in the OCDA Repository should be granted only to a limited set of users who need to make such changes and also know how to make them correctly.

Changes should be tested on a side copy of the Repository before being released for production use.

Modifying the Repository

The OCDA Repository is maintained as a versioned object in Oracle LSH. A copy of that Repository is deployed to the application server file system. This *deployed* Repository is the one that the Oracle BI Server uses. All changes to the Repository, however, must be made through a two-step process:

- Modify the versioned Repository object.
- Deploy the latest version of the Repository object.

Therefore, Oracle requires that you do not modify the deployed OCDA Repository directly.

If you do need to modify the Repository, perform the following tasks:

1. Check out the Business Area (BA) to a different domain in which you will customize the Repository, or use an existing customized Business Area.

   Important: Use the **Copy definition to the local Application Area and check out** option to check out the program to a different domain. This preserves the changes to the definitions in a different domain, and ensures that the changes are not overwritten automatically in the next upgrade of OCDA.

2. If the reason you are modifying the RPD is that you have modified the data warehouse:
   a. Verify the mappings of the tables in the BA.
   b. Remap table instances and table descriptors, if necessary.

      If you made any changes to the BA, reinstall the Work Area and check out the Business Area again.

      Note: In this checkout, do **not** use the **Copy definition to the local Application Area** option to check out the program.

3. Click **Launch IDE** on the Business Area's Properties screen.

   This downloads the versioned RPD object from the Business Area, and opens the Oracle BI Administration tool. Make the desired modifications to the downloaded RPD. Refer to Details for Selected Modifications for instructions on applying selected modifications.
4. Save the changes; exit the Oracle BI Administration tool.
5. In Oracle LSH, upload the modified RPD back into the Oracle LSH Business Area.

The modified RPD can be found in a location that has been defined for your LSH configuration.

6. Ensure that the OBIEE DP Server is up and running. Otherwise, the next step will indicate success, but the RPD will not be deployed.
7. Install the WorkArea that contains the BA that contains the modified Repository.
8. Launch the Oracle BI Presentation Server to verify the changes.

Details for Selected Modifications

This section contains details on how to perform certain modifications to the RPD.

To modify the frequency with which CURRENT_DAY is refreshed:

1. In Oracle BI Administration Tool, click **Manage** > **Variables**.
2. Expand Repository and click **Initialization Block** > **ETL_Refresh_Ranges**.
3. In the Repository Variable Init Block - ETL_Refresh_Ranges screen, modify the value of **Refresh interval**.

   Refresh interval indicates how often you want to refresh the value of CURRENT_DAY dynamic repository variable. By default, this value is set to 5 minutes. That is, the CURRENT_DAY dynamic repository variable is refreshed every five minutes. Modify Refresh interval to a suitable value.

See Also:

- *Oracle Life Sciences Data Hub Developer's Guide*
- *Oracle Business Intelligence Server Administration Guide* for more information about modifying the RPD.

Merging Changes Into a New Oracle-supplied Repository

OCDA releases include a copy of the Repository. The installation process for each release deploys that Repository. If you do modify your copy of the OCDA Repository, you must merge your changes into the Oracle-supplied Repository each time you receive a release or patch of OCDA that includes a repository. At upgrade time, use the OBIEE utility File > Merge in the Repository Administrator to merge your modified RPD with the Oracle-supplied RPD.

Maintaining the Oracle Clinical Development Analytics Data Warehouse

You may need to modify the OCDA data warehouse, typically for one of the following reasons:

- *Derivation*: Calculation of a new measure as a function of some supplied measures.
- *Extension*: Adding data that was not delivered with OCDA.
- *Substitution*: Swapping data from a different source for a column that was delivered with OCDA.

Caution: Exercise caution when you modify the data warehouse. Please conform to the recommendations mentioned in the subsequent sections.

Derivations

A *derivation* is a calculation of a new measure as a function of some supplied measures. OCDA displays all derivations as a column in Answers. You can use any of the following approaches to calculate derivations:

- Calculate the derivation as part of the creation of a request.

  In this approach, only the Web Catalog is modified. However, you must specify the calculation for each request, and the calculation is executed every time the request is executed.

- Calculate the derivation in the physical or business layer of the RPD file; it is propagated to the presentation layer. This makes the derivation you created appear in Answers as a column.

  Using this approach, you can specify the calculation once and use it for multiple requests. The derived value looks the same as any other Answers column.

- Calculate the derivation in the data warehouse.

  The calculation is run at ETL execution time and not at query time. The derived value looks the same as any other Answers column. In this approach, you must add the result column to the staging and target tables, modify the ETL procedures (both Source Dependent Extract (SDE) and Source Independent Load (SIL)), and then add the column to all the layers of the RPD.

Extensions

An *extension* is a new column added to the data warehouse for data not available in Oracle Clinical or Oracle's Siebel Clinical.

Example: Adding the study manager's name as an attribute of the study dimension for each study. The following are the assumptions:

- This information is available in a non-Oracle Clinical database, in a table named STUDY_MANAGERS.
- This table has a foreign key to the primary key in Oracle Clinical table OCL_ STUDIES.

To minimize the level of effort required when implementing a release with a new repository, Oracle recommends that you add extensions to the warehouse through user-defined extension tables, rather than by adding new columns directly into the relevant staging and target tables.

Perform the following tasks to add the study manager to the study dimension for each study:

1. Create a pass-through view of the STUDY_MANAGERS table so that the table is visible in Oracle LSH.
2. Modify staging table W_RXI_STUDY_DS, adding the STUDY_MANAGER column. To modify the staging table, perform the following tasks in Oracle LSH:
   a. Check out the table definition into another domain (to ensure that the changes are not overwritten in the next OCDA upgrade) or use an existing customized table definition.
   b. Add the new column and reinstall.

Important: Before you reinstall, ensure that the Informatica DP Server is up and running.

3. Modify the SDE that populates W_RXI_STUDY_DS, in two ways:
   - Add the STUDIES_MANAGERS table as a source of the program.
   - Add a mapping of column STUDY_MANAGER from STUDY_MANAGER to W_RXI_STUDY_DS.

   To modify the SDE, perform the following tasks in Oracle LSH:

   a. Check out the SDE into another domain (to ensure that the changes are not overwritten in the next OCDA upgrade) or use an existing customized SDE.

   b. Add the new column and reinstall.

   Important: Before you reinstall, ensure that the Informatica DP Server is up and running.

4. If it does not already exist to support some other extension, create extension table W_RXI_STDY_DX, containing one column [STDY_WID] to function as a foreign key that joins to the primary key in W_RXI_STDY_D. This table is populated with one row for each row in W_RXI_STDY_D when the Study SIL executes.
5. Add column STUDY_MANAGER to W_RXI_STDY_D to hold the name of the study manager. To add a column, perform the following tasks in Oracle LSH:

   a. Check out the table into another domain (to ensure that the changes are not overwritten in the next OCDA upgrade) or use an existing customized table definition.

   b. Add the new column and reinstall.

   Important: Before you reinstall, ensure that the Informatica DP Server is up and running.

6. Modify the SIL that populates W_RXI_STDY_D. Add instructions to create a record in W_RXI_STDY_DX for each record in W_RXI_STDY_D, and to copy W_RXI_STUDY_DS. STUDY_MANAGER into W_RXI_STDY_DX.STUDY_MANAGER for each record.

   To modify the SIL, perform the following tasks in Oracle LSH:

   a. Check out the SIL into another domain (to ensure that the changes are not overwritten in the next OCDA upgrade) or use an existing customized SIL.

   b. Add the new column and reinstall.

   Important: Before you reinstall, ensure that the Informatica DP Server is up and running.

7. Modify the repository:

Important: Before you modify the repository, ensure that you check out the Business Area containing the repository (`OCDA_OBIEE_WA`) to a different domain. This preserves the changes to the definitions in a different domain, and ensures that the changes are not overwritten automatically in the next upgrade of OCDA. Alternatively, you can use an existing customized Business Area.

a. Import the definition of the extension table, W_RXI_STDY_DX, into the Repository.

b. Using W_RXI_DISCREPANCY_FX as an example, propagate the extension table and its contents to the Business and Presentation layers.

Subsequent Releases

- If a subsequent OCDA release requires an update of the tables or ETL that you modified in a different domain, OCDA does not overwrite such modifications. You can choose to manually upgrade to the new OCDA releases by pointing your definitions to Oracle-supplied definitions.
- If a subsequent OCDA release requires an update to the Repository that you modified in a different domain, OCDA does not overwrite such modifications. You can use the OBIEE Repository merge utility `equalizerpds.exe` to merge your modified RPD with the Oracle-supplied RPD.
- If a subsequent OCDA release requires an update to the Web Catalog, the OBIEE Web Catalog merge capability will preserve your changes to the catalog while applying Oracle's changes.

Substitutions

A substitution occurs if you have a preferred alternative source of data for a column that OCDA populates from Oracle Clinical or Siebel Clinical. For example, you have a system for defining what data collection instruments (DCIs) are mandatory for a given study, subject, or subject visit, and you prefer that over the OCDA calculation that is based on expected data collection modules (DCMs) and subject visit schedules. In this case, your column will be present in a table, and the SDE that propagates the data to a staging table already exists. You will have to perform the following tasks:

1. Create a table or pass-through view in Oracle LSH containing the locally-sourced values of the column, and also add whatever keys are needed to join to the Oracle-supplied view.
2. Create a program that joins the two tables and creates a new table, in which the locally-sourced values replace the Oracle-supplied values for the column of interest. Call this the Substitution Table.
3. Modify the SDE to read from the Substitution Table, rather than the Oracle-supplied table.

   To modify the SDE, perform the following tasks in Oracle LSH:

   a. Check out the SDE into another domain (to ensure that the changes are not overwritten in the next OCDA upgrade) or use an existing customized SDE.

   b. Modify the definitions and reinstall.

Important: Before you reinstall, ensure that the Informatica DP Server is up and running.

If you make changes to a source table, you must propagate that change forward as far as necessary. Some of the scenarios and the related necessary adjustments are described in the Table 4-1:

Table 4–1 Scenarios Requiring Necessary Adjustments

Scenario	Adjustments Required
New table has the same layout as the old table, but is passed through from a different source	Change the SDE that reads the old table to instead read the new table.
Modified table has modified layout	1. Modify the SDE to read the modified layout. 2. Modify the staging table populated by the SDE to include the modified layout. 3. Modify the SIL to read the modified layout. 4. Modify the target table to include the modified layout. 5. Modify the RPD to accept the changed data warehouse table.
New table	1. Add a staging table to accept the new input. 2. Add an SDE to read from the new table and write to the staging table. 3. Add a warehouse table to make the new data available to the BI Server. 4. Add an SIL to populate the new data warehouse table from the new staging table. 5. Modify the RPD to accept the new warehouse table.

Modifying Data Warehouse Tables

Depending on what changes are required to the data warehouse, it is necessary to modify either the source table in Oracle LSH, or the source, staging, and target tables. In either case, use Oracle LSH capabilities to modify the definition of the relevant tables, or to create new tables.

Managing Indexes

OCDA is delivered with a set of indexes. If you wish, you can add appropriate indexes to meet your query requirements. Use Oracle LSH for this purpose.

If all indexes must be dropped and recreated, perform the following tasks in Oracle LSH:

1. Navigate to the Submit Execution Setup screen of the program instance.
2. In the Submission Parameters tabbed page, set the value of Drop and Recreate Index to **Yes**.

   If set to Yes, Oracle LSH drops all indexes on all target Table instances before the Oracle LSH Informatica Program is executed, and recreates them after execution.

If you do not want to drop and recreate indexes for all Table Descriptors, you can call the Oracle LSH API to drop and recreate specific indexes. For more information about

selective index management, refer to the *Oracle Life Sciences Data Hub Developer's Guide, (Selective Index Management).*

See Also:

Oracle Life Sciences Data Hub Developer's Guide, (Defining Table Constraints and Indexes)

5

Extract Transform Load Programs

This chapter contains the following topics:

To load data from the source systems to the data warehouse, OCDA uses Extract Transform and Load (ETL) programs that

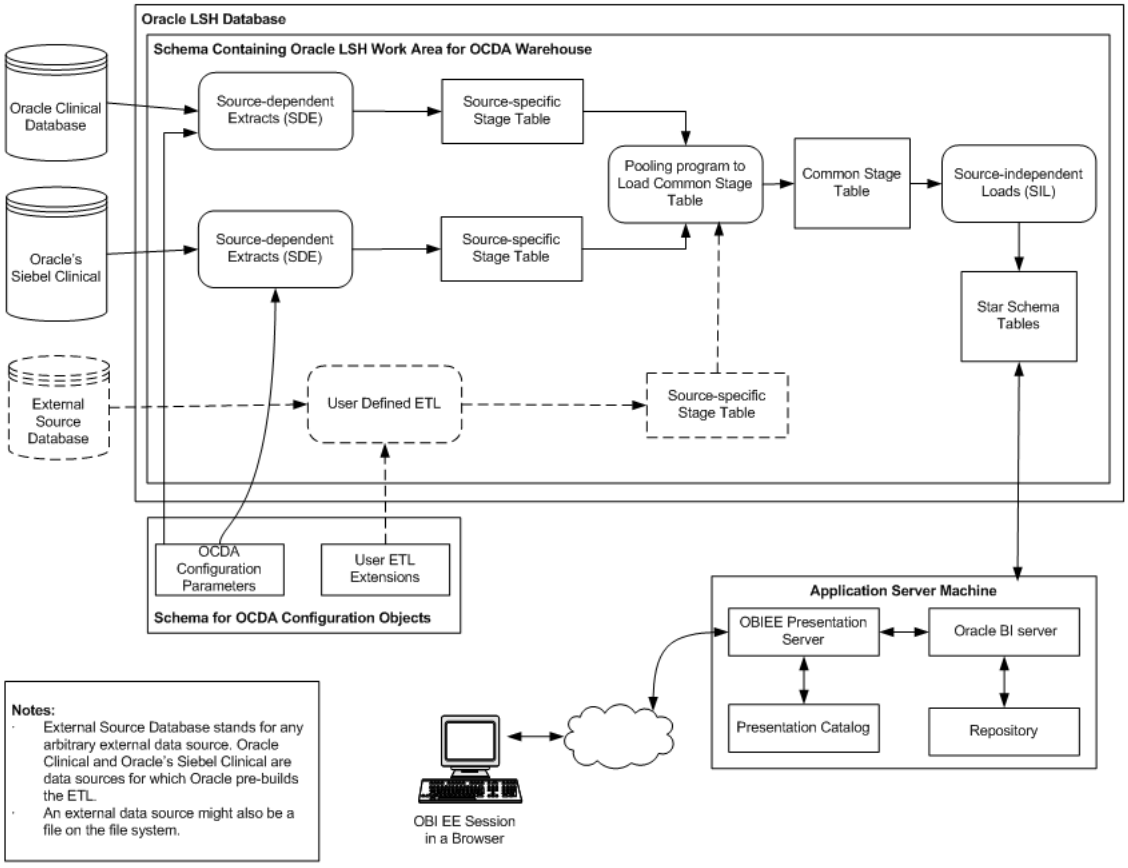
- Identify and read desired data from different data source systems,
- Clean and format data uniformly, and
- Write it to the target data warehouse.

In OCDA, Oracle Clinical and Oracle's Siebel Clinical are the source systems for which Oracle provides predefined ETL.

ETL Architecture

Figure 5-1 displays the ETL process delivered with OCDA.

Figure 5–1 The OCDA Architecture



OCDA uses Oracle Life Sciences Data Hub (Oracle LSH) to maintain star-schema tables that enable user reporting. Set up as a recurring job, the Oracle LSH Extraction, Transformation, and Load process (ETL) is designed to periodically capture targeted metrics (dimension and fact data) from multiple clinical trial databases, transform and organize them for efficient query, and populate the Oracle LSH star-schema tables.

While the OCDA data model supports data extraction from multiple sources, OCDA only includes source-dependent extract (SDE) mappings for the Oracle Clinical and Siebel Clinical databases. However, you can also define SDE mappings from additional external sources that write to the appropriate staging tables. Note that you are responsible for resolving any duplicate records that may be created as a consequence. For more information about how to add a new data source to OCDA, refer to Adding a New Data Source on page 5-6.

Oracle LSH uses pass-through views to access transactional data from source databases. The SDE programs map the transactional data to source specific staging tables, in which the data must conform to a standardized format, effectively merging the data from multiple, disparate database sources. This is the architectural feature that accommodates external database sourcing.

A pooling program reads the data from all the source specific staging tables, and loads it into the common staging table.

Oracle LSH thence transforms the staged data (in the common staging table) using source-independent loads (SILs) to internal Star-schema tables, where such data are organized for efficient query by the Oracle BI Server.

There is one SDE mapping for each target table, which extracts data from the source system and loads it to the respective source specific staging tables. SDEs have the following features:

- Incremental submission mode: OCDA supplied ETL uses timestamps and journal tables in the source transactional system to optimize periodic loads.
- Bulk and normal load: *Bulk load* uses block transfers to expedite loading of large data volume. It is intended for use during initial data warehouse population. Bulk load is faster, if data volume is sufficiently large. However, if load is interrupted (for example, disk space is exhausted, power failure), load cannot be restarted in the middle; you must restart the load.

  Normal load writes one record at a time. It is intended to be used for updates to the data warehouse, once population has been completed. Normal load is faster, if data volume is sufficiently small. You can also restart load if the load is interrupted.

  You must set the appropriate target load type for an ETL program in Oracle LSH to indicate bulk and normal load. In OCDA, by default, bulk load is enabled for all SDEs.

  See Also:

  Setting Up the Target Load Type on page 5-14 for information about setting the appropriate table processing type.

There is one SIL mapping for each target table. The SIL extracts the normalized data from the common staging table and inserts it into the data warehouse star-schema target table. SILs have the following attributes:

- Concerning changes to dimension values over time, OCDA overwrites old values with new ones. This strategy is termed as *Slowly Changing Dimension approach 1*.
- OCDA's data model includes aggregate tables and a number of indexes, designed to minimize query time.
- By default, bulk load is disabled for all SILs.
- The results of each ETL execution is logged. The logs hold information about errors encountered, during execution.

  Informatica provides the following four error tables:

  – PMERR_DATA
  – PMERR_MSG
  – PMERR_SESS
  – PMERR_TRANS

  During ETL execution, records which fail to be inserted in the target table (for example, some records violate a constraint) are placed in the Informatica PowerCenter error tables. You can review which records did not make it into the data warehouse, and decide on appropriate action with respect to them.

Adding Data Source Information

As you read data from different database instances, you need to specify the source of the data. OCDA provides the W_RXI_DATASOURCE_S table (in RXI schema) that stores all information about all data sources from which data is extracted for OCDA. The following are some of the columns in this table:

- ROW_WID - A unique ID for each record in the table.

- DATASOURCE_NUM_ID - The ID for the database. Must be coordinated with the value given to the database when ETL is run.
- DATASOURCE_NAME - A meaningful name of the database.
- DATASOURCE_TYPE - Application system that manages the database.
- DESC_TEXT - Optional text describing the purpose of the database.
- INTEGRATION_ID - Set this to the same values as DATASOURCE_NUM_ID

See Also:

- *Oracle Clinical Development Analytics Electronic Technical Reference Manual*, for more information about the W_RXI_DATASOURCE_S table.
- Adding a New Data Source, for more information about how to add a new data source to OCDA.

Handling Deletions in Siebel Clinical

OCDA provides an optional feature to manage hard deletion of records in Siebel Clinical. You create triggers in the source system to handle deletion of records. To do this:

1. Navigate to the temporary staging location where the OCDA installer copies the installation files.
2. Connect to the Siebel Clinical data source and run the `ocda_sc_del_trigger.sql` script delivered with OCDA. This script creates the RXI_DELETE_LOG_S table and triggers on tables provided as input. The following are the tables in Siebel Clinical for which OCDA supports creating triggers:
   - S_CL_PTCL_LS
   - S_PROD_INT
   - S_CL_SUBJ_LS
   - S_CONTACT
   - S_CL_PGM_LS
   - S_PTCL_SITE_LS
   - S_EVT_ACT

   Provide a list of comma separated values of table names for which the triggers needs to be created as the script's input. For example, S_CL_PTCL_LS,S_PROD_INT,S_CL_SUBJ_LS. The tables names that you provide can only be a subset of the tables listed above.

   Note that when the user deletes a record in the table, the primary key of the deleted record is inserted in the RXI_DELETE_LOG_S table on the Siebel source system.
3. Update the remote location of the OCDA_RXI_DELETE_LS load set in OCDA_DELETE_LOG_WA to Siebel Clinical source database connection and install this work area.
   1. Navigate to the OCDA_SOURCES_APP_AREA.
   2. Click **OCDA_DELETE_LOG_WA** work area.
   3. Click **OCDA_RXI_DELETE_LS** loadset.
   4. Click **Check Out.**

5. Click **Apply.**
6. In the Load Set Attributes section, click **Update**.
7. Click the Search icon.
8. Select **OCDA_SC_OLTP_RL/<Connection_Name>.**
9. Click **Apply.**
10. Reinstall the work area containing the load set and passthrough views.

For more information, refer to *Oracle Clinical Development Analytics Installation Guide (Post Installation Tasks)*

4. Modify the value of the DELETE_FLOW submission parameter for the following dimension programs based on the triggers created in step 2:
   - `OCDA_INFA_Study_Dim_SDE_SC_PRG`
   - `OCDA_INFA_Study_Site_Dim_SDE_SC_PRG`
   - `OCDA_INFA_Study_Region_Dim_SDE_SC_PRG`
   - `OCDA_INFA_Program_Dim_SDE_SC_PRG`
   - `OCDA_INFA_Product_Dim_SDE_SC_PRG`
   - `OCDA_INFA_Study_Subject_Dim_SDE_SC_PRG`
   - `OCDA_INFA_Party_Per_Dim_SDE_SC_PRG`
   - `OCDA_INFA_SS_Con_Dim_SDE_SC_PRG`

   Perform the following steps:
   a. Navigate **OCDA_domain** > **OCDA_CODE_APP_AREA** > **OCDA_SDE_SC_WORK_AREA**.
   b. Click the Name hyperlink of the program.
   c. Click **Submit**.
   d. Enter the following information in Submission Details:
      – Submission Type: **Backchain**
      – Force Execution: **Yes**
   e. In Submission Parameters, enter the value of DELETE_FLOW as **Y**. The default value is N, which indicates that OCDA does not handle deletion in Siebel Clinical.
   f. Click **Submit**.
5. Execute the ETLs as listed in the Executing the ETL Programs section.

   The Siebel Clinical related SDE mappings reads the above instance of the RXI_DELETE_LOG_S table.

> **Note:** Records that are deleted in the source system are soft deleted in the data warehouse.

See Also:

Oracle Life Sciences Data Hub User's Guide, (Tracking Job Execution), for more information about viewing job execution logs.

Adding a New Data Source

OCDA provides predefined ETL for Oracle Clinical and Siebel Clinical. To add a new data source, perform the following tasks:

See Also:

Oracle Life Sciences Data Hub Application Developer's Guide

1. Create a new Work Area to add the new load set for the source tables.
2. Create a new remote location.
3. Create a new load set in the new Work Area you created in step 1.
4. Assign the remote location to the load set created in step 3.
5. Import the metadata (source).
6. Create a new staging area.

   Tip: You can copy and rename the existing stage table definitions (W_RXI_OC_STUDY_DS or W_RXI_SC_STUDY_DS).

7. Create a new Work Area to add the new ETL program.
8. Create a new SDE programs to load the tables from source system to the staging area. For more information about creating a new SDE program, refer to Creating an ETL Program on page 5-11.
9. Customize the OCDA_POOL_WORK_AREA pooling program to include data from the new staging area. For more information about customizing the pooling program, refer to Customizing the Pooling Program on page 5-14.
10. Insert data into the W_RXI_DATASOURCE_S table and assign the source a DATASOURCE_NUM_ID. Set this value to a number greater than 100.

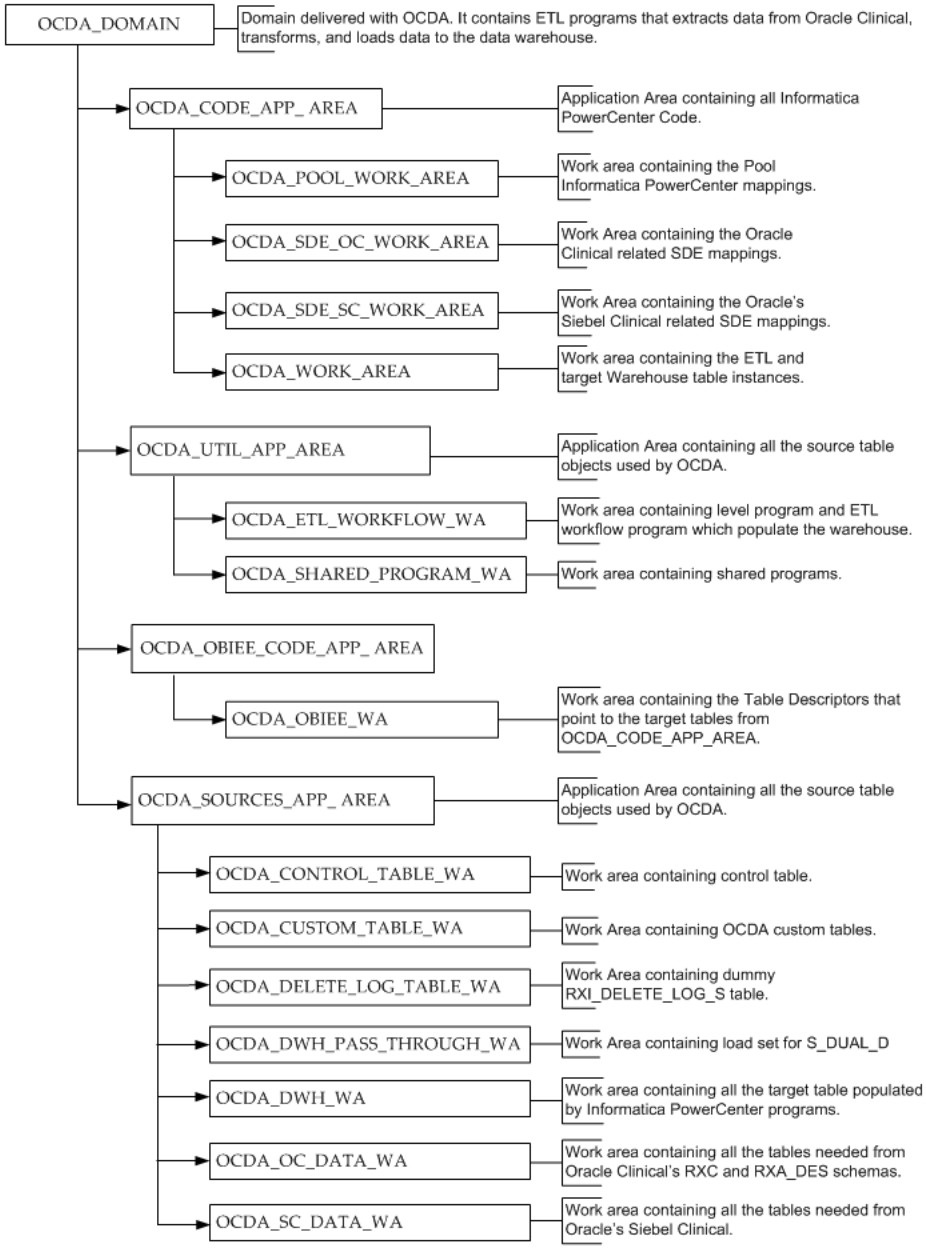
Important: Ensure the following:

- You pass DATASOURCE_NUM_ID and TENANT_ID (default value is 0) as parameters to the SDE.
- The DATASOURCE_NUM_ID column is populated in all your tables using the SDE.

Oracle Clinical Development Analytics Domain Structure in Oracle Life Sciences Data Hub

Figure 5-2 displays the OCDA domain hierarchy in Oracle LSH:

Figure 5–2 OCDA Domain Hierarchy in Oracle LSH



Executing the ETL Programs

To load data from the staging tables to their respective target tables in the data warehouse, execute the SIL programs packaged with OCDA. Perform the following tasks in Oracle LSH:

Important: Ensure the following:

- The Informatica Distributed Processing (DP) Server is up and running.
- You execute the base fact ETL programs first before you execute the aggregate fact ETL programs

1. Navigate to **OCDA_domain** > **OCDA_SOURCES_APP_AREA** > **OCDA_DWH_PASS_THROUGH_WA**

   Note: Ensure that you have installed the domain, Application Area, and Work Area in Oracle LSH before you can perform the subsequent steps.

   For more information, refer to *Oracle Clinical Development Analytics Installation Guide (Post Installation Tasks)*.

2. If you are executing the ETL programs for the first time after installing OCDA, submit the `OCDA_PLS_S_DUAL_D_PRG` program before submitting any fact in backchain.
3. Navigate to **OCDA_domain** > **OCDA_CODE_APP_AREA** > **OCDA_WORK_AREA**.

   Note: Ensure that you have installed the domain, Application Area, and Work Area in Oracle LSH before you can perform the subsequent steps.

   For more information, refer to *Oracle Clinical Development Analytics Installation Guide (Post Installation Tasks)*.

4. If you are executing the ETL programs for the first time after installing OCDA, submit the following programs in the given order before submitting any fact in backchain:
   a. `OCDA_PLS_DUAL_PRG`
   b. `OCDA_INFA_DayDimension_SIL_PRG`
   c. `OCDA_INFA_MonthDimension_SIL_PRG`

   Important: Ensure that you submit the above programs every time you modify them.

5. Set the *config_days* submission parameter in the `OCDA_CONTROL_TABLE_POPULATE_PRG` program. To do this:
   a. Navigate to **OCDA_domain** > **OCDA_SOURCES_APP_AREA** > **OCDA_CONTROL_TABLE_WA**.
   b. Click the `OCDA_CONTROL_TABLE_POPULATE_PRG` hyperlink.
   c. Click **Submit**.
   d. Enter the value of the *config_days* submission parameter.

Note: Control table stores the time range for which the records are extracted from the database. When a base fact SIL program is submitted or triggered in backchain, the data in the control table is populated first. This table stores the following information:

- DATASOURCE_NUM_ID
- ETL_RUN_ID
- MASTER_JOB_ID
- SOURCE_EXTRACTION_START_DT
- SOURCE_EXTRACTION_END_DT
- PROGRAM_NAME
- PROGRAM_RUN_DT

The *config_days* parameter is used to determine the extraction end date for the incremental load. By default, the value of this parameter is 1. This indicates that the source extraction end date is a day less than the ETL program run date. For example, if the ETL program run date is 28 July, 2010 the source extraction end date is 27 July, 2010.

The value of the config_days parameter can also be a fraction or a negative value. For example, if the value of this parameter is .5, the source extraction end date is 12 hours less than the system date in the target database.

e. In Submission Type, select **Backchain**.

f. In Force Execution, select **Yes**.

g. Click **Submit**.

6. Navigate to **OCDA_domain** > **OCDA_UTIL_APP_AREA** > **OCDA_ETL_WORKFLOW_WA**.

If Oracle Clinical is your *only* data source, remove the following Table Descriptors from `OCDA_PLS_LEVEL1_FACT_PRG`:

- `W_ACTIVITY_F`
- `W_RXI_RGN_ENRLMNT_PLN_F`

If Siebel Clinical is your *only* data source, remove the following Table Descriptors from `OCDA_PLS_LEVEL1_FACT_PRG`:

- `W_RXI_DISCREPANCY_F`
- `W_RXI_DISCRPNCY_STATUS_F`
- `W_RXI_RECEIVED_CRF_F`
- Install the program `OCDA_PLS_LEVEL1_FACT_PRG`.

If Siebel Clinical is your *only* data source, remove the following Table Descriptors from `OCDA_PLS_LEVEL1_AGG_FACT_PRG`:

- `W_RXI_DISCREPANCY_A`
- `W_RXI_DISCRPNCY_STATUS_A`
- `W_RXI_RECEIVED_CRF_A`

- Install the program OCDA_PLS_LEVEL1_AGG_FACT_PRG.

7. Submit the OCDA_PLS_ETL_WORKFLOW_PRG program.

Note: Enure the that the value of the config_days submission parameter is same as in Step 5 of this section.

Note: Execution of the ETL (specifically the OCDA_ETL_RUN_S_POP_PRG program) populates W_ETL_RUN_S.LOAD_DT with the timestamp for the execution of the ETL. This ETL execution timestamp is used in the calculation of OCDA measures concerning the amount of time that currently open discrepancies have been open.

While the timestamp is captured in CURRENT_ETL_LOAD_DT, it is only available for calculation of discrepancy intervals through the OBIEE Dynamic Repository Variable CURRENT_DAY. CURRENT_DAY is refreshed from LOAD_DT at a fixed interval, by default 5 minutes, starting each time the Oracle BI Service is started. Between the time that the ETL is run, and the time that CURRENT_DAY is refreshed, calculations of intervals that currently open discrepancies have been open will be inaccurate.

There are two remedies: (i) restart the Oracle BI Server after every execution of the ETL. This will cause CURRENT_DAY to be refreshed to the correct value. (ii) If this is inconvenient, you can modify the intervals between refreshes of the value of CURRENT_DAY. For more information on how to modify the refresh interval for CURRENT_DAY, refer to Maintaining the Oracle Clinical Development Analytics Repository on page 4-1.

Tip: You can schedule the jobs to execute at regular intervals. For more information on scheduling jobs, refer to Scheduling an ETL Program on page 5-14.

Customizing an ETL Program

The following rules apply when you customize an ETL program:

- You can customize ETL programs in different ways. You can create a new domain, new Application Area within same domain, or a new Work Area within the same Application Area. Creating a new domain, and storing customized definitions in the new domain will ensure that the definitions are not overwritten on the next OCDA upgrade.

  Oracle recommends that you set up a single domain for all customization to OCDA. This will ensure that all the customized object definitions are available in the same top-level container.

- After you create your own Work Area, clone the Oracle-supplied Work Area on to your own Work Area. This creates copies of object instances inside your Work Area, but they point to the object definitions inside the Oracle-supplied Application Area.

Caution: To correctly track the timing of OCDA ETL execution, Oracle recommends that no Program in the OCDA Domain, other than the SIL provided with OCDA, read from any OCDA staging table. The staging tables, at any given time, hold only transient records that were loaded during the most recent ETL execution. Ideally, you may not read from them. If it is necessary to read from an OCDA staging tables, Oracle recommends that you define the Program in a Domain other than the OCDA Domain containing the staging table, and execute it in that separate Domain.

Creating an ETL Program

Though OCDA includes ETL programs for extracting data from Oracle Clinical and Siebel Clinical to OCDA data warehouse, you may want to create your own ETL to extract data from other data sources.

Note: The value of DATASOURCE_NUM_ID is set to *1* for Oracle Clinical and *2* for Siebel Clinical. If you want to add your own data sources, set this value to a number greater than 100.

See Also:

- *Oracle Life Sciences Data Hub Application Developer's Guide (Defining Programs)*
- *Informatica PowerCenter Online Help*

To add one or more tables or columns along with the associated ETL programs to populate data into these table, perform the following tasks:

1. Create the new source and target table metadata inside your Work Area.

   If the tables exist outside Oracle LSH in some remote schema, flat file, or SAS file, you can upload the table structure into Oracle LSH using an Oracle LSH Load Set.

2. Create a Program in Oracle LSH and specify that the Program is an Informatica-type Program.
3. Add these tables as sources or targets.
4. Install the new Oracle LSH Program to ensure that the new tables are created in the Work Area schema.
5. Check out your new Oracle LSH program.

   Important: Do not use the **Copy definition to the local Application Area and check out** option when checking out the program.

6. In the Program's screen, click **Launch IDE**.

   This launches Informatica PowerCenter client installed on your machine.

7. Work in Informatica PowerCentre and create the ETL components (transformation or workflow) used by this Oracle LSH Program.
8. Go back to Oracle LSH and upload the ETL file from Informatica PowerCenter to Oracle LSH.
9. Install and run the Program in Oracle LSH.

Important: Before you reinstall, ensure that the Informatica DP Server is up and running.

Tip: If the target table you added relies on new source tables, and if you want the source tables to be automatically populated when you trigger the ETL program for the final target table, enable backchaining for the Oracle LSH Program that populates the source tables.

If there are no new source tables in your customization, Oracle LSH will automatically trigger the population of the source tables when the ETL program to populate the final target table is executed. Note that the backchain submissions are not cloned to the Work Area, and you have to manually create them.

For more information on backchaining, refer to *Oracle Life Sciences Data Hub Application Developer's Guide (Execution and Data Handling)*.

Modifying an ETL Program

You may also want to modify an existing ETL to meet your reporting requirements.

See Also:

- *Oracle Life Sciences Data Hub Application Developer's Guide (Defining Programs)*
- *Informatica PowerCenter Online Help*

To modify an ETL without any changes to the associated tables or columns, perform the following tasks:

1. Install your Work Area and run the ETL to ensure that you can see data populated in the target data warehouse tables.
2. Identify the Oracle LSH program that contains the metadata for the ETL that needs to be modified.
3. Check out the Oracle LSH program that contains the metadata for that ETL.

   Important: Use the **Copy definition to the local Application Area and check out** option to check out the program. This ensures that you do not modify the definitions inside the domain shipped with OCDA.

4. In the Program's screen, click **Launch IDE**.

   This launches Informatica PowerCenter client installed on your machine.
5. Modify the ETLs (transformation and/or workflow) used by the Oracle LSH Program.
6. Test and upload the ETL from Informatica PowerCenter to Oracle LSH.
7. Install the program in Oracle LSH, and run it to verify the changes.

Note: The ETL programs that extract data for the warehouse fact tables assume that the dimensions to which each fact is related are up-to-date at the time the fact ETL programs are executed. This assumption is the basis for certain fact calculations that would provide erroneous results if the assumption were not true. For example, in the *received CRFs* fact, the value of the pCRF entry *complete measure* depends on whether or not the study requires second pass entry. But that piece of information -- second pass entry required -- is obtained from an attribute of the Study dimension. So, if the second-pass requirement for a study changes, and the change is not applied to the Study dimension, the Received CRF fact attributes will contain incorrect values.

As shipped, OCDA ETL workflows ensure this interlock by executing the ETL for related dimensions immediately before running the ETL for a fact. This is standard warehouse management practice, but especially important given the interdependence of the dimensions and the fact. The need to execute dimension ETL immediately before corresponding fact ETL, and the danger of not doing it, is emphasized here because it is possible (though discouraged) to modify these shipped workflows.

To modify one or more tables or columns without any changes to the associated ETL programs:

1. Install your Work Area and run the ETL to ensure that you can see data populated in the target data warehouse tables.
2. Check out the Oracle LSH program that contains the metadata for that ETL.

   IMPORTANT: Use the **Copy definition to the local Application Area and check out** option when checking out the program. This ensures that you do not modify the definitions inside the domain shipped with OCDA.

3. Change the table properties.

   To change the underlying columns and variables, check out the variables that the columns are pointing to. Ensure that you use the **Copy definition to the local Application Area and check out** option when checking out the variable.

   Note: If the changes to the tables or columns are not compatible with the table that is installed in the data warehouse schema, you will get a warning while making the change. For example, if you are reducing the length of a number column from 15 to 10, the change is not compatible with the data existing in the table. Such changes will not let you perform an Upgrade install on the table. You will have to drop and create the table using Partial or Full install.

4. Install the changed table or column, and run the ETL program that populates it.

Customizing the Pooling Program

To modify the pooling program, perform the following tasks:

1. Identify the Oracle LSH program that contains the metadata for the ETL that needs to be modified.
2. Check out the Oracle LSH program that contains the metadata for that ETL.

   Important: Use the **Copy definition to the local Application Area and check out** option to check out the program. This ensures that you do not modify the definitions inside the domain shipped with OCDA.

3. In the Program's screen, click **Launch IDE**.

   This launches Informatica PowerCenter client installed on your machine.
4. Modify the pooling program. Add the newly created stage table (in step 6) as the source.
5. Test and upload the ETL from Informatica PowerCenter to Oracle LSH.
6. Install the program in Oracle LSH, and run it to verify the changes.

Scheduling an ETL Program

When you submit a Program for execution in Oracle LSH, you can schedule it execute at regular intervals. To schedule a Program, perform the following tasks:

1. In the appropriate Work Area, navigate to the installed executable instance you want to submit and click **Submit**.

   The Submit Execution Setup screen is displayed.

   For more information on how to submit an Execution Setup, refer to *Oracle Life Sciences Data Hub Application Developer's Guide (Submitting Jobs for Execution).*
2. In the Submission Details section, select Submission Type as **Scheduled**.

   The Schedule Submission section is displayed.
3. Enter the required details and click **Submit**.

Setting Up the Target Load Type

When you submit a Program for execution, perform the following tasks to specify the table processing type:

1. In the appropriate Work Area, navigate to the installed executable instance you want to submit.
2. In the Program's screen, click **Launch IDE**.

   This launches Informatica PowerCenter client installed on your machine.
3. In the Workflow Manager, modify the Target load type setting to **Bulk** or **Normal**.
4. Reinstall the program in Oracle LSH.
5. Navigate to the installed executable instance you want to submit, and click **Submit**.

   The Submit Execution Setup screen is displayed.

For more information on how to submit an Execution Setup, refer to *Oracle Life Sciences Data Hub Application Developer's Guide (Submitting Jobs for Execution).*

6. In the Submission Parameters section, select the Parameter Value for Bulk Load based on what you have set up in Step 3. Select **Yes** if the table processing type is bulk, and **No** if it is normal.
7. Enter the required details and click **Submit**.

6

Implementing Security

This chapter contains the following topics:

About Security in Oracle Clinical Development Analytics

Oracle Clinical Development Analytics (OCDA) spans several applications: Oracle Clinical and Oracle's Siebel Clinical are the data sources, Oracle Life Sciences Data Hub (Oracle LSH) loads and stores the data, and Informatica ETL Programs stored in Oracle LSH transform Oracle Clinical and Siebel Clinical data structures into the star schema required by Oracle Business Intelligence Enterprise Edition (OBIEE), which reads from the star schema and provides the user interface where end users can view and analyze data through dashboards and reports.

You perform almost all security tasks in Oracle LSH.

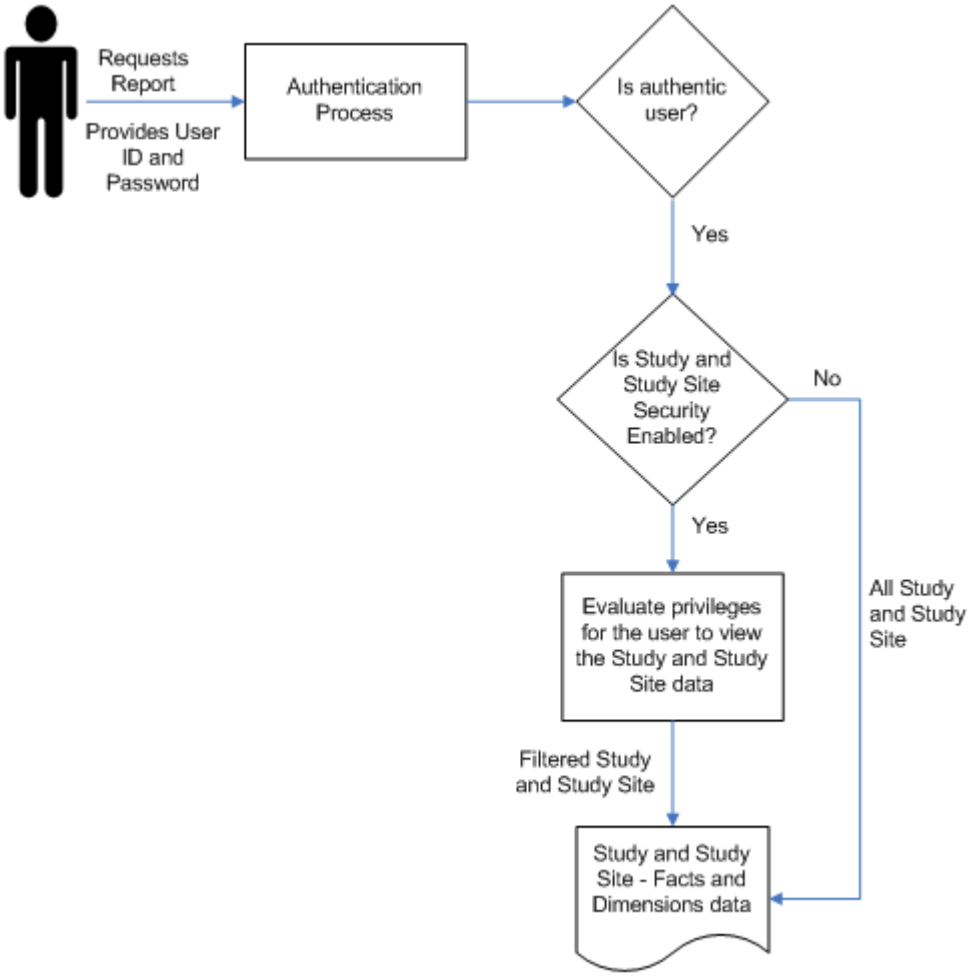
OCDA security includes:

- **Authentication**. OCDA user accounts are maintained in Oracle Life Sciences Data Hub (Oracle LSH). When a user logs in to OBIEE, OBIEE sends the user name and password to Oracle LSH for authentication. For more information, refer to Setting Up User Authentication on page 6-3.
- **Authorization**. You assign user accounts to user groups in Oracle LSH. On login, Oracle LSH passes the authenticated user's user group assignments to OBIEE, where user groups with the same name determine which parts of OCDA the user can use.

  Predefined OBIEE user groups determine the privileges allowed to users and allow access to the shipped OCDA dashboards and reports. You must define an Oracle LSH user group with the same name for each OBIEE user group you plan to use. You can create additional user groups as needed in both OBIEE and Oracle LSH. In addition, in Oracle LSH you must define roles, assign the roles to user groups, and assign users to roles in user groups. For more information, refer to Setting Up User Authorization on page 6-4.
- **Data Access**. In OCDA, *study-level data* means planned sites, documents, and enrollment, and *study site-level data* means all other OCDA data. You can allow all users to see study-level data from all studies and study site-level data from all study sites, or you can require explicit access to particular studies and study sites

for each user. You may need to create Oracle Clinical or Siebel Clinical user accounts in order to explicitly control access by OCDA users to Study and Study-site level data. For more information, refer to Setting Up Study and Study Site Data Access for Users on page 6-10.

Figure 6–1 Study and Study Site Security Implementation



Example

This document describes how to set up security for the following basic types of users as an example. To refine this example for your company's needs, refer to the Oracle LSH System Administrator's Guide chapter on setting up security.

- **OCDA End Users** are people who can view Oracle Clinical and Siebel Clinical data in OCDA through dashboards and reports. The specific dashboards and reports they can view is determined by the user groups they belong to.
- **OCDA Programmers** are people who are authorized to create their own reports in the Answers component of OBIEE/OCDA, which does not require any programming skills. You can distinguish between people who can simply create ad hoc reports and those who can save the reports they create to a dashboard so that other people can use them.

- **LSH Programmers** are people who can modify the functionality of OCDA by modifying the predefined ETL Programs that OCDA uses to transform transactional source data in Oracle LSH for use in OCDA. They may also create new ETL Programs to support custom dashboards and reports in OCDA.
- **LSH Schedulers** are people who schedule OCDA jobs, including the data loading job and the user data access jobs. They need privileges similar to LSH Programmers.
- **LSH Administrators** are people who set up Oracle LSH, including Oracle LSH security, and grant privileges to other users.

Setting up security for these user types is described in the following sections and summarized in Table 6–1, Summary of the Oracle LSH Security Setup Example.

Setting Up User Authentication

Oracle LSH handles user authentication for OCDA through its integration with Oracle Applications UMX. You create and maintain user accounts for OCDA in Oracle LSH. When a user logs in, OBIEE passes the user name and password to Oracle LSH, which verifies that they are a valid combination and populates the OBIEE Group session variable with a list of the user groups the user belongs to.

Creating User Accounts

You can create Oracle LSH user accounts in the following ways:

- Create each user account separately through the Oracle Applications UMX user interface. For more information, refer to the Oracle LSH System Administrator's Guide chapter on setting up security.
- If you have an Oracle LDAP Directory, migrate users to Oracle Applications. For more information, refer to My Oracle Support (ID 1508321.1).

When you create an Oracle LSH user account, you assign one or more application roles to it. These roles are different from the object security roles you create and assign to user groups and users within groups. For more information, refer to the Oracle LSH System Administrator's Guide chapter on setting up security. Different users need different roles:

- **OCDA End Users**: Give OCDA end users the LSH Consumer role.
- **LSH Administrators**: You must create at least one user with each of these application roles: LSH System Admin role, LSH Adapter Security Admin role, LSH Security Admin role, LSH Function Security Admin role, and LSH Groups Admin role.
- **LSH Programmers**: Give LSH Programmers the LSH Definer application role.
- **OCDA Programmers**: Give OCDA Programmers the LSH Consumer role.
- **LSH Schedulers**: Give LSH Schedulers the LSH Definer application role.

Creating Database Accounts

LSH Programmers need an Oracle LSH database account linked to their user account. For more information, refer to the Oracle LSH System Administrator's Guide chapter on database accounts for information.

Setting Up User Authorization

Authorization determines which parts of OCDA's OBIEE user interface, and in some cases which parts of Oracle LSH, users can access. The tasks required to set up user authorization are:

You can do all the Oracle LSH tasks in either of two ways:

- through the Oracle LSH user interface. For more information, refer to the Oracle LSH System Administrator's Guide chapter on setting up security.
- using Oracle LSH public APIs. For more information, refer to the Oracle LSH Application Developer's Guide chapter on using APIs.

For conceptual information on Oracle LSH security, refer to the Oracle LSH Implementation Guide chapter on designing a security system. For detailed instructions on all Oracle LSH security setup tasks, refer to the Oracle LSH System Administrator's Guide chapter on security. For background information on the integration of OBIEE with Oracle LSH, refer to the OBIEE section in the Business Areas chapter of the Oracle LSH Application Developer's Guide.

Using Predefined User Groups in OBIEE and Creating New Ones

All OCDA End Users—people who view Oracle Clinical and Siebel Clinical data in OBIEE—must be associated with one or more OBIEE user groups. The OBIEE groups determine privileges allowed to users and allow access to the shipped OCDA dashboards and reports. To associate users with an OBIEE user group, you assign their Oracle LSH user account to an Oracle LSH user group with the same name as the required OBIEE user group.

OCDA provides a set of predefined OBIEE user groups. You can create additional groups as needed.

> **Note:** To perform administrative tasks in OBIEE, you must be a member of OBIEE's predefined Administrator group.

Predefined OBIEE User Groups

OCDA includes predefined OBIEE user groups (called *groups* in OBIEE) to allow OCDA end users access to predefined dashboards. Each dashboard allows access to a predefined set of reports. For more information about predefined reports, refer to Appendix A, Dashboards and Reports.

The predefined user groups allow dashboard access as follows:

- OCDA-StudyManager: CO - Document Management, CO - Site and Recruitment Overview, CO - Study and Region Overview, and CO - Subject Retention
- OCDA-CRA: CRA EDC , CO - Document Management, CO - Site Recruitment Overview, CO - Study and Region Overview, and CO - Subject Retention

- OCDA-DataEntryManager: CO - Document Management, CO - Site Recruitment Overview, CO - Study and Region Overview, and CO - Subject Retention
- OCDA-DataManager: DM EDC, DM Paper, CO - Document Management, CO - Site Recruitment Overview, CO - Study and Region Overview, and CO - Subject Retention
- OCDA-ProjectManager: CO - Document Management, CO - Site Recruitment Overview, CO - Study and Region Overview, and CO - Subject Retention
- OCDA-Site: CO - Document Management, CO - Site Recruitment Overview, CO - Study and Region Overview, and CO - Subject Retention

The last two user groups are predefined, but if you want to use them you must associate the groups with dashboards.

For more information, refer to Assigning OBIEE User Groups to Dashboards and Reports on page 6-6.

Note: OCDA ships with both the Presentation catalog and Repository groups for each predefined user group.

Creating User Groups in OBIEE

You can create additional user groups in OBIEE as needed; for example:

- If you create new dashboards or reports, you may need new user groups to manage access to them.
- To create new dashboards and reports you must allow some users—OCDA Programmers in the example—access to the OBIEE Answers component, for which they need to be in a user group with access to Answers.

For each new user group you need, you must create identically named user groups in three places:

- Create a new group in the Presentation catalog: Log in to OBIEE, click **Settings** > **Administration** > **Manage Presentation Catalog Groups and Users**. For more information, refer to the *Oracle Business Intelligence Presentation Services Administration Guide*.
- Create a new group in the OBIEE Repository. If you wish, you can use the group to provide increased security at the RPD level. For more information, refer to the *Oracle Business Intelligence Server Administration Guide*.

  Then in Oracle LSH, navigate to **OCDA_domain** > **OCDA_OBIEE_CODE_APP_AREA** > **OCDA_OBIEE_WA** > **OCDA Data Warehouse**. Check out the Business Area, upload the revised RPD file as source code, and reinstall the Work Area to deploy the revised RPD file. For more information, refer to the *Oracle LSH Application Developer's Guide* Business Area chapter's section on OBIEE.
- Create a new user group in Oracle LSH. For more information, refer to Creating User Groups in Oracle LSH on page 6-6.

Note: The OBIEE Presentation catalog and Repository user groups and the corresponding Oracle LSH user group must all have **exactly** the same name.

Assigning OBIEE User Groups to Dashboards and Reports

To use a group to allow users access to particular dashboards or reports, you must assign the new group to one or more dashboards or reports.

Log in to OBIEE, click **Settings** > **Administration** > **Manage Interactive Dashboards**. For more information, refer to the *Oracle Business Intelligence Presentation Services Administration Guide*.

Creating User Groups in Oracle LSH

For users to access any part of OCDA's OBIEE user interface, they must belong to an Oracle LSH user group that has a corresponding OBIEE user group of the same name. The user can access the parts of the user interface specified for the OBIEE user group.

Some users, such as the LSH Definer, Scheduler, and Administrator in the example, need to work in Oracle LSH. For users to perform most tasks in Oracle LSH, they must belong to an Oracle LSH user group.

You must create one Oracle LSH user group with the same name as each OBIEE user group, including each of the predefined OBIEE user groups—OCDA-Site, OCDA-CRA, OCDA-DataEntryManager, OCDA-DataManager, OCDA-ProjectManager—that you want to use.

In addition, you must create Oracle LSH user groups for people who need access to Oracle LSH but not necessarily to OCDA.

Example To support the example user types, create these user groups:

- **OCDA End User Groups**: These correspond to the predefined OBIEE user groups or other OBIEE user groups you create to allow access to dashboards and reports.
- **OCDA Programmer Group**: This group is for people who have access to the Answers component of OBIEE.
- **LSH Programmer Group**: LSH Programmers and LSH Schedulers can belong to the same user group, with different roles to differentiate what they can do. You might want OCDA Programmers to be in the same group so that they can create and modify ETL Programs to support the dashboards and reports they create.
- **LSH Administrator Group**: You do not need this group unless you want to allow LSH Programmers to modify some ETL Programs but not others. For more information, refer to Assigning Roles to Oracle LSH User Groups on page 6-8 and Roles for Administrators on page 6-8.

Creating Roles in Oracle LSH

You must create roles in LSH that define which actions a user with that role can take on an object (such as a Program) in Oracle LSH. You then assign roles to user groups. When you assign a user to a group, you must assign them to a role in the group at the same time.

OCDA User Role OCDA End Users **must** have a role with the following privileges:

- View operation on Business Area instances of the Default subtype
- Read Data operation on Table instances of the Default subtype

Note: Do **NOT** give the role the View operation on Table instances of the Default subtype. If you do, OCDA End Users can use Oracle LSH to see all data in the Table instances to which their user group is assigned, even if you limit their access to particular studies and sites through OCDA.

Note: To give a role operations on an object subtype in Oracle LSH, you work in the **Security** tab. First define the role in the **Roles** subtab. Then go to the **Subtypes** subtab, find the object, then its Default subtype, and then add the role to the appropriate operation. For more information, refer to the Oracle LSH System Administrator's Guide chapter on setting up security.

Example To support the basic user types, you can create the following roles for the example user groups:

Role for OCDA End User Groups

Each Oracle LSH user group corresponding to an OCDA user group—including groups you create and the predefined OCDA user groups—must have the role described above, which we call the **OCDA User Role** in the example.

Role for OCDA Programmers

OCDA Programmers need the same Oracle LSH role as OCDA End Users: the OCDA User Role.

Roles for LSH Programmers

You can customize your installation of OCDA. For more information about how to customize the ETL programs, refer to Chapter 5, Extract Transform Load Programs. To support customization, create roles like the following:

Note: In all cases, assign the role to the operation on the Default subtype of the object type listed. All predefined OCDA objects are created using the Oracle LSH Default subtype.

- **ETL Modifier** is for people who need to modify the shipped Informatica ETL Programs in Oracle LSH. This role requires the View operation on Domains; the View and Modify operations on Application Areas, Execution Setups, Programs, Program instances, Parameters, and Work Areas; and the Install operation on Work Areas.

  In order to modify the data structures, the role also requires the View and Modify operations on Tables and Table instances and the Create Tables and Create Variables operations on Application Areas.

- **ETL Creator** is for people who need to create new Load Sets and Informatica ETL Programs in Oracle LSH in order to load additional data from Oracle Clinical and Siebel Clinical and transform it to the start schema format. This role requires the View operation on Domains; the View and Modify operations on Application Areas, Execution Setups, Load Sets, Load Set instances, Programs, Program instances, Parameters, Tables, Table instances and Work Areas; the Install

operation on Work Areas, and the Create Program, Create Table, and Create Variable operations operation on Application Areas.

- **RPD Modifier** is for people who need to modify the Repository and the corresponding RPD file in the OCDA Business Area in Oracle LSH. This role requires the View operation on Domains; the View and Modify operations on Application Areas, Business Areas, Business Area instances, Execution Setups, and Work Areas; and the Install operation on Work Areas.

  In order to modify the data structures, the role also requires the View and Modify operations on Tables and Table instances and the Create Tables and Create Variables operations on Application Areas.

- **ETL Scheduler**. At least one user needs to be able to schedule execution of the program that refreshes Oracle Clinical and Siebel Clinical data in the OCDA data warehouse. This role requires the View operation on Domains and Application Areas; the Submit operation on Execution Setups, and the View operation on Program instances and Work Areas.

In addition, programmers who need to create or modify ETL programs need privileges on the Informatica Adapter, and programmers who need to modify the RPD need privileges on the OBIEE adapter. For more information about the operations required, refer to the Oracle LSH System Administrator's Guide chapter on adapters, section on adapter security.

Roles for Administrators

Most administrator application roles do not need any object-security roles; that is, roles that grant privileges to perform operations on object subtypes. However, if you decide to specify which ETL Programs LSH Programmers can modify, create the **LSH Security Administrator** role with the Apply Security operation on all container and primary object types, Default subtype.

Assigning Roles to Oracle LSH User Groups

Assign the roles you have created to the appropriate Oracle LSH user group.

> **Note:** Every Oracle LSH user group is automatically assigned a role called Group Administrator. Only a user with this role in a group can add other users to the group and assign roles to them. Each Oracle LSH user group must have at least one group administrator. This user must have the LSH Groups Admin application role.

Example To support the basic user types, you can add roles to user groups as follows:

- **OCDA End User Groups**: These correspond to the predefined OBIEE user groups or other OBIEE user groups you create to allow access to dashboards and reports. Assign the **OCDA User Role** to each of these groups.
- **OCDA Programmer Group**: Assign the **OCDA User Role** to this group.
- **LSH Programmer Group**: Assign the roles **ETL Modifier**, **ETL Creator**, **RPD Modifier**, and **ETL Scheduler** to this group.
- **LSH Administrator Group**: Assign the role **LSH Security Administrator** to this group.

Assigning Oracle LSH User Groups to Objects

OCDA users cannot do anything in either OBIEE or Oracle LSH if they do not belong to a user group that is assigned to an Oracle LSH object. You can handle this in different ways:

- A user with the LSH Security Bootstrap Admin application role can assign all user groups to the OCDA_domain. All the predefined OCDA Programs, Tables, and other objects automatically inherit the user group assignments. The roles you define limit what users in the user groups can do.
- A user with the LSH Security Admin application role can assign selected user groups to selected objects. This has little advantage for controlling the activities of OCDA End Users, but does enable you to allow LSH Programmers to only certain ETL Programs, or to a new Application Area for the purpose of creating new ETL Programs without allowing access to the predefined ETL Programs.

Assigning Users to Oracle LSH User Groups

You must assign at least one user to the Group Administrator role in each group. Each group administrator then assigns users to the group with an appropriate role. Users can belong to more than one user group.

Example Summary

The following table summarizes the information in the preceding sections. In addition to the setup displayed in Table 6–1, the user groups must be assigned to Oracle LSH objects. For more information, refer to Assigning Oracle LSH User Groups to Objects on page 6-9.

Table 6–1 Summary of the Oracle LSH Security Setup Example

Example User	LSH Application Role	Example LSH User Group	Example Object Security Role
OCDA End User	LSH Consumer	One of the following: OCDA-StudyManager OCDA-Site OCDA-CRA OCDA-DataEntryManager OCDA-ProjectManager OCDA-DataManager	OCDA User Role
OCDA Programmer	LSH Consumer	OCDA Programmer Group	OCDA User Role*
LSH Programmer	LSH Definer	LSH Programmer User Group	One or more of the following: ETL Modifier ETL Creator RPD Modifier*
ETL Scheduler	LSH Definer	LSH Programmer User Group	ETL Scheduler
LSH Administrator	Each of the following roles must be assigned to at least one user: LSH System Admin LSH Adapter Security Admin LSH Security Admin LSH Groups Admin LSH Security Bootstrap Admin	Each user group must have an LSH Group Administrator. The LSH Security Admin belongs to the LSH Administrator user group (optional). Other Admin users do not need to be assigned to a user group.	LSH Administrator

***Note:** You may want the same person to have both the OCDA User Role in the OCDA Programmer user group and the RPD Modifier role in the LSH Programmer user group.

Setting Up Study and Study Site Data Access for Users

This section contains the following topics:

You can set two variables to either allow all users access to data from all studies and study sites or you can require each user to have explicit access to particular studies and study sites. For more information, refer to Setting the Systemwide Access Variables on page 6-10.

In OCDA:

- **Study data** means data pertaining to the study as a whole, including planned sites, planned enrollment, and the ratio of actual to planned subjects. It is not a roll-up of all patient data from all study sites. For security purposes, all documents are considered Study data as well, regardless of whether the document pertains to a Study, a Region, or a Study-Site.
- **Study site data** means all other OCDA data, including information about discrepancy management, CRF verification and approval, workloads, and more.

This means that if you set the variables to require explicit access:

- If users needs access to study-wide data on planned sites, enrollment, or documents, they must have explicit access to study data for that study. Having access to all study sites does not automatically allow access to study data.
- If users needs access to study site data from every site in a study, they must have explicit access to each study site. You can set up this access automatically by importing user privileges from Oracle Clinical or Siebel Clinical. For more information, refer to Importing Study and Study Site Data Access Privileges on page 6-12.

Note: If a user has access to multiple, but not all, sites in a study, the totals displayed in OCDA reports reflect the totals for the sites to which the user has access, not the totals for all sites in the study. For more information, refer to Study-Site Access Example on page 6-14.

Setting the Systemwide Access Variables

The following static repository variables determine whether explicit access to study or study site data is required for all users:

- **Enable_Study_Access_Sec**: If set to **Y**, all users must have explicit access granted to study-level data for a particular study in order to see that data. If set to **N**, all users can see study-level data for all studies.

- **Enable_Study_Site_Access_Sec**: If set to **Y**, all users must have explicit access to a particular study site in order to see site-level data for that study site. If set to **N**, all users can see site-level data for all study sites.

  The default value for both variables is **N**.

  Note: If you set these variables to **Y** you must populate a set of tables with user access data. For more information, refer to Importing Study and Study Site Data Access Privileges on page 6-12.

  Oracle recommends that you set both variables to the same value.

To change the value for either variable:

1. Stop the BI Server and the BI Presentation Server Services.
2. In Oracle LSH, navigate to **OCDA_domain** > **OCDA_OBIEE_CODE_APP_AREA** > **OCDA_OBIEE_WA** > **OCDA Data Warehouse**, and check out the Business Area.
3. Using the OBIEE Administrator tool, edit the Repository:
   a. On the **Manage** Menu, choose **Variables**.
   b. In the **Variable Manager** dialog, choose **Repository**, then **Variables**, then **Static**.
   c. Open the properties of the variable, either by double-clicking it or through the context menu.
   d. Edit the value of Default Initializer for the variable: **Y** enables access control; **N** disables access control.
   e. Exit the Static Repository Variable dialog.
   f. Exit the Variable Manager.
   g. Save the modified Repository.
4. Upload the new RPD file as the Business Area's Source Code.

   For more information, refer to the Oracle LSH Application Developer's Guide chapter on Business Areas for instructions.
5. Check in the Business Area.
6. Install Work Area OCDA_OBIEE_WA.

   For more information, refer to the Oracle LSH Application Developer's Guide for instructions.
7. Start the BI Server and BI Presentation Server Services.

Data Access Tables

OCDA uses three database tables to control users' access to rows of data in the star schema fact tables that pertain to particular studies and study sites. The data access tables are:

- W_HS_APPLICATION_USER_D contains a list of the user accounts that can have data access granted to particular studies and study sites. It must be populated from an external source. OCDA includes a sample ETL Program for this purpose.

For more information, refer to Importing Study and Study Site Data Access Privileges on page 6-12.

- W_HS_STUDY_ACCESS_SEC controls which users can see study-level data on which studies.
- W_HS_STUDY_SITE_ACCESS_SEC controls which users can see study site-level data on which study sites.

Importing Study and Study Site Data Access Privileges

The data access tables must be populated with data. OCDA includes a set of template ETL programs for this purpose. The programs are called *template* programs because you will need to adjust them according to your particular configuration, if you are enabling access control. If you are not enabling access control, the template programs can be used as they are. The following list enumerates the degrees to which you may want to modify the template programs:

- If you set the systemwide access variables to **N**, run the template ETL programs as is to populate the tables with a dummy user. All users have access to all study-level and study site-level data for all studies and sites.
- If you set the systemwide access variables to **Y**, modify the ETL programs as necessary to import user access information from Oracle Clinical and Siebel Clinical. If there are people who should be able to use OCDA but do not currently have either Oracle Clinical or Siebel Clinical user accounts with privileges for specific studies or sites set, you must up create user accounts with the desired privileges in one of the source transactional systems.
- If you set the systemwide access variables to **Y**, modify the ETL programs as necessary to import user access information from some other source.

About Oracle Clinical Template Programs

The template ETL programs for Oracle Clinical are:

- OCDA_INFA_Application_User_D_SDE_OC_PRG
- OCDA_INFA_Study_Access_Sec_SDE_OC_PRG
- OCDA_INFA_Study_Site_Access_Sec_SDE_OC_PRG

The Oracle Clinical table OPA.OPA_LEVEL_PRIVS stores study and study site data access information for Oracle Clinical and Oracle Clinical Remote Data Capture (RDC) Onsite users. The Oracle Clinical or RDC administrator sets these privileges in the Maintain Access to Studies and Maintain Access to Sites windows in either Oracle Clinical or the RDC Administration application.

The template OC ETL programs read data from this table and populate the data access tables in the OCDA warehouse in Oracle LSH.

OCDA uses this data to allow users access to study and study site data in OBIEE. In Oracle Clinical and RDC the concept of study and study site data access is different from OCDA's, and you can specify a variety of privileges on studies and study sites, which is not required in OCDA where all data access is view-only. The template OCDA ETL programs interpret the Oracle Clinical/RDC data as follows:

- If a user has been granted any privileges on a study site in OPA_LEVEL_PRIVS, the programs give the user study site-level access to that study site in OCDA.
- If a user has been given any privileges on a study in OPA_LEVEL_PRIVS, the programs give the user:

  - Study-level access to that study in OCDA
  - Study site-level access to all the study sites in that study

The template ETL programs also remove the Oracle Clinical `OPS$` prefix from each user name. You will likely need to alter this translation of Oracle Clinical user name to OCDA user name. For more information, refer to Modifying the Data Access Programs on page 6-13.

About Siebel Clinical Security ETL Programs

The secuirty ETL programs for Siebel Clinical are:

- OCDA_INFA_Application_User_D_SDE_SC_PRG
- OCDA_INFA_Study_Access_Sec_SDE_SC_PRG
- OCDA_INFA_Study_Site_Access_Sec_SDE_SC_PRG
- OCDA_S_PARTY_LS
- OCDA_INFA_Party_Parent_SDE_SC_PRG
- OCDA_PLS_SC_PARTY_HIERARCHY_PRG
- OCDA_INFA_Study_Hierarchy_SDE_SC_PRG
- OCDA_INFA_Study_Site_Hierarchy_SDE_SC_PRG

These programs read from the standard tables describing Siebel Clinical users and protocols, and the access that users have to studies. Review the programs, and adjust them to correspond to any changes you have made from the standard Siebel Clinical model.

The other security ETL programs are:

- OCDA_INFA_Application_User_D_SDE_Pool_PRG
- CDA_INFA_Study_Access_Sec_SDE_Pool_PRG
- OCDA_INFA_Study_Site_Access_Sec_SDE_Pool_PRG
- OCDA_INFA_Application_User_D_SIL_PRG
- CDA_INFA_Study_Access_Sec_SIL_PRG
- OCDA_INFA_Study_Site_Access_Sec_SIL_PRG

Modifying the Data Access Programs

You may need to modify the data access ETL programs for the following reasons:

User Name Conversion Modification You may need to edit the SDE programs to adapt the user name conversion to your input Oracle Clinical or Siebel Clinical user names and your output OCDA user names. Be careful; if the following conditions are not met, names will not match up and access control will fail.

- The conversion performed in the all three SDE programs must be identical
- The resultant user name must be the same as the Oracle LSH user name used for OCDA purposes. SDE ETL programs that execute the ETL to populate the data access tables have a parameter for entering the email portion of the standard Oracle LSH user name format.

Interpretation Logic Modification You may prefer to interpret the Oracle Clinical or Siebel Clinical privileges differently in OCDA.

Source Modification You may want to import data access information from another source.

For instructions on modifying ETL programs, refer to Customizing an ETL Program on page 5-10.

Running the Template Data Access Control ETL Programs

You should run your versions of these programs:

- when you first set up OCDA
- when new users need access
- when new studies are added
- when new sites are added to studies
- when the systemwide access variable settings are modified

You must run the programs in the order in which they are listed in Importing Study and Study Site Data Access Privileges on page 6-12. For more information, refer to Scheduling an ETL Program on page 5-14.

Study-Site Access Example

In Study 012345, users U2 and U3 have study-site access defined in the OCDA data access table W_STUDY_ACCESS_STUDY_SITE_SEC as follows (note that user U1 is not in the table at all):

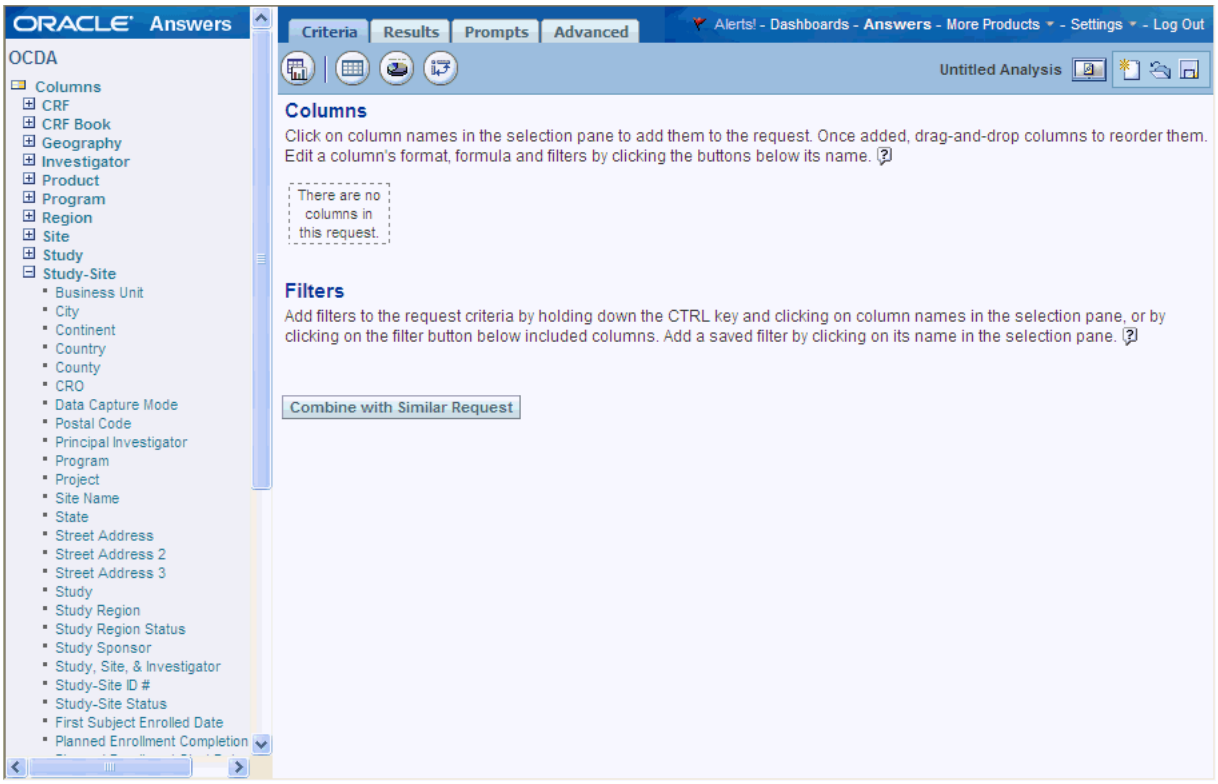
APPLICATION_USER_WID	STUDY_WID	STUDY_SITE_WID
U2	A	A1
U2	A	A2
U3	B	B1
U3	B	B2

The distribution of discrepancies by study site, as stored in the discrepancies aggregate table in the warehouse, is:

Study	Study Site	Number Of Discrepancies
A	A1	20
A	A2	15
B	B1	30
B	B2	10
B	B3	20

A query on this data has been created and saved as a report:

Figure 6–2 OCDA User Interface



Users U1, U2, and U3 can run the report. When user U1 runs the report, nothing can be seen. U1 has no access to any study site data.

When user U2 runs the report, U2 sees the following:

Study	Number of Discrepancies
A	35

And U2 drills down within Study A, the following can be seen:

Study	Site	Number of Discrepancies
A	A1	20
A	A2	15
Total		35

When user U3 runs the report, U3 sees the following:

Study	Number of Discrepancies
B	40

That is, U3 sees the sum of the values for the sites U3 is entitled to see, not the sum for the study. For user U3, it is as if site B3 does not exist. Drilling down shows the same effect:

Study	Site	Number of Discrepancies
B	B1	30
B	B2	10
Total		40

Note: A given document can pertain to study-site, a region, or a study. Ideally, there would be separate security controls for each level. However, in OCDA Release 2.0, we are applying the same security to all documents. As every region and study-site belongs to a study, we control documents at the study level.

Part III

Appendixes

Part III contains the following appendixes:

- Appendix A, Dashboards and Reports
- Appendix B, Oracle Clinical Development Analytics Presentation Catalog
- Appendix C, Troubleshooting

A

Dashboards and Reports

This section describes predefined dashboards and reports delivered with Oracle Clinical Development Analytics (OCDA):

- Oracle Clinical Development Analytics Dashboards on page A-1
- Oracle Clinical Development Analytics Reports on page A-10

See Also:

- Chapter 2, Using Oracle Clinical Development Analytics
- Chapter 3, Working with Reports

Oracle Clinical Development Analytics Dashboards

OCDA is delivered with seven dashboards. These dashboards can be accessed by users with a specific job responsibility and security privileges. Each dashboard has tabbed pages that displays reports.

OCDA includes the following dashboards:

- CO - Document Management
- CO - Site and Recruitment Overview
- CO - Study and Region Overview
- CO - Subject Retention
- CRA EDC Dashboard
- DM EDC Dashboard
- DM Paper Dashboard

Log in to OCDA, and select the dashboard you want to view. For more information, refer to Accessing Oracle Clinical Development Analytics on page 2-2.

CO - Document Management

This dashboard can be accessed by a Study Manager or Clinical Research Associate (CRA). It provides some initial reports related to document management and related cycle times.

This dashboard includes the following prompts, which are common to all its pages:

- **Program**: Lists the names of the Programs that own a Study.
- **Product Name**: Lists the names of the Products that own a Study.

- **Study**: Lists Studies within a Program or Product.
- **Study Status**: Lists the Statuses of a Study.
- **Study Region**: Lists the Regions for a Study.
- **Study Region Status**: Lists the Statuses of a Study Region.
- **Study-Site ID #**: Lists Sites within a Study, by site number.
- **Site Name**: Lists the name of the center or institution for a Study-Site.
- **Study-Site Status**: Lists the Statuses of a Study-Site.
- **Activity Type**: Lists types of clinical documents collected for a Study or at a Study-Site.
- **Document Sent Date**: Indicates the date a Document was Sent.
- **Document Received Date**: Indicates the date a Document was Received.

Note: The following prompts only apply to Study-Site documents. The dataset returned from filtering on one of these prompts will only include Study-Site documents.

- Program
- Product Name
- Study
- Study Status
- Study Region
- Region Status
- Study-Site ID #
- Site Name
- Study-Site Status

CO - Document Management Dashboard Pages

This dashboard includes the following tabbed pages:

- Document List Page
- Document Collection Cycle Times Page

Document List Page Displays reports that lists clinical documents, as well as a chart summarizing outstanding documents.

This page includes the following reports:

- Outstanding Documents by Category, Type (Report 8SDP-2)
- Documents List (Report 8SDP-1)

Document Collection Cycle Times Page Displays reports on cycle times related to document collection.

This page includes the following reports:

- Document Collection Cycle Times - Days Outstanding by Type (Report 3SS04-1b)
- Document Collection Cycle Times -Turn Around Time by Type (Report 3SS04-1c)

- Document Collection Cycle Times Table (Report 3SS04-1)

CO - Site and Recruitment Overview

This dashboard can be accessed by a Study Manager or CRA. It provides some initial reports related to site start up and recruitment.

This dashboard includes the following prompts, which are common to all its pages:

- **Program**: Lists the names of the Programs that own a Study.
- **Product Name**: Lists the names of the Products that own a Study.
- **Study**: Lists Studies within a Program or Product.
- **Study Status**: Lists the Statuses of a Study.
- **Study Region**: Lists the Regions for a Study.
- **Study Region Status**: Lists the Statuses of a Study Region.
- **Study-Site ID #**: Lists Sites within a Study, by site number.
- **Site Name**: Lists the name of the center or institution for a Study-Site.
- **Principal Investigator**: Lists the Principal Investigators for a Study-Site.
- **Study-Site Status**: Lists the Statuses of a Study-Site.

CO - Site and Recruitment Overview Dashboard Pages

This dashboard includes the following tabbed pages:

- Site Status Overview Page
- Comparative Site Enrollment Page
- Screening Overview Page
- Screen Failure Overview Page
- Enrollment Overview Page
- Randomization Overview Page
- Subject Recruitment Over Time Page

Site Status Overview Page Displays a report that provides site status by region.

This page includes the following reports:

- Site Status by Region Chart (Report 3SS07-2)

Comparative Site Enrollment Page Displays a report that compares sites based on progress toward site enrollment goals and contribution toward study recruitment goals.

This page includes the following reports:

- Comparative Site Enrollment Status Table (Report 8SDP-3)

Screening Overview Page Displays a report related to subject screening.

This page includes the following reports:

- Screening Overview By Region Chart (Report 8SDP-28)

Screen Failure Overview Page Displays reports related to screening failures.

This page includes the following reports:

- Screen Failure Reason Chart (Report 4PR02-1b)
- Screen Failure Reason Counts by Site Table (Report 4PR02-1)
- Screen Failure Reason by Site Chart (Top 10 # Screen Failures) (Report 4PR02-1c)

Enrollment Overview Page Displays reports related to subject enrollment.

This page includes the following reports:

- Enrollment Overview By Region Chart (Report 8SDP-10b)
- Enrollment Overview By Site (Report 8SDP-10)

Randomization Overview Page Displays reports related to subject randomization.

This page includes the following reports:

- Randomization Overview By Region Chart (Report 8SDP-30)
- Randomization Overview By Site Table (Report 8SDP-29)

Subject Recruitment Over Time Page Displays reports related to subject recruitment.

This page includes the following reports:

- Enrollment Progress Over Time (Report 4PR01-2)

CO - Study and Region Overview

This dashboard can be accessed by a Study Manager or CRA. It provides some initial reports related to a study or region overall and is intended as a starting point for an implementation.

This dashboard includes the following prompts, which are common to all its pages:

- **Program**: Lists the names of all Programs.
- **Product Name**: Lists the names of all Products.
- **Study**: Lists Studies within a Program or Product.
- **Study Status**: Lists the Statuses of a Study.
- **Study Region**: Lists the Regions for a Study.
- **Study Region Status**: Lists the Statuses of a Study Region.

CO - Study and Region Overview Dashboard Pages

This dashboard includes the following tabbed pages:

- Site Overview Page
- Enrollment Overview Page

Site Overview Page Displays reports related to site readiness and enrollment.

This page includes the following reports:

- Planned Sites vs. Sites Screening & Enrolling Chart (Top 10) (Report 3SS02-1b)
- Planned Sites vs. Sites Screening & Enrolling Chart (Bottom 10) (Report 3SS02-1d)

Enrollment Overview Page Displays reports related to subject screening and enrollment.

This page includes the following reports:

- Screening Overview By Region Chart (Report 8SDP-28)
- Enrollment Overview By Region Chart (Report 8SDP-10b)

CO - Subject Retention

This is the subject retentian and early termination dashboard for a Study Manager or CRA. It provides some initial reports related to site start up and recruitment.

This dashboard includes the following prompts, which are common to all its pages:

- **Program**: Lists the names of the Programs that own a Study.
- **Product Name**: Lists the names of the Products that own a Study.
- **Study**: Lists Studies within a Program or Product.
- **Study Status**: Lists the Statuses of a Study.
- **Study Region**: Lists the Regions for a Study.
- **Study Region Status**: Lists the Statuses of a Study Region.
- **Study-Site ID #**: Lists Sites within a Study, by site number.
- **Site Name**: Lists the name of the center or institution for a Study-Site.
- **Principal Investigator**: Lists the Principal Investigators for a Study-Site.
- **Study-Site Status**: Lists the Statuses of a Study-Site.

CO - Subject Retention Dashboard Pages

This dashboard includes the following tabbed pages:

- Subject Retention Overview Page
- Early Termination Overview Page
- Subject Retention Over Time Page

Subject Retention Overview Page Displays reports related to subject retention.

This page includes the following reports:

- Withdrawn Reason Chart (Report 4PR02-2)
- Patient Retention Table (Report 5SC01-1)

Early Termination Overview Page Displays reports related to subject early termination.

This page includes the following reports:

- Withdrawn Reason Chart (Report 4PR02-2)
- Withdrawn Reason Overview Chart (Top 10 # Early Terms) (Report 8SDP-25)
- Withdrawn Reason Counts by Site Table (Report 4PR02-2b)

Subject Retention Over Time Page Displays reports related to subject retention.

This page includes the following reports:

- Subject Retention Over Time Chart (Report 8SDP-4)

CRA EDC Dashboard

This is the basic dashboard for a Clinical Research Associate (CRA). It provides some initial reports for a CRA, and is intended as starting point for an implementation.

This dashboard includes the following prompts, which are common to all its pages:

- **Sponsor**: Lists the name of the Sponsor companies for which this study is being conducted.
- **Program**: Lists the name of the Programs that owns the Study.
- **Study**: Lists Studies within a Program.
- **Study Site**: Lists Sites within a Study.

CRA EDC Dashboard Pages

This dashboard includes the following tabbed pages:

- Home Page
- eCRF Workload Page
- Key Rates Page
- Performance Page
- Discrepancy Workload Page

Home Page Displays key study based reports.

This page includes the following reports:

- Average Duration of Currently Open Discrepancies, by Site (Report CDA-DM-205)
- Approval & Verification Rates - Worst 25 (Report CDA-DM-350)

eCRF Workload Page Displays reports on the current workload.

This page includes the following reports:

- Key EDC processing volumes (Report CDA-DM-305)

Key Rates Page Displays reports on key performance rates.

The Key Rates page includes the following reports:

- Low Approved to Entered Rate - Worst 25 (Report CDA-DM-335)
- Low Verified to Entered Rate - Worst 25 (Report CDA-DM-340)

Performance Page Displays reports on key cycle times.

The Performance page includes the following reports:

- Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)
- Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)
- Key EDC Cycle Times (Report CDA-DM-300)
- Average Days from Complete to Initially Approved - Top 25 (Report CDA-DM-325)
- Average Days from Complete to Initially Verified - Top 25 (Report CDA-DM-330)

Discrepancy Workload Page Displays reports on discrepancy workload.

The Discrepancy Workload page includes the following reports:

- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)
- Discrepancy Overview with Ratios (Report CDA-DM-240)

DM EDC Dashboard

This dashboard is the Data Management dashboard for EDC studies. It can be accessed by a Data Manager (DM), and provides numerous reports and charts to monitor performance of EDC studies.

The DM EDC dashboard includes these prompts, which are common to all its pages:

- **Sponsor**: Lists the name of the Sponsor companies for which this study is being conducted.
- **Program**: Lists the name of the Programs that owns the Study.
- **Study**: Lists Studies within a Program.
- **Study Site**: Lists Sites within a Study.

DM EDC Dashboard Pages

This dashboard includes the following tabbed pages:

- Home Page
- eCRF Workload Page
- Discrepancy Workload Page
- Quality Page
- Key Rates Page
- Performance Page
- Study Discrepancies Page
- Study Processing Summary Page
- Study Processing Detail Page

Home Page Displays key study based reports.

The Home page includes the following reports:

- Average Duration of Currently Open Discrepancies, by Site (Report CDA-DM-205)
- Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank (Report CDA-DM-230)
- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)
- Approval & Verification Rates - Worst 25 (Report CDA-DM-350)

eCRF Workload Page Displays reports on the current workload.

The eCRF Workload page includes the following reports:

- Key EDC processing volumes (Report CDA-DM-305)

Discrepancy Workload Page Displays reports on the discrepancy workload.

The Discrepancy Workload page includes the following reports:

- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)
- Counts of Discrepancies, by State and Review Status (Report CDA-DM-225)
- Discrepancy Overview with Ratios (Report CDA-DM-240)

Quality Page Displays reports on the key quality indicators.

The Quality page includes the following reports:

- Discrepancies per Subjects Enrolled - Top 25 (Report CDA-DM-250)
- Discrepancies per Pages Entered - Top 25 (Report CDA-DM-255)

Key Rates Page Displays reports on the key performance rates.

The Key Rates page includes the following reports:

- Low Approved to Entered Rate - Worst 25 (Report CDA-DM-335)
- Low Verified to Entered Rate - Worst 25 (Report CDA-DM-340)

Performance Page Displays reports on the key cycle times.

The Performance page includes the following reports:

- Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)

  Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)
- Key EDC Cycle Times (Report CDA-DM-300)
- Average Days from Complete to Initially Approved - Top 25 (Report CDA-DM-325)
- Average Days from Complete to Initially Verified - Top 25 (Report CDA-DM-330)

Study Discrepancies Page Displays reports on the key study based discrepancy indicators.

The Study Discrepancies page includes the following reports:

- Average Duration of Currently Open Discrepancies, by Site (Report CDA-DM-205)
- Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank (Report CDA-DM-230)
- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)

Study Processing Summary Page Displays reports on eCRFs waiting processing summary.

The Study Processing Summary page includes the following page-specific prompts:

- Subject ID: Lists IDs for the subject about whom the data were collected.

The Study Processing Summary page includes the following reports:

- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Study Processing Detail Page Displays reports on eCRFs waiting processing detail.

The Study Processing Detail page includes the following reports:

- Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310)

DM Paper Dashboard

This dashboard is Data Management dashboard for paper studies. It can be accessed by a Data Manager (DM), and provides numerous reports and charts to monitor performance of Paper studies.

This dashboard includes the following prompts, which are common to all its pages:

- **Sponsor**: Lists the name of the Sponsor companies for which this study is being conducted.
- **Program**: Lists the name of the Programs that owns the Study.
- **Study**: Lists Studies within a Program.
- **Study Site**: Lists Sites within a Study.

DM Paper Dashboard Pages

This dashboard includes the following tabbed pages:

- Home Page
- Page Workload Page
- Discrepancy Workload Page
- Quality Page
- Performance Page
- Study Processing Summary Page
- Study Processing Detail Page

Home Page Displays key study based reports.

The Home page includes the following reports:

- Average Duration of Currently Open Discrepancies, by Site (Report CDA-DM-205)
- Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank (Report CDA-DM-230)
- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)
- Pages Awaiting Entry Completion (Report CDA-DM-450)

Page Workload Page Displays reports on the current workload.

The Page Workload page includes the following reports:

- Key Paper processing volumes (Report CDA-DM-405)

Discrepancy Workload Page Displays reports on the discrepancy workload.

The Discrepancy Workload page includes the following reports:

- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)
- Counts of Discrepancies, by State and Review Status (Report CDA-DM-225)
- Discrepancy Overview with Ratios (Report CDA-DM-240)

Quality Page Displays reports on the key quality indicators.

The Quality page includes the following reports:

- Discrepancies per Subjects Enrolled - Top 25 (Report CDA-DM-250)
- Discrepancies per Pages Entered - Top 25 (Report CDA-DM-255)

Performance Page Displays reports on the key performance rates.

The Performance page includes the following reports:

- Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)

  Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)
- Key Cycle Times for Paper Studies (Report CDA-DM-400)
- Paper Processing Cycle Times - 25 Longest (Report CDA-DM-415)

Study Processing Summary Page Displays reports on paper CRFs waiting processing summary.

The Study Processing Summary page includes the following page-specific prompts:

- Subject ID: Lists IDs for the subject about whom the data were collected.

The Study Processing Summary page includes the following reports:

- Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)

Study Processing Detail Page Displays reports on paper CRFs waiting processing detail.

The Study Processing Detail page includes the following reports:

- Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410)

Oracle Clinical Development Analytics Reports

OCDA includes the following reports:

- Approval & Verification Rates - Worst 25 (Report CDA-DM-350)
- Average Days from Complete to Initially Approved - Top 25 (Report CDA-DM-325)
- Average Days from Complete to Initially Verified - Top 25 (Report CDA-DM-330)
- Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)
- Average Duration of Currently Open Discrepancies, by Site (Report CDA-DM-205)
- Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)
- Comparative Site Enrollment Status Table (Report 8SDP-3)
- Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank (Report CDA-DM-230)
- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)
- Counts of Discrepancies, by State and Review Status (Report CDA-DM-225)

- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)
- Discrepancies per Pages Entered - Top 25 (Report CDA-DM-255)
- Discrepancies per Subjects Enrolled - Top 25 (Report CDA-DM-250)
- Discrepancy Overview with Ratios (Report CDA-DM-240)
- Document Collection Cycle Times - Days Outstanding by Type (Report 3SS04-1b)
- Document Collection Cycle Times Table (Report 3SS04-1)
- Document Collection Cycle Times -Turn Around Time by Type (Report 3SS04-1c)
- Documents List (Report 8SDP-1)
- Enrollment Overview By Region Chart (Report 8SDP-10b)
- Enrollment Overview By Site (Report 8SDP-10)
- Enrollment Progress Over Time (Report 4PR01-2)
- Key Cycle Times for Paper Studies (Report CDA-DM-400)
- Key EDC Cycle Times (Report CDA-DM-300)
- Key EDC processing volumes (Report CDA-DM-305)
- Key Paper processing volumes (Report CDA-DM-405)
- List Discrepancy Details (Report CDA-DM-245)
- Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310)
- Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410)
- Low Approved to Entered Rate - Worst 25 (Report CDA-DM-335)
- Low Verified to Entered Rate - Worst 25 (Report CDA-DM-340)
- Outstanding Documents by Category, Type (Report 8SDP-2)
- Pages Awaiting Entry Completion (Report CDA-DM-450)
- Paper Processing Cycle Times - 25 Longest (Report CDA-DM-415)
- Patient Retention Table (Report 5SC01-1)
- Planned Sites vs. Sites Screening & Enrolling Chart (Bottom 10) (Report 3SS02-1d)
- Planned Sites vs. Sites Screening & Enrolling Chart (Top 10) (Report 3SS02-1b)
- Randomization Overview By Region Chart (Report 8SDP-30)
- Randomization Overview By Site Table (Report 8SDP-29)
- Screen Failure Reason by Site Chart (Top 10 # Screen Failures) (Report 4PR02-1c)
- Screen Failure Reason Chart (Report 4PR02-1b)
- Screen Failure Reason Counts by Site Table (Report 4PR02-1)
- Screening Overview By Region Chart (Report 8SDP-28)
- Site Detail Table (Report 3SS02-3)
- Site Status by Region Chart (Report 3SS07-2)
- Subject Retention Over Time Chart (Report 8SDP-4)
- Subjects who Failed Screening Table (Report 8SDP-24)
- Subjects Withdrawn List Table (Report 8SDP-26)

- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)
- Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)
- Withdrawn Reason Chart (Report 4PR02-2)
- Withdrawn Reason Counts by Site Table (Report 4PR02-2b)
- Withdrawn Reason Overview Chart (Top 10 # Early Terms) (Report 8SDP-25)

To locate a report, you need to select a dashboard and access a page that contains the report.

Approval & Verification Rates - Worst 25 (Report CDA-DM-350)

Identifies the top 25 combined approval and verification rates for EDC studies.

This report can be used to compare across sites to see quickly identify which sites and CRAs are taking the longest to approve and verify pages. This indicates the resource shortfalls, process inefficiencies, and potential training needs.

Audience

Data Manager

CRA

Project Manager

Report Type

Graph: Horizontal bar

Location

- **CRA EDC** dashboard, **Home** page
- **DM EDC** dashboard, **Home** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-1 describes the columns in the Approval & Verification Rates - Worst 25 report:

Table A–1 Approval & Verification Rates - Worst 25 Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Study Name

Table A–1 (Cont.) Approval & Verification Rates - Worst 25 Column Descriptions

Table Heading	Column Heading	Measure
% of Entry-Complete eCRFs	Approved	Received CRFs.% eCRFs Approved / Entry Complete
% of Entry-Complete eCRFs	Verified	Received CRFs.% eCRFs Verified / Entry Complete

Average Days from Complete to Initially Approved - Top 25 (Report CDA-DM-325)

Identifies the average number of days for eCRFs to be approved following entry completion.

This report indicates the lag between when an eCRF was entered to when it was initially approved. This measure can be used to compare site performance, and to highlight poor performing sites. When compared across studies, it can be an indicator of study site team inefficiencies.

Audience

Data Manager

CRA

Project Manager

Report Type

Graph: Horizontal bar

Location

- **CRA EDC** dashboard, **Performance** page
- **DM EDC** dashboard, **Performance** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-2 describes the columns in the Average Days from Complete to Initially Approved - Top 25 report:

Table A–2 Average Days from Complete to Initially Approved - Top 25 Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Study Name
NA	NA	Received CRFs.Avg # Days from eCRF Entry Complete to Initially Approved

Average Days from Complete to Initially Verified - Top 25 (Report CDA-DM-330)

Identifies the average number of days for eCRFs to be verified following entry completion.

This report indicates the lag between when an eCRF was entered to when it was initially verified. This measure can be used to compare site performance, and can be used to infer the performance of the sites's CRA. When compared across studies, it can be an indicator of study team inefficiencies.

Audience

Data Manager

CRA

Project Manager

Report Type

Graph: Horizontal bar

Location

- **CRA EDC** dashboard, **Performance** page
- **DM EDC** dashboard, **Performance** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-3 describes the columns in the Average Days from Complete to Initially Verified - Top 25 report:

Table A–3 Average Days from Complete to Initially Verified - Top 25 Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Study Name
NA	NA	Received CRFs.Avg # Days from eCRF Complete to Initially Verified

Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210)

Identifies the average number of days discrepancies are within a grouping of review status.

This report indicates which functional teams (or categories) are taking the longest to resolve or progress a discrepancy. This information can be used to identify process and resource inefficiencies.

Audience

Data Manager

CRA

Project Manager

Report Type

Table

Pivot table: rows=Study; columns=Categorized Review Status; cells=Average duration in Review Status, in days

Location

- **CRA EDC** dashboard, **Performance** page
- **DM EDC** dashboard, **Performance** page
- **DM Paper** dashboard, **Performance** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-4 describes the columns in the Average Duration in Categorized Discrepancy Review Status report:

Table A–4 Average Duration in Categorized Discrepancy Review Status Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study Name	Study-Site.Study Name
Discrepancies	State	Discrepancies.Discrepancy State
Discrepancies	Categorized Review Status	Discrepancy Review Statuses.Discrepancy Review Status
Discrepancies	Average duration in Review Status	Discrepancy Review Statuses.Avg # Days Discrepancy Ever in Review Status
Discrepancies	# Discrepancies	Discrepancies.# Total Discrepancies

Average Duration of Currently Open Discrepancies, by Site (Report CDA-DM-205)

Identifies distribution of open discrepancies, by the number of days they have been open.

This report indicates which sites have the oldest currently open discrepancies.

Audience

Data Manager

CRA

Report Type

Graph: Pie

Type: Default

Style: Default

Location

- **CRA EDC** dashboard, **Home** page
- **DM EDC** dashboard, **Home** page
- **DM EDC** dashboard, **Study Discrepancies** page
- **DM Paper** dashboard, **Home** page

Dimensions

Study-Site.Study Name

Study-Site.Site Name

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)

Reports Referencing This Report

None

Column Descriptions

Table A-5 describes the columns in the Average Duration of Currently Open Discrepancies, by Site report:

Table A–5 Average Duration of Currently Open Discrepancies, by Site Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study Site.Study Name
NA	NA	Study Site.Site Name
NA	NA	Study-site Metrics.Avg Duration of Currently Open Discrepancies

Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215)

Identifies the average number of days discrepancies are open within a review status.

This report indicates the average length of time that discrepancies are remaining at a specific review state. This information can be used to identify process and resource inefficiencies.

Audience

Data Manager

CRA

Project Manager

Report Type

Table

Pivot table: rows=Study; columns=Review Status; cells=Average duration in Review Status

Graph attached to the Pivot table: Horizontal bar, 2D stacked rectangle

Location

- **CRA EDC** dashboard, **Performance** page
- **DM EDC** dashboard, **Performance** page
- **DM Paper** dashboard, **Performance** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

Discrepancies.Discrepancy State

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-6 describes the columns in the Average Duration of Open Discrepancies in Review Statuses report:

Table A–6 Average Duration of Open Discrepancies in Review Statuses Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study Name	Study-Site.Study Name
Discrepancies	Review Status	Discrepancy Review Statuses.Discrepancy Review Status
Discrepancies	Average duration in Review Status[1]	Discrepancy Review Statuses.Avg # Days Open Discrepancy Ever in Review Status

[1] Conditional Formatting Threshold: Yellow - between 30 and 60
Conditional Formatting Threshold: Red - greater than or equal to 60

Comparative Site Enrollment Status Table (Report 8SDP-3)

For each study, lists all sites (grouped by region) and the percentage of the study's total screening, enrollment, and randomization the site is responsible for. Also includes the percentage of enrollment completed compared to number planned at site.

This report indicates which sites are responsible for the most subjects screened, enrolled and randomized. It also specifies the percentages of the study's planned enrollment and total enrollment is the site responsible for.

Audience

Study Manager

CRA

Report Type

Pivot Table

Location

- **CO - Site and Recruitment Overview** dashboard, **Comparative Site Enrollment** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID #

Study-Site.Site Name

Study-Site.Study-Site Status

Supplementary Prompts

None

Reports Referenced

You can navigate to the following report from this report:

- Site Detail Table (Report 3SS02-3)

Reports Referencing This Report

None

Column Descriptions

Table A-7 describes the columns in the Comparative Site Enrollment Status Table report:

Table A–7 Comparative Site Enrollment Status Table Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Product	Product Name	Product.Product Name
Study-Site	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Study-Site	Study Region	Study-Site.Study Region
Region	Region Status	Region.Region Status
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Study-Site Status	Study-Site.Study-Site Status
NA	% Of Total Screened In Study	Study-Site Metrics.% Of Total Screened In Study
NA	% Of Planned Site Enrollment Completed	Study-Site Metrics.% Of Planned Site Enrollment Completed
NA	% Of Total Enrolled In Study	Study-Site Metrics.% Of Total Enrolled In Study
NA	% Of Total Randomized In Study	Study-Site Metrics.% Of Total Randomized In Study

Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank (Report CDA-DM-230)

Identifies the top 10 CRFs which are producing the most discrepancies.

A CRF which is associated with a high number of discrepancies is often an indication that the validation procedure or the CRF have been poorly designed. Alternatively, it can indicate a misunderstanding on the completion guidelines for the CRF, and can therefore imply a training need for the study site. Early identification of such issues, at an early stage in the study, can dramatically reduce the number of discrepancies created.

Audience

Data Manager

Report Type

Graph: Vertical/2D Stacked

Location

- **DM EDC** dashboard, **Home** page
- **DM EDC** dashboard, **Study Discrepancies** page
- **DM Paper** dashboard, **Home** page

Dimensions

CRF.Name

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)

Reports Referencing This Report

None

Column Descriptions

Table A-8 describes the columns in the Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank report:

Table A–8 Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	CRF.Name
NA	NA	Discrepancies.# Open Discrepancies
NA	NA	Discrepancies.Type

Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)

Identifies how many discrepancies are open, by review status.

This report indicates the number of open discrepancies, within a number of categorized review groups. This information can be used to identify which functional team or area has the most outstanding discrepancies, which could indicate a resource shortage.

Audience

Data Manager

CRA

Project Manager

Report Type

Table

Pivot table: rows=Study; columns=Categorized Review Status; cells=#Open Discrepancies

Graph attached to the Pivot table

Location

- **CRA EDC** dashboard, **Discrepancy Workload** page
- **DM EDC** dashboard, **Discrepancy Workload** page
- **DM Paper** dashboard, **Discrepancy Workload** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)

Reports Referencing This Report

You can navigate to this report from the following reports:

- Discrepancy Overview with Ratios (Report CDA-DM-240)

Column Descriptions

Table A-9 describes the columns in the Counts of Categorized Open Discrepancies, by Review Status report:

Table A–9 Counts of Categorized Open Discrepancies, by Review Status Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study Name	Study-Site.Study Name

Table A–9 (Cont.) Counts of Categorized Open Discrepancies, by Review Status Column Descriptions

Table Heading	Column Heading	Measure
Discrepancies	Categorized Review Status	Discrepancy Review Statuses.Discrepancy Review Status
Discrepancies	# Open Discrepancies	Discrepancies.# Total Discrepancies

Counts of Discrepancies, by State and Review Status (Report CDA-DM-225)

Identifies the number of open and closed discrepancies, by review status.

This report indicates which review states are creating the largest volumes of discrepancies. This information can be used to identify high discrepancy volumes with a review state which may indicate lack of resource or process inefficiency.

Audience

Data Manager

Project Manager

Report Type

Table

Pivot table: rows=Study; columns=Review Status; cells=#Discrepancies

Location

- **DM EDC** dashboard, **Discrepancy Workload** page
- **DM Paper** dashboard, **Discrepancy Workload** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-10 describes the columns in the Counts of Discrepancies, by State and Review Status report:

Table A–10 Counts of Discrepancies, by State and Review Status Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study	Study-Site.Study Name

Table A–10 (Cont.) Counts of Discrepancies, by State and Review Status Column

Table Heading	Column Heading	Measure
Discrepancies	Review Status	Discrepancy Review Statuses.Discrepancy Review Status
Discrepancies	State	Discrepancies.Discrepancy State
Discrepancies	# Discrepancies	Discrepancies.# Total Discrepancies

Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)

Identifies the distribution of discrepancies, by validation procedure.

This report indicates which validation procedures are creating the most discrepancies. A procedure which is associated with a high number of discrepancies is often an indication that the validation procedure has been poorly designed, or that the related actual data exceeds any expected parameters. Alternatively, it may indicate a misunderstanding on the completion guidelines for the CRF, and may therefore imply a training need for the study site. Early identification of such issues, at an early stage in the study, can dramatically reduce the number of discrepancies created.

Audience

Data Manager

Report Type

Graph: Pie chart

Location

- **DM EDC** dashboard, **Home** page
- **DM EDC** dashboard, **Study Discrepancies** page
- **DM Paper** dashboard, **Home** page

Dimensions

CRF.Name

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)

Reports Referencing This Report

None

Column Descriptions

Table A-11 describes the columns in the Counts of Open Multivariate Discrepancies, by Procedure report:

Table A–11 Counts of Open Multivariate Discrepancies, by Procedure Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Discrepancies.Validation Procedure Name
NA	NA	Discrepancies.# Open Discrepancies

Discrepancies per Pages Entered - Top 25 (Report CDA-DM-255)

Identifies the rate of discrepancies per pages entered.

This report displays the top 25 studies and associated sites which have the highest numbers of discrepancies per page. This information can be used to identify poor performance across studies and across sites.

Audience

Data Manager

Report Type

Graph: Horizontal bar

Location

- **DM EDC** dashboard, **Quality** page
- **DM Paper** dashboard, **Quality** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-12 describes the columns in the Discrepancies per Pages Entered - 25 highest rates report:

Table A–12 Discrepancies per Pages Entered - 25 highest rates Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Study Name
NA	NA	Study-site Metrics.Total Discrepancies per CRF

Discrepancies per Subjects Enrolled - Top 25 (Report CDA-DM-250)

Identifies the rate of discrepancies per subjects enrolled.

This report identifies the top 25 studies and associated sites which have the highest numbers of discrepancies per enrolled subject. This information can be used to identify poor performance across studies and across sites.

Audience

Data Manager

Report Type

Graph: Horizontal bar

Location

- **DM EDC** dashboard, **Quality** page
- **DM Paper** dashboard, **Quality** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-13 describes the columns in the Discrepancies per Subjects Enrolled - Top 25 report:

Table A–13 Discrepancies per Subjects Enrolled - Top 25 Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Study Name
NA	NA	Study-site Metrics.Total Discrepancies per Enrolled Subject

Discrepancy Overview with Ratios (Report CDA-DM-240)

Identifies how many discrepancies are open and closed. In addition, the report also shows ratios of the number of discrepancies per CRF entered. If these ratios vary significantly by site they may indicate a poor performing site with a training need. Also, comparing these measures across studies can highlight inefficiencies between study teams, although it is important to also note that study variances are often a factor of study complexity and therapeutic area.

Audience

Data Manager

CRA

Report Type

Table

Location

- **CRA EDC** dashboard, **Discrepancy Workload** page
- **DM EDC** dashboard, **Discrepancy Workload** page
- **DM Paper** dashboard, **Discrepancy Workload** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)

Reports Referencing This Report

None

Column Descriptions

Table A-14 describes the columns in the Discrepancy Overview with Ratios report:

Table A–14 Discrepancy Overview with Ratios Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study Name	Study-Site.Study Name
NA	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# CRFs Present	Received CRFs.# CRFs Present
# Discrepancies	Open[1]	Discrepancies.# Open Discrepancies
# Discrepancies	Closed	Discrepancies.# Closed Discrepancies
# Discrepancies	Total[2]	Discrepancies.# Total Discrepancies
Discrepancies per Received CRF	Open	Study-site Metrics.Open Discrepancies per CRF
Discrepancies per Received CRF	Total	Study-site Metrics.Total Discrepancies per CRF

[1] Conditional Formatting Threshold: Yellow - between 5 and 9
Conditional Formatting Threshold: Red - greater than or equal to 10

[2] Conditional Formatting Threshold: Yellow - between 5 and 10
Conditional Formatting Threshold: Red - greater than or equal to 11

Document Collection Cycle Times - Days Outstanding by Type (Report 3SS04-1b)

Displays (by document type) the average days a document has been outstanding.

This report indicates how long have documents been outstanding. It also indicates the documents that lag the most.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Document Management** dashboard, **Document Collection Cycle Times** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-15 describes the columns in the Document Collection Cycle Times - Days Outstanding by Type report:

Table A–15 Document Collection Cycle Times - Days Outstanding by Type Column Descriptions

Table Heading	Column Heading	Measure
NA	Activity Type	Document Metrics.Activity Type
NA	Avg # Days Document Outstanding	Document Metrics.Avg # Days Document Outstanding

Document Collection Cycle Times Table (Report 3SS04-1)

Lists (by program, study, and region) all documents collected, the number of days from sent to received, and the number of days outstanding if not received.

The report indicates how long have documents been outstanding, and how long does it typically take to receive documents. It also indicates the documents that lag the most.

Audience

Study Manager

CRA

Report Type

Table

Location

- **CO - Document Management** dashboard, **Document Collection Cycle Times** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Region.Region Name

Region.Region Status

Study-Site.Study-Site ID#

Study-Site.Site Name

Study-Site.Principal Investigator

Study-Site.Study-Site Status

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-16 describes the columns in the Document Collection Cycle Times Table report:

Table A–16 Document Collection Cycle Times Table Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Product	Product Name	Product.Product Name
Study-Site	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Region	Region Name	Region.Region Name
Region	Region Status	Region.Region Status
Study-Site	Study-Site ID#	Study-Site.Study-Site ID#
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
NA	Activity Type	Document Metrics.Activity Type
NA	Document Name	Document Metrics.Document Name
NA	Document Sent Date	Document Metrics.Document Sent Date
NA	Document Received Date	Document Metrics.Document Received Date
NA	# Days from Document Sent to Document Received	Document Metrics.# Days from Document Sent to Document Received
NA	# Days Document Outstanding	Document Metrics.# Days Document Outstanding

Document Collection Cycle Times -Turn Around Time by Type (Report 3SS04-1c)

Displays (by document type) the average turn around time from document sent to document received.

This report indicates if essential documents are being gathered on time, and how long does it typically take to receive a document. It also indicates the documents that lag the most.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Document Management** dashboard, **Document Collection Cycle Times** page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-17 describes the columns in the Document Collection Cycle Times -Turn Around Time by Type report:

Table A–17 Document Collection Cycle Times -Turn Around Time by Type Column Descriptions

Table Heading	Column Heading	Measure
NA	Activity Type	Document Metrics.Activity Type
NA	Avg # Days from Document Sent to Document Received	Document Metrics.Avg # Days from Document Sent to Document Received

Documents List (Report 8SDP-1)

Lists (by program, study, region and site) all documents collected, including document status, sent date, received date, and comments.

This report indicates which documents are missing. It also indicates the essential documents are missing for those sites that are not ready to enroll.

Audience

Study Manager

CRA

Report Type

Table

Location

- **CO - Document Management** dashboard, **Document List** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID#

Study-Site.Site Name

Study-Site.Study-Site Status

Study-Site.Principal Investigator

Study-Site Team Member.Full Name

Study-Site Team Member.Role

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-18 describes the columns in the Documents List report:

Table A–18 Documents List Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Product	Product Name	Product.Product Name
Study-Site.	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Study-Site	Study Region	Study-Site.Study Region
Region	Region Status	Region.Region Status
Study-Site	Study-Site ID#	Study-Site.Study-Site ID#
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site Team Member	Full Name	Study-Site Team Member.Full Name
Study-Site Team Member	Role	Study-Site Team Member.Role
NA	Activity Type	Document Metrics.Activity Type
NA	Document Name	Document Metrics.Document Name
NA	Document Sent Date	Document Metrics.Document Sent Date

Table A–18 (Cont.) Documents List Column Descriptions

Table Heading	Column Heading	Measure
NA	Document Received Date	Document Metrics.Document Received Date
NA	Document Expiration Date	Document Metrics.Document Expiration Date
NA	Document Comments	Document Metrics.Document Comments

Enrollment Overview By Region Chart (Report 8SDP-10b)

Displays (by study) the number of subjects enrolled.

This report indicates the progress each region is making towards enrollment. It also shows the progress of subject recruitment, and how many subjects have been screened, enrolled, and randomized.

This report also indicates the progress of each region towards enrollment.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Site and Recruitment Overview** dashboard, **Enrollment Overview** page
- **CO - Study and Region Overview** dashboard, **Enrollment Overview** page

Dimensions

Study.Study

Region.Region Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-19 describes the columns in the Enrollment Overview by Region Chart report:

Table A–19 Enrollment Overview by Region Chart Column Descriptions

Table Heading	Column Heading	Measure
Study	Study	Study.Study
Region	Region Name	Region.Region Name
NA	# Subjects Enrolled	Study-Site Metrics.# Subjects Enrolled

Enrollment Overview By Site (Report 8SDP-10)

Lists (by program, study, and region) all sites and the number of planned and actual subjects enrolled.

This report indicates how well are we progressing against planned enrollment. It also shows the progress of subject recruitment, and how many subjects have been screened, enrolled, and randomized.

This report also indicates the progress of each region towards enrollment.

Audience

Study Manager

CRA

Report Type

Pivot Table

Location

- **CO - Site and Recruitment Overview** dashboard, **Enrollment Overview** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID#

Study-Site.Site Name

Study-Site.Principal Investigator

Study-Site Team Member.Full Name

Study-Site Team Member.Role

Study-Site.Study-Site Status

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Site Detail Table (Report 3SS02-3)

Reports Referencing This Report

None

Column Descriptions

Table A-20 describes the columns in the Enrollment Overview By Site report:

Table A–20 Enrollment Overview By Site Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Product	Product Name	Product.Product Name
Study-Site	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Study-Site	Study Region	Study-Site.Study Region
Region	Region Status	Region.Region Status
Study-Site	Study-Site ID#	Study-Site.Study-Site ID#
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site Team Member	Full Name	Study-Site Team Member.Full Name
Study-Site Team Member	Role	Study-Site Team Member.Role
Study-Site	Study-Site Status	Study-Site.Study-Site Status
NA	# Subjects Planned for Study-Site	Study-site Metrics.# Subjects Planned for Study-Site
NA	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled

Enrollment Progress Over Time (Report 4PR01-2)

Displays (by month) the cumulative number of subjects enrolled compared to the number of subjects planned to be enrolled.

This report indicates how much progress is being made towards planned enrollment targets.

Audience

Study Manager

CRA

Report Type

Graph: Line

Location

- **CO - Site and Recruitment Overview** dashboard, **Subject Recruitment Over Time** page

Dimensions

Date

Study-Site

Supplementary Prompts

Date

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-21 describes the columns in the Enrollment Progress Over Time report:

Table A–21 Enrollment Progress Over Time Column Descriptions

Table Heading	Column Heading	Measure
NA	100% Planned Site Enrollment	Max(sum((CASE WHEN"- Study-site Metrics"."# Subjects Planned for Study-Site">0 THEN "- Study-site Metrics"."# Subjects Planned for Study-Site" ELSE 0 END)))
NA	90% Planned Site Enrollment	MAX(sum((CASE WHEN"- Study-site Metrics"."# Subjects Planned for Study-Site">0 THEN "- Study-site Metrics"."# Subjects Planned for Study-Site" ELSE 0 END))*.9)
NA	75% Planned Site Enrollment	MAX(sum((CASE WHEN"- Study-site Metrics"."# Subjects Planned for Study-Site">0 THEN "- Study-site Metrics"."# Subjects Planned for Study-Site" ELSE 0 END))*.75)
NA	50% Planned Site Enrollment	MAX(sum((CASE WHEN"- Study-site Metrics"."# Subjects Planned for Study-Site">0 THEN "- Study-site Metrics"."# Subjects Planned for Study-Site" ELSE 0 END))*.5)
NA	# Subjects Enrolled	'- Study-site Metrics."# Subjects Enrolled"
NA	Year and Month	Date."Year and Month"

Key Cycle Times for Paper Studies (Report CDA-DM-400)

Identifies key cycle times for paper studies, and can be used to compare studies against each other.

This report indicates key lags in process steps, and potential inefficiencies.

Audience

Data Manager

Project Manager

Report Type

Table

Location

- **DM Paper** dashboard, **Performance** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-22 describes the columns in the Key Cycle Times for Paper Studies report:

Table A–22 Key Cycle Times for Paper Studies Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study Name	Study-Site.Study Name
NA	#Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
# pCRFs	Present	Received CRFs.# pCRFs Present
# pCRFs	Entry Complete	Received CRFs.# pCRFs Entry Complete
Average Days	Visit to First Entry[1]	Received CRFs.Avg # Days from pCRF Visit to First Entry
Average Days	First Entry to Second Entry Complete[2]	Received CRFs.Avg # Days from pCRF First Entry to Second Entry Complete

Table A–22 (Cont.) Key Cycle Times for Paper Studies Column Descriptions

Table Heading	Column Heading	Measure
Average Days	Visit to Entry Complete[3]	Received CRFs.Avg # Days from pCRF Visit to Entry Complete
Average Days	Entry Complete to Soft Locked	Received CRFs.Avg # Days from pCRF Entry Complete to Soft Locked

[1] Conditional Formatting Threshold: Yellow - between 30 and 59
Conditional Formatting Threshold: Red - greater than or equal to 60

[2] Conditional Formatting Threshold: Yellow - between 3 and 9
Conditional Formatting Threshold: Red - greater than or equal to 10

[3] Conditional Formatting Threshold: Yellow - between 33 and 70
Conditional Formatting Threshold: Red - greater than or equal to 70

Key EDC Cycle Times (Report CDA-DM-300)

Identifies the key cycle times for EDC studies, and can be used to compare sites within study, and to compare studies against each other.

This report indicates key lags in process steps, and potential inefficiencies.

Audience

Data Manager

CRA

Project Manager

Report Type

Table

Location

- **CRA EDC** dashboard, **Performance** page
- **DM EDC** dashboard, **Performance** page

Dimensions

- Study-Site.Program
- Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-23 describes the columns in the Key EDC Cycle Times report:

Table A–23 Key EDC Cycle Times Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Program
Study-Site	Study Name	Study-Site.Study Name
NA	#Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Entry Complete[1]	Received CRFs.# eCRFs Entry Complete
Average Days From Visit To	Entry Complete	Received CRFs.Avg # Days from eCRF Visit to eCRF Complete
Average Days From Entry Completion To	Initially Approved	Received CRFs.Avg # Days from eCRF Entry Complete to Initially Approved
Average Days From Entry Completion To	Initially Verified	Received CRFs.Avg # Days from eCRF Complete to Initially Verified
Average Days From Entry Completion To	Soft Locked	Received CRFs.Avg # Days from eCRF Complete to Soft Locked

[1] Conditional Formatting Threshold: Yellow - between 10 and 20
Conditional Formatting Threshold: Red - greater than 20

Key EDC processing volumes (Report CDA-DM-305)

Identifies the key processing volumes for EDC studies.

This report displays page processing volumes for EDC studies. It also displays eCRFs processed and to be processed. Ratios of approved and verified data can also be used to show progress through the study. This report can be used to understand resource requirements based on work volumes.

Audience

Data Manager

CRA

Project Manager

Report Type

Table

Location

- **CRA EDC** dashboard, **eCRF Workload** page
- **DM EDC** dashboard, **eCRF Workload** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)
- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Reports Referencing This Report

None

Column Descriptions

Table A-24 describes the columns in the Key EDC processing volumes report:

Table A–24 Key EDC processing volumes Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study Name	Study-Site.Study Name
NA	#Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Open Discrepancies	Discrepancies.# Open Discrepancies
# eCRFs	Entry Complete	Received CRFs.# eCRFs Entry Complete
# eCRFs	Not Verified	Received CRFs.# eCRFs Not Verified
# eCRFs	Verified	Received CRFs.# eCRFs Verified
# eCRFs	Not Approved	Received CRFs.# eCRFs To Be Approved
# eCRFs	Approved	Received CRFs.# eCRFs Approved
# eCRFs	Soft Locked	Received CRFs.# eCRFs Soft Locked
# eCRFs	Hard Locked	Received CRFs.# eCRFs Hard Locked
0f Entry-Complete eCRFs	Approved	Received CRFs.% eCRFs Approved / Entry Complete
0f Entry-Complete eCRFs	Verified[1]	Received CRFs.% eCRFs Verified / Entry Complete
0f Entry-Complete eCRFs	Soft Locked	Received CRFs.% eCRFs Soft Locked / Entry Complete
0f Entry-Complete eCRFs	Hard Locked	Received CRFs.% eCRFs Hard Locked / Entry Complete
NA	Navigate to Detail	Not Applicable.Navigate

[1] Conditional Formatting Threshold: Yellow - between 30 and 50
Conditional Formatting Threshold: Red - less than or equal to 30

Key Paper processing volumes (Report CDA-DM-405)

Identifies key page processing volumes for paper studies.

This report displays pages processed and to be processed. This information can be used to understand resource requirements based on work volumes.

Audience

Data Manager

Project Manager

Report Type

Table

Location

- **DM Paper** dashboard, **Page Workload** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)

Reports Referencing This Report

None

Column Descriptions

Table A-25 describes the columns in the Key Paper processing volumes report:

Table A–25 Key Paper processing volumes Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study	Study-Site.Study Name
NA	#Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Open Discrepancies	Discrepancies.# Open Discrepancies **Note**: This is all discrepancies, not just those arising from CRFs.
# CRFs	Present	Received CRFs.# pCRFs Present
# CRFs	Awaiting First Entry Completion	Received CRFs.# pCRFs Awaiting Pass 1 Entry Completion

Table A–25 (Cont.) Key Paper processing volumes Column Descriptions

Table Heading	Column Heading	Measure
# CRFs	Awaiting Second Entry Completion	Received CRFs.# pCRFs Awaiting Pass 2 Entry Completion
# CRFs	Entry Complete	Received CRFs.# pCRFs Entry Complete
# CRFs	Blank	Received CRFs.# pCRFs Blank
# CRFs	Soft Locked	Received CRFs.# pCRFs Soft Locked
# CRFs	Hard Locked	Received CRFs.# pCRFs Hard Locked
0f Entry-Complete CRFs	Soft Locked	Received CRFs.% pCRFs Soft Locked / Entry Complete
0f Entry-Complete CRFs	Hard Locked	Received CRFs.% pCRFs Hard Locked / Entry Complete
NA	Navigate to Detail	Not Applicable.Navigate

List Discrepancy Details (Report CDA-DM-245)

Lists open discrepancies and associated details, and is used as a detailed drill down report to list all discrepancies and associated details.

This report can be used to explore the open discrepancies, and identify any patterns or clusters through the use of sorting.

Audience

Data Manager

Report Type

Table

Dimensions

- CRF.Name
- Study-Site.Site Name
- Study-Site.Program
- Study-Site.Study Name
- Subject.Subject ID

Supplementary Prompts

- Subject.Subject ID
- Discrepancies.Visit Name
- Discrepancies.CRF Name
- Discrepancies.Validation Procedure Name

- Discrepancies.Current Review Status
- Discrepancies.Discrepancy State

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220)
- Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank (Report CDA-DM-230)
- Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235)
- Key EDC processing volumes (Report CDA-DM-305)
- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Column Descriptions

Table A-26 describes the columns in the List Discrepancy Details report:

Table A–26 List Discrepancy Details Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Program
Study-Site	Study	Study-Site.Study Name
NA	Site	Study-Site.Site Name
NA	Subject ID	Subject.Subject ID
Visit	Name	Discrepancies.Visit Name
Visit	Number	Discrepancies.Complete Visit Number
NA	Days Open[1]	Discrepancies.# Days Discrepancy Open
CRF	Name	CRF.Name
CRF	Page Section	Discrepancies.CRF Page Section
CRF	Question Group	Discrepancies.CRF Question Group
CRF	Question Name	Discrepancies.CRF Question Name
CRF	Question Occurrence	Discrepancies.CRF Question Occurrence
Discrepancy	Discrepancy ID	Discrepancies.Discrepancy ID
Discrepancy	Procedure Name	Discrepancies.Validation Procedure Name
Discrepancy	Review Status	Discrepancies.Current Review Status

Table A–26 (Cont.) List Discrepancy Details Column Descriptions

Table Heading	Column Heading	Measure
Discrepancy	Comment Text	Discrepancies.Comment Text
Discrepancy	Sent in DCF	Discrepancies.Sent in DCF
Discrepancy	State	Discrepancies.Discrepancy State

[1] Conditional Formatting Threshold: Yellow - between 5 and 10
Conditional Formatting Threshold: Red - greater than or equal to 10

Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310)

Identifies specific eCRFs, and the process steps they are awaiting.

This report lists, for a subject, the eCRFs which are awaiting processing. This information can be used to drive an activity.

Audience

Data Manager

Report Type

Table

Location

- **DM EDC** dashboard, **Study Processing Detail** page

Dimensions

- CRF.Name
- Study-Site.Site Name
- Study-Site.Program
- Study-Site.Study Name
- Subject.Subject ID

Supplementary Prompts

Study, Study-Site

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Column Descriptions

Table A-27 describes the columns in the Listing of Subject-Pages, Awaiting EDC Processing report:

Table A–27 Listing of Subject-Pages, Awaiting EDC Processing Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Program
NA	NA	Study-Site.Study Name
Study-Site	Site	Study-Site.Site Name
Subject	Subject ID	Subject.Subject ID
Visit	Name	Received CRFs.Visit Name
Visit	Number	Received CRFs.Complete Visit Number
Visit	Date	Received CRFs.Visit Date
CRF	Name	CRF.Name
Processing Required	Not Verified	Received CRFs.Is not in Verified state
Processing Required	Awaiting Re-verification	Received CRFs.Is Awaiting Re-Verification
Processing Required	Not Approved	Received CRFs.Is not in Approved state
Processing Required	Requires Re-Approval	Received CRFs.s Awaiting Re-Approval

Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410)

Identifies specific CRFs, and the process steps they are awaiting.

This report lists, for a subject, the pages which are awaiting processing. This information can be used to drive activity.

Audience

Data Manager

Report Type

Table

Location

- **DM Paper** dashboard, **Study Processing Detail** page

Dimensions

- CRF.Name
- Study-Site.Program
- Study-Site.Study Name
- Subject.Subject ID

Supplementary Prompts

Study, Study-Site

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)

Column Descriptions

Table A-28 describes the columns in the Listing of Subject-Pages, Awaiting Paper Processing report:

Table A–28 Listing of Subject-Pages, Awaiting Paper Processing Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Program
NA	NA	Study-Site.Study Name
Subject	Subject ID	Subject.Subject ID
Visit	Name	Received CRFs.Visit Name
Visit	Number	Received CRFs.Complete Visit Number
Visit	Date	Received CRFs.Visit Date
CRF	Name	CRF.Name
Processing Required	Awaiting First Entry	Received CRFs.Is Awaiting First Entry completion
Processing Required	Awaiting Second Entry	Received CRFs.Is Awaiting Second entry completion

Low Approved to Entered Rate - Worst 25 (Report CDA-DM-335)

Identifies sites who are slow at approving eCRFs.

This report indicates the top 25 sites whose approval rates are less than 80% of those eCRFs entered. This information can be identify poor performing sites.

> **Note:** The 80% rate is based on those studies where the sites are requested to approve eCRFs immediately after entry. For those studies where this process is not relevant, the 80% threshold can be reduced.

Audience

Data Manager

CRA

Project Manager

Report Type

Graph: Horizontal bar

Location

- **CRA EDC** dashboard, **Key Rates** page

- **DM EDC** dashboard, **Key Rates** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-29 describes the columns in the Low Approved to Entered Rate - Worst 25 report:

Table A–29 Low Approved to Entered Rate - Worst 25 Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Study Name
Received CRFs	% eCRFs Approved / Entry Complete	Received CRFs.% eCRFs Approved / Entry Complete

Low Verified to Entered Rate - Worst 25 (Report CDA-DM-340)

Identifies sites where verification has been slow.

This report displays the top 25 sites whose verification rates are less than 50% of those pages entered. This information can be used to identify CRA resource shortfalls.

Audience

Data Manager

CRA

Project Manager

Report Type

Graph: Horizontal bar

Location

- **CRA EDC** dashboard, **Key Rates** page
- **DM EDC** dashboard, **Key Rates** page

Dimensions

Study-Site.Study Name

Supplementary Prompts
None

Reports Referenced
None

Reports Referencing This Report
None

Column Descriptions
Table A-30 describes the columns in the Low Verified to Entered Rate report:

Table A–30 Low Verified to Entered Rate - Worst 25 Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Study Name
Received CRFs	% eCRFs Verified / Entry Complete	Received CRFs.% eCRFs Verified / Entry Complete

Outstanding Documents by Category, Type (Report 8SDP-2)
Displays (by document category) the number of documents currently outstanding. Each bar in the report is stacked by document type.

This report indicates the documents that are missing.

Audience
Study Manager

CRA

Report Type
Graph: Horizontal bar

Location
- **CO - Document Management** dashboard, **Document List** page

Dimensions
None

Supplementary Prompts
None

Reports Referenced
None

Reports Referencing This Report
None

Column Descriptions

Table A-31 describes the columns in the Outstanding Documents by Category, Type report:

Table A–31 Outstanding Documents by Category, Type Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Document Metrics.Activity Type
NA	NA	Document Metrics.# of Documents

Pages Awaiting Entry Completion (Report CDA-DM-450)

Identifies specific subjects who have CRFs awaiting processing.

This report indicates those subjects which require processing, and the number of CRFs to be processed. This information can be used as a summary worklog to drive activity.

Audience

Data Entry Manager

Data Manager

Report Type

Graph: Horizontal bar

Location

- **DM Paper** dashboard, **Home** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-32 describes the columns in the Pages Awaiting Entry Completion - Sites with 25 largest backlogs report:

Table A–32 Pages Awaiting Entry Completion Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Study Name

Table A–32 (Cont.) Pages Awaiting Entry Completion Column Descriptions

Table Heading	Column Heading	Measure
# CRFs	Awaiting First Entry Completion	Received CRFs.# pCRFs Awaiting Pass 1 Entry Completion
# CRFs	Awaiting Second Entry Completion	Received CRFs.# pCRFs Awaiting Pass 2 Entry Completion

Paper Processing Cycle Times - 25 Longest (Report CDA-DM-415)

Identifies the cycle times from subject visit to entry completion.

This report displays the top 25 studies with the longest cycle times for paper processing. This information can be used to highlight process inefficiencies and potential resource shortfalls.

Audience

Data Manager

Report Type

Graph: Horizontal bar

Location

- **DM Paper** dashboard, **Performance** page

Dimensions

Study-Site.Study Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-33 describes the columns in the Paper Processing Cycle Times - 25 Longest report:

Table A–33 Paper Processing Cycle Times - 25 Longest Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Study Name
Received CRFs	Avg # Days from First Entry to Second Entry Complete	Received CRFs.Avg # Days from pCRF First Entry to Second Entry Complete

Table A–33 (Cont.) Paper Processing Cycle Times - 25 Longest Column Descriptions

Table Heading	Column Heading	Measure
Received CRFs	Avg # Days from Visit to First Entry	Received CRFs.Avg # Days from pCRF Visit to First Entry

Patient Retention Table (Report 5SC01-1)

Lists (by program, study, and region) all sites and the number of subjects enrolled, completed, early terminated, as well as the percentage of subjects early terminated.

This report indicates the progress of subject retention, and the rate of subject retention.

Audience

Study Manager

CRA

Report Type

Pivot Table

Location

- **CO - Subject Retention** dashboard, **Subject Retention Overview** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID#

Study-Site.Site Name

Study-Site.Principal Investigator

Study-Site Team Member.Full Name

Study-Site Team Member.Role

Study-Site.Study-Site Status

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Site Detail Table (Report 3SS02-3)

Reports Referencing This Report

None

Column Descriptions

Table A-34 describes the columns in the Patient Retention Table report:

Table A–34 Patient Retention Table Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Product	Product Name	Product.Product Name
Study-Site.	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Study-Site	Study Region	Study-Site.Study Region
Region	Region Status	Region.Region Status
Study-Site	Study-Site ID#	Study-Site.Study-Site ID#
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site Team Member	Full Name	Study-Site Team Member.Full Name
Study-Site Team Member	Role	Study-Site Team Member.Role
Study-Site	Study-Site Status	Study-Site.Study-Site Status
NA	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Subjects who have completed Study	Study-site Metrics.# Subjects who have completed Study
NA	# Early Terminations	Study-site Metrics.# Early Terminations
NA	% Subjects Early Terminated for Study-site	Study-site Metrics.% Subjects Early Terminated for Study-site

Planned Sites vs. Sites Screening & Enrolling Chart (Bottom 10) (Report 3SS02-1d)

Displays (by study) the number of planned sites, the number of sites that have screened 1 or more subjects, and the number of sites that have enrolled 1 or more subjects. Bottom 10 based on # Enrolled.

This report indicates the progress of site activation. It also indicates the number of sites that are enrolling and screening.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Study and Region Overview** dashboard, **Site Overview** page

Dimensions

Study.Study

Study.Study Status

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-35 describes the columns in the Planned Sites vs. Sites Screening & Enrolling Chart (Bottom 10) report:

Table A–35 Planned Sites vs. Sites Screening & Enrolling Chart (Bottom 10) Column Descriptions

Table Heading	Column Heading	Measure
Study	Study	Study.Study
Study	Study Status	Study.Study Status
NA	# Study-Sites Planned for Study	Study Metrics.# Study-Sites Planned for Study
NA	# Sites with 1 or More Subjects Screened	Study-site Metrics.# Sites with 1 or More Subjects Screened
NA	# Study-Sites with 1 or more Subjects Enrolled	Study-site Metrics.# Study-Sites with 1 or more Subjects Enrolled

Planned Sites vs. Sites Screening & Enrolling Chart (Top 10) (Report 3SS02-1b)

Displays (by study) the number of planned sites, the number of sites that have screened 1 or more subjects, and the number of sites that have enrolled 1 or more subjects. Top 10 based on # Enrolled.

This report indicates the progress of site activation. It also indicates the number of sites that are enrolling and screening.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Study and Region Overview** dashboard, **Site Overview** page

Dimensions

Study.Study

Study.Study Status

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Site Detail Table (Report 3SS02-3)

Reports Referencing This Report

None

Column Descriptions

Table A-36 describes the columns in the Planned Sites vs. Sites Screening & Enrolling Chart (Top 10) report:

Table A–36 Planned Sites vs. Sites Screening & Enrolling Chart (Top 10) Column Descriptions

Table Heading	Column Heading	Measure
Study	Study	Study.Study
Study	Study Status	Study.Study Status
NA	# Study-Sites Planned for Study	Study Metrics.# Study-Sites Planned for Study
NA	# Sites with 1 or More Subjects Screened	Study-site Metrics.# Sites with 1 or More Subjects Screened
NA	# Study-Sites with 1 or more Subjects Enrolled	Study-site Metrics.# Study-Sites with 1 or more Subjects Enrolled

Randomization Overview By Region Chart (Report 8SDP-30)

Displays (by study) the number of subjects randomized. Each bar in the report is stacked by region.

This report indicates how many subjects are in which status. It also indicates the number of subjects that have been screened, enrolled, and randomized.

This report also displays the progress of each region towards enrollment.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Site and Recruitment Overview** dashboard, **Randomization Overview** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID #

Study-Site.Site Name

Study-Site.Study-Site Status

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-37 describes the columns in the Randomization Overview By Region Chart report:

Table A–37 Randomization Overview By Region Chart Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
NA	# Randomized	Study-Site Metrics.# Randomized

Randomization Overview By Site Table (Report 8SDP-29)

Lists all sites and the number of subjects planned and number of subjects randomized.

This report indicates how many subjects are in which status. It also indicates the number of subjects that have been screened, enrolled and randomized.

Audience

Study Manager

CRA

Report Type
Pivot Table

Location
- **CO - Site and Recruitment Overview** dashboard, **Randomization Overview** page

Dimensions
Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID#

Study-Site.Site Name

Study-Site.Principal Investigator

Study-Site Team Member.Full Name

Study-Site Team Member.Role

Study-Site.Study-Site Status

Supplementary Prompts
None

Reports Referenced
You can navigate to the following reports from this report:

- Site Detail Table (Report 3SS02-3)

Reports Referencing This Report
None

Column Descriptions
Table A-38 describes the columns in the Randomization Overview By Site Table report:

Table A–38 Randomization Overview By Site Table Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Product	Product Name	Product.Product Name
Study-Site	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Study-Site	Study Region	Study-Site.Study Region

Table A–38 (Cont.) Randomization Overview By Site Table Column Descriptions

Table Heading	Column Heading	Measure
Region	Region Status	Region.Region Status
Study-Site	Study-Site ID#	Study-Site.Study-Site ID#
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site Team Member	Full Name	Study-Site Team Member.Full Name
Study-Site Team Member	Role	Study-Site Team Member.Role
Study-Site	Study-Site Status	Study-Site.Study-Site Status
NA	# Subjects Planned for Study-Site	Study-site Metrics.# Subjects Planned for Study-Site
NA	# Randomized	Study-site Metrics.# Randomized

Screen Failure Reason by Site Chart (Top 10 # Screen Failures) (Report 4PR02-1c)

Displays (by site) the number of subjects who failed screening.

This report indicates which screen failure reasons account for the most screen failures.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Site and Recruitment Overview** dashboard, **Screen Failure Overview** page

Dimensions

Subject.Screen Failure Reason

Study-Site.Study, Site, & Investigator

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects who Failed Screening Table (Report 8SDP-24)

Reports Referencing This Report

None

Column Descriptions

Table A-39 describes the columns in the Screen Failure Reason by Site Chart (Top 10 # Screen Failures) report:

Table A–39 Screen Failure Reason by Site Chart (Top 10 # Screen Failures) Column Descriptions

Table Heading	Column Heading	Measure
NA	Subject Status	COUNT("- Subject Metrics"."Subject Status")
Subject	Screen Failure Reason	Subject.Screen Failure Reason
Study-Site	Study, Site, & Investigator	Study-Site.Study, Site, & Investigator

Screen Failure Reason Chart (Report 4PR02-1b)

Displays (by screen failure reason) the number of subjects who failed screening.

This report indicates which screen failure reasons account for the most screen failures.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Site and Recruitment Overview** dashboard, **Screen Failure Overview** page

Dimensions

Subject.Screen Failure Reason

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects who Failed Screening Table (Report 8SDP-24)

Reports Referencing This Report

None

Column Descriptions

Table A-40 describes the columns in the Screen Failure Reason Chart report:

Table A–40 Screen Failure Reason Chart Column Descriptions

Table Heading	Column Heading	Measure
Subject	Screen Failure Reason	Subject.Screen Failure Reason

Table A–40 (Cont.) Screen Failure Reason Chart Column Descriptions

Table Heading	Column Heading	Measure
NA	Subject Status	COUNT("- Subject Metrics"."Subject Status")

Screen Failure Reason Counts by Site Table (Report 4PR02-1)

Lists (by program, study, and region) all sites that have screen failures and the number of screen failures that fall into a given screen failure reason.

This report indicates which screen failure reasons account for the most screen failures.

Audience

Study Manager

CRA

Report Type

Pivot Table

Location

- **CO - Site and Recruitment Overview** dashboard, **Screen Failure Overview** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID#

Study-Site.Site Name

Study-Site.Principal Investigator

Study-Site.Study-Site Status

Subject.Screen Failure Reason

Supplementary Prompts

You can navigate to the following reports from this report:

- Site Detail Table (Report 3SS02-3)

Reports Referenced

You can navigate to the following reports from this report:

- Subjects who Failed Screening Table (Report 8SDP-24)

Reports Referencing This Report

None

Column Descriptions

Table A-41 describes the columns in the Screen Failure Reason Counts by Site Table report:

Table A–41 Screen Failure Reason Counts by Site Table Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Product	Product Name	Product.Product Name
Study-Site	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Study-Site	Study Region	Study-Site.Study Region
Region	Region Status	Region.Region Status
Study-Site	Study-Site ID#	Study-Site.Study-Site ID#
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Subject	Screen Failure Reason	Subject.Screen Failure Reason
NA	Subject Status	Subject Metrics.Subject Status
NA	Subject Status	COUNT("- Subject Metrics"."Subject Status")

Screening Overview By Region Chart (Report 8SDP-28)

Displays (by study) the number of subjects screened. Each bar in the report is stacked by region.

This report indicates how many subjects are in which status. It also indicates the number of subjects that have been screened, enrolled and randomized, and the progress of each region towards enrollment.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Site and Recruitment Overview** dashboard, **Screening Overview** page
- **CO - Study and Region Overview** dashboard, **Enrollment Overview** page

Dimensions

Study.Study

Region.Region Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-42 describes the columns in the Screening Overview By Region Chart report:

Table A–42 Screening Overview By Region Chart Column Descriptions

Table Heading	Column Heading	Measure
Study	Study	Study.Study
Region	Region Name	Region.Region Name
NA	# Screened	Study-Site Metrics.# Screened

Site Detail Table (Report 3SS02-3)

Lists (by program, study, and region) site details, including status, and first subject screened, enrolled and randomized dates.

This report indicates the progress of site selection and number of sites ready to enroll. It also indicates the sites and investigators selected.

Audience

Study Manager

CRA

Report Type

Pivot Table

Location

- **CO - Study and Region Overview** dashboard, **Site Overview** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID#

Study-Site.Site Name

Study-Site.Principal Investigator

Study-Site Team Member.Full Name

Study-Site Team Member.Role

Study-Site.Study-Site Status

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Comparative Site Enrollment Status Table (Report 8SDP-3)
- Enrollment Overview By Site (Report 8SDP-10)
- Patient Retention Table (Report 5SC01-1)
- Planned Sites vs. Sites Screening & Enrolling Chart (Top 10) (Report 3SS02-1b)
- Randomization Overview By Site Table (Report 8SDP-29)
- Screen Failure Reason Counts by Site Table (Report 4PR02-1)
- Site Status by Region Chart (Report 3SS07-2)
- Withdrawn Reason Counts by Site Table (Report 4PR02-2b)

Column Descriptions

Table A-43 describes the columns in the Site Detail Table report:

Table A–43 Site Detail Table Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Product	Product Name	Product.Product Name
Study-Site	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Study-Site	Study Region	Study-Site.Study Region
Region	Region Status	Region.Region Status
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site Team Member	Full Name	Study-Site Team Member.Full Name
Study-Site Team Member	Role	Study-Site Team Member.Role
Study-Site	Study-Site Status	Study-Site.Study-Site Status
NA	First Subject Screened Date	Study-Site Metrics.First Subject Screened Date
NA	First Subject Enrolled Date	Study-Site Metrics.First Subject Enrolled Date

Table A–43 (Cont.) Site Detail Table Column Descriptions

Table Heading	Column Heading	Measure
NA	First Subject Randomized Date	Study-Site Metrics.First Subject Randomized Date
NA	# Subjects Planned for Study-Site	Study-site Metrics.# Subjects Planned for Study-Site
NA	# Screened	Study-site Metrics.# Screened
NA	# Re-Screened	Study-site Metrics.# Re-Screened
NA	# Subjects Enrolled	Study-site Metrics.# Subjects Enrolled
NA	# Randomized	Study-site Metrics.# Randomized

Site Status by Region Chart (Report 3SS07-2)

Displays (by region) the number of sites in each status.

This report indicates the progress of each region towards enrollment. It also indicates the progress of site selection and the number of sites that are ready to enroll.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Site and Recruitment Overview** dashboard, **Site Status Overview** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID#

Study-Site.Study-Site Status

Study-Site.Principal Investigator

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Site Detail Table (Report 3SS02-3)

Reports Referencing This Report

None

Column Descriptions

Table A-44 describes the columns in the Site Status by Region Chart report:

Table A–44 Site Status by Region Chart

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Product	Product Name	Product.Product Name
Study-Site	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Study-Site	Study Region	Study-Site.Study Region
Region	Region Status	Region.Region Status
Study-Site	Study-Site ID#	Study-Site.Study-Site ID#
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Study-Site	Principal Investigator	Study-Site.Principal Investigator
NA	# Study-Sites	Study Metrics.# Study-Sites

Subject Retention Over Time Chart (Report 8SDP-4)

Displays (by month) the cumulative number of subjects completed compared to the number of subjects planned to be enrolled.

This report indicates how many subjects are being retained, and not early terminated from the study, compared to the number of subjects planned to be enrolled.

Audience

Study Manager

CRA

Report Type

Graph: Line

Location

- **CO - Subject Retention** dashboard, **Subject Retention Over Time** page

Dimensions

Date

Study-Site

Supplementary Prompts

Year and Month

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

Table A-45 describes the columns in the Subject Retention Over Time report:

Table A–45 Subject Retention Over Time Column Descriptions

Table Heading	Column Heading	Measure
NA	100% Planned Site Enrollment	Max(sum((CASE WHEN"- Study-site Metrics"."# Subjects Planned for Study-Site">0 THEN "- Study-site Metrics"."# Subjects Planned for Study-Site" ELSE 0 END)))
NA	90% Planned Site Enrollment	MAX(sum((CASE WHEN"- Study-site Metrics"."# Subjects Planned for Study-Site">0 THEN "- Study-site Metrics"."# Subjects Planned for Study-Site" ELSE 0 END))*.9)
NA	75% Planned Site Enrollment	MAX(sum((CASE WHEN"- Study-site Metrics"."# Subjects Planned for Study-Site">0 THEN "- Study-site Metrics"."# Subjects Planned for Study-Site" ELSE 0 END))*.75)
NA	50% Planned Site Enrollment	MAX(sum((CASE WHEN"- Study-site Metrics"."# Subjects Planned for Study-Site">0 THEN "- Study-site Metrics"."# Subjects Planned for Study-Site" ELSE 0 END))*.5)
NA	# Subjects Enrolled	RSUM("- Study-site Metrics"."# Subjects who have completed Study")
NA	Year and Month	Date."Year and Month"

Subjects who Failed Screening Table (Report 8SDP-24)

Lists (by program, study, and site) all subjects who have failed screening, including screen failure reason and subject comments.

This report indicates which screen failure reasons account for the most screen failures.

Audience

Study Manager

CRA

Report Type

Table

Location

- **CO - Site and Recruitment Overview** dashboard, **Screen Failure Overview** page

Dimensions

Study-Site.Study, Site, & Investigator

Study-Site.Study-Site Status

Subject.Screening #

Subject.Screen Failure Reason

Subject.Subject Comments

Subject Metrics.Subject Status

Subject Metrics.Status Comment

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Screen Failure Reason Counts by Site Table (Report 4PR02-1)
- Screen Failure Reason Chart (Report 4PR02-1b)
- Screen Failure Reason by Site Chart (Top 10 # Screen Failures) (Report 4PR02-1c)

Column Descriptions

Table A-46 describes the columns in the Subjects who Failed Screening Table report:

Table A–46 Subjects who Failed Screening Table Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Study, Site, & Investigator	Study-Site.Study, Site, & Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Subject	Screening #	Subject.Screening #
Subject	Screen Failure Reason	Subject.Screen Failure Reason
Subject	Subject Comments	Subject.Subject Comments
NA	Subject Status	Subject Metrics.Subject Status
NA	Status Comment	Subject Metrics.Status Comment

Subjects Withdrawn List Table (Report 8SDP-26)

Lists (by program, study, region, and site) all subjects who terminated the study early, including withdrawn reason and subject comments.

This report indicates which withdrawn reasons account for the most early terminations.

Audience

Study Manager

CRA

Report Type

Table

Location

- **CO - Subject Retention** dashboard, **Early Termination Overview** page

Dimensions

Study-Site.Study, Site, & Investigator

Subject.Enrollment Id

Subject.Withdrawn Reason

Subject.Subject Comments

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

You can navigate to this report from the following reports:

- Withdrawn Reason Chart (Report 4PR02-2)
- Withdrawn Reason Counts by Site Table (Report 4PR02-2b)
- Withdrawn Reason Overview Chart (Top 10 # Early Terms) (Report 8SDP-25)

Column Descriptions

Table A-47 describes the columns in the Subjects Withdrawn List Table report:

Table A–47 Subjects Withdrawn List Table Column Descriptions

Table Heading	Column Heading	Measure
Product	Product Name	Product.Product Name
Region	Region Status	Region.Region Status
Study	Study Status	Study.Study Status
Study-Site	Principal Investigator	Study-Site.Principal Investigator

Table A–47 (Cont.) Subjects Withdrawn List Table Column Descriptions

Table Heading	Column Heading	Measure
Study-Site	Program	Study-Site.Program
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Study	Study-Site.Study
Study-Site	Study Region	Study-Site.Study Region
Study-Site	Study-Site ID #	Study-Site.Study-Site ID #
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Subject	Enrollment Id	Subject.Enrollment Id
Subject	Withdrawn Reason	Subject.Withdrawn Reason
Subject	Subject Comments	Subject.Subject Comments
NA	Subject Status	Subject Metrics.Subject Status
NA	Status Comment	Subject Metrics.Status Comment

Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320)

Identifies specific subjects who have eCRFs awaiting processing.

This report indicates those subjects which require processing, and the number of eCRFs to be processed. This information can be used as a summary worklog to take to a site visit to drive activity.

Audience

Data Manager

Report Type

Table

Location

- **DM EDC** dashboard, **Study Processing Summary** page

Dimensions

- Study-Site.Program
- Study-Site.Study Name
- Subject.Subject ID

Supplementary Prompts

Study, Study-Site

Reports Referenced

You can navigate to the following reports from this report:

- List Discrepancy Details (Report CDA-DM-245)
- Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310)

Reports Referencing This Report

You can navigate to this report from the following reports:

- Key EDC processing volumes (Report CDA-DM-305)

Column Descriptions

Table A-48 describes the columns in the Summary of Subjects Awaiting EDC Processing report:

Table A–48 Summary of Subjects Awaiting EDC Processing Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Program
NA	NA	Study-Site.Study Name
Subject	Subject ID	Subject.Subject ID
# eCRFs	Entry Complete	Received CRFs.# eCRFs Entry Complete
# eCRFs	Not Verified	Received CRFs.# eCRFs Never Verified
# eCRFs	Awaiting Re-Verification	Received CRFs.# eCRFs Awaiting Re-Verification
# eCRFs	Not Approved	Received CRFs.# eCRFs Not Approved
# eCRFs	Awaiting Re-Approval	Received CRFs.# eCRFs Awaiting Re-Approval

Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420)

Identifies specific CRFs, and the process steps they are awaiting.

This report lists, for a subject, the pages which are awaiting processing. This information can be used to drive activity

Audience

Data Entry Manager

Data Manager

Report Type

Table

Location

- **DM Paper** dashboard, **Study Processing Summary** page

Dimensions

- Study-Site.Program
- Study-Site.Study Name
- Subject.Subject ID

Supplementary Prompts

Study, Study-Site

Reports Referenced

You can navigate to the following reports from this report:

- Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410)

Reports Referencing This Report

You can navigate to this report from the following reports:

- Key Paper processing volumes (Report CDA-DM-405)

Column Descriptions

Table A-49 describes the columns in the Summary of Subjects Awaiting Paper Processing report:

Table A–49 Summary of Subjects Awaiting Paper Processing Column Descriptions

Table Heading	Column Heading	Measure
NA	NA	Study-Site.Program
NA	NA	Study-Site.Study Name
Subject	Subject ID	Subject.Subject ID
# CRFs	Present	Received CRFs.# pCRFs Present
# CRFs	Awaiting First Entry Completion	Received CRFs.# pCRFs Awaiting Pass 1 Entry Completion
# CRFs	Awaiting Second Entry Completion	Received CRFs.# pCRFs Awaiting Pass 2 Entry Completion

Withdrawn Reason Chart (Report 4PR02-2)

Displays (by withdrawn reason) the number of subjects who terminated early.

This report indicates which withdrawn reasons account for the most early terminations.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Subject Retention** dashboard, **Subject Retention Overview** page
- **CO - Subject Retention** dashboard, **Early Termination Overview** page

Dimensions

Subject.Withdrawn Reason

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects Withdrawn List Table (Report 8SDP-26)

Reports Referencing This Report

None

Column Descriptions

Table A-50 describes the columns in the Withdrawn Reason Chart report:

Table A–50 Withdrawn Reason Chart Column Descriptions

Table Heading	Column Heading	Measure
NA	Subject Status	Subject Metrics.Subject Status
Subject	Withdrawn Reason	Subject.Withdrawn Reason

Withdrawn Reason Counts by Site Table (Report 4PR02-2b)

Lists (by program, study, and region) all sites that have early terminations and the number of early terminations that fall into a given withdrawn reason.

This report indicates which withdrawn reasons account for the most early terminations.

Audience

Study Manager

CRA

Report Type

Table

Location

- **CO - Subject Retention** dashboard, **Early Termination Overview** page

Dimensions

Study-Site.Program

Product.Product Name

Study-Site.Study

Study.Study Status

Study-Site.Study Region

Region.Region Status

Study-Site.Study-Site ID#

Study-Site.Site Name

Study-Site.Principal Investigator

Study-Site.Study-Site Status

Subject.Withdrawn Reason

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects Withdrawn List Table (Report 8SDP-26)
- Site Detail Table (Report 3SS02-3)

Reports Referencing This Report

None

Column Descriptions

Table A-51 describes the columns in the Withdrawn Reason Counts by Site Table report:

Table A–51 Withdrawn Reason Counts by Site Table Column Descriptions

Table Heading	Column Heading	Measure
NA	Program	Study-Site.Program
Subject	Product Name	Product.Product Name
Study-Site	Study	Study-Site.Study
Study	Study Status	Study.Study Status
Study-Site	Study Region	Study-Site.Study Region
Region	Region Status	Region.Region Status
Study-Site	Study-Site ID#	Study-Site.Study-Site ID#
Study-Site	Site Name	Study-Site.Site Name
Study-Site	Principal Investigator	Study-Site.Principal Investigator
Study-Site	Study-Site Status	Study-Site.Study-Site Status
Subject	Withdrawn Reason	Subject.Withdrawn Reason
NA	Subject Status	COUNT("- Subject Metrics"."Subject Status")

Withdrawn Reason Overview Chart (Top 10 # Early Terms) (Report 8SDP-25)

Displays (by site) the number of early terminations.

This report indicates which withdrawn reasons account for the most early terminations.

Audience

Study Manager

CRA

Report Type

Graph: Horizontal bar

Location

- **CO - Subject Retention** dashboard, **Early Termination Overview** page

Dimensions

Subject.Withdrawn Reason

Study-Site.Study, Site, & Investigator

Supplementary Prompts

None

Reports Referenced

You can navigate to the following reports from this report:

- Subjects Withdrawn List Table (Report 8SDP-26)

Reports Referencing This Report

You can navigate to this report from the following reports:

- Screen Failure Reason Counts by Site Table (Report 4PR02-1)
- Screen Failure Reason Chart (Report 4PR02-1b)
- Screen Failure Reason by Site Chart (Top 10 # Screen Failures) (Report 4PR02-1c)

Column Descriptions

Table A-52 describes the columns in the Withdrawn Reason Overview Chart (Top 10 # Early Terms) report:

Table A–52 Withdrawn Reason Overview Chart (Top 10 # Early Terms) Column Descriptions

Table Heading	Column Heading	Measure
NA	Subject Status	Subject Metrics.Subject Status
NA	# Early Terminations	Study-site Metrics.# Early Terminations
Subject	Withdrawn Reason	Subject.Withdrawn Reason
Study-Site	Study, Site, & Investigator	Study-Site.Study, Site, & Investigator

B

Oracle Clinical Development Analytics Presentation Catalog

The OCDA Presentation Catalog displays columns that you can use to create requests.

This appendix contains the following topics:

See Also:

Chapter 3, Working with Reports

Dimensions in OCDA Presentation Catalog

Table B-1 describes the Dimensions displayed in the OCDA Presentation Catalog. For each column, it shows the name of the Column, its description, and the Dimension containing the column. The table is sorted by Dimension, and by Column within Dimension. This corresponds to how the Dimension columns are organized in the Presentation Catalog. Each Dimension column has an ID number, which is provided for cross-reference to other tables in this appendix.

Please note that some columns have been de-normalized, so that they appear in more than one Dimension. This de-normalization speeds query execution by eliminating the need for a join to that column in another Dimension. It also supports the ability to constrain columns in a Prompt, so that when you select a value in one column, the other columns are constrained to those related to your selection. When you select a de-normalized column from a Dimension, your results will be limited to the grain of the Dimension.

Table B–1 Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD2	Date	Date	Attributes of a date
AD02-02	Date	Julian Day	Julian Day
AD02-03	Date	Month	Month within calendar year
AD02-04	Date	Quarter	Quarter within calendar year
AD02-05	Date	Year	Calendar year

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD02-06	Date	Week	Week within calendar year
AD02-07	Date	Date	Calendar Date
AD02-08	Date	Julian Month	Julian Month
AD02-09	Date	Julian Week	Julian Week
AD02-10	Date	Month Name	Full name of the month
AD02-11	Date	Year and Month	Year and month (For example, 1994 / 02)
AD02-12	Date	Year and Week	Year and week (For example, 1994 Week10)
AD02-13	Date	Year and Quarter	Year and quarter (For example, 1994 Q1)
AD4	Geography	Geography	Location of a site, in terms of a fixed hierarchy. State >- Country >- Continent.
AD04-01	Geography	Continent	Continent
AD04-03	Geography	Country	Country
AD04-04	Geography	State or Province	State or Province
AD04-05	Geography	County or District	County or District
AD04-06	Geography	City	City
AD04-07	Geography	Postal Code	Zip or Postal Code
AD5	Investigator	Investigator	Attributes of an Investigator, who may participate in multiple studies.
AD05-01	Investigator	Investigator Last Name	Investigator's surname
AD05-02	Investigator	Investigator First Name	Investigator's given name
AD05-03	Investigator	Investigator Full Name	First name, then last name
AD05-04	Investigator	Investigator Street Address	Investigator's street address
AD05-05	Investigator	Investigator City	The city where the investigator is located.
AD05-06	Investigator	Investigator Postal code	Postal or zip code
AD05-07	Investigator	Investigator State	The state where the investigator is located
AD05-08	Investigator	Investigator Country	Country where the investigator is located
AD05-09	Investigator	Investigator Continent	Continent where the investigator is located
AD05-10	Investigator	Investigator Work Phone	Investigator's work telephone
AD05-11	Investigator	Investigator Business Unit	Organizational business unit
AD05-12	Investigator	Investigator Mobile #	Investigator mobile number
AD05-13	Investigator	Investigator Email Address	Investigator email address
AD05-14	Investigator	Investigator Fax/Phone #	Investigator fax/phone number
AD05-15	Investigator	Investigator Middle Name	Investigator middle name
AD05-16	Investigator	Investigator Type	Investigator type
AD05-17	Investigator	Investigator Street Address 2	Investigator's street address - 2nd line

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD05-18	Investigator	Investigator Street Address 3	Investigator's street address - 3rd line
AD05-19	Investigator	Investigator Action Link	ROW_ID for the Siebel Clinical Contact table. You can use it in Siebel Clinical for an Action Link.
AD7	Product	Product	Product dimension
AD07-01	Product	Product Name	Name of the product
AD07-02	Product	Product Type	Type of the product
AD07-03	Product	Product Type Code	Organization's type code for the product
AD07-04	Product	Description	Product Description
AD07-07	Product	Product Number	Product #
AD07-08	Product	Product Status	Product Status
AD07-09	Product	Product Action Link	ROW_ID for the Siebel Clinical Product table. You can use it in Siebel Clinical for an Action Link.
AD8	Site	Site	A physical setting at which one or more studies may be conducted.
AD08-01	Site	Site Name	Name of the Site
AD08-02	Site	State	State in which the Site is located
AD08-03	Site	Country	Country in which the Site is located
AD08-04	Site	Continent	Continent in which the Site is located
AD08-05	Site	Business Unit	Business Unit within Site organization. Part of unique key for SC Site
AD08-06	Site	Site Action Link	ROW_ID for the Siebel Clinical Account table. You can use it in Siebel Clinical for an Action Link.
AD9	Study	Study	A description of the study
AD09-01	Study	Study	Unique identifier for the Study
AD09-02	Study	Study Short Title	A unique short title for the Study
AD09-03	Study	Program	Name of the Program that owns the Study
AD09-04	Study	Project	OC Project containing the Study
AD09-05	Study	Study Sponsor	Name of the Sponsor company for which this study is being conducted
AD09-06	Study	Data Capture Mode	The mode of doing data entry in this study. Possible values are {'EDC' | 'Paper' | 'Paper and EDC' | 'Unknown'}
AD09-07	Study	Comparative Agent	Comparative Agent
AD09-08	Study	Diagnosis	Diagnosis
AD09-09	Study	EUDRA Number	EUDRA Number
AD09-10	Study	Study Phase	Phase
AD09-11	Study	Study Status	Protocol Status
AD09-12	Study	Study Title	Title
AD09-13	Study	Study Type	Type
AD09-14	Study	Database Lock Date	Database lock date

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD09-15	Study	Study Action Link	ROW_ID for the Siebel Clinical Study table. You can use it in Siebel Clinical for an Action Link.
AD10	Study-Site	Study-Site	The use of a site for a study
AD10-01	Study-Site	Site Name	Name of the Site being used for this Study Site.
AD10-02	Study-Site	Study-Site ID #	Unique name given the site in the context of the Study.
AD10-03	Study-Site	Study Region	Name of the study-specific region in which the study site is located
AD10-04	Study-Site	Study	Unique identifier for the Study
AD10-05	Study-Site	Program	Name of the OC Program that owns the Study
AD10-06	Study-Site	Project	Name of the Project that owns the Study
AD10-07	Study-Site	Planned Enrollment Start Date	Date on which enrollment is (or was) expected to start. This is the date at which subjects start being sought, not the date of the enrollment of the first subject.
AD10-08	Study-Site	Planned Enrollment Completion Date	Date on which enrollment is (or was) planned to be complete
AD10-10	Study-Site	First Subject Enrolled Date	Date on which first subject was enrolled at the study-site.
AD10-22	Study-Site	Principal Investigator	Full name of Investigator currently responsible for the study at the site
AD10-24	Study-Site	CRO	CRO conducting the study at this site
AD10-25	Study-Site	Data Capture Mode	The mode of doing data entry at this study-site. Possible values are {'EDC' | 'Paper' | 'Paper and EDC' | 'Unknown'}
AD10-26	Study-Site	Study Sponsor	Sponsor of the research being done at the study-site. This is meaningful only if the user is a CRO. Will be defaulted with a value of Not Specified
AD10-29	Study-Site	Study-Site Status	Site Status
AD10-31	Study-Site	County	Site Country
AD10-32	Study-Site	City	Site City
AD10-33	Study-Site	Postal Code	Site Postal Code
AD10-34	Study-Site	Street Address	Study-site Street Address line 1
AD10-35	Study-Site	Street Address 2	Study-site Street Address line 2
AD10-36	Study-Site	Street Address 3	Study-site Street Address line 3
AD10-37	Study-Site	Study, Site, & Investigator	Concatenation of Study #, Site #, and Principal Investigator Last Name
AD10-38	Study-Site	Study Region Status	Status of the Study Region (denormalized from Study.Region Status)
AD10-39	Study-Site	Study-Site Action Link	ROW_ID for the Siebel Clinical Study Site table. You can use it in Siebel Clinical for an Action Link.
AD10-40	Study-Site	Study Status	Status of the Study (denormalized from Study.Status)

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD11	CRF	CRF	A Case Report Form. This is the form itself, as defined in a study, and which is assigned to be collected at various subject visits during a study.
AD11-01	CRF	Study	Study in which the form is specified.
AD11-02	CRF	CRF Name	Name of the form.
AD11-03	CRF	Description	Free text description of the particular CRF
AD11-04	CRF	CRF Short Name	Short name of the form
AD11-05	CRF	DCI_ID	Oracle Clinical ID for the form.
AD12	CRF Book	CRF Book	A specification of which CRFs are to be collected at what subject visits
AD12-01	CRF Book	CRF Book Name	Case Report Form Book (a set of forms to be collected, organized by visit): name of the book
AD12-02	CRF Book	Study	Case Report Form Book (a set of forms to be collected, organized by visit): study in which the book is to be used
AD13	Validation Procedure	Validation Procedure	A specification of a rule that validates a particular aspect of collected data
AD13-01	Validation Procedure	Study	Study in which the Procedure is specified.
AD13-02	Validation Procedure	Validation Procedure Name	Name of the Validation Procedure
AD13-03	Validation Procedure	Validation Procedure Description	Description of the validation procedure
AD13-04	Validation Procedure	Validation Procedure Scope	Scope of data used in the Procedure: 1-EVENT 1-DCM 1-EVENT M-DCM M-EVENT 1-DCM M-EVENT M-DCM THES_DERIVATION
AD14	Study-Site Team Member	Study-Site Team Member	-
AD14-01	Study-Site Team Member	First Name	Team member first name
AD14-02	Study-Site Team Member	Last Name	Team member last name
AD14-03	Study-Site Team Member	Full Name	Last Name, First Name
AD14-04	Study-Site Team Member	Role	Role in the Team History view
AD14-05	Study-Site Team Member	Start Date	Start Date in the Team History view
AD14-06	Study-Site Team Member	End Date	End Date in the Team History view

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD14-07	Study-Site Team Member	Team Member Comment	Comment in the Team History view
AD14-08	Study-Site Team Member	Team Member Action Link	ROW_ID for the Siebel Clinical Employee table. You can use it in Siebel Clinical for an Action Link.
AD15	Study-Site Contacts	Study-Site Contacts	-
AD15-01	Study-Site Contacts	City	Study-Site contact city
AD15-02	Study-Site Contacts	Country	Study-Site contact country
AD15-03	Study-Site Contacts	County	Study-Site contact county
AD15-04	Study-Site Contacts	Email Address	Study-Site contact email address
AD15-05	Study-Site Contacts	Employee Flag	Study-Site Contact Employee Flag
AD15-06	Study-Site Contacts	Fax #	Study-Site contact fax number
AD15-07	Study-Site Contacts	First name	Contact First Name
AD15-08	Study-Site Contacts	Full Name	Last name, then first name
AD15-09	Study-Site Contacts	Last Name	Contact Last Name
AD15-10	Study-Site Contacts	Middle Name	Contact Middle Name
AD15-11	Study-Site Contacts	Mobile #	Study-Site Contact mobile number
AD15-12	Study-Site Contacts	Phone #	Study-Site Contact phone number
AD15-13	Study-Site Contacts	Postal Code	Study-Site Contact postal code
AD15-15	Study-Site Contacts	State	Study-Site Contact state
AD15-16	Study-Site Contacts	Street Address	Study-Site Contact street address
AD15-17	Study-Site Contacts	Street Address 2	Study-Site Contact Address Line 2
AD15-18	Study-Site Contacts	Street Address 3	Study-Site Contact Address Line 3
AD15-19	Study-Site Contacts	Contact Action Link	ROW_ID for the Siebel Clinical Contact table. You can use it in Siebel Clinical for an Action Link.
AD16	Program	Program	Program
AD16-01	Program	Program Description	Program Description

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
AD16-02	Program	Program	Program Name
AD16-03	Program	Program Mechanism	Program Mechanism
AD16-04	Program	Program Action Link	ROW_ID for the Siebel Clinical Program table. You can use it in Siebel Clinical for an Action Link.
AD17	Region	Region	Study Region
AD17-01	Region	Region Name	Study Region Name
AD17-02	Region	Region Status	Status of Study Region
AD17-03	Region	Region CRO	CRO for a Study Region
AD17-04	Region	Region Action Link	ROW_ID for the Siebel Clinical Region table. You can use it in Siebel Clinical for an Action Link.
TD1	Subject	Subject	A person taking part in a study. While a person may participate in multiple studies, each participation corresponds to a unique subject
TD01-01	Subject	Study	Name of the clinical study in which this subject is a participant
TD01-02	Subject	Subject ID	A unique code for the patient position within the clinical study.
TD01-03	Subject	CRF Book	The ID of the DCI book to be used for this patient.
TD01-04	Subject	Is Hard Locked	A flag to show if the system prevents any changes to the data for this patient.
TD01-05	Subject	Is Early Terminated	A flag to show if the patient was terminated early from the study. VARCHAR2(1)
TD01-06	Subject	Enrollment date	Date and time when this patient was enrolled in this study.
TD01-07	Subject	Is Active	Is the subject one about whom CRFs are to be expected? This is to differentiate between two classes of people who may be given Subject IDs: (1) people who have not yet been screened or enrolled, and thus about whom no clinical trial data is to be expected, (2) people about who clinical trial data is to be expected. Setting for this will have to be user-dependent, since it hinges on when the user assigns a subject ID, and what that signifies with respect to expectation of clinical trial data. Defaults to 'Y'.
TD01-08	Subject	Subject Initials	The patient's initials, in mixed case.
TD01-09	Subject	Birth Date	The patients date of birth.
TD01-10	Subject	Death Date	The date that the patient was reported to have died.
TD01-11	Subject	Subject Status	Subject's current status
TD01-12	Subject	Subject Termination Date	Date on which the Subject ended participation in the study.
TD01-16	Subject	Gender	The patient's gender. Values are M for male and F for female.
TD01-17	Subject	Screening date	Date on which subject passed screening.
TD01-18	Subject	Eligible Flag	Subject Eligible Flag
TD01-19	Subject	Subject Comments	Subject comment

Table B–1 (Cont.) Presentation Catalog - Dimensions

ID	Dimension	Column	Description
TD01-20	Subject	Enrollment ID	Enrollment ID
TD01-21	Subject	Randomization ID	Randomization ID
TD01-22	Subject	Protocol Violation Flag	Subject Protocol Violation Flag
TD01-23	Subject	Screen Failure Reason	Screen Failure Reason
TD01-24	Subject	Screening #	Screening #
TD01-25	Subject	Protocol Deviation Flag	Subject Protocol Deviation Flag
TD01-26	Subject	Withdrawn Reason	Withdrawn reason
TD01-27	Subject	Subject Age	Current date minus subject Birth Date
TD01-28	Subject	Subject Current Status Date	Date of subject's current status
TD01-29	Subject	Randomization Date	Date on which the Subject was randomized
TD01-30	Subject	Subject Action Link	ROW_ID for the Siebel Clinical Subject table. You can use it in Siebel Clinical for an Action Link.

Facts in OCDA Presentation Catalog

Table B-2 describes the Facts displayed in the OCDA Presentation Catalog, and their Columns. For each Column, it shows the name of the Column, its description, and the Fact and Group within the Fact that contain the Column. The table is sorted by Group and Column, within Fact. This corresponds to how the Fact columns are organized in the Presentation Catalog, within the Fact folder. Each Fact Column has an ID number, which is provided for cross-reference to other tables in this Appendix.

Table B–2 Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-DOC01	Document Metrics	Counts	# of Documents	Count of all Activities where Activity is Document or Site-Initiation
M-DRS01	Discrepancy Review Statuses	Transactional Data	Discrepancy Review Status	A review status occupied by a discrepancy over the life of the discrepancy.
M-DRS02	Discrepancy Review Statuses	Transactional Data	# Days Discrepancy Ever in Review Status	Number of days a discrepancy ever occupied a particular discrepancy review status.
M-DRS03	Discrepancy Review Statuses	Statistics	Avg # Days Discrepancy Ever in Review Status	Number of days a discrepancy ever occupied a particular discrepancy review status, divided by the number of discrepancies ever in that review status
M-DRS04	Discrepancy Review Statuses	Statistics	Avg # Days Open Discrepancy Ever in Review Status	Number of days a currently open discrepancy ever occupied a discrepancy review status, divided by the number of discrepancies ever in that review status
M-DSC01	Discrepancies	Counts	# Total Discrepancies	Number of discrepancies, both open and closed

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-DSC02	Discrepancies	Counts	# Open Discrepancies	Number of discrepancies awaiting either being resolved or being marked irresolvable.
M-DSC03	Discrepancies	Counts	# Closed Discrepancies	Number of discrepancies that have either been obsolete or have been marked irresolvable.
M-DSC04	Discrepancies	Counts	# Discrepancies sent in DCFs	Number of discrepancies that have been included in one or more DCFs.
M-DSC09	Discrepancies	Counts	# Discrepancies Irresolvable	Number of discrepancies that have been marked irresolvable
M-DSC11	Discrepancies	Transactional Data	# Days Discrepancy Open	For those discrepancies that have been closed: Discrepancy close date - Discrepancy creation date; For currently open discrepancies: last ETL date - Discrepancy creation date.
M-DSC12	Discrepancies	Counts	# Days Current Discrepancies Open	For currently open discrepancies, number of days since creation.
M-DSC15	Discrepancies	Counts	# Days to Close Discrepancy	NULL if open; Days from creation of discrepancy to: date closed, if discrepancy closed
M-RCF01	Received CRFs	Counts	# CRFs Entry Complete	Total number of CRFs for which entry has been completed
M-RCF05	Received CRFs	Counts	# pCRFs Received, Not Entered	Number of pCRFs at Received
M-RCF06	Received CRFs	Counts	# pCRFs Pass 1 Entry Started, but Incomplete	Number of pCRFs at Pass 1 Started
M-RCF07	Received CRFs	Counts	# pCRFs Pass 1 Entry Complete	Number of pCRFs at Pass 1 Complete
M-RCF08	Received CRFs	Counts	# pCRFs Awaiting Pass 1 Entry Completion	Number of pCRFs awaiting completion of first data entry, including those at Received status
M-RCF09	Received CRFs	Counts	# CRFs Blank	Count of Blank CRFs. This is the Total number of CRFs where a user has opened and marked the CRF as blank intentionally.
M-RCF10	Received CRFs	Counts	# CRFs Present	Count of Present CRFs.
M-RCF11	Received CRFs	Intervals	# Days pCRF Awaiting Pass 1 Entry	Number of days pCRF received inhouse, awaiting first entry, to today's date
M-RCF13	Received CRFs	Counts	# pCRFs Pass 2 Entry Started, but Incomplete	Number of pCRFs at Pass 2 Started or Pass 2 Pending
M-RCF14	Received CRFs	Counts	# pCRFs Pass 2 Entry Complete	Number of pCRFs completed second entry
M-RCF15	Received CRFs	Counts	# pCRFs Awaiting Double Entry Reconciliation	Number of pCRFs awaiting double-entry reconciliation
M-RCF16	Received CRFs	Counts	# pCRFs Awaiting Pass 2 Entry Completion	Number of pCRFs awaiting completion of second data entry

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF17	Received CRFs	Counts	# pCRFs Awaiting Entry Completion	Number of pCRFs awaiting completion of either first or second data entry
M-RCF18	Received CRFs	Counts	# CRFs Awaiting Entry Completion	Count of CRFs that meet the criteria for Incomplete
M-RCF19	Received CRFs	Counts	# CRFs Electronically Loaded	Number of CRFs that were electronically, i.e. batch, loaded
M-RCF20	Received CRFs	Counts	# eCRFs Verified	Number of eCRFs which have been source-data verified by the CRA/Monitor
M-RCF21	Received CRFs	Counts	# eCRFs in Not Verified State	Number of eCRFs that are not in a verified state?
M-RCF21.1	Received CRFs	Counts	# eCRFs To Be Approved	Number of eCRFs that either have never been approved or that are awaiting re-approval.
M-RCF22	Received CRFs	Counts	# eCRFs Awaiting Re-Verification	Number of eCRFs which require source-data Verification to be redone by the CRA/Monitor, after a change by the Investigator
M-RCF23	Received CRFs	Counts	# eCRFs Never Verified	Number of eCRFs that have never been verified
M-RCF24	Received CRFs	Counts	# eCRFs Approved	Number of eCRFs which have been approved by Investigator
M-RCF25	Received CRFs	Counts	# eCRFs Not Approved	Number of eCRFs which require initial Approval by Investigator
M-RCF26	Received CRFs	Counts	# eCRFs Awaiting Re-Approval	Number of eCRFs requiring Re-Approval by Investigator
M-RCF29	Received CRFs	Counts	# CRFs Soft Locked	Number of Soft Locked CRFs
M-RCF29.1	Received CRFs	Counts	# CRFs Hard Locked	Number of Hard Locked CRFs
M-RCF30	Received CRFs	Intervals	# Days from eCRF Initially Verified to Finally Approved	For an eCRF currently both Verified and Approved, the interval, in days, between those initial verification and final approval, calculated as date(final approval) - date(initial verification)
M-RCF31	Received CRFs	Intervals	# Days from pCRF Visit to Pass 1 Entry	Interval between pCRF visit date and date of first entry
M-RCF31.1	Received CRFs	Intervals	# Days from pCRF Visit to Entry Complete	Interval between pCRF visit date and completion of all required entry passes.
M-RCF32	Received CRFs	Intervals	# Days from pCRF Pass 1 Entry to Pass 2 Entry Complete	Interval between pCRF first entry and second entry
M-RCF33	Received CRFs	Intervals	# Days pCRF Awaiting Pass 2 Entry from Pass 1 Entry	Number of days pCRF achieved first entry completion, to today's date, where pCRF status is still Pass 1 complete, and second pass is required

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF34	Received CRFs	Intervals	# Days from CRF Visit to Entry Complete	Interval between CRF visit date and (1) for eCRF: date on which first data entry completed; (2) for pCRF: date on which second data entry completed, if required for study, else first entry completed.
M-RCF35	Received CRFs	Intervals	# Days from eCRF Complete to Initial Verified	Interval between eCRF entry date and date of Initial Verification
M-RCF36	Received CRFs	Intervals	# Days from eCRF Entry Complete to Initially Approved	Number of days from eCRF entry completion to date when initially approved.
M-RCF37	Received CRFs	Intervals	# Days from CRF Entry Complete to Soft Locked	Interval between CRF Entry Complete and Soft Locked
M-RCF38	Received CRFs	Intervals	# Days from eCRF Final Approval to Soft Locked	Number of days from most recent eCRF Approved to Soft Locked.
M-RCF39	Received CRFs	Intervals	# Days from eCRF Visit to eCRF Complete	# Days from date of eCRF Visit to Date when entry complete
M-RCF40	Received CRFs	Intervals	# Days from eCRF Complete to Soft Locked	# Days from date of eCRF Complete to Date when eCRF was Soft Locked.
M-RCF41	Received CRFs	Statistics	Avg # Days from eCRF Visit to eCRF Complete	Across all eCRFs that are complete at the current level of analysis, the average number of days between the date of the visit when the CRF was collected and the date when it was Complete.
M-RCF42	Received CRFs	Statistics	Avg # Days from pCRF Visit to First Entry	Average interval between pCRF visit date and date of first entry
M-RCF43	Received CRFs	Statistics	Avg # Days from pCRF First Entry to Second Entry Complete	Average interval between pCRF first entry and second entry
M-RCF44	Received CRFs	Statistics	Avg # Days pCRF Awaiting Pass 2 Entry from Pass 1 Entry	Average number of days pCRF achieved first entry completion, to today's date, where pCRF status is still Pass 1 complete, and second pass is required
M-RCF45	Received CRFs	Statistics	Avg # Days from CRF Visit to Entry Complete	Average interval between CRF visit date and (1) for eCRF: date on which first data entry completed; (2) for pCRF: date on which second data entry completed, if required for study, else first entry completed.
M-RCF45.1	Received CRFs	Statistics	Avg # Days from pCRF Visit to Entry Complete	Average interval between pCRF visit date and date on which second data entry completed, if required for study, else first entry completed.
M-RCF46	Received CRFs	Statistics	Avg # Days from eCRF Complete to Initially Verified	Across all eCRFs that have every been set to Verified at the current level of analysis, the average number of days in the interval between eCRF entry date and date of Initial Verification

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF47	Received CRFs	Statistics	Avg # Days from eCRF Entry Complete to Initially Approved	Across all eCRFs that have every been set to Approved at the current level of analysis, the average number of days in the interval between eCRF entry completion to date when initially approved.
M-RCF48	Received CRFs	Statistics	Avg # Days from eCRF Initially Verified to Finally Approved	For all eCRFs currently both Verified and Approved, the average interval between initial verification and final approval dates.
M-RCF49	Received CRFs	Statistics	Avg # Days from eCRF Complete to Soft Locked	For all Soft Locked eCRFs, the average number of Days from date of eCRF Complete to Date when eCRF was Soft Locked.
M-RCF49.1	Received CRFs	Statistics	Avg # Days from pCRF Entry Complete to Soft Locked	For all Soft Locked pCRFs, the average number of Days from date of pCRF Complete to Date when pCRF was Soft Locked.
M-RCF49.2	Received CRFs	Statistics	Avg # Days from CRF Entry Complete to Soft Locked	For all Soft Locked CRFs, the average number of Days from date of CRF Complete to Date when CRF was Soft Locked.
M-RCF50	Received CRFs	Statistics	Avg # Days from eCRF Final Approval to Soft Locked	For all Soft Locked eCRFs, the average number of days from most recent eCRF Approved to Soft Locked.
M-RCF52	Received CRFs	Ratios	% eCRFs Verified / Present	%# eCRFs Verified /# eCRFs Present
M-RCF52.1	Received CRFs	Ratios	% eCRFs Approved / Present	%# eCRFs Verified /# eCRFs Entry Complete
M-RCF55.1	Received CRFs	Ratios	% eCRFs Approved / Entry Complete	%#eCRFs Approved /# eCRFs Entry Complete
M-RCF55.2	Received CRFs	Ratios	% eCRFs Verified / Entry Complete	%#eCRFs Verified /# eCRFs Entry Complete
M-RCF58	Received CRFs	Ratios	% eCRFs Soft Locked / Present	%# eCRFs Soft Locked /# eCRFs Present
M-RCF62	Received CRFs	Ratios	% CRFs Soft Locked / Entry Complete	The ratio of CRFs Soft Locked to number of CRFs with Entry Complete, expressed as a percentage.
M-RCF62.1	Received CRFs	Ratios	% eCRFs Soft Locked / Entry Complete	The ratio of eCRFs Soft Locked to number of eCRFs with Entry Complete, expressed as a percentage.
M-RCF62.2	Received CRFs	Ratios	% pCRFs Soft Locked / Entry Complete	The ratio of pCRFs Soft Locked to number of pCRFs with Entry Complete, expressed as a percentage.
M-RCF63	Received CRFs	Ratios	% Re-Verification / Verified	The ratio of number of eCRFs awaiting re-verification to the number currently verified, expressed as a percentage.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF64	Received CRFs	Ratios	% Re-Approval / Approved	The ratio of number of eCRFs requiring re-approval to the number currently approved expressed as a percentage.
M-RCF64.1	Received CRFs	Ratios	% Soft Locked / Present	% CRF Soft Locked/#CRFs Present
M-RCF64.2	Received CRFs	Ratios	% Hard Locked / Entry Complete	100 *# CRFs Hard Locked/# CRFs Entry Complete
M-RCF64.3	Received CRFs	Ratios	% eCRFs Hard Locked / Entry Complete	100 *# eCRFs Hard Locked/# CRFs Entry Complete
M-RCF64.4	Received CRFs	Ratios	% pCRFs Hard Locked / Entry Complete	100 *# pCRFs Hard Locked/# CRFs Entry Complete
M-RCF65	Received CRFs	Ratios	% Processed / Present	% CRF completely entered /#CRFs Present
M-RCF68	Received CRFs	Counts	# eCRFs Entry Complete	Total number of eCRFs for which entry has been completed
M-RCF69	Received CRFs	Counts	# eCRFs Initially Verified	Total number of eCRFs that were verified at least once
M-RCF70	Received CRFs	Counts	# eCRFs Initially Approved	Total number of eCRFs there were approved at least once
M-RCF71	Received CRFs	Counts	# eCRFs Finally Approved	Total number of eCRFs that were finally approved
M-RCF71.1	Received CRFs	Counts	# eCRFs Hard Locked	Total # of Hard Locked eCRFs
M-RCF72	Received CRFs	Counts	# eCRFs Soft Locked	Total number of Soft Locked eCRFs
M-RCF73	Received CRFs	Counts	# pCRFs Awaiting Pass 2 Entry	Total number of pCRFs Awaiting Pass 2 Entry
M-RCF74	Received CRFs	Counts	# pCRFs Soft Locked	Total # of Soft Locked pCRFs
M-RCF74.1	Received CRFs	Counts	# pCRFs Hard Locked	Total # of Hard Locked pCRFs
M-RCF75	Received CRFs	Counts	# eCRFs Present	Total # of Present # eCRFs
M-RCF76	Received CRFs	Intervals	# Days from pCRF Entry Complete to Soft Locked	Total # Days from pCRF Entry Complete to Soft Locked
M-RCF77	Received CRFs	Statistics	Avg # of Days pCRF Awaiting First Entry	Average # of Days pCRF Awaiting First Entry
M-RCF78	Received CRFs	Counts	# pCRFs Entry Complete	Total number of pCRFs for which entry has been completed
M-RCF81	Received CRFs	Counts	# eCRFs Blank	Count of Blank eCRFs. This is the Total number of eCRFs where a user has opened and marked the eCRF as blank intentionally.
M-RCF82	Received CRFs	Counts	# pCRFs Blank	Count of Blank pCRFs. This is the Total number of pCRFs where a user has opened and marked the pCRF as blank intentionally.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-RCF83	Received CRFs	Counts	# pCRFs Present	Count of Present pCRFs
M-RCF84	Received CRFs	Counts	# eCRFs Unplanned	Number of eCRFs that are Present but collected at an unplanned event
M-RCF85	Received CRFs	Counts	# pCRFs Unplanned	Number of pCRFs that are Present but collected at an unplanned event
M-RCF86	Received CRFs	Counts	# eCRFs Awaiting Entry Completion	Count of eCRFs that meet the criteria for Incomplete
M-REG01	Region Metrics	Counts	# Study-Sites Planned for Region	# Planned Sites
M-REG02	Region Metrics	Counts	# Subjects Planned for Region	# Planned Subjects
M-SST01	Study-site Metrics	Counts	# Subjects Planned	Total number of subjects planned to be enrolled at the Study-Site
M-SST02	Study-site Metrics	Counts	# Subjects Enrolled	Number of subjects who ever have had status Enrolled
M-SST02C	Study-site Metrics	Counts	# Subjects - Current Status Enrolled	Number of subjects with a current status of Enrolled
M-SST03	Study-site Metrics	Counts	# Currently Enrolled plus # Normally Terminated	The total number of subjects who are either currently enrolled or who have normally completed the study protocol
M-SST04	Study-site Metrics	Counts	# Current Active Subjects	Total number of Patients currently conducting Study
M-SST05	Study-site Metrics	Counts	# Subjects who have completed Study	Number of subjects who ever have had status Completed
M-SST05C	Study-site Metrics	Counts	# Subjects - Current Status Completed	Number of subjects whose current status is Completed
M-SST06	Study-site Metrics	Counts	# Early Terminations	Number of subjects who ever have had status Early Terminated
M-SST06C	Study-site Metrics	Counts	# Subjects - Current Status Early Terminated	Number of subjects whose current status is Early Terminated
M-SST08	Study-site Metrics	Counts	# Planned Subject Visits Completed	Number of planned Subject visits which have occurred. This is the count, across all CRFs received for all subjects at the site, of distinct planned visits at which the CRFs were collected. Planned visits are those for which sub-event number is zero.
M-SST09	Study-site Metrics	Counts	# Unplanned Subject Visits Completed	Number of unplanned Subject visits which have occurred. This is the count, across all CRFs received for all subjects at the site, of distinct unplanned visits at which the CRFs were collected. Unplanned visits are those for which sub-event number is greater than zero.
M-SST15.1	Study-site Metrics	Ratios	% Enrolled to Total Planned at Study-Site	Ratio of number of enrolled subjects to total planned number of subjects for the study site.

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SST17	Study-site Metrics	Ratios	Open Discrepancies per CRF	Number of Open Discrepancies per CRF currently Present
M-SST18	Study-site Metrics	Ratios	Total Discrepancies per CRF	Number of all Discrepancies (Open or Closed) per CRF currently Present
M-SST19	Study-site Metrics	Ratios	Closed Discrepancies per CRF	Number of Closed Discrepancies per CRF currently Present
M-SST20	Study-site Metrics	Ratios	Open Discrepancies per Enrolled Subject	Number of Open Discrepancies per currently enrolled Subject
M-SST21	Study-site Metrics	Ratios	Total Discrepancies per Enrolled Subject	Number of all Discrepancies (Open or Closed) per currently enrolled Subject
M-SST23	Study-site Metrics	Ratios	Closed Discrepancies per Enrolled Subject	Number of closed discrepancies per currently enrolled Subject
M-SST24	Study-site Metrics	Statistics	Avg Duration of Currently Open Discrepancies	For all open discrepancies at a study-site, the average number of days open
M-SST24.1	Study-site Metrics	Statistics	Avg Duration of All Discrepancies	For all discrepancies ever open at a study-site, the average number of days they were open.
M-SST24.2	Study-site Metrics	Statistics	Min Duration of All Discrepancies	For all discrepancies ever open at a study-site, the minimum number of days they were open.
M-SST24.3	Study-site Metrics	Statistics	Max Duration of All Discrepancies	For all discrepancies ever open at a study-site, the maximum number of days they were open.
M-SST27	Study-site Metrics	Statistics	Min Duration of Currently Open Discrepancies	For all open discrepancies at a study-site, the minimum number of days open
M-SST28	Study-site Metrics	Statistics	Max Duration of Currently Open Discrepancies	For all discrepancies currently open, the maximum number of days any of them has been open.
M-SST29	Study-site Metrics	Statistics	Avg Duration of Closed Discrepancies	For those discrepancies that are closed, the average number of days from creation to Closed.
M-SST30	Study-site Metrics	Statistics	Min Duration of Closed Discrepancies	For all closed discrepancies at a study-site, the minimum number of days it took to close them.
M-SST31	Study-site Metrics	Statistics	Max Duration of Closed Discrepancies	For all closed discrepancies at a study-site, the maximum number of days it took to close them.
M-SST32	Study-Site Metrics	Counts	# Randomized	Subjects who ever have had status Randomized.
M-SST32C	Study-Site Metrics	Counts	# Subjects - Current Status Randomized	Number of subjects whose current status is Randomized
M-SST33	Study-Site Metrics	Counts	# Re-Screened	Subjects who ever have had status Re-Screened
M-SST33C	Study-Site Metrics	Counts	# Subjects - Current Status Re-Screened	Number of subjects whose current status is Re-Screened

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SST34	Study-Site Metrics	Counts	# Screen Failure	Subjects who ever have had status Screen Failure
M-SST34C	Study-Site Metrics	Counts	# Subjects - Current Status Screen Failure	Number of subjects whose current status is Screen Failure
M-SST35	Study-Site Metrics	Counts	# Screened	Subjects who ever have had status Screened
M-SST35C	Study-Site Metrics	Counts	# Subjects - Current Status Screened	Number of subjects whose current status is Screened
M-SST36	Study-Site Metrics	Counts	# Subjects	Count of the number of subject records returned
M-SST37	Study-Site Metrics	Counts	# Subjects Deviation	Number of subjects with the Protocol Deviation flag checked
M-SST38	Study-Site Metrics	Counts	# Subjects Violation	Number of subjects with the Protocol Violation flag checked
M-SST39	Study-site Metrics	Counts	Days Since Initiation	Number of days from current date to Site Initiation Date
M-SST40	Study-Site Metrics	Statistics	First Subject Withdrawn Date	Earliest date on which a subject withdrew (Status is Early Terminated) from the study
M-SST41	Study-Site Metrics	Statistics	First Subject Completed Date	Earliest date on which a subject completed the study
M-SST42	Study-Site Metrics	Statistics	First Subject Enrolled Date	First Subject Enrolled
M-SST43	Study-Site Metrics	Statistics	First Subject Randomized Date	First Subject Randomized
M-SST44	Study-Site Metrics	Statistics	First Subject Screened Date	First Subject Screened
M-SST45	Study-Site Metrics	Statistics	Latest Subject Completed Date	Most recent date on which a subject completed the study
M-SST46	Study-Site Metrics	Statistics	Latest Subject Enrolled Date	Most recent date on which a subject enrolled in the study
M-SST47	Study-Site Metrics	Statistics	Latest Subject Randomized Date	Most recent date on which a subject was randomized
M-SST48	Study-Site Metrics	Statistics	Latest Subject Screened Date	Most recent date on which a subject was screened
M-SST49	Study Metrics	Counts	# Sites with 1 or More Subjects Screened	Number of study-sites with 1 or more subjects screened
M-SST50	Document Metrics	Counts	# Days from Document Sent to Document Received	Number of days between Document Sent date and Document Received Date
M-SST51	Document Metrics	Counts	# Days Document Outstanding	Number of days between Document Sent date and today's date, when Document Received date is null
M-SST52	Study-site Metrics	Intervals	# Days Since Last Enrolllment for Study-site	Number of days between today's date and the most recent enrollment date at the study-site

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
M-SST53	Study-site Metrics	Ratios	% of Planned Site Enrollment Completed	The number of subjects enrolled at study-site divided by the number of subjects planned at site
M-SST54	Study-site Metrics	Ratios	% of Total Enrolled in Study	The number of subjects enrolled at study-site divided by the number of subjects enrolled in the study
M-SST55	Study-site Metrics	Ratios	% of Total Randomized in Study	The number of subjects randomized at study-site divided by the number of subjects randomized in study
M-SST56	Study-site Metrics	Ratios	% of Total Screened in Study	The number of subjects screened at study-site divided by the number of subjects screened in study
M-SST57	Study-site Metrics	Ratios	% Subjects Early Terminated for Study-site	The number of subjects early terminated at study-site divided by the number of subjects enrolled at study-site
M-SST58	Study-site Metrics	Ratios	% Subjects Early Terminated for Study	The number of subjects early terminated in study divided by the number of subjects enrolled in study
M-SST59	Study-site Metrics	Statistics	Avg # Days Document Outstanding	Average number of days between Document Sent date and today's date,
M-SST60	Study-site Metrics	Statistics	Avg # Days from Document Sent to Document Received	Average number of days between Document Sent date and Document Received Date
M-STD01	Study Metrics	Counts	# Planned Sites	Number of sites planned to execute the study
M-STD02	Study Metrics	Counts	# Enrollments Planned for Study	Total number of subjects planned to be enrolled for the Study
M-STD06	Study Metrics	Ratios	% Enrolled / Planned in Study	Ratio of number of enrolled subjects to total planned number of subjects for the study
M-STD07	Study Metrics	Counts	# Study-Sites	# of protocol sites created for the study
M-STD08	Study Metrics	Counts	# Study-Sites with 1 or more Subjects Enrolled	Number of sites with a value in the first subject enrolled date
TA-DISC01	Discrepancies	Transactional Data	Discrepancy ID	Unique ID of the discrepancy
TA-DISC02	Discrepancies	Transactional Data	Study	Study in which the discrepancy was created
TA-DISC03	Discrepancies	Transactional Data	Site	Site at which the discrepancy was created
TA-DISC04	Discrepancies	Transactional Data	Investigator	Study-site Investigator
TA-DISC05	Discrepancies	Transactional Data	Subject	Patient ID for the patient about whom the data were collected.
TA-DISC06	Discrepancies	Transactional Data	Visit Name	Name of the visit at which the value causing the discrepancy was collected

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
TA-DISC07	Discrepancies	Transactional Data	Visit Number	Number of the visit at which the value causing the discrepancy was collected
TA-DISC08	Discrepancies	Transactional Data	Sub-event Number	Sub-event number of the visit at which the value causing the discrepancy was collected
TA-DISC09	Discrepancies	Transactional Data	Complete Visit Number	Planned event number ||.|| subevent number
TA-DISC10	Discrepancies	Transactional Data	Visit Date	Date of the visit when the value causing the discrepancy was collected
TA-DISC11	Discrepancies	Transactional Data	CRF Entry Date	Date on which the CRF containing the discrepant value was entered.
TA-DISC12	Discrepancies	Transactional Data	CRF Name	Name of the CRF (e.g. Demog) containing the discrepancy
TA-DISC13	Discrepancies	Transactional Data	CRF Book Page	Page within subject's CRF book where the question giving rise to the discrepancy is located
TA-DISC14	Discrepancies	Transactional Data	CRF Page Section	Within the Page containing the discrepancy, the Section containing the discrepancy
TA-DISC15	Discrepancies	Transactional Data	CRF Question Group	Within the Page and Section, the Question Group containing the discrepancy
TA-DISC16	Discrepancies	Transactional Data	CRF Question Name	Within the Page and Section containing the discrepancy, the Question giving rise to the discrepancy
TA-DISC17	Discrepancies	Transactional Data	CRF Question Occurrence	For the Question giving rise to the discrepancy, the Occurrence Sequence Number of Question. Has value of zero if there is only one occurrence; has value in 1..n, where number of occurrences, n, is greater than zero.
TA-DISC19	Discrepancies	Transactional Data	Irresolvable?	Y' if the discrepancy has been marked as irresolvable; 'N' otherwise.
TA-DISC20	Discrepancies	Transactional Data	Validation Procedure Name	If the discrepancy arose from execution of a validation procedure, the name of that procedure. Null otherwise.
TA-DISC21	Discrepancies	Transactional Data	Current Review Status	The current review status of the discrepancy. This tells where the discrepancy is in its movement through a processing workflow. The status values are initially defined by Oracle Clinical, with extensions allowed by customer.
TA-DISC22	Discrepancies	Transactional Data	Status	OC Discrepancy Status. Takes value of CURRENT, OBSOLETE

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
TA-DISC22.1	Discrepancies	Transactional Data	Discrepancy State	'Open', 'Answered', 'Closed', possibly others.
TA-DISC23	Discrepancies	Transactional Data	Type	How the discrepancy came into existence: Values are UNIVARIATE, MULTIVARIATE, MANUAL, and INDICATOR
TA-DISC24	Discrepancies	Transactional Data	resolution type	How the discrepancy was resolved. NULL if not currently resolved. The possible values are initially defined by Oracle Clinical, with extensions allowed by customer.
TA-DISC25	Discrepancies	Transactional Data	Creation Date	Date when the discrepancy was created
TA-DISC26	Discrepancies	Transactional Data	Close Date	Date when the discrepancy was closed (i.e. closed, made obsolete, or marked irresolvable).
TA-DISC26.1	Discrepancies	Transactional Data	Answered Date	Date when a query about the discrepancy was answered
TA-DISC30	Discrepancies	Transactional Data	Comment Text	Text associated with the discrepancy
TA-DISC31	Discrepancies	Transactional Data	Sent in DCF	Flag to indicate whether a discrepancy was sent in DCF
TA-DISC32	Discrepancies	Transactional Data	Origin	The origin of the discrepancy. Takes one of these values: {System; Non-system}
TA-DISC33	Discrepancies	Transactional Data	Study-site	Name of the Study-site at which the discrepancy was created
TA-DOC01	Document Metrics	Transactional Data	Activity	Document Activity
TA-DOC02	Document Metrics	Transactional Data	Document Comments	Document Comments
TA-DOC03	Document Metrics	Transactional Data	Document Name	Document Name
TA-DOC04	Document Metrics	Transactional Data	Activity Type	Activity Type
TA-DOC05	Document Metrics	Transactional Data	Document Expected Date	Document Expected Date
TA-DOC06	Document Metrics	Transactional Data	Document Received Date	Document Received Date
TA-DOC07	Document Metrics	Transactional Data	Document Sent Date	Document Sent Date
TA-DOC08	Document Metrics	Transactional Data	Document Expiration Date	Document Expiration Date
TA-RCRF01	Received CRFs	Transactional Data	Document ID	External identifier for the CRF
TA-RCRF02	Received CRFs	Transactional Data	Study	Study in which the CRF was created
TA-RCRF03	Received CRFs	Transactional Data	Site	Site at which the CRF was created

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
TA-RCRF04	Received CRFs	Transactional Data	Investigator	Study-site Investigator
TA-RCRF05	Received CRFs	Transactional Data	Subject	Patient ID for the patient about whom the data were collected.
TA-RCRF06	Received CRFs	Transactional Data	Visit Name	Name of the visit at which the CRF was collected
TA-RCRF07	Received CRFs	Transactional Data	Visit Number	Number of the visit at which CRF was collected
TA-RCRF08	Received CRFs	Transactional Data	Sub-event Number	Sub-event number of the visit at which the CRF was collected
TA-RCRF09	Received CRFs	Transactional Data	Complete Visit Number	Planned event number ||.|| subevent number
TA-RCRF10	Received CRFs	Transactional Data	Visit Date	Date of the visit when the CRF was collected
TA-RCRF11	Received CRFs	Transactional Data	CRF Name	Name of the CRF (e.g. Demog)
TA-RCRF12	Received CRFs	Transactional Data	CRF Book Name	Name of the CRF Book used to organize collected pages
TA-RCRF13	Received CRFs	Transactional Data	Page in CRF Book	Page number within subject's CRF book on which this CRF is located.
TA-RCRF14	Received CRFs	Transactional Data	Entry Date	Date on which the CRF was entered.
TA-RCRF15	Received CRFs	Transactional Data	Received CRF Status	Current status of the received CRF
TA-RCRF16	Received CRFs	Transactional Data	In not verified state?	Flag indicating whether a received CRF is in not verified state. "Y' means "not verified, else "N".
TA-RCRF17	Received CRFs	Transactional Data	Awaiting Re-Verification?	Flag indicating whether a received CRF is awaiting re-verification
TA-RCRF19	Received CRFs	Transactional Data	In not approved state?	Flag indicating whether a received CRF is awaiting approval
TA-RCRF20	Received CRFs	Transactional Data	Awaiting Re-Approval?	Flag indicating whether a received CRF is awaiting re-approval
TA-RCRF22	Received CRFs	Transactional Data	Blank?	Flag indicating whether there is any data for this received DCI.
TA-RCRF23	Received CRFs	Transactional Data	Soft Locked?	Flag indicating whether it is acceptable to change data for this received CRF without privileged update
TA-RCRF24	Received CRFs	Transactional Data	Awaiting first entry completion?	Flag indicating that a CRF is awaiting first entry completion
TA-RCRF25	Received CRFs	Transactional Data	Awaiting second entry completion?	Flag indicating that a CRF is awaiting second entry completion
TA-RCRF26	Received CRFs	Transactional Data	Completely entered?	Flag indicating that a CRF is completely entered

Table B–2 (Cont.) Presentation Catalog - Facts

ID	Topic	Group	Column	Description
TA-RCRF28	Received CRFs	Transactional Data	Hard Locked?	If a Received CRF is Hard Locked, data in the CRF is prevented from being modified. This can only be reversed by extraordinary means.
TA-RCRF29	Received CRFs	Transactional Data	Soft Lock Date	Date when last Soft locked
TA-RCRF30	Received CRFs	Transactional Data	Initial Source Verification Date	Date on which the CRF was initially source-verified
TA-RCRF31	Received CRFs	Transactional Data	Most Recent Source Verification Date	Most recent date on which the CRF was source-verified
TA-RCRF32	Received CRFs	Transactional Data	Initial Approval Date	Initial date on which the CRF was approved by the Investigator
TA-RCRF33	Received CRFs	Transactional Data	Most Recent Approval Date	Most recent date on which the CRF was approved by the Investigator
TA-RCRF34	Received CRFs	Transactional Data	Hard Lock Date	Date when last Hard Locked
TA-RCRF35	Received CRFs	Transactional Data	Data Capture Mode	Mode in which this CRF was capture. Values = {Paper, EDC}
TA-SITE01	Study-site Metrics	Statistics	Initial IRB Approval Date	Earliest IRB Approval date for a Site
TA-SUBJ01	Subject Metrics	Transactional Data	Subject Status	Subject Status
TA-SUBJ02	Study-Site Metrics	Statistics	Initial Informed Consent Date	Earliest Informed Consent date for a subject
TA-SUBJ03	Subject Metrics	Transactional Data	Status Comment	Subject Status Comments

Oracle Clinical Sources for OCDA Presentation Catalog

There are two tables in this section:

- Table B–3, Presentation Catalog - Oracle Clinical Sourceslists Oracle Clinical sources for presentation catalog.
- Table B–4, Aliases for Table Names lists the aliases used for table names in Table B-3.

Oracle Clinical Sources

Table B-3 describes how OCDA populates each column from an Oracle Clinical database. Each Measure has an ID number, which is provided for cross-reference to other tables in this Appendix. To display the information compactly, Table B-3 uses aliases for table names. Refer to Table B-4 for the correspondence between aliases and table names.

Table B–3 Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-02	-	-
AD02-03	-	-
AD02-04	-	-
AD02-05	-	-
AD02-06	-	-
AD02-07	-	-
AD02-08	-	-
AD02-09	-	-
AD02-10	-	-
AD02-11	-	-
AD02-12	-	-
AD02-13	-	-
AD04-01	ocl_regions.continent	where the continent is composed of country, and the country has only one continent. Else null.
AD04-03	os.country and inv.country	-
AD04-04	os.state and inv.country	-
AD04-05	-	Not sourced from OC
AD04-06	os.city and inv.city	-
AD04-07	os.postal_code and inv.postal_code	-
AD05-01	inv.last_name	-
AD05-02	inv.first_name	-
AD05-03	inv.first_name ||' '|| inv.last_name	-
AD05-04	inv.address _line%	catenation of 3 lines
AD05-05	inv.city	-
AD05-06	inv.postal_code	-
AD05-07	inv.state	-
AD05-08	inv.country	-
AD05-09	inv.continent	-
AD05-10	-	Not sourced from OC
AD05-11	-	Not sourced from OC
AD05-12	-	Not sourced from OC
AD05-13	-	Not sourced from OC
AD05-14	-	Not sourced from OC
AD05-15	-	Not sourced from OC
AD05-16	-	Not sourced from OC
AD05-17	-	Not sourced from OC
AD05-18	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD05-19	-	Not sourced from OC
AD07-01	pm.product_name	-
AD07-02	-	Not sourced from OC
AD07-03	pm.pm_type_code	-
AD07-04	-	Not sourced from OC
AD07-07	-	Not sourced from OC
AD07-08	-	Not sourced from OC
AD07-09	-	Not sourced from OC
AD08-01	site.name	-
AD08-02	site.state	-
AD08-03	site.country	-
AD08-04	region_components.part_of_region_code	Continent, given country
AD08-05	-	Not sourced from OC
AD08-06	-	Not sourced from OC
AD09-01	os.study	-
AD09-02	cs.short_title	-
AD09-03	os.program_code	-
AD09-04	os.project_code	-
AD09-05	-	Not sourced from OC
AD09-06	os.project_code	If all received CRFs have a single Data Capture mode, that is the mode of the study. If mixed, the 'Paper and EDC'; If no data collected, mode is 'Unknown'.
AD09-07	-	Not sourced from OC
AD09-08	-	Not sourced from OC
AD09-09	-	Not sourced from OC
AD09-10	os.clinical_phase	Not sourced from OC
AD09-11	cs.study_status_type_code	Not sourced from OC
AD09-12	cs.title	Not sourced from OC
AD09-13	-	Not sourced from OC
AD09-14	-	Not sourced from OC
AD09-15	-	Not sourced from OC
AD10-01	site.name	-
AD10-02	ss.study_site	-
AD10-03	-	Not sourced from OC
AD10-04	cs.study	-
AD10-05	os.program_code	-
AD10-06	os.project_code	-

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD10-07	ep.planned_start_date	-
AD10-08	ep.planned_target_date	-
AD10-10	min(pp.patient_enrollment_date)	-
AD10-22	inv.first_name ||' '|| inv.last_name	-
AD10-24	-	Not sourced from OC
AD10-25	-	If all received CRFs have a single Data Capture mode, that is the mode of the study. If mixed, the 'Paper and EDC'; If no data collected, mode is 'Unknown'.
AD10-29	-	Not sourced from OC
AD10-31	-	Not sourced from OC
AD10-32	-	Not sourced from OC
AD10-33	-	Not sourced from OC
AD10-34	-	Not sourced from OC
AD10-35	-	Not sourced from OC
AD10-36	-	Not sourced from OC
AD10-37	-	Not sourced from OC
AD10-38	-	Not sourced from OC
AD10-39	-	Not sourced from OC
AD10-40	CLINICAL_STUDIES	STUDY_STATUS_TYPE_CODE
AD11-01	cs.study	exclude GLIB
AD11-02	dci.name	-
AD11-03	dci.help_text	-
AD11-04	dci.short_name	-
AD11-05	dcis.dci_id	-
AD12-01	book.name	-
AD12-02	cs.study	exclude GLIB
AD13-01	cs.study	exclude GLIB
AD13-02	proc.name	-
AD13-03	proc.description	-
AD13-04	proc.procedure_type_code	-
AD14-01	-	Not sourced from OC
AD14-02	-	Not sourced from OC
AD14-03	-	Not sourced from OC
AD14-04	-	Not sourced from OC
AD14-05	-	Not sourced from OC
AD14-06	-	Not sourced from OC
AD14-07	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD14-08	-	Not sourced from OC
AD15-01	-	Not sourced from OC
AD15-02	-	Not sourced from OC
AD15-03	-	Not sourced from OC
AD15-04	-	Not sourced from OC
AD15-05	-	Not sourced from OC
AD15-06	-	Not sourced from OC
AD15-07	-	Not sourced from OC
AD15-08	-	Not sourced from OC
AD15-09	-	Not sourced from OC
AD15-10	-	Not sourced from OC
AD15-11	-	Not sourced from OC
AD15-12	-	Not sourced from OC
AD15-13	-	Not sourced from OC
AD15-15	-	Not sourced from OC
AD15-16	-	Not sourced from OC
AD15-17	-	Not sourced from OC
AD15-18	-	Not sourced from OC
AD15-19	-	Not sourced from OC
AD16-01	-	Not sourced from OC
AD16-02	-	Not sourced from OC
AD16-03	-	Not sourced from OC
AD16-04	-	Not sourced from OC
AD17-01	-	Not sourced from OC
AD17-02	-	Not sourced from OC
AD17-03	-	Not sourced from OC
AD17-04	-	Not sourced from OC
M-DOC01	-	Not sourced from OC
M-DRS01	derh.discrepancy_rev_status_code	-
M-DRS02	sum(derh.next_status_ts - derh.creation_ts)	For each particular review status (the summation is needed in case the discrepancy enters the review status more than once)
M-DRS03	M-DRS02/(number of discrepancies that occupied a given review status)	-
M-DRS04	(M-DRS02/(number of discrepancies that occupied a given review status)) given currently open discrepancies only	-
M-DSC01	disc	count

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-DSC02	disc	count where not OBSOLETE and not irresolvable
M-DSC03	disc	count where discrepancy_status_code = OBSOLETE or irresolvable
M-DSC04	disc	count where disc.dcf_id is not null
M-DSC09	disc	count where irresolvable
M-DSC11	close date - creation date	where State = CLOSED;
M-DSC12	last ETL date - creation date	where State = OPEN;
M-DSC15	close date - creation date	where State = CLOSED
M-RCF01	rdci.received_dcis	count where required entry passes are complete. For eCRF, this is Pass 1. For pCRF, it is Pass 1 unless second pass is required for the study.
M-RCF05	rdci	where received_dci_status_code = 'RECEIVED'
M-RCF06	rdci	where received_dci_status_code = 'PASS 1 STARTED
M-RCF07	rdci	count where PASS 1 COMPLETE
M-RCF08	rdci	where RECEIVED or PASS 1 STARTED
M-RCF09	rdci	where BLANK_FLAG = 'Y'
M-RCF10	rdci	count
M-RCF11	rdci	last ETL - log_in_ts, where RECEIVED
M-RCF13	rdci	count where rdci.received_dci_status_code in ('PASS 2 STARTED', 'PASS 2 PENDING')
M-RCF14	rdci	count where rdci.received_dci_status_code = 'PASS 2 COMPLETE'
M-RCF15	rdci	count where rdci.received_dci_status_code = 'PASS 2 PENDING'
M-RCF16	rdci	count where rdci.received_dci_status_code in ('PASS 1 COMPLETE', 'PASS 2 STARTED', 'PASS 2 PENDING')
M-RCF17	rdci	count where: rdci is paper (i.e. substr(rdci.document_number, 1,1) != 'R') and either received_dci_status_code = 'PASS 1 STARTED', if PASS 2 not required, or received_ dci_status_code in ('PASS 1 COMPLETE', 'PASS 2 STARTED', 'PASS 2 PENDING')
M-RCF18	rdci	count where: (rdci is paper (i.e. substr(rdci.document_number, 1,1) != 'R') and either received_dci_status_code = 'PASS 1 STARTED', if PASS 2 not required, or received_ dci_status_code in ('PASS 1 COMPLETE', 'PASS 2 STARTED', 'PASS 2 PENDING')) or /* eCRF */ received_dci_status_code = 'PASS 1 STARTED')
M-RCF19	rdci	count where received_dci_status_code = 'BATCH'
M-RCF20	rh	count where trans_type = 'SYS VER YES'
M-RCF21	rh	count where trans_type in ('SYS VER NO', 'SYS VER UNDONE', 'SYS VER DATACHG)

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF21.1	rh	count where trans_type in ('SYS APP NO', 'SYS APP UNDONE', 'SYS APP DATACHG')
M-RCF22	rh	count where trans_type = 'SYS VER DATACHG'
M-RCF23	rh	count where trans_type = 'SYS VER NO', ' SYS VER UNDONE'
M-RCF24	rh	count where trans_type = 'SYS APP YES'
M-RCF25	rh	count where trans_type = ('SYS APP NO', 'SYS APP UNDONE')
M-RCF26	rh	count where trans_type = 'SYS APP DATACHG'
M-RCF29	rdci	count all received DCIs that are locked (data_ lock_flag = 'Y') but not yet frozen (freeze_flag = 'N')
M-RCF29.1	rdci	count where TA-RCRF28 is 'Y'
M-RCF30	rh	interval from first verification to latest approval, using trans_type
M-RCF31	rdci	-
M-RCF31.1	rdci	ENTRY_COMPLETE_DT - ACTL_SUBJ_VIST_ DT
M-RCF32	rdci	pass2_compltn_dt - pass1_compltn_dt
M-RCF33	rdci	for pCRFs in studies requiring pass 2 entry only. If pass 2 complete, then pass2_compltn_dt - pass1_compltn_dt; else LAST_ETL_DT - pass1_ compltn_dt.
M-RCF34	rdci	ENTRY_COMPLETE_DT - ACTL_SUBJ_VIST_ DT
M-RCF35	rh	for eCRFs only: Date of first verification that is not undone - PASS1_COMPLTN_DT
M-RCF36	rh	for eCRFs only: Date of first approval that is not undone - PASS1_COMPLTN_DT
M-RCF37	rdci	data_lock_ts - ENTRY_COMPLETE_DT
M-RCF38	rh	for eCRFs only: data_lock_ts - Date of latest approval
M-RCF39	rdci	for eCRFs only: pass1_compltn_dt - ACTL_SUBJ_ VIST_DT
M-RCF40	rh	for eCRFs only: data_lock_dt - actl_subj_vist_dt
M-RCF41	rdci	avg(M-RCF39)
M-RCF42	rdci	avg(M-RCF31)
M-RCF43	rdci	avg(M-RCF32)
M-RCF44	rdci	avg(M-RCF33)
M-RCF45	rdci	avg(M-RCF34) for eCRFs
M-RCF45.1	rdci	avg(M-RCF34) for pCRFs
M-RCF46	rdci	avg(M-RCF35)
M-RCF47	rdci	avg(M-RCF36)

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF48	rdci	M-RCF30/M-RCF71
M-RCF49	rdci	avg(M-RCF40)
M-RCF49.1	rdci	avg(M-RCF76)
M-RCF49.2	rdci	avg(M-RCF37)
M-RCF50	rdci	avg(M-RCF38)
M-RCF52	rdci	100 * M-RCF20/M-RCF75
M-RCF52.1	rdci	100 * M-RCF24/M-RCF75
M-RCF55.1	rdci	100 * M-RCF24/M-RCF01
M-RCF55.2	rdci	100 * M-RCF20/M-RCF01
M-RCF58	rdci	100 * M-RCF72 /M-RCF75
M-RCF62	rdci	100 * M-RCF29/M-RCF1
M-RCF62.1	rdci	100 * M-RCF72/M-RCF64.3
M-RCF62.2	rdci	100 * M-RCF74/M-RCF78
M-RCF63	rdci	100 * M-RCF22/M-RCF20
M-RCF64	rdci	100 * M-RCF26l/M-RCF24
M-RCF64.1	rdci	100 * M-RCF29/M-RCF75
M-RCF64.2	rdci	100 * (M-RCF74 + M-RCRF74.1)/M-RCF64.3
M-RCF64.3	rdci	100 * M-RCF71.1/M-RCF64.3
M-RCF64.4	rdci	100 * M-RCF74.1/M-RCF78
M-RCF65	rdci	100 * M-RCF1/M-RCF10
M-RCF68	rdci	count where eCRF and received_dci_status_code = 'PASS 1 COMPLETE'
M-RCF69	rdci	count where at least one non-undone verification has occurred.
M-RCF70	rdci	count where at least one non-undone approval has occurred.
M-RCF71	rdci	count where latest approval has not been undone.
M-RCF71.1	-	-
M-RCF72	rdci	count all DCIs received via RDC that are locked (data_lock_flag = 'Y') but not yet frozen (freeze_ flag = 'N')
M-RCF73	rdci	pCRFs requiring pass 2 entry only: count where received_dci_status_code = 'PASS 1 COMPLETE'
M-RCF74	rdci	count all received paper DCIs that are locked (data_lock_flag = 'Y') but not yet frozen (freeze_ flag = 'N')
M-RCF74.1	rdci	pCRFs only: count where TA-RCRF28 is 'Y'
M-RCF75	rdci	eCRFs only: count *
M-RCF76	rdci	For pCRFs:data_lock_ts - ENTRY_COMPLETE_ DT
M-RCF77	rdci	Avg(Pass 1 complete dt - ACTL_SUBJ_VIST_DT)

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF78	rdci	for pCRFs: count where ENTRY-COMPLETE
M-RCF81	rdci	eCRFs only: count where blank_flag = 'Y'
M-RCF82	rdci	pCRFs only: count where blank_flag = 'Y'
M-RCF83	rdci	-
M-RCF84	rdci	eCRFs only: count where subevent_number > 0
M-RCF85	rdci	pCRFs only: count where subevent_number > 0
M-RCF86	rdci	eCRFs only: count where received_dci_status_ code = 'PASS 1 STARTED'
M-REG01	-	Not sourced from OC
M-REG02	-	Not sourced from OC
M-SST01	ep.planned_patient_enrollment	-
M-SST02	pp	count(*) where .patient_enrollment_date is not null and screening_position_flag = 'N'
M-SST02C	-	Not sourced from OC
M-SST03	pp	Calculate as # Subjects Enrolled - (# Early Terminations + # Subjects Lost to Follow up)
M-SST04	pp	Calculate as # Subjects Enrolled - (# Early Terminations + # Subjects Lost to Follow up + # Subjects Completed)
M-SST05	pp	A subject who has completed the study is one with an entry in patient_statuses with status of "COMPLETE"
M-SST05C	-	Not sourced from OC
M-SST06	pp	An early terminator is one with an entry in patient_statuses with status of "EARLY TERM"
M-SST06C	-	Not sourced from OC
M-SST08	ae	count actual events where sub-event number is 0.
M-SST09	ae	count actual events where sub-event number > 0.
M-SST15.1	-	100* (M-SST2/M-SST1)
M-SST17	-	M-DSC2/M-RCF10
M-SST18	-	M-DSC1/M-RCF10
M-SST19	-	M-DSC3/M-RCF10
M-SST20	-	M-DSC2/M-SST2
M-SST21	-	M-DSC1/M-SST2
M-SST23	-	M-DSC3/M-RCF10
M-SST24	-	M-DSC11/M-DSC2
M-SST24.1	-	(M-DSC11+M-DSC15)/(M-DSC2+M-DSC3)
M-SST24.2	-	min(min(M-DSC11), min(M-DSC15))
M-SST24.3	-	max(max(M-DSC11), max(M-DSC15))
M-SST27	-	min(M-DSC11)

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST28	-	max(M-DSC11)
M-SST29	-	M-DSC15/M-DSC3
M-SST30	-	min(M-DSC15)
M-SST31	-	max(M-DSC15)
M-SST32	-	Not sourced from OC
M-SST32C	-	Not sourced from OC
M-SST33	-	Not sourced from OC
M-SST33C	-	Not sourced from OC
M-SST34	-	Not sourced from OC
M-SST34C	-	Not sourced from OC
M-SST35	-	Not sourced from OC
M-SST35C	-	Not sourced from OC
M-SST36	-	Not sourced from OC
M-SST37	-	Not sourced from OC
M-SST38	-	Not sourced from OC
M-SST39	-	Not sourced from OC
M-SST40	-	Not sourced from OC
M-SST41	-	Not sourced from OC
M-SST42	-	Not sourced from OC
M-SST43	-	Not sourced from OC
M-SST44	-	Not sourced from OC
M-SST45	-	Not sourced from OC
M-SST46	-	Not sourced from OC
M-SST47	-	Not sourced from OC
M-SST48	-	Not sourced from OC
M-SST49	-	Not sourced from OC
M-SST50	-	Not sourced from OC
M-SST51	-	Not sourced from OC
M-SST52	-	Not sourced from OC
M-SST53	-	Not sourced from OC
M-SST54	-	Not sourced from OC
M-SST55	-	Not sourced from OC
M-SST56	-	Not sourced from OC
M-SST57	-	Not sourced from OC
M-SST58	-	Not sourced from OC
M-SST59	-	Not sourced from OC
M-SST60	-	Not sourced from OC

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-STD01	ep	count (*) where plan_sub_type_code = 'SITE'
M-STD02	csv, ep	For a given study, first look at the number of patients to enroll in the live study version to determine planned enrollment for that study. If that is null, use study enrollment plan
M-STD06	-	100 * # Enrolled/# Enrollments Planned
M-STD07	-	Not sourced from OC
M-STD08	-	Not sourced from OC
TA-DISC01	disc.discrepancy_entry_id	-
TA-DISC02	cs.study	where cs.clinical_study_id = disc.clinical_study_ id
TA-DISC03	os.name	where os.site_id = disc.site_id
TA-DISC04	inv	inv.last_name, inv.first_name where inv.investigator_id = disc.investigator_id
TA-DISC05	pp.patient	-
TA-DISC06	cpe.name	-
TA-DISC07	cpe.visit_number	-
TA-DISC08	disc.subevent_number	-
TA-DISC09	cpe.visit_number || '.' || disc.subevent_number where cpe.clin_plan_eve_id = disc.clin_ plan_eve_id	-
TA-DISC10	rcdi.dci_date	-
TA-DISC11	rcdi.log_in_ts	-
TA-DISC12	dci.dci_id	-
TA-DISC13	disc.CRF_PAGE_NUMBER	-
TA-DISC14	dcm.name	-
TA-DISC15	dqg.name	-
TA-DISC16	dq.question_name	-
TA-DISC17	dq.occurrence_sn	-
TA-DISC19	disc.discrepancy_rev_status_code	where DISC_IRRESOLVABLE
TA-DISC20	proc.name	-
TA-DISC21	disc.DISCREPANCY_REV_STATUS_ CODE	-
TA-DISC22	disc.discrepancy_rev_status_code	-
TA-DISC22.1	disc.discrepancy_rev_status_code	where STATE = 'CLOSED'
TA-DISC23	disc.DE_SUB_TYPE_CODE	-
TA-DISC24	discrepancy_entries.discrepancy_ resolu_type_code	-
TA-DISC25	disc.creation_ts	-
TA-DISC26	disc	Date discrepancy STATE became CLOSED.

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-DISC26.1	disc.DE_SUB_TYPE_CODE	Not sourced from OC
TA-DISC30	disc.comment_text	-
TA-DISC31	disc	Y' if disc.discrepancy_entry_id in (select discrepancy_id from dcf_discrepancies)
TA-DISC32	-	case disc.de_sub_type_code in ('MANUAL','MANUAL HEADER') then 'Non-System' else 'System' end origin
TA-DISC33	ss.study_site	where ss.SITE_ID = disc.site_id and ss.CLINICAL_STUDY_ID = disc.CLINICAL_ STUDY_ID
TA-DOC01	-	Not sourced from OC
TA-DOC02	-	Not sourced from OC
TA-DOC03	-	Not sourced from OC
TA-DOC04	-	Not sourced from OC
TA-DOC05	-	Not sourced from OC
TA-DOC06	-	Not sourced from OC
TA-DOC07	-	Not sourced from OC
TA-DOC08	-	Not sourced from OC
TA-RCRF01	rdci.document_id	-
TA-RCRF02	cs.study	where cs.clinical_study_id = rdci.clinical_study_ id
TA-RCRF03	os.name	where os.site_id = rdci.site_id
TA-RCRF04	inv	first_name || ' ' || last_name
TA-RCRF05	pp.patient	-
TA-RCRF06	rdci.clin_plan_eve_name	-
TA-RCRF07	cpe.visit_number	-
TA-RCRF08	rdci.subevent_number	-
TA-RCRF09	rdci.visit_number, subevent_number	-
TA-RCRF10	rdci.dci_date	-
TA-RCRF11	rdci.dci_id	-
TA-RCRF12	book.name	-
TA-RCRF13	page.start_page_number	-
TA-RCRF14	rdci.received_dci_login_ts	-
TA-RCRF15	rdci.received_dci_status_code	-
TA-RCRF16	rdci.received_dci_id	case when rdcih.trans_type in 'SYS VER NO', 'SYS VER UNDONE') then 'Y' else 'N'
TA-RCRF17	rdci.received_dci_id	case when rdcih.trans_type ='SYS VER DATACHG' then 'Y' else 'N'
TA-RCRF19	rdci.received_dci_id	case when rdcih.trans_type in 'SYS APP NO', 'SYS APP UNDONE') then 'Y' else 'N'

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-RCRF20	select rdci.received_dci_id,	case when rdcih.trans_type ='SYS APP DATACHG' then 'Y' else 'N'
TA-RCRF22	rdci.blank_flag	-
TA-RCRF23	rdci.data_lock_flag	-
TA-RCRF24	rdci	when rdci.received_dci_status_code in 'RECEIVED', 'PASS 1 STARTED') then 'Y' else 'N' end
TA-RCRF25	rdci	case when rdci.received_dci_status_code in 'PASS 1 COMPLETE', 'PASS 2 STARTED', 'PASS 2 PENDING') then 'Y' else 'N' end
TA-RCRF26	-	ENTRY_COMPLETE
TA-RCRF28	book.name	A received DCI is hard locked if the patient position for which that received DCI is collected has been frozen. Freezing the patient position means all of that patient position's received dcis are hard-locked. So we use pp.freeze_flag as hard-lock flag
TA-RCRF29	rdci.data_lock_ts	-
TA-RCRF30	rdci	Date of first non-undone verification, using rh.
TA-RCRF31	rdci.received_dci_status_code	Date of most recent non-undone verification, using rh.
TA-RCRF32	rdci	Date of first non-undone approval using rh.
TA-RCRF33	rdci	Date of most recent non-undone approval using rh.
TA-RCRF34	-	-
TA-RCRF35	-	see eCRF, pCRF
TA-SITE01	-	Not sourced from OC
TA-SUBJ01	-	Not sourced from OC
TA-SUBJ02	-	Not sourced from OC
TA-SUBJ03	-	Not sourced from OC
TD01-01	pp.clinical_study_id	-
TD01-02	pp.patient	-
TD01-03	pp.dci_book_id	-
TD01-04	pp.freeze_flag	-
TD01-05	pp.early_termination_flag	-
TD01-06	ps, pp	icase when ps.patient_status_code ='ENROLLED' then ps.status_date when pp.patient_enrollment_ date is not null then pp.patient_enrollment_date else null end
TD01-07	pp	Case when <TD01-06> is not null then 'Y' else 'N' end
TD01-08	pp.reported_initials	-
TD01-09	pp.reported_birth_date	-
TD01-10	pp.reported_death_date	-

Table B–3 (Cont.) Presentation Catalog - Oracle Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TD01-11	ps	Use the latest status code for the subject
TD01-12	ps,pp	case when ps.patient_status_code ='COMPLETE' then ps.status_date when pp.termination_date is not null and pp.early_termination_flag != 'Y' then pp.termination_date else null end
TD01-16	pp.reported_sex	-
TD01-17	-	Not sourced from OC
TD01-18	-	Not sourced from OC
TD01-19	-	Not sourced from OC
TD01-20	-	Not sourced from OC
TD01-21	-	Not sourced from OC
TD01-22	-	Not sourced from OC
TD01-23	-	Not sourced from OC
TD01-24	-	Not sourced from OC
TD01-25	-	Not sourced from OC
TD01-26	-	Not sourced from OC
TD01-27	-	Not sourced from OC
TD01-28	-	Not sourced from OC
TD01-29	-	Not sourced from OC
TD01-30	-	Not sourced from OC

Aliases

To display the information compactly, Table B-3 uses aliases for table names. Table B-4 lists these aliases:

Table B–4 Aliases for Table Names

Alias	Table Name
book	rxc.dci_books
cpe	rxa_des.clinical_planned_events
cs	rxa_des.clinical_studies
dci	rxc.dcis
derh	rxc.discrepancy_review_hist
disc	rxc.discrepancy_entries
dq	rxc.dcm_questions
dqg	rxc.dcm_question_groups
ep	rxa_des.enrollment_plans
inv	rxa_des.ocl_investigators
os	rxa_des.ocl_studies
page	rxc.dci_book_pages

Table B–4 (Cont.) Aliases for Table Names

Alias	Table Name
pp	rxa_des.patient_positions
pm	rxa_des.ocl_product_masters
proc	rxc.procedures
ps	rxa_des.patient_statuses
rcv	rxc.reference_codelist_values
rdci	rxc.received_dcis
rdcm	rxc.received_dcms
site	rxa_des.ocl_sites
ss	rxa_des.ocl_study_sites

Caution: Where source location is described in snippets of SQL code, it should be read as an indication of how the information is to be extracted. This is typically not the actual code used in the OC-specific ETL programs. Consult the ETL for actual extraction queries.

Note that:

- eCRF is distinguished from pCRF by the first character in the document ID. If this is 'R', the document is assumed to be entered through RDC, and therefore an eCRF. Otherwise, it is considered to be an eCRF.
- ACTL_SUBJ_VIST_DT is the date when the RDCI was collected. This is taken to be the first non-null of these: rdci.visit_date; min(rdcm.visit_date) for the rdci; min(rdci.visit_date) for the rdci's visit; min(rdcm.visit_date) for the rdci's visit.
- ENTRY_COMPLETE: an eCRF is entry complete if it is pass 1 complete; a pCRF is entry complete if either (a) pass 2 is required and it is pass 2 complete, or (b) it is pass 1 complete.
- ENTRY_COMPLETE_DT is the date when RDCI became ENTRY_COMPLETE.
- LAST_ETL_DT is the date when the ETL was last executed.
- All queries on received_dcis look only at records where end_ts = to_date(3000000, 'J')
- A discrepancy is DISC_IRRESOLVABLE if disc.discrepancy_rev_status_code in (select rcv.ref_codelist_value_short_val from reference_codelist_values rcv where rcv.ref_codelist_name = 'DISCREPANCY REV STATUS CODE' and rcv.long_value = 'IRRESOLVABLE');
- A discrepancy's STATE is CLOSED {DISCREPANCY_REV_STATUS_CODE is 'CLOSED', or DISCREPANCY_STATUS_CODE = 'OBSOLETE', or DISC_ IRRESOLVABLE). OPEN otherwise.

Oracle's Siebel Clinical Sources for OCDA Presentation Catalog

Table B-5 describes how OCDA populates each column from an Siebel Clinical (SC) database. Each Measure has an ID number, which is provided for cross-reference to other tables in this Appendix.

Table B–5 Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD02-02	-	-
AD02-03	-	-
AD02-04	-	-
AD02-05	-	-
AD02-06	-	-
AD02-07	-	-
AD02-08	-	-
AD02-09	-	-
AD02-10	-	-
AD02-11	-	-
AD02-12	-	-
AD02-13	-	-
AD04-01	-	Not sourced from SC
AD04-03	-	Not sourced from SC
AD04-04	-	Not sourced from SC
AD04-05	-	Not sourced from SC
AD04-06	-	Not sourced from SC
AD04-07	-	Not sourced from SC
AD05-01	S_CONTACT.LAST_NAME	-
AD05-02	S_CONTACT.FST_NAME	-
AD05-03	S_CONTACT.LAST_NAME + S_ CONTACT.FST_NAME	-
AD05-04	S_ADDR_PER.ADDR	-
AD05-05	S_ADDR_PER.CITY	-
AD05-06	S_ADDR_PER.ZIPCODE	-
AD05-07	S_ADDR_PER.STATE	-
AD05-08	S_ADDR_PER.COUNTRY	-
AD05-09	-	Not sourced from SC
AD05-10	S_CONTACT.WORK_PH_NUM	-
AD05-11	-	Not sourced from SC
AD05-12	S_CONTACT.CELL_PH_NUM	-
AD05-13	S_CONTACT.EMAIL_ADDR	-
AD05-14	S_CONTACT.FAX_PH_NUM	-
AD05-15	S_CONTACT.MID_NAME	-
AD05-16	S_CONTACT.CON_CD	-
AD05-17	S_ADDR_PER.ADDR_LINE_2	-
AD05-18	S_ADDR_PER.ADDR_LINE_3	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD05-19	S_CONTACT.ROW_ID	-
AD07-01	S_PROD_INT.NAME	S_PROD_INT.TYPE ="Compound" OR S_PROD_INT.TYPE ="Molecule" OR S_PROD_INT.TYPE ="Device" OR S_PROD_INT.TYPE ="Equipment"
AD07-02	S_PROD_INT.TYPE	S_PROD_INT.TYPE ="Compound" OR S_PROD_INT.TYPE ="Molecule" OR S_PROD_INT.TYPE ="Device" OR S_PROD_INT.TYPE ="Equipment"
AD07-03	-	Not sourced from SC
AD07-04	S_PROD_INT.DESC_TEXT	S_PROD_INT.TYPE ="Compound" OR S_PROD_INT.TYPE ="Molecule" OR S_PROD_INT.TYPE ="Device" OR S_PROD_INT.TYPE ="Equipment"
AD07-07	S_PROD_INT.PART_NUM	S_PROD_INT.TYPE ="Compound" OR S_PROD_INT.TYPE ="Molecule" OR S_PROD_INT.TYPE ="Device" OR S_PROD_INT.TYPE ="Equipment"
AD07-08	S_PROD_INT.STATUS_CD	S_PROD_INT.TYPE ="Compound" OR S_PROD_INT.TYPE ="Molecule" OR S_PROD_INT.TYPE ="Device" OR S_PROD_INT.TYPE ="Equipment"
AD07-09	S_PROD_INT.ROW_ID	S_PROD_INT.TYPE ="Compound" OR S_PROD_INT.TYPE ="Molecule" OR S_PROD_INT.TYPE ="Device" OR S_PROD_INT.TYPE ="Equipment"
AD08-01	-	Not sourced from SC
AD08-02	S_ADDR_PER.STATE	-
AD08-03	S_ADDR_PER.COUNTRY	-
AD08-04	-	Not sourced from SC
AD08-05	-	Not sourced from SC
AD08-06	S_ORG_EXT.ROW_ID	-
AD09-01	S_CL_PTCL_LS.PTCL_NUM	-
AD09-02	S_CL_PTCL_LS.PTCL_ABBR_TL	-
AD09-03	S_CL_PGM_LS.NAME	-
AD09-04	-	Not sourced from SC
AD09-05	-	Not sourced from SC
AD09-06	-	Not sourced from SC
AD09-07	S_CL_PTCL_LS.PTCL_COMP_AGNT	-
AD09-08	S_CL_PTCL_LS.PTCL_DIAGNOSIS	-
AD09-09	S_CL_PTCL_LS.EUDRA_NUM	-
AD09-10	S_CL_PTCL_LS.PTCL_PHASE	-
AD09-11	S_CL_PTCL_LS.PTCL_STAT_CD	-
AD09-12	S_CL_PTCL_LS.PTCL_TITLE	-
AD09-13	S_CL_PTCL_LS.PTCL_TYPE_CD	-
AD09-14	S_CL_PTCL_LS.DB_LOCK_DT	-
AD09-15	S_CL_PTCL_LS.ROW_ID	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD10-01	S_ORG_EXT.NAME	-
AD10-02	S_PTCL_SITE_LS.SITE_NUM	-
AD10-03	S_CL_PTCL_LS.REGION_CD	-
AD10-04	S_CL_PTCL_LS.PTCL_NUM	-
AD10-05	S_CL_PGM_LS.NAME	-
AD10-06	-	Not sourced from SC
AD10-07	-	Not sourced from SC
AD10-08	-	Not sourced from SC
AD10-10	S_PTCL_SITE_LS.FST_SUBJ_ENRL_DT	-
AD10-22	S_CONTACT.LAST_NAME+FST_NAME	S_PTL_ST_CON_LS.AFFL_CON_ID=S_CONTACT.PAR_ROW_ID AND RELATION_TYPE_CD ='Principal Investigator'
AD10-24	S_ORG_EXT.NAME	-
AD10-25	-	Not sourced from SC
AD10-26	-	Not sourced from SC
AD10-29	S_PTCL_SITE_LS.STATUS_CD	-
AD10-31	-	Not sourced from SC
AD10-32	S_ADDR_PER.CITY	-
AD10-33	S_ADDR_PER.ZIPCODE	-
AD10-34	S_ADDR_PER.ADDR	-
AD10-35	S_ADDR_PER.ADDR_LINE_2	-
AD10-36	S_ADDR_PER.ADDR_LINE_3	-
AD10-37	-	Not sourced from SC
AD10-38	S_CL_PTCL_LS.PTCL_STAT_CD	REGION_CD NOT NULL
AD10-39	S_PTCL_SITE_LS.ROW_ID	-
AD10-40	S_CL_PTCL_LS.PTCL_STAT_CD	-
AD11-01	-	Not sourced from SC
AD11-02	-	Not sourced from SC
AD11-03	-	Not sourced from SC
AD11-04	-	Not sourced from SC
AD11-05	-	Not sourced from SC
AD12-01	-	Not sourced from SC
AD12-02	-	Not sourced from SC
AD13-01	-	Not sourced from SC
AD13-02	-	Not sourced from SC
AD13-03	-	Not sourced from SC
AD13-04	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
AD14-01	S_CONTACT.FST_NAME	-
AD14-02	S_CONTACT.LAST_NAME	-
AD14-03	S_CONTACT.FULL_NAME	-
AD14-04	S_ST_HST_POS_LS.ROLE_CD	-
AD14-05	S_ST_HST_POS_LS.START_DT	-
AD14-06	S_ST_HST_POS_LS.END_DT	-
AD14-07	S_ST_HST_POS_LS.COMMENTS	-
AD14-08	S_CONTACT.ROW_ID	-
AD15-01	S_ADDR_PER.CITY	-
AD15-02	S_ADDR_PER.COUNTRY	-
AD15-03	-	Not sourced from SC
AD15-04	S_CONTACT.EMAIL_ADDR	-
AD15-05	S_CONTACT.EMP_FLG	-
AD15-06	S_CONTACT.FAX_PH_NUM	-
AD15-07	S_CONTACT.FST_NAME	-
AD15-08	S_CONTACT.FULL_NAME	-
AD15-09	S_CONTACT.LAST_NAME	-
AD15-10	S_CONTACT.MID_NAME	-
AD15-11	S_CONTACT.CELL_PH_NUM	-
AD15-12	S_CONTACT.WORK_PHONE	-
AD15-13	S_ADDR_PER.ZIPCODE	-
AD15-15	S_ADDR_PER.STATE	-
AD15-16	S_ADDR_PER.ST_ADDRESS	-
AD15-17	S_ADDR_PER.ADDR_LINE_2	-
AD15-18	S_ADDR_PER.ADDR_LINE_3	-
AD15-19	S_CONTACT.ROW_ID	-
AD16-01	S_CL_PGM_LS.DESC_TEXT	-
AD16-02	S_CL_PGM_LS.NAME	-
AD16-03	S_CL_PGM_LS.PROG_MCHNSM_CD	-
AD16-04	S_CL_PGM_LS.ROW_ID	-
AD17-01	S_CL_PTCL_LS.REGION_CD	-
AD17-02	S_CL_PTCL_LS.PTCL_STAT_CD	REGION_CD NOT NULL
AD17-03	S_ORG_EXT.NAME	-
AD17-04	S_CL_PTCL_LS.ROW_ID	-
M-DOC01	S_EVT_ACT.ROW_ID	SUBTYPE_CD='Document'
M-DRS01	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-DRS02	-	Not sourced from SC
M-DRS03	-	Not sourced from SC
M-DRS04	-	Not sourced from SC
M-DSC01	-	Not sourced from SC
M-DSC02	-	Not sourced from SC
M-DSC03	-	Not sourced from SC
M-DSC04	-	Not sourced from SC
M-DSC09	-	Not sourced from SC
M-DSC11	-	Not sourced from SC
M-DSC12	-	Not sourced from SC
M-DSC15	-	Not sourced from SC
M-RCF01	-	Not sourced from SC
M-RCF05	-	Not sourced from SC
M-RCF06	-	Not sourced from SC
M-RCF07	-	Not sourced from SC
M-RCF08	-	Not sourced from SC
M-RCF09	-	Not sourced from SC
M-RCF10	-	Not sourced from SC
M-RCF11	-	Not sourced from SC
M-RCF13	-	Not sourced from SC
M-RCF14	-	Not sourced from SC
M-RCF15	-	Not sourced from SC
M-RCF16	-	Not sourced from SC
M-RCF17	-	Not sourced from SC
M-RCF18	-	Not sourced from SC
M-RCF19	-	Not sourced from SC
M-RCF20	-	Not sourced from SC
M-RCF21	-	Not sourced from SC
M-RCF21.1	-	Not sourced from SC
M-RCF22	-	Not sourced from SC
M-RCF23	-	Not sourced from SC
M-RCF24	-	Not sourced from SC
M-RCF25	-	Not sourced from SC
M-RCF26	-	Not sourced from SC
M-RCF29	-	Not sourced from SC
M-RCF29.1	-	Not sourced from SC
M-RCF30	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF31	-	Not sourced from SC
M-RCF31.1	-	Not sourced from SC
M-RCF32	-	Not sourced from SC
M-RCF33	-	Not sourced from SC
M-RCF34	-	Not sourced from SC
M-RCF35	-	Not sourced from SC
M-RCF36	-	Not sourced from SC
M-RCF37	-	Not sourced from SC
M-RCF38	-	Not sourced from SC
M-RCF39	-	Not sourced from SC
M-RCF40	-	Not sourced from SC
M-RCF41	-	Not sourced from SC
M-RCF42	-	Not sourced from SC
M-RCF43	-	Not sourced from SC
M-RCF44	-	Not sourced from SC
M-RCF45	-	Not sourced from SC
M-RCF45.1	-	Not sourced from SC
M-RCF46	-	Not sourced from SC
M-RCF47	-	Not sourced from SC
M-RCF48	-	Not sourced from SC
M-RCF49	-	Not sourced from SC
M-RCF49.1	-	Not sourced from SC
M-RCF49.2	-	Not sourced from SC
M-RCF50	-	Not sourced from SC
M-RCF52	-	Not sourced from SC
M-RCF52.1	-	Not sourced from SC
M-RCF55.1	-	Not sourced from SC
M-RCF55.2	-	Not sourced from SC
M-RCF58	-	Not sourced from SC
M-RCF62	-	Not sourced from SC
M-RCF62.1	-	Not sourced from SC
M-RCF62.2	-	Not sourced from SC
M-RCF63	-	Not sourced from SC
M-RCF64	-	Not sourced from SC
M-RCF64.1	-	Not sourced from SC
M-RCF64.2	-	Not sourced from SC
M-RCF64.3	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-RCF64.4	-	Not sourced from SC
M-RCF65	-	Not sourced from SC
M-RCF68	-	Not sourced from SC
M-RCF69	-	Not sourced from SC
M-RCF70	-	Not sourced from SC
M-RCF71	-	Not sourced from SC
M-RCF71.1	-	Not sourced from SC
M-RCF72	-	Not sourced from SC
M-RCF73	-	Not sourced from SC
M-RCF74	-	Not sourced from SC
M-RCF74.1	-	Not sourced from SC
M-RCF75	-	Not sourced from SC
M-RCF76	-	Not sourced from SC
M-RCF77	-	Not sourced from SC
M-RCF78	-	Not sourced from SC
M-RCF81	-	Not sourced from SC
M-RCF82	-	Not sourced from SC
M-RCF83	-	Not sourced from SC
M-RCF84	-	Not sourced from SC
M-RCF85	-	Not sourced from SC
M-RCF86	-	Not sourced from SC
M-REG01	S_CL_PTCL_LS.NUM_PLAN_SITE	REGION_CD not null AND PAR_PTCL_ID IS NOT NULL
M-REG02	S_CL_PTCL_LS.NUM_PLAN_SUBJ	REGION_CD not null AND PAR_PTCL_ID IS NOT NULL
M-SST01	S_PTCL_SITE_LS.NUM_PLAN_ SUBJ	-
M-SST02	Count Distinct S_CL_SUBJ_ST_ LS.PAR_ROW_ID where S_CL_ SUBJ_ST_LS.STATUS_ID = "Enrolled"	-
M-SST02C	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_ CD="Enrolled"	-
M-SST03	S_PTCL_SITE_LS.NUM_SUBJ_ ENRL+S_PTCL_SITE_LS.NUM_ COMPLTD	-
M-SST04	S_PTCL_SITE_LS.NUM_SUBJ_ENRL	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST05	Count Distinct S_CL_SUBJ_ST_ LS.PAR_ROW_ID where S_CL_ SUBJ_ST_LS.STATUS_ID = "Completed"	-
M-SST05C	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_ CD="Completed"	-
M-SST06	Count Distinct S_CL_SUBJ_ST_ LS.PAR_ROW_ID where S_CL_ SUBJ_ST_LS.STATUS_ID = "Early Terminated"	-
M-SST06C	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_ CD="Early Terminated"	-
M-SST08	-	Not sourced from SC
M-SST09	-	Not sourced from SC
M-SST15.1	(S_PTCL_SITE_LS.NUM_SUBJ_ ENRL/ S_PTCL_SITE_LS.NUM_ PLAN_SUBJ) * 100	-
M-SST17	-	Not sourced from SC
M-SST18	-	Not sourced from SC
M-SST19	-	Not sourced from SC
M-SST20	-	Not sourced from SC
M-SST21	-	Not sourced from SC
M-SST23	-	Not sourced from SC
M-SST24	-	Not sourced from SC
M-SST24.1	-	Not sourced from SC
M-SST24.2	-	Not sourced from SC
M-SST24.3	-	Not sourced from SC
M-SST27	-	Not sourced from SC
M-SST28	-	Not sourced from SC
M-SST29	-	Not sourced from SC
M-SST30	-	Not sourced from SC
M-SST31	-	Not sourced from SC
M-SST32	Count Distinct S_CL_SUBJ_ST_ LS.PAR_ROW_ID where S_CL_ SUBJ_ST_LS.STATUS_ID = "Randomized"	-

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST32C	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_CD='Randomized'	-
M-SST33	Count Distinct S_CL_SUBJ_ST_LS.PAR_ROW_ID where S_CL_SUBJ_ST_LS.STATUS_ID = "Re-Screened"	-
M-SST33C	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_CD='Re-Screened'	-
M-SST34	Count Distinct S_CL_SUBJ_ST_LS.PAR_ROW_ID where S_CL_SUBJ_ST_LS.STATUS_ID = "Screen Failure"	-
M-SST34C	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_CD='Screen Failure'	-
M-SST35	Count Distinct S_CL_SUBJ_ST_LS.PAR_ROW_ID where S_CL_SUBJ_ST_LS.STATUS_ID = "Screened"	-
M-SST35C	Count of S_CL_SUBJ_LS.ROW_ID Where S_CL_SUBJ_LS.PR_STATUS_ID = S_CL_SUBJ_ST_LS.ROW_ID and S_CL_SUBJ_ST_LS.STATUS_CD='Screened'	-
M-SST36	S_CL_SUBJ_LS.INTEGRATION_ID	-
M-SST37	S_CL_SUBJ_LS.PTCL_DEV_FLG	-
M-SST38	S_CL_SUBJ_LS.PTCL_VLTN_FLG	-
M-SST39	S_PTCL_SITE_LS.ST_INITN_CMPL_DT	-
M-SST40	S_CL_SUBJ_LS.WTHDWN_DT	-
M-SST41	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Completed'
M-SST42	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Enrolled'
M-SST43	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Randomized'
M-SST44	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Screened'
M-SST45	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Completed'
M-SST46	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Enrolled'

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
M-SST47	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_ STATUS' and NAME='Randomized'
M-SST48	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_ STATUS' and NAME='Screened'
M-SST49	COUNT (S_PTCL_SITE_LS.ROW_ ID)	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_ STATUS' and NAME='Screened'
M-SST50	S_EVT_ACT.DOC_SENT_DT - S_ EVT_ACT.DOC_RCVD_DT	-
M-SST51	S_EVT_ACT.DOC_SENT_DT - Current timestamp	Where S_EVT_ACT.DOC_RCVD_DT is null
M-SST52	Current timestamp - M-SST46	-
M-SST53	M-SST02 / M-SST01	-
M-SST54	M-SST02 / # Subjects Enrolled at Study	-
M-SST55	M-SST32 / # Randomized at Study	-
M-SST56	M-SST35 / # Screened at Study	-
M-SST57	M-SST06 / M-SST02	Total for Study-site
M-SST58	M-SST06 / M-SST02	Total for Study
M-SST59	M-SST51 / # Documents	-
M-SST60	Avg (M-SST50)	-
M-STD01	S_CL_PTCL_LS.NUM_PLAN_SITE	-
M-STD02	S_CL_PTCL_LS.NUM_PLAN_SUBJ	-
M-STD06	S_CL_PTCL_LS.DB_LOCK_DT	-
M-STD07	COUNT (S_PTCL_SITE_LS.ROW_ ID)	-
M-STD08	S_PTCL_SITE_LS.NUM_SUBJ_ENRL	-
TA-DISC01	-	Not sourced from SC
TA-DISC02	-	Not sourced from SC
TA-DISC03	-	Not sourced from SC
TA-DISC04	-	Not sourced from SC
TA-DISC05	-	Not sourced from SC
TA-DISC06	-	Not sourced from SC
TA-DISC07	-	Not sourced from SC
TA-DISC08	-	Not sourced from SC
TA-DISC09	-	Not sourced from SC
TA-DISC10	-	Not sourced from SC
TA-DISC11	-	Not sourced from SC
TA-DISC12	-	Not sourced from SC
TA-DISC13	-	Not sourced from SC
TA-DISC14	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-DISC15	-	Not sourced from SC
TA-DISC16	-	Not sourced from SC
TA-DISC17	-	Not sourced from SC
TA-DISC19	-	Not sourced from SC
TA-DISC20	-	Not sourced from SC
TA-DISC21	-	Not sourced from SC
TA-DISC22	-	Not sourced from SC
TA-DISC22.1	-	Not sourced from SC
TA-DISC23	-	Not sourced from SC
TA-DISC24	-	Not sourced from SC
TA-DISC25	-	Not sourced from SC
TA-DISC26	-	Not sourced from SC
TA-DISC26.1	-	Not sourced from SC
TA-DISC30	-	Not sourced from SC
TA-DISC31	-	Not sourced from SC
TA-DISC32	-	Not sourced from SC
TA-DISC33	-	Not sourced from SC
TA-DOC01	S_EVT_ACT.SUBTYPE_CD	-
TA-DOC02	S_EVT_ACT.COMMENTS_LONG	-
TA-DOC03	S_EVT_ACT.NAME	-
TA-DOC04	S_EVT_ACT.TODO_CD	-
TA-DOC05	S_EVT_ACT.DOC_EXPCTD_DT	-
TA-DOC06	S_EVT_ACT.DOC_RCVD_DT	-
TA-DOC07	S_EVT_ACT.DOC_SENT_DT	-
TA-DOC08	S_EVT_ACT.APPT_END_DT	-
TA-RCRF01	-	Not sourced from SC
TA-RCRF02	-	Not sourced from SC
TA-RCRF03	-	Not sourced from SC
TA-RCRF04	-	Not sourced from SC
TA-RCRF05	-	Not sourced from SC
TA-RCRF06	-	Not sourced from SC
TA-RCRF07	-	Not sourced from SC
TA-RCRF08	-	Not sourced from SC
TA-RCRF09	-	Not sourced from SC
TA-RCRF10	-	Not sourced from SC
TA-RCRF11	-	Not sourced from SC
TA-RCRF12	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TA-RCRF13	-	Not sourced from SC
TA-RCRF14	-	Not sourced from SC
TA-RCRF15	-	Not sourced from SC
TA-RCRF16	-	Not sourced from SC
TA-RCRF17	-	Not sourced from SC
TA-RCRF19	-	Not sourced from SC
TA-RCRF20	-	Not sourced from SC
TA-RCRF22	-	Not sourced from SC
TA-RCRF23	-	Not sourced from SC
TA-RCRF24	-	Not sourced from SC
TA-RCRF25	-	Not sourced from SC
TA-RCRF26	-	Not sourced from SC
TA-RCRF28	-	Not sourced from SC
TA-RCRF29	-	Not sourced from SC
TA-RCRF30	-	Not sourced from SC
TA-RCRF31	-	Not sourced from SC
TA-RCRF32	-	Not sourced from SC
TA-RCRF33	-	Not sourced from SC
TA-RCRF34	-	Not sourced from SC
TA-RCRF35	-	Not sourced from SC
TA-SITE01	S_PS_STMPVER_LS.IRB_APPRV_DT	-
TA-SUBJ01	S_CL_SUBJ_ST_LS.STATUS_CD	-
TA-SUBJ02	S_CL_SJ_CSNT_LS.INFO_CONSNT_DT	S_CL_SJ_CSNT_LS.CL_SUBJ_ID = S_CL_SUBJ_LS.ROW_ID S_CL_SJ_CSNT_LS.SUBJ_TMPL_VER_ID = S_SBJTMP_VER_LS.ROW_ID
TA-SUBJ03	S_CL_SUBJ_ST_LS.COMMENTS	-
TD01-01	S_CL_PTCL_LS.PTCL_NUM	-
TD01-02	S_CL_SUBJ_LS.SUBJ_NUM	-
TD01-03	-	Not sourced from SC
TD01-04	-	Not sourced from SC
TD01-05	S_CL_SUBJ_ST_LS.STATUS_CD	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Early Terminated'
TD01-06	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_STATUS' and NAME='Enrolled'
TD01-07	-	Not sourced from SC
TD01-08	S_CL_SUBJ_LS.SUBJ_INITL	-
TD01-09	S_CL_SUBJ_LS.BIRTH_DT	-
TD01-10	-	Not sourced from SC

Table B–5 (Cont.) Presentation Catalog - Siebel Clinical Sources

Attribute ID	Source Table/Column	Comments/Details
TD01-11	S_CL_SUBJ_ST_LS.STATUS_CD	-
TD01-12	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_ STATUS' and NAME='Early Terminated'
TD01-16	-	Not sourced from SC
TD01-17	S_CL_SUBJ_ST_LS.STATUS_DATE	S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_ STATUS' and NAME='Screened'
TD01-18	S_CL_SUBJ_LS.ELGBL_FLG	-
TD01-19	S_CL_SUBJ_LS.COMMENTS	-
TD01-20	S_CL_SUBJ_LS.ENRL_NUM	-
TD01-21	S_CL_SUBJ_LS.RDMZATN_NUM	-
TD01-22	S_CL_SUBJ_LS.PTCL_VLTN_FLG	-
TD01-23	S_CL_SUBJ_LS.EXCLD_RSN_CD	-
TD01-24	S_CL_SUBJ_LS.SUBJ_NUM+BIRTH_ DT	-
TD01-25	S_CL_SUBJ_LS.PTCL_DEV_FLG	-
TD01-26	S_CL_SUBJ_LS.WTHDWN_RSN_ CD	-
TD01-27	.CURRENT_DATE - BIRTH_DT	-
TD01-28	S_CL_SUBJ_ST_LS.STATUS_DATE	-
TD01-29	-	Not sourced from SC
TD01-30	S_CL_SUBJ_ST_LS.ROW_ID	-

C

Troubleshooting

This appendix contains the following topics:

Sorting and Displaying of Null Values in Reports

In order to understand results shown in OBIEE reports, it may be necessary to understand how null values are sorted and displayed in reports.

Oracle uses NULL as a pseudo-value for a table cell when there is no actual value. For example, if the number of documents awaiting completion for a site is unknown, the column containing that attribute of the site will be set to null in the database.

As null values can appear in among data, OBIEE has rules that determine how to display the null values. And as OBIEE supports sorting of data in a column, it has rules for how nulls should be sorted.

The following are the rules:

- Oracle's sorting order cause a null value to be treated as greater than any non-null value.
- In table views, OBIEE generally displays null values as empty cells.

  The exception is when the request designer has specified that the user can navigate to a different request by clicking on a value in the column that contains null. In that case, in order to give the user something to click on, OBIEE displays the null value as a zero.

These rules can produce unexpected results. This following section describes how to interpret such unexpected results. It also describes actions you can take in creating OBIEE requests to override OBIEE's default rules.

The results of these rules are:

If the data in a column contain nulls and non-nulls, and the column is sorted, and navigation is not enabled from cells in the column, then (i) nulls will display as blank cells, and (ii) the blank cells will sort as larger than the largest non-null value.

If the data in a column contain nulls and non-nulls, and the column is sorted, and navigation is enabled from cells in the column, then (i) nulls will display as zeros, (ii) the cells representing nulls (but now displaying as zeros) will sort as larger than the largest non-null value. If there are actual zeros in the column as well, they will sort as smaller than the smallest positive value in the column. So, if you have both real zero values and null values, and cell-based navigation is enabled, and you sort the column,

you will get two clumps of zeros - one representing the nulls, the other representing the actual zeros - separated by the non-negative actual values.

OBIEE does have a capability that can be used to make it easier to identify null values. In requests, you can use the IFNULL function to specify that NULL should be replaced by a large negative value that could not be a "real" value for the column. For instance, if "# Documents Outstanding" could be null in your data, and you want to include it in a request, you could change the functional definition of the column in the request from "# DocumentsOutstanding" to IFNULL("# Documents Outstanding", -99). This would cause nulls to sort and display as if their value was -99.

If you use IFNULL, it is important that you:

- Choose a value that could not also be a legitimate value (this may vary from column to column, though it is preferable to use the same IFNULL replacement across all columns).
- Communicate to your end users the meaning of the IFNULL values.

Cancelling Jobs in Oracle Life Sciences Data Hub

Cancelling jobs (Informatica programs) submitted in Oracle LSH does not automatically abort the workflow in Informatica PowerCenter. This needs to be done manually. To abort the workflow:

1. Identify the folder that contains the particular workflow. For more information, refer to Identifying the Folder Containing the Workflow.
2. Abort the workflow in Informatica PowerCenter. For more information, refer to Aborting a Workflow.

Identifying the Folder Containing the Workflow

Use the particular job's command log file in Oracle LSH (cmdlog.log), to identify the Informatica folder that contains the workflow. Perform the following steps in Oracle LSH to view the log file:

1. In the Job Execution section of My Home, click the Job ID hyperlink of the particular job you want to cancel.

   The Job Execution Details screen is displayed. The Master Job Id field displays the system-generated unique ID of the job that calls this job (parent job).
2. Click **Outputs**, and then click the hyperlink in the View column.
3. Choose to save or open the command log file (cmdlog.log).

See Also:

Oracle Life Sciences Data Hub Developer's Guide, (Monitoring Jobs)

Aborting a Workflow

Perform the following steps in Informatica PowerCenter to abort a workflow:

1. Open the Informatica PowerCenter Workflow Monitor.
2. In the Repositories tree, navigate to the particular folder that contains the Informatica job.

   For more information on how to identify the folder that contains a particular workflow, refer to Identifying the Folder Containing the Workflow
3. In the Workflow Run pane, select and right-click the workflow, and click **Abort**.

See Also:

Informatica PowerCenter Online Help

Glossary

Case Report Form

A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject. The CRF is the way the **Clinical Data** for Patients is collected.

CDMS

Clinical Data Management System (For example, Oracle Clinical)

Central Laboratory

A location, under contract to a Clinical Trial sponsor, where samples are sent from multiple sites for analysis.

Clinical Data

Data pertaining to the medical characteristics or status of a patient or subject.

Clinical Research Organization

A company or organization that conducts all or part of a clinical trial under contract to a Clinical Trial sponsor.

Clinical Study

See **Clinical Trial**

Clinical Trial

Before a pharmaceutical or biotech company can initiate testing on humans, it must conduct extensive pre-clinical or laboratory research. This research typically involves years of experiments on animal and human cells. The compounds are also extensively tested on animals. If this stage of testing is successful, a pharmaceutical company provides this data to the Food and Drug Administration (FDA), requesting approval to begin testing the drug on humans. This is called an Investigational New Drug application (IND). A clinical trial is a carefully designed investigation of the effects of drug, medical treatment, or device on a group of patients (also called Subjects).

compound

The product being tested or researched within the Clinical Trial.

CRA

Clinical Research Associate. An employee of the Sponsor, responsible for getting a site prepared to conduct a trial and getting cleaned data back from the site to the Sponsor.

CRF

See **Case Report Form**

CRF Book

A set of paper forms or electronic forms that record the results of the set of assessments performed on a subject taking part in a clinical trial.

CRF Page

A single form within a CRF Book.

CRO

Clinical Research Organization

CTMS

Clinical Trial Management System (For example, Oracle's Siebel Clinical)

discrepancy

Problems found with data reported in the CRF pages by Investigators for specific Patients

eCRF

A single electronic **CRF**.

EDC

Electronic Data Capture system (For example, Oracle Remote Data Capture (RDC))

informed consent

A discussion of all procedures, benefits, risks, and expectations of a clinical trial between clinical investigators and potential patients. The FDA requires all patients to sign an informed consent form before participating in a trial.

investigator

A person responsible for the conduct of the clinical trial at a trial site. When a Clinical Trial is conducted at a Site by a team the Investigator is the responsible leader of the team and may be called Principal Investigator (PI). Other investigators are called Sub-investigators. Investigators are qualified health care professionals, often are MDs, PhDs or Pham Ds.

patient

A person who participates in a **Clinical Study** and is the focus of the Clinical Trial's research.

patient visits

A series of scheduled visits by a Patient to an Investigator based interval specified in the Clinical Trial's Protocol. During the Patient visits the Investigators undertakes the required medical procedures defined in the Clinical Trial Protocol and completes the corresponding CRFs.

phase

Phase of trial, typically 1,2,3 or 4.

program

Groups of Clinical Studies or Clinical Trials for the same compound.

projects

Groups of Studies within a Program (Oracle Clinical Only)

Protocol

A Protocol is a document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. It is a plan that states what will be done in the study and why. It outlines how many people will take part in the study, what types of Subjects may take part, what tests they will receive how often, and the treatment plan. The Sponsor of the Clinical Trial typically designs the Protocol.

Protocol amendment

A written description of a change(s) to or formal clarification of a protocol.

queries

Each query is a request for information, sent to an Investigator, to resolve a Discrepancy detected in data signed for by that Investigator.

randomization

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

region

A geographic region in which the Clinical Study or Clinical Trial will be carried out.

Regulatory Authority

An authority such as FDA and EMEA regulating clinical development processes.

site coordinator

The individual who manages the conduct of the clinical trial. Coordinators are often nurses.

site visit

A visit or trip by a CRA to a Site for monitoring and support activities.

sites

Sites are locations where clinical trials are conducted. They are typically a clinic or hospitals where **investigator**s see subjects and perform study procedures, such as medical checks.

Sponsor

The organization funding the clinical trial. This is typically the Pharmaceutical company whose product is being tested with the clinical trial.

study document

A required Document to initiate or start a Clinical Trial at a Site (For example, Investigator Resume.)

study

See **Clinical Trial**

subject

See **patient**

Index

A

B

C

D

E

F

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W