

# **Oracle® Clinical Development Analytics**

User and Administrator Guide

Release 2.0.0.3 for Standard Configuration

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# Contents

|                                                            |       |
|------------------------------------------------------------|-------|
| <b>Preface</b> .....                                       | xix   |
| Audience .....                                             | xix   |
| Documentation Accessibility .....                          | xix   |
| Finding Information and Patches on My Oracle Support ..... | xx    |
| Finding Documentation on Oracle Technology Network .....   | xxii  |
| Related Documents .....                                    | xxii  |
| Conventions .....                                          | xxiii |

## **Part I Using Oracle Clinical Development Analytics**

### **1 Getting Started with Oracle Clinical Development Analytics**

|                                                                  |     |
|------------------------------------------------------------------|-----|
| <b>Overview</b> .....                                            | 1-1 |
| What Can I Do Using Oracle Clinical Development Analytics? ..... | 1-2 |
| <b>Architecture</b> .....                                        | 1-2 |
| <b>Reporting</b> .....                                           | 1-3 |
| <b>Regulatory Compliance</b> .....                               | 1-3 |
| Tracking Data .....                                              | 1-3 |
| Managing ETL Versions .....                                      | 1-4 |
| Security .....                                                   | 1-4 |

### **2 Using Oracle Clinical Development Analytics**

|                                                                       |     |
|-----------------------------------------------------------------------|-----|
| <b>Overview</b> .....                                                 | 2-1 |
| <b>Accessing Oracle Clinical Development Analytics</b> .....          | 2-2 |
| Logging In .....                                                      | 2-3 |
| Viewing a Dashboard .....                                             | 2-3 |
| <b>Using Oracle Business Intelligence</b> .....                       | 2-4 |
| Oracle Business Intelligence Presentation Services Components .....   | 2-4 |
| Oracle Business Intelligence Answers .....                            | 2-4 |
| Oracle Business Intelligence Interactive Dashboards .....             | 2-4 |
| Oracle Business Intelligence Delivers .....                           | 2-4 |
| <b>Performing Common Tasks in Oracle Business Intelligence</b> .....  | 2-5 |
| Exiting from Oracle Business Intelligence .....                       | 2-5 |
| Viewing Descriptions of Oracle BI Dashboards and Saved Requests ..... | 2-5 |
| Using Online Help .....                                               | 2-5 |
| Printing an Oracle BI Dashboard or Saved Request .....                | 2-6 |

|                                                                          |      |
|--------------------------------------------------------------------------|------|
| Emailing an Oracle BI Dashboard Page or Request .....                    | 2-7  |
| Downloading Oracle BI Results .....                                      | 2-8  |
| Refreshing an Oracle BI Interactive Dashboard or Oracle BI Request ..... | 2-8  |
| Refreshing Information in the Oracle BI Selection Pane .....             | 2-9  |
| <b>Navigating in Oracle Business Intelligence</b> .....                  | 2-9  |
| What is Available to You After Accessing Oracle BI? .....                | 2-9  |
| Using Oracle BI Feature Links.....                                       | 2-10 |
| Working with Oracle BI Pages .....                                       | 2-11 |
| Drilling Down in Oracle BI.....                                          | 2-11 |
| Sorting Columns in Tables in Oracle BI.....                              | 2-11 |
| <b>Using the Oracle BI My Account Page</b> .....                         | 2-11 |
| Setting Your Oracle BI Preferences.....                                  | 2-12 |
| Setting Your Oracle BI Time Zone .....                                   | 2-12 |

### 3 Working with Reports

|                                                                                     |      |
|-------------------------------------------------------------------------------------|------|
| <b>Predefined Reports</b> .....                                                     | 3-1  |
| Viewing a Predefined Report .....                                                   | 3-2  |
| <b>Custom Reports</b> .....                                                         | 3-3  |
| <b>Action Links</b> .....                                                           | 3-4  |
| <b>Viewing Reports With Your Apple iPhone</b> .....                                 | 3-4  |
| <b>About Oracle BI Answers</b> .....                                                | 3-4  |
| Example of an Oracle BI Answers Start Page .....                                    | 3-5  |
| Using Oracle BI Answers to Create, Modify, and Save Requests.....                   | 3-6  |
| Accessing Subject Areas and Requests Using the Oracle BI Answers Start Page .....   | 3-6  |
| Accessing the Tabs in the Oracle BI Answers Workspace .....                         | 3-8  |
| Running a Request from the Oracle BI Answers Start Page.....                        | 3-10 |
| Creating a New Oracle BI Request or Changing the Criteria for an Existing Request.. | 3-10 |
| Specifying the Sort Order for Columns in Oracle BI Requests .....                   | 3-13 |
| Refreshing Information in the Oracle BI Answers Selection Pane .....                | 3-13 |
| Viewing and Working with Oracle BI Answers Results .....                            | 3-14 |
| Saving an Oracle BI Request to a Personal or Shared Folder .....                    | 3-14 |
| Embedding an Oracle BI Request in an Oracle BI Dashboard .....                      | 3-15 |
| Using Variables to Display Values in Request Results and Dashboards.....            | 3-15 |
| About Session, Repository, and Presentation Variables .....                         | 3-15 |
| Referencing Session Variables.....                                                  | 3-16 |
| Syntax for Referencing Session Variables.....                                       | 3-16 |
| Syntax for Referencing Repository and Presentation Variables .....                  | 3-16 |
| Referencing Predefined Variables .....                                              | 3-17 |

## Part II Administration

### 4 Maintaining the Repository and Warehouse

|                                                                               |     |
|-------------------------------------------------------------------------------|-----|
| <b>Maintaining the Oracle Clinical Development Analytics Repository</b> ..... | 4-1 |
| Modifying the Repository .....                                                | 4-2 |
| Details for Selected Modifications .....                                      | 4-2 |
| Merging Changes Into a New Oracle-supplied Repository.....                    | 4-2 |

|                                                                                  |            |
|----------------------------------------------------------------------------------|------------|
| <b>Maintaining the Oracle Clinical Development Analytics Data Warehouse.....</b> | <b>4-3</b> |
| Derivations.....                                                                 | 4-3        |
| Extensions.....                                                                  | 4-3        |
| Substitutions .....                                                              | 4-5        |
| Modifying Data Warehouse Tables.....                                             | 4-6        |

## **5 Extract Transform Load Programs**

|                                                      |            |
|------------------------------------------------------|------------|
| <b>ETL Architecture.....</b>                         | <b>5-1</b> |
| Adding a New Data Source.....                        | 5-4        |
| Oracle Clinical Development Analytics Hierarchy..... | 5-5        |
| <b>Executing the ETL Execution Plans.....</b>        | <b>5-6</b> |
| <b>Customizing an ETL Execution Plan .....</b>       | <b>5-7</b> |
| <b>Creating an ETL Execution Plan.....</b>           | <b>5-7</b> |
| <b>Modifying an ETL Execution Plan.....</b>          | <b>5-8</b> |
| <b>Scheduling an ETL Execution Plan.....</b>         | <b>5-9</b> |

## **6 Implementing Security**

|                                                                     |            |
|---------------------------------------------------------------------|------------|
| <b>About Security in Oracle Clinical Development Analytics.....</b> | <b>6-1</b> |
| Example.....                                                        | 6-2        |
| <b>Setting Up User Authentication .....</b>                         | <b>6-3</b> |
| Creating User Accounts in DAC.....                                  | 6-3        |
| Setting Up User Authorization in OBIEE .....                        | 6-3        |
| Using Predefined User Groups in OBIEE and Creating New Ones.....    | 6-3        |
| Predefined OBIEE User Groups .....                                  | 6-3        |
| Creating User Groups in OBIEE.....                                  | 6-4        |
| Assigning OBIEE User Groups to Dashboards and Reports.....          | 6-4        |
| <b>Setting Up Study and Study Site Data Access for Users .....</b>  | <b>6-5</b> |
| Setting the Systemwide Access Variables.....                        | 6-5        |
| Data Access Tables.....                                             | 6-6        |
| Importing Study and Study Site Data Access Privileges .....         | 6-6        |
| Modifying the Data Access Programs .....                            | 6-8        |
| Running the Template Data Access Control ETL Programs .....         | 6-8        |
| Study-Site Access Example.....                                      | 6-9        |

## **Part III   Appendixes**

### **A   Dashboards and Reports**

|                                                               |            |
|---------------------------------------------------------------|------------|
| <b>Oracle Clinical Development Analytics Dashboards .....</b> | <b>A-1</b> |
| CO - Document Management .....                                | A-1        |
| CO - Document Management Dashboard Pages .....                | A-2        |
| Document List Page.....                                       | A-2        |
| Document Collection Cycle Times Page .....                    | A-2        |
| CO - Site and Recruitment Overview.....                       | A-3        |
| CO - Site and Recruitment Overview Dashboard Pages.....       | A-3        |
| Site Status Overview Page.....                                | A-3        |
| Comparative Site Enrollment Page.....                         | A-3        |

|                                                                   |             |
|-------------------------------------------------------------------|-------------|
| Screening Overview Page .....                                     | A-3         |
| Screen Failure Overview Page .....                                | A-3         |
| Enrollment Overview Page .....                                    | A-4         |
| Randomization Overview Page .....                                 | A-4         |
| Subject Recruitment Over Time Page .....                          | A-4         |
| CO - Study and Region Overview .....                              | A-4         |
| CO - Study and Region Overview Dashboard Pages .....              | A-4         |
| Site Overview Page.....                                           | A-4         |
| Enrollment Overview Page .....                                    | A-4         |
| CO - Subject Retention.....                                       | A-5         |
| CO - Subject Retention Dashboard Pages.....                       | A-5         |
| Subject Retention Overview Page .....                             | A-5         |
| Early Termination Overview Page.....                              | A-5         |
| Subject Retention Over Time Page .....                            | A-5         |
| CRA EDC Dashboard .....                                           | A-6         |
| CRA EDC Dashboard Pages.....                                      | A-6         |
| Home Page.....                                                    | A-6         |
| eCRF Workload Page .....                                          | A-6         |
| Key Rates Page .....                                              | A-6         |
| Performance Page .....                                            | A-6         |
| Discrepancy Workload Page .....                                   | A-7         |
| DM EDC Dashboard .....                                            | A-7         |
| DM EDC Dashboard Pages .....                                      | A-7         |
| Home Page.....                                                    | A-7         |
| eCRF Workload Page .....                                          | A-7         |
| Discrepancy Workload Page.....                                    | A-7         |
| Quality Page .....                                                | A-8         |
| Key Rates Page .....                                              | A-8         |
| Performance Page .....                                            | A-8         |
| Study Discrepancies Page.....                                     | A-8         |
| Study Processing Summary Page.....                                | A-8         |
| Study Processing Detail Page.....                                 | A-8         |
| DM Paper Dashboard .....                                          | A-9         |
| DM Paper Dashboard Pages .....                                    | A-9         |
| Home Page.....                                                    | A-9         |
| Page Workload Page .....                                          | A-9         |
| Discrepancy Workload Page .....                                   | A-9         |
| Quality Page .....                                                | A-10        |
| Performance Page .....                                            | A-10        |
| Study Processing Summary Page.....                                | A-10        |
| Study Processing Detail Page.....                                 | A-10        |
| <b>Oracle Clinical Development Analytics Reports .....</b>        | <b>A-10</b> |
| Approval & Verification Rates - Worst 25 (Report CDA-DM-350)..... | A-12        |
| Audience .....                                                    | A-12        |
| Report Type .....                                                 | A-12        |
| Location .....                                                    | A-12        |
| Dimensions .....                                                  | A-12        |

|                                                                                     |      |
|-------------------------------------------------------------------------------------|------|
| Supplementary Prompts .....                                                         | A-12 |
| Reports Referenced .....                                                            | A-12 |
| Reports Referencing This Report .....                                               | A-12 |
| Column Descriptions .....                                                           | A-12 |
| Average Days from Complete to Initially Approved - Top 25 (Report CDA-DM-325) ..... | A-13 |
| Audience .....                                                                      | A-13 |
| Report Type .....                                                                   | A-13 |
| Location .....                                                                      | A-13 |
| Dimensions .....                                                                    | A-13 |
| Supplementary Prompts .....                                                         | A-13 |
| Reports Referenced .....                                                            | A-13 |
| Reports Referencing This Report .....                                               | A-13 |
| Column Descriptions .....                                                           | A-13 |
| Average Days from Complete to Initially Verified - Top 25 (Report CDA-DM-330) ..... | A-14 |
| Audience .....                                                                      | A-14 |
| Report Type .....                                                                   | A-14 |
| Location .....                                                                      | A-14 |
| Dimensions .....                                                                    | A-14 |
| Supplementary Prompts .....                                                         | A-14 |
| Reports Referenced .....                                                            | A-14 |
| Reports Referencing This Report .....                                               | A-14 |
| Column Descriptions .....                                                           | A-14 |
| Average Duration in Categorized Discrepancy Review Status (Report CDA-DM-210) ..... | A-15 |
| Audience .....                                                                      | A-15 |
| Report Type .....                                                                   | A-15 |
| Location .....                                                                      | A-15 |
| Dimensions .....                                                                    | A-15 |
| Supplementary Prompts .....                                                         | A-15 |
| Reports Referenced .....                                                            | A-15 |
| Reports Referencing This Report .....                                               | A-15 |
| Column Descriptions .....                                                           | A-15 |
| Average Duration of Currently Open Discrepancies, by Site (Report CDA-DM-205) ..... | A-16 |
| Audience .....                                                                      | A-16 |
| Report Type .....                                                                   | A-16 |
| Location .....                                                                      | A-16 |
| Dimensions .....                                                                    | A-16 |
| Supplementary Prompts .....                                                         | A-16 |
| Reports Referenced .....                                                            | A-16 |
| Reports Referencing This Report .....                                               | A-17 |
| Column Descriptions .....                                                           | A-17 |
| Average Duration of Open Discrepancies in Review Statuses (Report CDA-DM-215) ..... | A-17 |
| Audience .....                                                                      | A-17 |
| Report Type .....                                                                   | A-17 |
| Location .....                                                                      | A-17 |
| Dimensions .....                                                                    | A-17 |
| Supplementary Prompts .....                                                         | A-17 |
| Reports Referenced .....                                                            | A-18 |

|                                                                                                 |      |
|-------------------------------------------------------------------------------------------------|------|
| Reports Referencing This Report .....                                                           | A-18 |
| Column Descriptions.....                                                                        | A-18 |
| Comparative Site Enrollment Status Table (Report 8SDP-3).....                                   | A-18 |
| Audience .....                                                                                  | A-18 |
| Report Type .....                                                                               | A-18 |
| Location .....                                                                                  | A-18 |
| Dimensions .....                                                                                | A-18 |
| Supplementary Prompts .....                                                                     | A-19 |
| Reports Referenced.....                                                                         | A-19 |
| Reports Referencing This Report .....                                                           | A-19 |
| Column Descriptions.....                                                                        | A-19 |
| Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank (Report CDA-DM-230) A-20 |      |
| Audience .....                                                                                  | A-20 |
| Report Type .....                                                                               | A-20 |
| Location .....                                                                                  | A-20 |
| Dimensions .....                                                                                | A-20 |
| Supplementary Prompts .....                                                                     | A-20 |
| Reports Referenced.....                                                                         | A-20 |
| Reports Referencing This Report .....                                                           | A-20 |
| Column Descriptions.....                                                                        | A-20 |
| Counts of Categorized Open Discrepancies, by Review Status (Report CDA-DM-220).....             | A-21 |
| Audience .....                                                                                  | A-21 |
| Report Type .....                                                                               | A-21 |
| Location .....                                                                                  | A-21 |
| Dimensions .....                                                                                | A-21 |
| Supplementary Prompts .....                                                                     | A-21 |
| Reports Referenced.....                                                                         | A-21 |
| Reports Referencing This Report .....                                                           | A-21 |
| Column Descriptions.....                                                                        | A-21 |
| Counts of Discrepancies, by State and Review Status (Report CDA-DM-225).....                    | A-22 |
| Audience .....                                                                                  | A-22 |
| Report Type .....                                                                               | A-22 |
| Location .....                                                                                  | A-22 |
| Dimensions .....                                                                                | A-22 |
| Supplementary Prompts .....                                                                     | A-22 |
| Reports Referenced.....                                                                         | A-22 |
| Reports Referencing This Report .....                                                           | A-22 |
| Column Descriptions.....                                                                        | A-22 |
| Counts of Open Multivariate Discrepancies, by Procedure (Report CDA-DM-235) .....               | A-23 |
| Audience .....                                                                                  | A-23 |
| Report Type .....                                                                               | A-23 |
| Location .....                                                                                  | A-23 |
| Dimensions .....                                                                                | A-23 |
| Supplementary Prompts .....                                                                     | A-23 |
| Reports Referenced.....                                                                         | A-23 |
| Reports Referencing This Report .....                                                           | A-23 |
| Column Descriptions.....                                                                        | A-23 |

|                                                                                    |      |
|------------------------------------------------------------------------------------|------|
| Discrepancies per Pages Entered - Top 25 (Report CDA-DM-255) .....                 | A-24 |
| Audience .....                                                                     | A-24 |
| Report Type .....                                                                  | A-24 |
| Location .....                                                                     | A-24 |
| Dimensions .....                                                                   | A-24 |
| Supplementary Prompts .....                                                        | A-24 |
| Reports Referenced .....                                                           | A-24 |
| Reports Referencing This Report .....                                              | A-24 |
| Column Descriptions .....                                                          | A-24 |
| Discrepancies per Subjects Enrolled - Top 25 (Report CDA-DM-250) .....             | A-25 |
| Audience .....                                                                     | A-25 |
| Report Type .....                                                                  | A-25 |
| Location .....                                                                     | A-25 |
| Dimensions .....                                                                   | A-25 |
| Supplementary Prompts .....                                                        | A-25 |
| Reports Referenced .....                                                           | A-25 |
| Reports Referencing This Report .....                                              | A-25 |
| Column Descriptions .....                                                          | A-25 |
| Discrepancy Overview with Ratios (Report CDA-DM-240) .....                         | A-25 |
| Audience .....                                                                     | A-26 |
| Report Type .....                                                                  | A-26 |
| Location .....                                                                     | A-26 |
| Dimensions .....                                                                   | A-26 |
| Supplementary Prompts .....                                                        | A-26 |
| Reports Referenced .....                                                           | A-26 |
| Reports Referencing This Report .....                                              | A-26 |
| Column Descriptions .....                                                          | A-26 |
| Document Collection Cycle Times - Days Outstanding by Type (Report 3SS04-1b) ..... | A-27 |
| Audience .....                                                                     | A-27 |
| Report Type .....                                                                  | A-27 |
| Location .....                                                                     | A-27 |
| Dimensions .....                                                                   | A-27 |
| Supplementary Prompts .....                                                        | A-27 |
| Reports Referenced .....                                                           | A-27 |
| Reports Referencing This Report .....                                              | A-27 |
| Column Descriptions .....                                                          | A-27 |
| Document Collection Cycle Times Table (Report 3SS04-1) .....                       | A-28 |
| Audience .....                                                                     | A-28 |
| Report Type .....                                                                  | A-28 |
| Location .....                                                                     | A-28 |
| Dimensions .....                                                                   | A-28 |
| Supplementary Prompts .....                                                        | A-28 |
| Reports Referenced .....                                                           | A-28 |
| Reports Referencing This Report .....                                              | A-28 |
| Column Descriptions .....                                                          | A-28 |
| Document Collection Cycle Times -Turn Around Time by Type (Report 3SS04-1c) .....  | A-29 |
| Audience .....                                                                     | A-29 |

|                                                             |      |
|-------------------------------------------------------------|------|
| Report Type .....                                           | A-29 |
| Location .....                                              | A-29 |
| Dimensions .....                                            | A-30 |
| Supplementary Prompts .....                                 | A-30 |
| Reports Referenced .....                                    | A-30 |
| Reports Referencing This Report .....                       | A-30 |
| Column Descriptions .....                                   | A-30 |
| Documents List (Report 8SDP-1) .....                        | A-30 |
| Audience .....                                              | A-30 |
| Report Type .....                                           | A-30 |
| Location .....                                              | A-30 |
| Dimensions .....                                            | A-30 |
| Supplementary Prompts .....                                 | A-31 |
| Reports Referenced .....                                    | A-31 |
| Reports Referencing This Report .....                       | A-31 |
| Column Descriptions .....                                   | A-31 |
| Enrollment Overview By Region Chart (Report 8SDP-10b) ..... | A-32 |
| Audience .....                                              | A-32 |
| Report Type .....                                           | A-32 |
| Location .....                                              | A-32 |
| Dimensions .....                                            | A-32 |
| Supplementary Prompts .....                                 | A-32 |
| Reports Referenced .....                                    | A-32 |
| Reports Referencing This Report .....                       | A-32 |
| Column Descriptions .....                                   | A-32 |
| Enrollment Overview By Site (Report 8SDP-10) .....          | A-33 |
| Audience .....                                              | A-33 |
| Report Type .....                                           | A-33 |
| Location .....                                              | A-33 |
| Dimensions .....                                            | A-33 |
| Supplementary Prompts .....                                 | A-33 |
| Reports Referenced .....                                    | A-34 |
| Reports Referencing This Report .....                       | A-34 |
| Column Descriptions .....                                   | A-34 |
| Enrollment Progress Over Time (Report 4PR01-2) .....        | A-34 |
| Audience .....                                              | A-34 |
| Report Type .....                                           | A-34 |
| Location .....                                              | A-35 |
| Dimensions .....                                            | A-35 |
| Supplementary Prompts .....                                 | A-35 |
| Reports Referenced .....                                    | A-35 |
| Reports Referencing This Report .....                       | A-35 |
| Column Descriptions .....                                   | A-35 |
| Key Cycle Times for Paper Studies (Report CDA-DM-400) ..... | A-36 |
| Audience .....                                              | A-36 |
| Report Type .....                                           | A-36 |
| Location .....                                              | A-36 |

|                                                                             |      |
|-----------------------------------------------------------------------------|------|
| Dimensions .....                                                            | A-36 |
| Supplementary Prompts .....                                                 | A-36 |
| Reports Referenced .....                                                    | A-36 |
| Reports Referencing This Report .....                                       | A-36 |
| Column Descriptions .....                                                   | A-36 |
| Key EDC Cycle Times (Report CDA-DM-300) .....                               | A-37 |
| Audience .....                                                              | A-37 |
| Report Type .....                                                           | A-37 |
| Location .....                                                              | A-37 |
| Dimensions .....                                                            | A-37 |
| Supplementary Prompts .....                                                 | A-37 |
| Reports Referenced .....                                                    | A-37 |
| Reports Referencing This Report .....                                       | A-37 |
| Column Descriptions .....                                                   | A-37 |
| Key EDC processing volumes (Report CDA-DM-305) .....                        | A-38 |
| Audience .....                                                              | A-38 |
| Report Type .....                                                           | A-38 |
| Location .....                                                              | A-38 |
| Dimensions .....                                                            | A-38 |
| Supplementary Prompts .....                                                 | A-38 |
| Reports Referenced .....                                                    | A-39 |
| Reports Referencing This Report .....                                       | A-39 |
| Column Descriptions .....                                                   | A-39 |
| Key Paper processing volumes (Report CDA-DM-405) .....                      | A-40 |
| Audience .....                                                              | A-40 |
| Report Type .....                                                           | A-40 |
| Location .....                                                              | A-40 |
| Dimensions .....                                                            | A-40 |
| Supplementary Prompts .....                                                 | A-40 |
| Reports Referenced .....                                                    | A-40 |
| Reports Referencing This Report .....                                       | A-40 |
| Column Descriptions .....                                                   | A-40 |
| List Discrepancy Details (Report CDA-DM-245) .....                          | A-41 |
| Audience .....                                                              | A-41 |
| Report Type .....                                                           | A-41 |
| Dimensions .....                                                            | A-41 |
| Supplementary Prompts .....                                                 | A-41 |
| Reports Referenced .....                                                    | A-42 |
| Reports Referencing This Report .....                                       | A-42 |
| Column Descriptions .....                                                   | A-42 |
| Listing of Subject-Pages, Awaiting EDC Processing (Report CDA-DM-310) ..... | A-43 |
| Audience .....                                                              | A-43 |
| Report Type .....                                                           | A-43 |
| Location .....                                                              | A-43 |
| Dimensions .....                                                            | A-43 |
| Supplementary Prompts .....                                                 | A-43 |
| Reports Referenced .....                                                    | A-43 |

|                                                                               |      |
|-------------------------------------------------------------------------------|------|
| Reports Referencing This Report .....                                         | A-43 |
| Column Descriptions.....                                                      | A-43 |
| Listing of Subject-Pages, Awaiting Paper Processing (Report CDA-DM-410) ..... | A-44 |
| Audience .....                                                                | A-44 |
| Report Type .....                                                             | A-44 |
| Location .....                                                                | A-44 |
| Dimensions .....                                                              | A-44 |
| Supplementary Prompts .....                                                   | A-44 |
| Reports Referenced .....                                                      | A-45 |
| Reports Referencing This Report .....                                         | A-45 |
| Column Descriptions.....                                                      | A-45 |
| Low Approved to Entered Rate - Worst 25 (Report CDA-DM-335).....              | A-45 |
| Audience .....                                                                | A-45 |
| Report Type .....                                                             | A-45 |
| Location .....                                                                | A-45 |
| Dimensions .....                                                              | A-46 |
| Supplementary Prompts .....                                                   | A-46 |
| Reports Referenced .....                                                      | A-46 |
| Reports Referencing This Report .....                                         | A-46 |
| Column Descriptions.....                                                      | A-46 |
| Low Verified to Entered Rate - Worst 25 (Report CDA-DM-340).....              | A-46 |
| Audience .....                                                                | A-46 |
| Report Type .....                                                             | A-46 |
| Location .....                                                                | A-46 |
| Dimensions .....                                                              | A-46 |
| Supplementary Prompts .....                                                   | A-47 |
| Reports Referenced .....                                                      | A-47 |
| Reports Referencing This Report .....                                         | A-47 |
| Column Descriptions.....                                                      | A-47 |
| Outstanding Documents by Category, Type (Report 8SDP-2).....                  | A-47 |
| Audience .....                                                                | A-47 |
| Report Type .....                                                             | A-47 |
| Location .....                                                                | A-47 |
| Dimensions .....                                                              | A-47 |
| Supplementary Prompts .....                                                   | A-47 |
| Reports Referenced .....                                                      | A-47 |
| Reports Referencing This Report .....                                         | A-47 |
| Column Descriptions.....                                                      | A-48 |
| Pages Awaiting Entry Completion (Report CDA-DM-450).....                      | A-48 |
| Audience .....                                                                | A-48 |
| Report Type .....                                                             | A-48 |
| Location .....                                                                | A-48 |
| Dimensions .....                                                              | A-48 |
| Supplementary Prompts .....                                                   | A-48 |
| Reports Referenced .....                                                      | A-48 |
| Reports Referencing This Report .....                                         | A-48 |
| Column Descriptions.....                                                      | A-48 |

|                                                                                         |      |
|-----------------------------------------------------------------------------------------|------|
| Paper Processing Cycle Times - 25 Longest (Report CDA-DM-415) .....                     | A-49 |
| Audience .....                                                                          | A-49 |
| Report Type .....                                                                       | A-49 |
| Location .....                                                                          | A-49 |
| Dimensions .....                                                                        | A-49 |
| Supplementary Prompts .....                                                             | A-49 |
| Reports Referenced .....                                                                | A-49 |
| Reports Referencing This Report .....                                                   | A-49 |
| Column Descriptions .....                                                               | A-49 |
| Patient Retention Table (Report 5SC01-1) .....                                          | A-50 |
| Audience .....                                                                          | A-50 |
| Report Type .....                                                                       | A-50 |
| Location .....                                                                          | A-50 |
| Dimensions .....                                                                        | A-50 |
| Supplementary Prompts .....                                                             | A-50 |
| Reports Referenced .....                                                                | A-50 |
| Reports Referencing This Report .....                                                   | A-51 |
| Column Descriptions .....                                                               | A-51 |
| Planned Sites vs. Sites Screening & Enrolling Chart (Bottom 10) (Report 3SS02-1d) ..... | A-51 |
| Audience .....                                                                          | A-51 |
| Report Type .....                                                                       | A-51 |
| Location .....                                                                          | A-52 |
| Dimensions .....                                                                        | A-52 |
| Supplementary Prompts .....                                                             | A-52 |
| Reports Referenced .....                                                                | A-52 |
| Reports Referencing This Report .....                                                   | A-52 |
| Column Descriptions .....                                                               | A-52 |
| Planned Sites vs. Sites Screening & Enrolling Chart (Top 10) (Report 3SS02-1b) .....    | A-52 |
| Audience .....                                                                          | A-52 |
| Report Type .....                                                                       | A-52 |
| Location .....                                                                          | A-53 |
| Dimensions .....                                                                        | A-53 |
| Supplementary Prompts .....                                                             | A-53 |
| Reports Referenced .....                                                                | A-53 |
| Reports Referencing This Report .....                                                   | A-53 |
| Column Descriptions .....                                                               | A-53 |
| Randomization Overview By Region Chart (Report 8SDP-30) .....                           | A-53 |
| Audience .....                                                                          | A-53 |
| Report Type .....                                                                       | A-54 |
| Location .....                                                                          | A-54 |
| Dimensions .....                                                                        | A-54 |
| Supplementary Prompts .....                                                             | A-54 |
| Reports Referenced .....                                                                | A-54 |
| Reports Referencing This Report .....                                                   | A-54 |
| Column Descriptions .....                                                               | A-54 |
| Randomization Overview By Site Table (Report 8SDP-29) .....                             | A-54 |
| Audience .....                                                                          | A-54 |

|                                                                                        |      |
|----------------------------------------------------------------------------------------|------|
| Report Type .....                                                                      | A-55 |
| Location .....                                                                         | A-55 |
| Dimensions .....                                                                       | A-55 |
| Supplementary Prompts .....                                                            | A-55 |
| Reports Referenced .....                                                               | A-55 |
| Reports Referencing This Report .....                                                  | A-55 |
| Column Descriptions .....                                                              | A-55 |
| Screen Failure Reason by Site Chart (Top 10 # Screen Failures) (Report 4PR02-1c) ..... | A-56 |
| Audience .....                                                                         | A-56 |
| Report Type .....                                                                      | A-56 |
| Location .....                                                                         | A-56 |
| Dimensions .....                                                                       | A-56 |
| Supplementary Prompts .....                                                            | A-56 |
| Reports Referenced .....                                                               | A-56 |
| Reports Referencing This Report .....                                                  | A-56 |
| Column Descriptions .....                                                              | A-57 |
| Screen Failure Reason Chart (Report 4PR02-1b) .....                                    | A-57 |
| Audience .....                                                                         | A-57 |
| Report Type .....                                                                      | A-57 |
| Location .....                                                                         | A-57 |
| Dimensions .....                                                                       | A-57 |
| Supplementary Prompts .....                                                            | A-57 |
| Reports Referenced .....                                                               | A-57 |
| Reports Referencing This Report .....                                                  | A-57 |
| Column Descriptions .....                                                              | A-57 |
| Screen Failure Reason Counts by Site Table (Report 4PR02-1) .....                      | A-58 |
| Audience .....                                                                         | A-58 |
| Report Type .....                                                                      | A-58 |
| Location .....                                                                         | A-58 |
| Dimensions .....                                                                       | A-58 |
| Supplementary Prompts .....                                                            | A-58 |
| Reports Referenced .....                                                               | A-58 |
| Reports Referencing This Report .....                                                  | A-58 |
| Column Descriptions .....                                                              | A-59 |
| Screening Overview By Region Chart (Report 8SDP-28) .....                              | A-59 |
| Audience .....                                                                         | A-59 |
| Report Type .....                                                                      | A-59 |
| Location .....                                                                         | A-59 |
| Dimensions .....                                                                       | A-59 |
| Supplementary Prompts .....                                                            | A-60 |
| Reports Referenced .....                                                               | A-60 |
| Reports Referencing This Report .....                                                  | A-60 |
| Column Descriptions .....                                                              | A-60 |
| Site Detail Table (Report 3SS02-3) .....                                               | A-60 |
| Audience .....                                                                         | A-60 |
| Report Type .....                                                                      | A-60 |
| Location .....                                                                         | A-60 |

|                                                                       |      |
|-----------------------------------------------------------------------|------|
| Dimensions .....                                                      | A-60 |
| Supplementary Prompts .....                                           | A-61 |
| Reports Referenced .....                                              | A-61 |
| Reports Referencing This Report .....                                 | A-61 |
| Column Descriptions.....                                              | A-61 |
| Site Status by Region Chart (Report 3SS07-2) .....                    | A-62 |
| Audience .....                                                        | A-62 |
| Report Type .....                                                     | A-62 |
| Location .....                                                        | A-62 |
| Dimensions .....                                                      | A-62 |
| Supplementary Prompts .....                                           | A-62 |
| Reports Referenced .....                                              | A-63 |
| Reports Referencing This Report .....                                 | A-63 |
| Column Descriptions.....                                              | A-63 |
| Subject Retention Over Time Chart (Report 8SDP-4) .....               | A-63 |
| Audience .....                                                        | A-63 |
| Report Type .....                                                     | A-63 |
| Location .....                                                        | A-63 |
| Dimensions .....                                                      | A-63 |
| Supplementary Prompts .....                                           | A-64 |
| Reports Referenced .....                                              | A-64 |
| Reports Referencing This Report .....                                 | A-64 |
| Column Descriptions.....                                              | A-64 |
| Subjects who Failed Screening Table (Report 8SDP-24).....             | A-64 |
| Audience .....                                                        | A-64 |
| Report Type .....                                                     | A-65 |
| Location .....                                                        | A-65 |
| Dimensions .....                                                      | A-65 |
| Supplementary Prompts .....                                           | A-65 |
| Reports Referenced .....                                              | A-65 |
| Reports Referencing This Report .....                                 | A-65 |
| Column Descriptions.....                                              | A-65 |
| Subjects Withdrawn List Table (Report 8SDP-26).....                   | A-66 |
| Audience .....                                                        | A-66 |
| Report Type .....                                                     | A-66 |
| Location .....                                                        | A-66 |
| Dimensions .....                                                      | A-66 |
| Supplementary Prompts .....                                           | A-66 |
| Reports Referenced .....                                              | A-66 |
| Reports Referencing This Report .....                                 | A-66 |
| Column Descriptions.....                                              | A-66 |
| Summary of Subjects Awaiting EDC Processing (Report CDA-DM-320) ..... | A-67 |
| Audience .....                                                        | A-67 |
| Report Type .....                                                     | A-67 |
| Location .....                                                        | A-67 |
| Dimensions .....                                                      | A-67 |
| Supplementary Prompts .....                                           | A-67 |

|                                                                               |      |
|-------------------------------------------------------------------------------|------|
| Reports Referenced .....                                                      | A-67 |
| Reports Referencing This Report .....                                         | A-68 |
| Column Descriptions .....                                                     | A-68 |
| Summary of Subjects Awaiting Paper Processing (Report CDA-DM-420) .....       | A-68 |
| Audience .....                                                                | A-68 |
| Report Type .....                                                             | A-68 |
| Location .....                                                                | A-68 |
| Dimensions .....                                                              | A-68 |
| Supplementary Prompts .....                                                   | A-69 |
| Reports Referenced .....                                                      | A-69 |
| Reports Referencing This Report .....                                         | A-69 |
| Column Descriptions .....                                                     | A-69 |
| Withdrawn Reason Chart (Report 4PR02-2) .....                                 | A-69 |
| Audience .....                                                                | A-69 |
| Report Type .....                                                             | A-69 |
| Location .....                                                                | A-69 |
| Dimensions .....                                                              | A-70 |
| Supplementary Prompts .....                                                   | A-70 |
| Reports Referenced .....                                                      | A-70 |
| Reports Referencing This Report .....                                         | A-70 |
| Column Descriptions .....                                                     | A-70 |
| Withdrawn Reason Counts by Site Table (Report 4PR02-2b) .....                 | A-70 |
| Audience .....                                                                | A-70 |
| Report Type .....                                                             | A-70 |
| Location .....                                                                | A-70 |
| Dimensions .....                                                              | A-70 |
| Supplementary Prompts .....                                                   | A-71 |
| Reports Referenced .....                                                      | A-71 |
| Reports Referencing This Report .....                                         | A-71 |
| Column Descriptions .....                                                     | A-71 |
| Withdrawn Reason Overview Chart (Top 10 # Early Terms) (Report 8SDP-25) ..... | A-71 |
| Audience .....                                                                | A-72 |
| Report Type .....                                                             | A-72 |
| Location .....                                                                | A-72 |
| Dimensions .....                                                              | A-72 |
| Supplementary Prompts .....                                                   | A-72 |
| Reports Referenced .....                                                      | A-72 |
| Reports Referencing This Report .....                                         | A-72 |
| Column Descriptions .....                                                     | A-72 |

## **B Oracle Clinical Development Analytics Presentation Catalog**

|                                                                      |      |
|----------------------------------------------------------------------|------|
| Dimensions in OCDA Presentation Catalog .....                        | B-1  |
| Facts in OCDA Presentation Catalog .....                             | B-8  |
| Oracle Clinical Sources for OCDA Presentation Catalog .....          | B-21 |
| Oracle Clinical Sources .....                                        | B-21 |
| Aliases .....                                                        | B-34 |
| Oracle's Siebel Clinical Sources for OCDA Presentation Catalog ..... | B-35 |

## **C Troubleshooting**

|                                                       |     |
|-------------------------------------------------------|-----|
| Sorting and Displaying of Null Values in Reports..... | C-1 |
| Aborting a Workflow .....                             | C-2 |

## **Glossary**

## **Index**



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# Preface

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

This preface contains the following topics:

- [Audience](#) on page xix
- [Documentation Accessibility](#) on page xix
- [Finding Information and Patches on My Oracle Support](#) on page xx
- [Finding Documentation on Oracle Technology Network](#) on page xxii
- [Related Documents](#) on page xxii
- [Conventions](#) on page xxiii

## 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 Business Intelligence Enterprise Edition Plus.
- Knowledge of Oracle Business Intelligence Data Warehouse Administration Console.
- 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 account before 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 Business Intelligence Data Warehouse Administration Console 10.1.3.4.1* documentation set, or the *Oracle Business Intelligence Enterprise Edition Release 10.1.3.4.1* documentation set:

### 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 Business Intelligence Data Warehouse Administration Console (DAC) Documentation

The Oracle Business Intelligence Data Warehouse Administration Console (DAC) documentation set includes:

- *Oracle Business Intelligence Data Warehouse Administration Console User's Guide* (Part E12652)
- *Oracle Business Intelligence Data Warehouse Administration Console Installation, Configuration, and Upgrade Guide* (Part E12653)

### 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:

| <b>Convention</b>      | <b>Meaning</b>                                                                                                                         |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| <b>boldface</b>        | Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.         |
| <i>italic</i>          | Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.                          |
| <code>monospace</code> | 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:

- [Chapter 1, Getting Started with Oracle Clinical Development Analytics](#)
- [Chapter 2, Using Oracle Clinical Development Analytics](#)
- [Chapter 3, Working with Reports](#)



---

# Getting Started with Oracle Clinical Development Analytics

This chapter contains the following topics:

- [Overview](#) on page 1-1
- [Architecture](#) on page 1-2
- [Reporting](#) on page 1-3
- [Regulatory Compliance](#) on page 1-3

## 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.

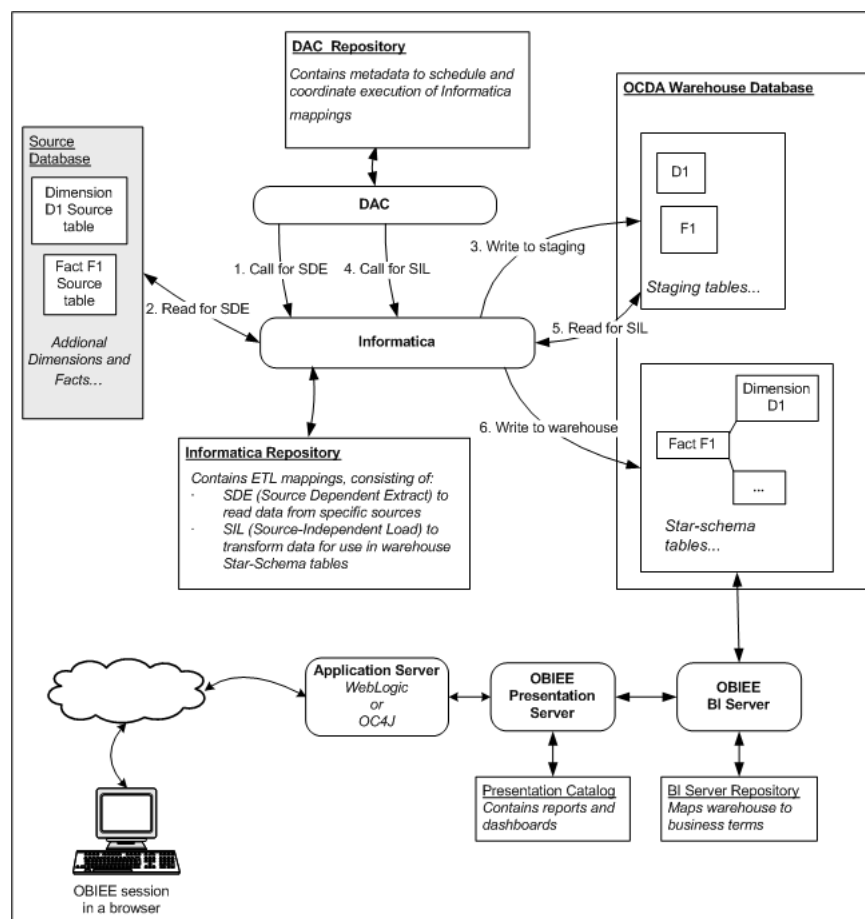
## What Can I Do Using Oracle Clinical Development Analytics?

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.

## 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 can be versioned and saved permanently in a third-party versioning tool.
- 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

You can use a third-party versioning tool or in-built functionality of Informatica to manage ETL versions.

## 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](#)

---

# Using Oracle Clinical Development Analytics

This chapter contains the following topics:

- [Overview](#) on page 2-1
- [Accessing Oracle Clinical Development Analytics](#) on page 2-2
- [Using Oracle Business Intelligence](#) on page 2-4
- [Performing Common Tasks in Oracle Business Intelligence](#) on page 2-5
- [Navigating in Oracle Business Intelligence](#) on page 2-9
- [Using the Oracle BI My Account Page](#) on page 2-11

---

**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.

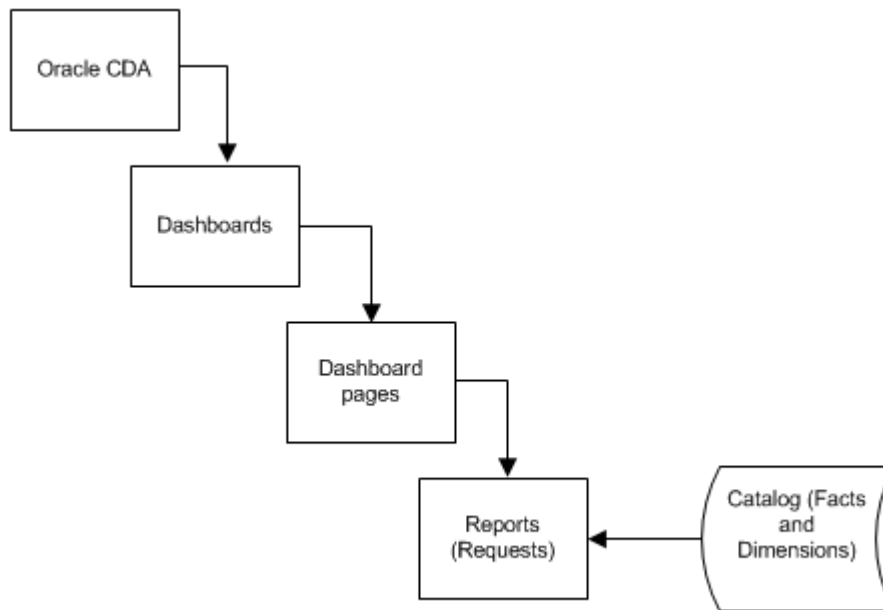
*Dashboards* are access points for information. Each dashboard is designed for a specific job responsibility. For example, a data manager can access only the DM EDC and DM Paper dashboards.

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**

Oracle Business Intelligence

Please enter your User ID and Password below, and then press the Log In button.

User ID

Password

Select a Language English

Oracle Business Intelligence 10.1.3.4

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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**

ORACLE Clinical Development Analytics

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

My Dashboard Welcome, Administrator! Alerts! - Dashboards - Answers - More Products - Settings - Log Out

Alerts!  
Clinical Scorecard

Date of last warehouse refresh is 7/25/2010 10:16:15 PM

powered by ORACLE

## 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...                       |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------|
|  <a href="#">OCDA Help</a>                                    | each dashboard page             | master OCDA online help page.      |
|  <a href="#">CO - Document Management Reference</a>           | each page within this dashboard | specific help for this dashboard.  |
|  <a href="#">CO - Site and Recruitment Overview Reference</a> | each page within this dashboard | specific help for this dashboard.  |
|  <a href="#">CO - Study and Region Overview Reference</a>     | each page within this dashboard | specific help for this dashboard.  |
|  <a href="#">CO - Subject Retention Reference</a>             | each page within this dashboard | specific help for this dashboard.  |
|  <a href="#">CRA EDC Reference</a>                          | each page within this dashboard | specific help for this dashboard.  |
|  <a href="#">DM EDC Reference</a>                           | each page within this dashboard | specific help for this dashboard.  |
|  <a href="#">DM paper Reference</a>                         | 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?

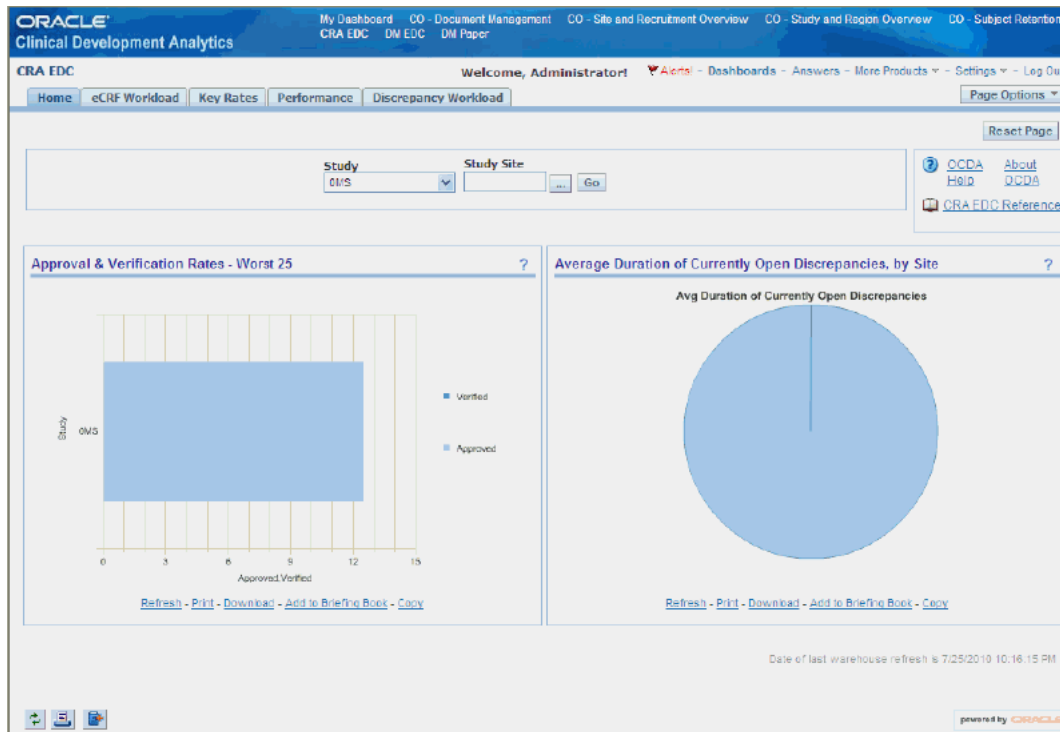
When you access Oracle BI, the first screen that is displayed is your personal dashboard, named My Dashboard, or a dashboard for your job function. Dashboards typically contain reports and other information for your area of responsibility.

**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**

**My Account** ?

Make changes to your account information. Finished Cancel

**General**

Display Name   
 User ID

**Preferences**

Default Dashboard   
 Locale (location)   
 User Interface Language   
 Time Zone

**Delivery Options**

Configure devices and delivery profiles for Oracle BI Delivers.

**Devices**

☐ Email ☐ Phone ☐ Pager ☐ Handheld ☐ Other

| Default                                  | Device Name |
|------------------------------------------|-------------|
| No devices of this category are defined. |             |

[Add Email Device](#)

**Delivery Profiles**

| Active                            | Profile Name |
|-----------------------------------|--------------|
| No delivery profiles are defined. |              |

[Add Delivery Profile](#)

**Group Membership**

This list shows the groups to which you belong.

|                                    |
|------------------------------------|
| Presentation Server Administrators |
| Authenticated Users                |

[Join Catalog Group \(password required\)](#)

## 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**.



---

## 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:

- [Predefined Reports](#) on page 3-1
- [Custom Reports](#) on page 3-3
- [Action Links](#) on page 3-4
- [Viewing Reports With Your Apple iPhone](#) on page 3-4
- [About Oracle BI Answers](#) on page 3-4

**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*

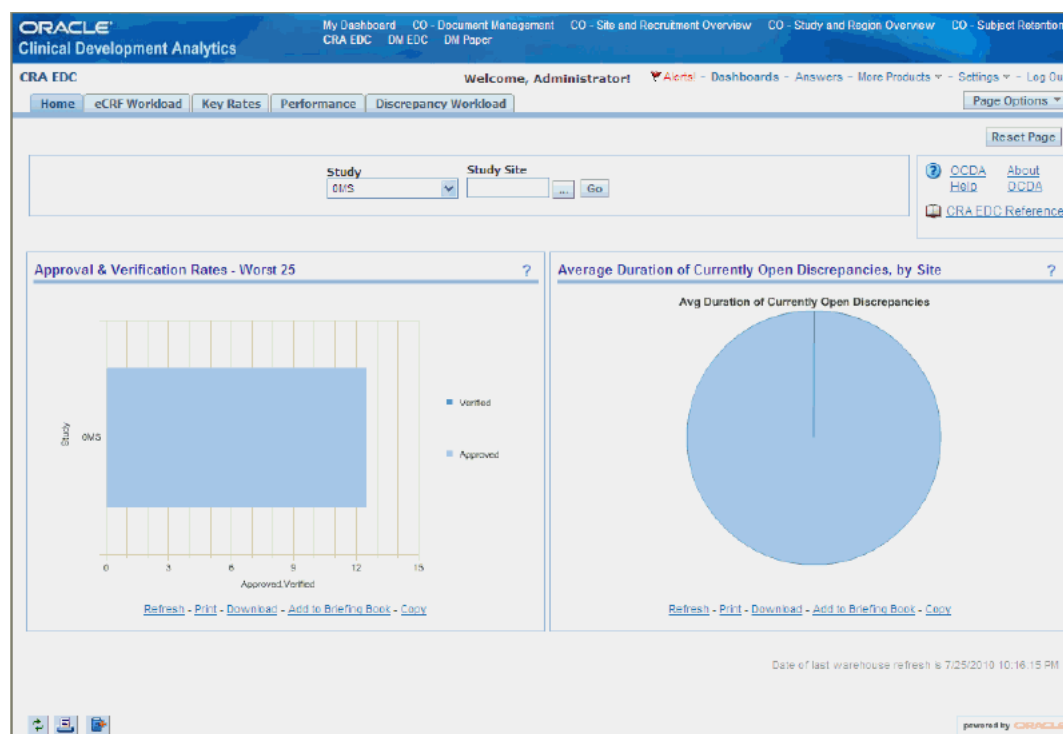
## Viewing a Predefined Report

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

**Oracle Clinical Development Analytics**

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

**CRA EDC** | Welcome, Administrator! | Alerts | Dashboards | Answers | More Products | Settings | Log Out

Home | **eCRF Workload** | Key Rates | Performance | Discrepancy Workload | Page Options

Reset Page

**Filter Parameters:**

- Sponsor: [Dropdown]
- Program: [Text]
- Study: [Text] OMS
- Study Site: [Text]
- Go

**Key EDC processing volumes**

| Study-Site         | #Subjects Enrolled | # Open Discrepancies | # eCRFs        |              |          |              |          |             |             | Of Entry-Complete eCRFs |            |             |             | Navigate to Detail |
|--------------------|--------------------|----------------------|----------------|--------------|----------|--------------|----------|-------------|-------------|-------------------------|------------|-------------|-------------|--------------------|
|                    |                    |                      | Entry Complete | Not Verified | Verified | Not Approved | Approved | Soft Locked | Hard Locked | Approved                | Verified   | Soft Locked | Hard Locked |                    |
| OMS                | 27                 | 8                    | 8              | 14           | 0        | 8            | 1        | 1           | 0           | 12.5                    | 0.0        | 12.5        | 0.0         |                    |
| <b>Grand Total</b> | <b>27</b>          | <b>8</b>             | <b>8</b>       | <b>14</b>    | <b>0</b> | <b>8</b>     | <b>1</b> | <b>1</b>    | <b>0</b>    | <b>12.5</b>             | <b>0.0</b> | <b>12.5</b> | <b>0.0</b>  |                    |

Refresh - Print - Download - Add to Briefing Book - Copy

Date of last warehouse refresh is 7/25/2010 10:16:15 PM

powered by ORACLE

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 columns in OCDA 2.0.0.3:

- 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 <i>Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Using Prompts to Simplify Filtering in an Oracle BI Request)</i> .                                                                                                                                                                                                                                                        |
| Filter               | A filter is a mechanism that restricts the result set. 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.<br><br>For more information on the Presentation Catalog delivered with OCDA, refer to <a href="#">Appendix B, Oracle Clinical Development Analytics Presentation Catalog</a> .                                                                 |

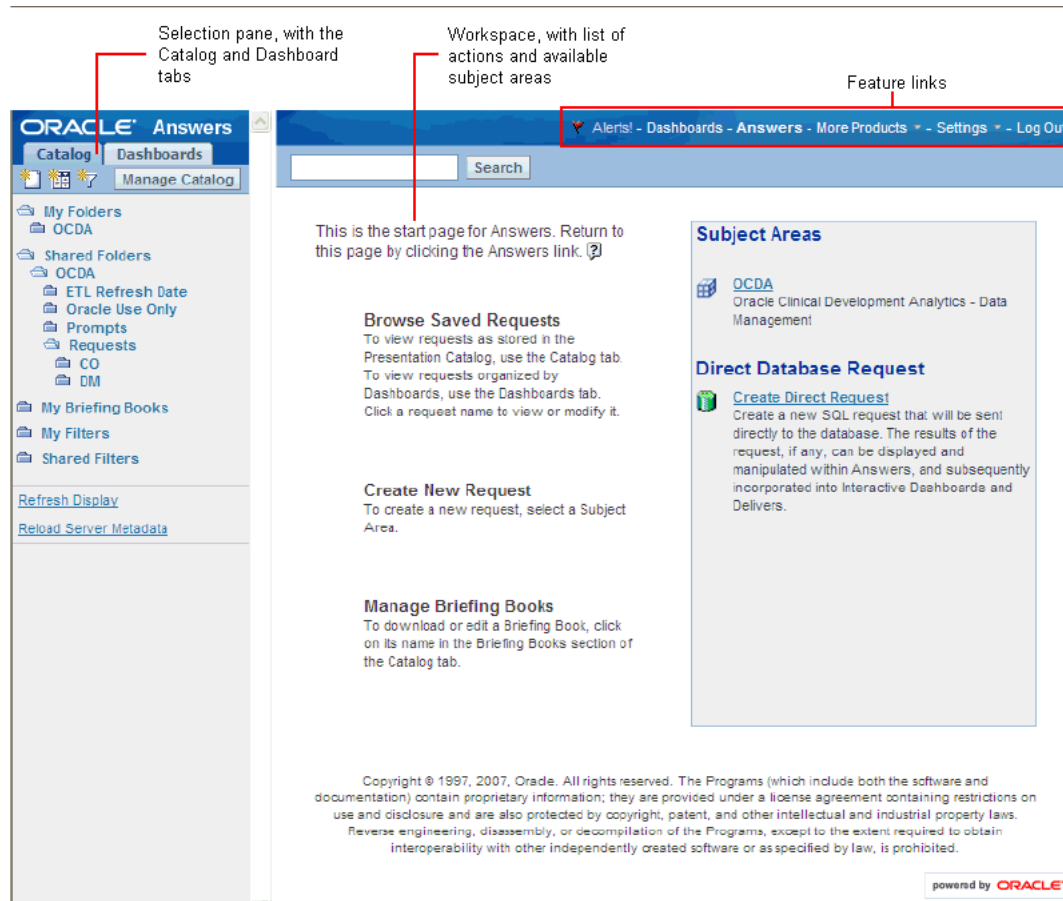
## Example of an Oracle BI Answers Start Page

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.

**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.

---

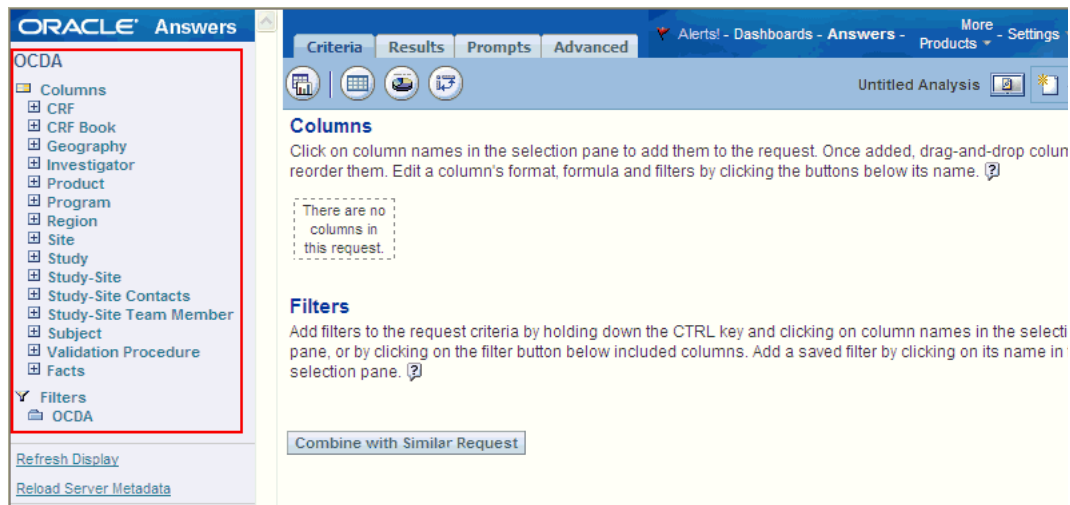
The start page has two main areas:

- **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 | <p>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.</p> <p>Four common views are available from this tab by clicking the appropriate view icon:</p> <div data-bbox="699 491 756 548"></div> <p>Displays the compound layout view, where you can combine individual views and arrange them for display on a dashboard.</p> <div data-bbox="699 657 756 714"></div> <p>Displays the table view, where you can show results in a table.</p> <div data-bbox="699 798 756 854"></div> <p>Displays the chart view, where you can show results in different kinds of charts.</p> <div data-bbox="699 961 756 1018"></div> <p>Displays the pivot table view, where you can take row, column, and section headings and swap them around to obtain different perspectives.</p> |
| Results  | <p>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.</p> <p>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.</p> <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prompts  | <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

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

| Tab      | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Advanced | <p>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.</p> <p>The Advanced tab also provides access to links that you can use to execute saved requests from an external Web page, portal, or application.</p> <p><b>NOTE:</b> 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.</p> |

### 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      | <p><b>Order By:</b> 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.</p> <p>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.</p> <p>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 <a href="#">Table 3–4 Sort Orders Available in Oracle BI Answers</a> on page 3-13.</p> |
|      | <p><b>Format Column:</b> 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.</p> <p>For more information, refer to <i>Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Using Column Formatting Functions in Oracle BI Answers)</i>.</p>                                                                                                                                                                                                                                                                                                                                                |
|      | <p><b>Edit Formula:</b> 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.</p> <p>For more information, refer to <i>Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Editing the Formula of a Column)</i>.</p>                                                                                                                                                                                                                                                   |
|      | <p><b>Filter By Column:</b> The Add Filter icon lets you create or edit a filter for the column. The icon displays the image of a funnel.</p> <p>For more information, see <i>Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User Guide, (Using Column Filters in an Oracle BI Request)</i>.</p>                                                                                                                                                                                                                                                                                                                                                                                                                        |
|      | <p><b>Remove Column:</b> The Delete icon removes the column from the request. The icon displays the image of an uppercase X.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

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



# Part II

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## 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](#)



---

## Extract Transform Load Programs

This chapter contains the following topics:

- [ETL Architecture](#) on page 5-1
- [Executing the ETL Execution Plans](#) on page 5-6
- [Customizing an ETL Execution Plan](#) on page 5-7
- [Creating an ETL Execution Plan](#) on page 5-7
- [Modifying an ETL Execution Plan](#) on page 5-8
- [Scheduling an ETL Execution Plan](#) on page 5-9

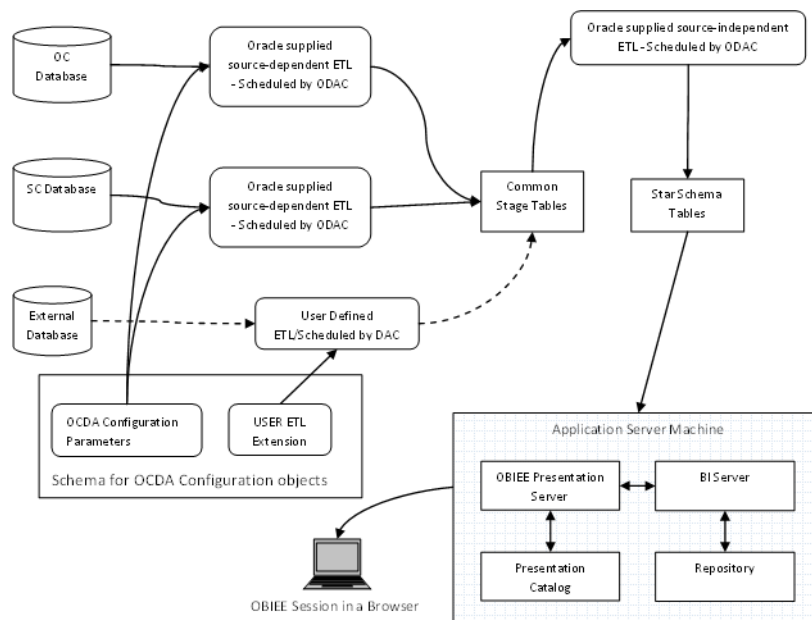
To load data from the source systems to the data warehouse, OCDA uses Extract Transform and Load (ETL) programs that

- 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 ETL Architecture**

Set up as a recurring job in DAC, the 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 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 5-4.

The SDE programs map the transactional data to 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.

The staged data is transformed using the source-independent loads (SILs) to 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 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.

Setting Bulk or Normal load option should be done at Workflow session in Informatica. Perform the following steps to set the load option:

1. Navigate to Session in a workflow and edit the task properties.
2. Navigate to the Mappings subtab and select '**Bulk/Normal**' under Target Load type.
3. Save the workflow.

There is one SIL mapping for each target table. The SIL extracts the normalized data from the 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 by Informatica. 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 need 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. Modify the value of the `DELETE_FLOW` submission parameter to **Y**, on the **Source System Parameters** tab within the **Design** view:
4. Execute the ETLs as listed in the [Executing the ETL Execution Plans](#) 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.

---

---

## Adding a New Data Source

OCDA provides predefined source-dependent extract (SDE) mappings for Oracle Clinical and Siebel Clinical. OCDA pre-creates entries for one instance of each of these application databases in the `W_RXI_DATASOURCE_S` table. If you want to add another database (whether for one of these applications or for another application), perform the following tasks:

1. 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 Execution Plan](#) on page 5-7.

2. Insert a record into the W\_RXI\_DATASOURCE\_S table, assigning the source a unique DATASOURCE\_NUM\_ID. Set this value to a number greater than 100.

---

**Important:**

- When calling an SDE mapping to read from a particular database instance, ensure that you pass in the value of DATASOURCE\_NUM\_ID that corresponds to that database. Also pass TENANT\_ID (normally 0) to the SDE.
  - If you write new SDE, ensure that it sets the value of DATASOURCE\_NUM\_ID in the staging table to which it writes.
- 

3. In DAC, navigate to the **Setup** view, then select the **Physical Data Sources** tab.
4. Enter values in the following fields:

**Name** — Logical name for the database connection.

**Type** — Select **Source** for the database connection for a database.

**Connection Type** — Type of database.

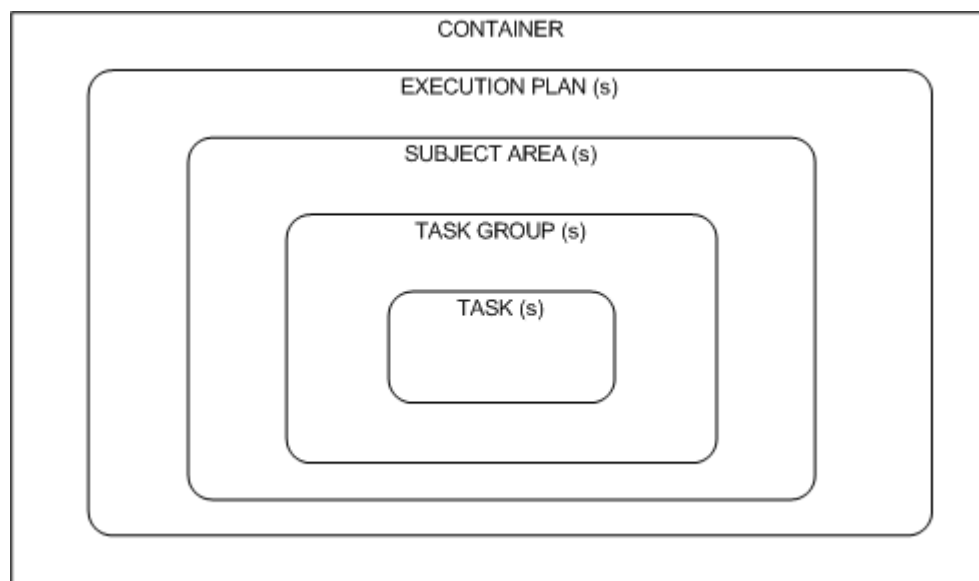
**Dependency Priority** — Number used to generate dependencies when designing execution plans.

**Data Source Number** — Unique number assigned to the data source category so that the data can be identified in the data warehouse. Enter the same value as you have given in the W\_RXI\_DATASOURCE\_S table.

## Oracle Clinical Development Analytics Hierarchy

Figure 5-2 displays the OCDA hierarchy:

**Figure 5–2 OCDA Hierarchy**



Following is the OCDA hierarchy:

- CONTAINER (CDA\_Warehouse) - A single container that holds all objects used for OCDA.
- EXECUTION PLAN (CDA – Complete Warehouse) - A data transformation plan defined on subject areas that needs to be transformed at certain frequencies of time. An execution plan is defined based on business requirements for when the data warehouse needs to be loaded. Single Execution Plan to Load Complete Warehouse.
- SUBJECT AREAS - A logical grouping of tables related to a particular subject or application context. It also includes the tasks that are associated with the tables, as well as the tasks required to load the tables. Subject areas are assigned to execution plans, which can be scheduled for full or incremental loads.
- TASK GROUPS - This is a group of tasks that should be run in a given order.
- TASKS - A unit of work for loading one or more tables. A task comprises the following: source and target tables, phase, execution type, truncate properties, and commands for full or incremental loads. A single Informatica workflow.

## Executing the ETL Execution Plans

To load data from the source to their target tables in the data warehouse, run the Execution Plan packaged with OCDA. Perform the following tasks in DAC:

1. Navigate to the **Execute** view.
2. Select **CDA – Complete Warehouse** execution plan.
3. Set the parameter values under the **Parameter** tab.
4. Build the execution plan.
5. Click **Run**.

---

**Note:** The `prune_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.

---

6. If Oracle Clinical is your *only* data source:
  1. Navigate to **Execution Plan** tab.
  2. Click **CDA - Oracle Clinical Warehouse Execution Plan**.
  3. Set the required parameters.
  4. Build the **Execution Plan**.
  5. Click **Run**.

If Siebel Clinical is your *only* data source:

1. Navigate to **Execution Plan** tab.
2. Click **CDA - Siebel Clinical Warehouse Execution Plan**.
3. Set the required parameters.
4. Build the **Execution Plan**.

## 5. Click **Run**.

---

**Note:** Execution of the ETL (specifically the OCDA\_ETL\_RUN\_S\_POP 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 Execution Plan](#) on page 5-9.

## Customizing an ETL Execution Plan

When you customize an ETL Execution Plan, it is your responsibility to maintain version control over changes to ETL mappings.

Oracle recommends that you carefully track the changes you make to Oracle-supplied ETL so that you can re-apply these changes in subsequent releases.

## Creating an ETL Execution Plan

Though OCDA includes ETL Execution Plans 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:

- *Informatica PowerCenter Online Help*

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

1. Create the new source and target table metadata inside Informatica.

2. Work in Informatica PowerCentre and create the ETL components (transformation or workflow) for this program.
3. Create the required workflow for this mapping.
4. Connect to DAC and create a new task for this new mapping.
5. Synchronize the task.
6. Add the task to subject area.
7. Build the Execution Plan (CDA - Complete Warehouse).

## Modifying an ETL Execution Plan

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

### See Also:

- *Informatica PowerCenter Online Help*

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

1. Identify the Execution Plan that needs to be modified in Informatica repository.
2. Open and Modify the ETLs (transformation and/or workflow).
3. Test and save the changes in repository.
4. Connect to DAC and navigate to the corresponding task.
5. Right-click the task and synchronize it.
6. Navigate to the execution plan and execute ETL to verify the changes.

---

**Note:** The ETL Execution Plans 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 Execution Plans 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 (typically to widen a column):

1. Change the table properties as needed.

2. Save the mapping and refresh the workflow.
3. Connect to DAC and navigate to corresponding task and refresh it.

---

**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.

---

## Scheduling an ETL Execution Plan

When you submit a Execution Plan for execution in DAC, you can schedule it execute at regular intervals. To schedule a Execution Plan, perform the following tasks:

1. Navigate to the **Scheduler** tab within the **Execute** view.
2. Create a new schedule plan.
3. Enter the required details and click **Save**.



---

## Maintaining the Repository and Warehouse

This chapter contains the following topics:

- [Maintaining the Oracle Clinical Development Analytics Repository](#) on page 4-1
- [Maintaining the Oracle Clinical Development Analytics Data Warehouse](#) on page 4-3

### 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 a version controlling software. 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. Open RPD using the Administration tool and make the desired modifications.  
Make the desired modifications to the downloaded RPD. Refer to [Details for Selected Modifications](#) for instructions on applying selected modifications.
2. 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 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. Modify staging table W\_RXI\_STUDY\_DS, adding the STUDY\_MANAGER column. To modify the staging table, perform the following tasks in Oracle Business Intelligence Data Warehouse Administration Console (DAC):
  - a. Duplicate the container in DAC (to ensure that the changes are not overwritten in the next OCDA upgrade) or use an existing customized table definition.
  - b. Navigate to the **Design > Tables** subtab and add the new column under W\_RXI\_STUDY\_DS and save it.
2. Modify the SDE that populates W\_RXI\_STUDY\_DS, in two steps:
  - Copy the SDE into another folder (to ensure that the changes are not overwritten in the next OCDA upgrade) or use an existing customized SDE.
  - Add the STUDIES\_MANAGERS table as a source in the Informatica 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 DAC:

- a. Navigate to **Design > Tasks** subtab.
- b. Navigate to SDE of Study Dimension. Right click and select **Synchronize**.
3. If it does not already exist to support some other extension, create extension table W\_RXI\_STUDY\_DX, containing one column [STUDY\_WID] to function as a foreign key that joins to the primary key in W\_RXI\_STUDY\_D. This table is populated with one row for each row in W\_RXI\_STUDY\_D when the Study SIL executes.
4. Add column STUDY\_MANAGER to W\_RXI\_STUDY\_D to hold the name of the study manager. To add a column, perform the following tasks in DAC:
  - a. Duplicate the container in DAC (to ensure that the changes are not overwritten in the next OCDA upgrade) or use an existing customized table definition.
  - b. Navigate to Tables subtab Under Design Tab and add the new column under W\_RXI\_STUDY\_DS and save it.
5. Modify the SIL that populates W\_RXI\_STUDY\_D. Add instructions to create a record in W\_RXI\_STUDY\_DX for each record in W\_RXI\_STUDY\_D, and to copy W\_RXI\_STUDY\_DS.STUDY\_MANAGER into W\_RXI\_STUDY\_DX.STUDY\_MANAGER for each record.

To modify the SIL, perform the following tasks in DAC:

- a. Copy the SIL into another folder (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 save.
6. Modify the repository:

---

**Important:** Before you modify the repository, ensure that you have copied the repository to a different location. This ensures that the changes are not overwritten automatically in the next upgrade of OCDA. Alternatively, you can use an existing customized repository.

---

- a. Import the definition of the extension table, W\_RXI\_STUDY\_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 at database 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 Informatica:

- a. Copy the SDE into another folder (to ensure that the changes are not overwritten in the next OCDA upgrade) or use an existing customized SDE.
- b. Modify the definitions and save.

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. |

**Table 4–1 (Cont.) Scenarios Requiring Necessary Adjustments**

| Scenario                           | Adjustments Required                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Modified table has modified layout | <ol style="list-style-type: none"> <li>1. Modify the SDE to read the modified layout.</li> <li>2. Modify the staging table populated by the SDE to include the modified layout.</li> <li>3. Modify the SIL to read the modified layout.</li> <li>4. Modify the target table to include the modified layout.</li> <li>5. Modify the RPD to accept the changed data warehouse table.</li> </ol>                                    |
| New table                          | <ol style="list-style-type: none"> <li>1. Add a staging table to accept the new input.</li> <li>2. Add an SDE to read from the new table and write to the staging table.</li> <li>3. Add a warehouse table to make the new data available to the BI Server.</li> <li>4. Add an SIL to populate the new data warehouse table from the new staging table.</li> <li>5. Modify the RPD to accept the new warehouse table.</li> </ol> |

## Modifying Data Warehouse Tables

Depending on what changes are required to the data warehouse, it is necessary to modify either the source table in Informatica and DAC, or the source, staging, and target tables.

### Managing Indexes

OCDA is delivered with a set of indexes. If you wish, you can create additional indexes to meet your query requirements. Use DAC for this purpose.

---

**Note:** Oracle recommends that you Drop and re-create all indexes only for full load. This should be disabled for incremental load.

---

It is useful to drop all indexes on the warehouse tables before loading large volumes of data, and to recreate them afterward. DAC can automate this process for you. To drop indexes before a load, and recreate them afterward, perform the following tasks in DAC:

1. Navigate to the **Execute > CDA-Complete Warehouse** execution tab.
2. Select **Drop and Re-create Index** and save.

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

---

## Implementing Security

This chapter contains the following topics:

- [About Security in Oracle Clinical Development Analytics](#) on page 6-1
- [Setting Up User Authentication](#) on page 6-3
- [Setting Up User Authorization in OBIEE](#) on page 6-3
- [Setting Up Study and Study Site Data Access for Users](#) on page 6-5

### About Security in Oracle Clinical Development Analytics

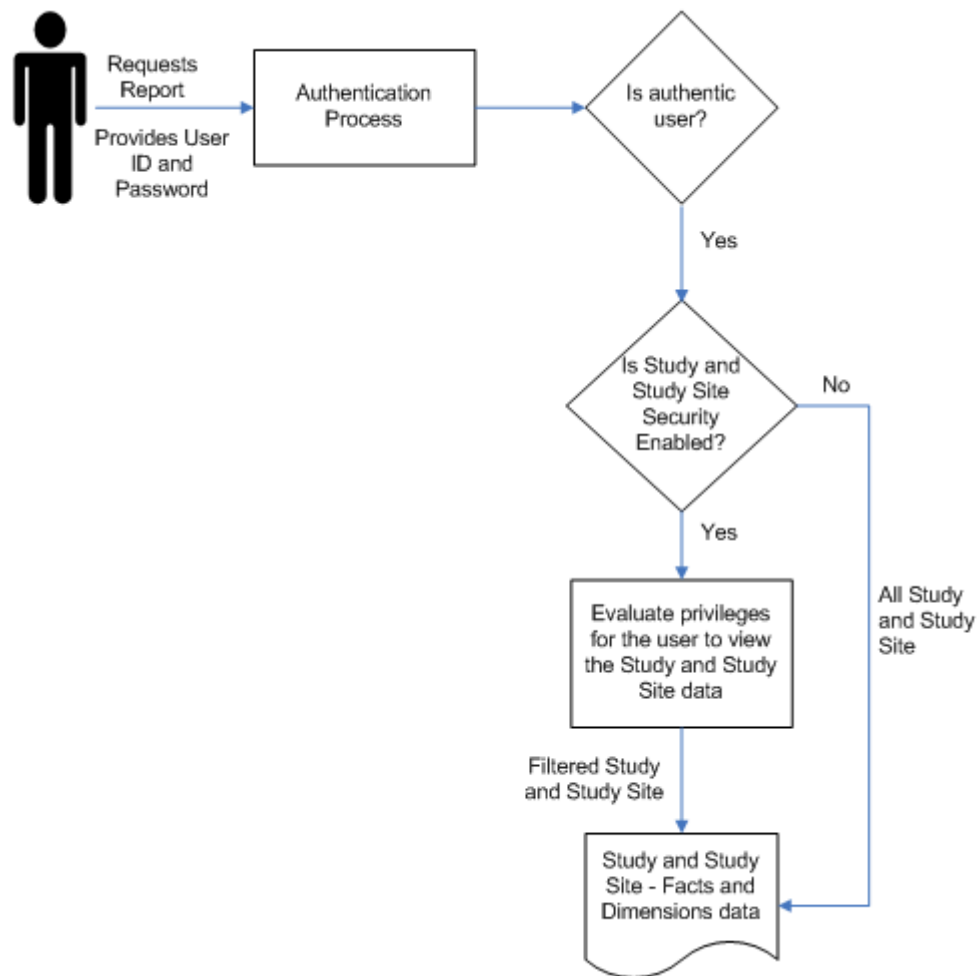
Oracle Clinical Development Analytics (OCDA) spans several applications: Oracle Clinical and Oracle's Siebel Clinical are the data sources, and Informatica ETL Execution Plans and transform Oracle Clinical and Siebel Clinical data structures into the star schemas required by Oracle Business Intelligence Enterprise Edition (OBIEE), which reads from the star schemas and provides the user interface where end users can view and analyze data through dashboards and reports.

OCDA security includes:

- **Authentication.** OCDA user accounts are maintained in OBIEE RPD.
- **Authorization.** You assign user accounts to user groups in OBIEE RPD. On login, OBIEE ascertains the authenticated user's user group, 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 can create additional user groups as needed in OBIEE.

- **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 6-5.

**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.

- **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.
- **INFA 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 Infa repository for use in OCDA. They may also create new ETL Programs to support custom dashboards and reports in OCDA.
- **OCDA Schedulers** are people who schedule OCDA jobs, including the data loading job and the user data access jobs. They need privileges similar to INFA Programmers.

- **DAC/INFA Administrators** are people who set up DAC, including Informatica Setups, and grant privileges to other users.

## Setting Up User Authentication

DAC handles creation and maintenance of users for ETL administration of OCDA. OBIEE handles reports related user authentication for OCDA .

### Creating User Accounts in DAC

You can create user accounts in the following ways:

- Create users in DAC. For more information, refer to the *Oracle® Business Intelligence Data Warehouse Administration Console Guide*.
- If you have an Oracle LDAP Directory, migrate users to Oracle Applications. For more information, refer to My Oracle Support (ID 1508321.1).

### Setting Up User Authorization in OBIEE

When a user logs in, OBIEE verifies that they have valid credentials and populates the OBIEE Group session variable with a list of the user groups the user belongs to.

Authorization at the OBIEE level determines which parts of OCDA's OBIEE user interface, users can access. The tasks required to set up user authorization are:

- [Using Predefined User Groups in OBIEE and Creating New Ones](#) on page 6-3

#### 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 OBIEE account to an OBIEE user group.

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

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

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**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 6-4.

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

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**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*.

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

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**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*.

**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.

- **DAC/INFA Administrator Group:** You do not need this group unless you want to allow INFA Programmers to modify some ETL Programs but not others.

## Setting Up Study and Study Site Data Access for Users

This section contains the following topics:

- [Setting the Systemwide Access Variables](#) on page 6-5
- [Data Access Tables](#) on page 6-6
- [Importing Study and Study Site Data Access Privileges](#) on page 6-6
- [Study-Site Access Example](#) on page 6-9

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 6-5.

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 6-6.

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**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 6-9.

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## 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 6-6.

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

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To change the value for either variable:

1. Stop the BI Server and the BI Presentation Server Services.
2. 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.
3. 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 6-6.
- **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:

- SDE\_OC\_Application\_User\_D
- SDE\_OC\_Study\_Access\_Sec
- SDE\_OC\_Study\_Site\_Access\_Sec

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 .

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 6-8.

### About Siebel Clinical Security ETL Programs

The securirty ETL programs for Siebel Clinical are:

- SDE\_SC\_Application\_User\_D
- SDE\_SC\_Study\_Access\_Sec
- SDE\_SC\_Study\_Site\_Access\_Sec
- SDE\_SC\_Party\_Parent

- OCDA\_SC\_PARTY\_HIERARCHY
- SDE\_SC\_Study\_Hierarchy
- SDE\_SC\_Study\_Site\_Hierarchy

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:

- SIL\_Application\_User\_D
- SIL\_Study\_Access\_Sec
- SIL\_Study\_Site\_Access\_Sec

### 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 the SDE programs must be identical
- The resultant user name must be the same as the 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 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 Execution Plan](#) on page 5-7.

### 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 6-6. For more information, refer to [Scheduling an ETL Execution Plan](#) on page 5-9.

## 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):

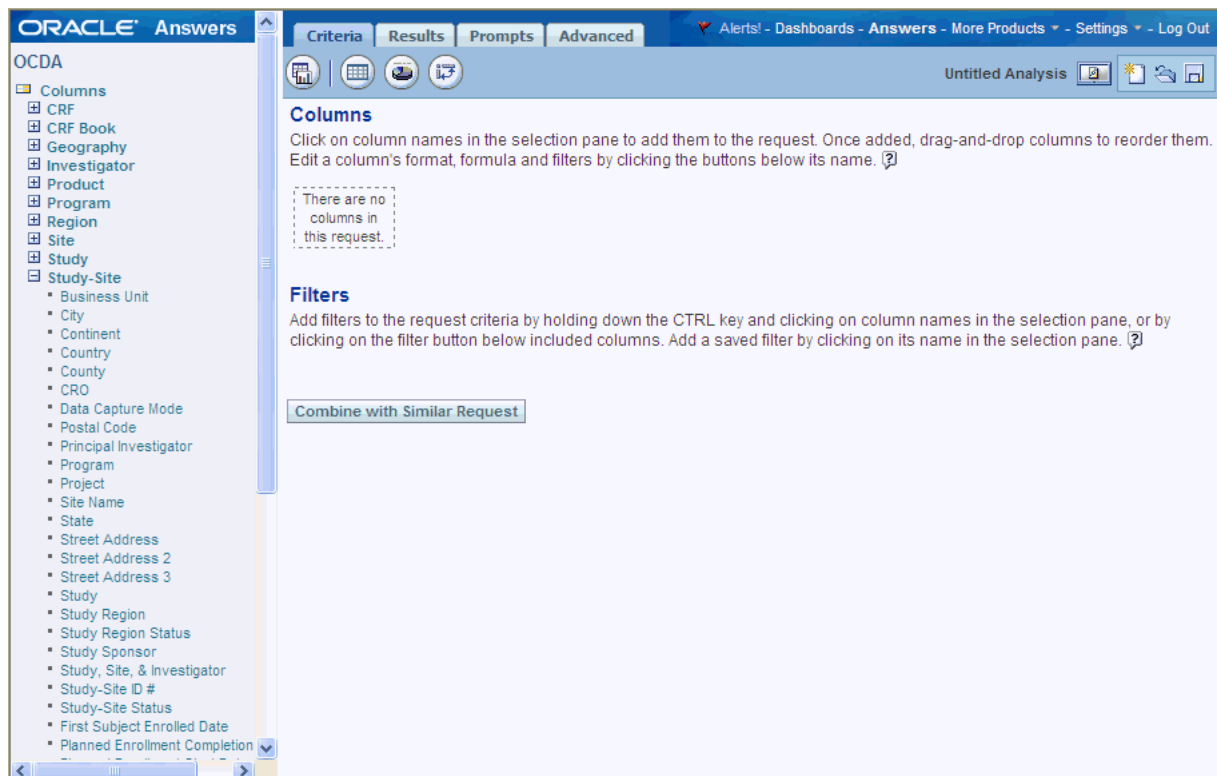
| APPLICATION_USER_WID | STUDY_WID | STUDY_SITE_WID |
|----------------------|-----------|----------------|
| U2                   | A         | A1             |
| U2                   | A         | A2             |
| U3                   | B         | B1             |
| U3                   | B         | 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                      |

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**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 2.0.0.3, 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.

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# Part III

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## Appendixes

Part III contains the following appendixes:

- [Appendix A, Dashboards and Reports](#)
- [Appendix B, Oracle Clinical Development Analytics Presentation Catalog](#)
- [Appendix C, Troubleshooting](#)



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## 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 retention 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 Statues \(Report CDA-DM-215\)](#)
- [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 <sup>1</sup> | Discrepancy Review Statuses.Avg # Days Open Discrepancy Ever in Review Status |

<sup>1</sup> 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<br>Procedure Name |
| NA            | NA             | Discrepancies.# Open<br>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<br>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 <sup>1</sup>   | Discrepancies.# Open Discrepancies             |
| # Discrepancies                | Closed              | Discrepancies.# Closed Discrepancies           |
| # Discrepancies                | Total <sup>2</sup>  | 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 |

- <sup>1</sup> Conditional Formatting Threshold: Yellow - between 5 and 9  
Conditional Formatting Threshold: Red - greater than or equal to 10
- <sup>2</sup> 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 <sup>1</sup>                 | Received CRFs.Avg # Days from pCRF Visit to First Entry                 |
| Average Days  | First Entry to Second Entry Complete <sup>2</sup> | 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 <sup>3</sup> | 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 |

<sup>1</sup> Conditional Formatting Threshold: Yellow - between 30 and 59  
Conditional Formatting Threshold: Red - greater than or equal to 60

<sup>2</sup> Conditional Formatting Threshold: Yellow - between 3 and 9  
Conditional Formatting Threshold: Red - greater than or equal to 10

<sup>3</sup> 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 <sup>1</sup> | 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              |

<sup>1</sup> 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 <sup>1</sup> | 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                            |

<sup>1</sup> 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<br><b>Note:</b> 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                      |
| Of Entry-Complete CRFs | Soft Locked                      | Received CRFs.% pCRFs Soft Locked / Entry Complete     |
| Of 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 <sup>1</sup> | 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 |

<sup>1</sup> 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<br>Awaiting Pass 1 Entry<br>Completion |
| # CRFs        | Awaiting Second Entry<br>Completion | Received CRFs.# pCRFs<br>Awaiting Pass 2 Entry<br>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<br>Second Entry Complete | Received CRFs.Avg # Days<br>from pCRF First Entry to<br>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))*0.9 )  |
| 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))*0.75 ) |
| 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))*0.5 )  |
| 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, &amp; 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<br>Entry Complete           |
| # eCRFs       | Not Verified             | Received CRFs.# eCRFs<br>Never Verified           |
| # eCRFs       | Awaiting Re-Verification | Received CRFs.# eCRFs<br>Awaiting Re-Verification |
| # eCRFs       | Not Approved             | Received CRFs.# eCRFs Not<br>Approved             |
| # eCRFs       | Awaiting Re-Approval     | Received CRFs.# eCRFs<br>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, &amp; 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  |

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# 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:

- [Dimensions in OCDA Presentation Catalog](#) on page B-1
- [Facts in OCDA Presentation Catalog](#) on page B-1
- [Oracle Clinical Sources for OCDA Presentation Catalog](#) on page B-21
- [Oracle's Siebel Clinical Sources for OCDA Presentation Catalog](#) on page B-35

**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<br>>- 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 whom 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;<br><br>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 Enrollment 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 Sources](#) lists 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 -<br>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-RCF26I/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 DATAHG' 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 rdcj.received_dci_id,  | case when rdcj.trans_type ='SYS APP DATAHG' then 'Y' else 'N'                                                                                                                                                                                                |
| TA-RCRF22    | rdci.blank_flag               | -                                                                                                                                                                                                                                                            |
| TA-RCRF23    | rdci.data_lock_flag           | -                                                                                                                                                                                                                                                            |
| TA-RCRF24    | rdci                          | when rdcj.received_dci_status_code in 'RECEIVED', 'PASS 1 STARTED') then 'Y' else 'N' end                                                                                                                                                                    |
| TA-RCRF25    | rdci                          | case when rdcj.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  | rxcdci_books                   |
| cpe   | rxades.clinical_planned_events |
| cs    | rxades.clinical_studies        |
| dci   | rxcdcis                        |
| derh  | rxcd.discrepancy_review_hist   |
| disc  | rxcd.discrepancy_entries       |
| dq    | rxcdcm_questions               |
| dqg   | rxcdcm_question_groups         |
| ep    | rxades.enrollment_plans        |
| inv   | rxades.ocl_investigators       |
| os    | rxades.ocl_studies             |
| page  | rxcdci_book_pages              |

**Table B–4 (Cont.) Aliases for Table Names**

| Alias | Table Name                   |
|-------|------------------------------|
| pp    | rx_des.patient_positions     |
| pm    | rx_des.ocl_product_masters   |
| proc  | rxc.procedures               |
| ps    | rx_des.patient_statuses      |
| rcv   | rx.reference_codelist_values |
| rdci  | rxc.received_dcis            |
| rdcm  | rxc.received_dcms            |
| site  | rx_des.ocl_sites             |
| ss    | rx_des.ocl_study_sites       |

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**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.

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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.DISC_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**

| <b>Attribute ID</b> | <b>Source Table/Column</b> | <b>Comments/Details</b> |
|---------------------|----------------------------|-------------------------|
| 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<br>Where S_CL_SUBJ_LS.PR_STATUS_<br>ID = S_CL_SUBJ_ST_LS.ROW_ID<br>and S_CL_SUBJ_ST_LS.STATUS_<br>CD='Randomized'     | -                                                                  |
| M-SST33      | Count Distinct S_CL_SUBJ_ST_<br>LS.PAR_ROW_ID where S_CL_<br>SUBJ_ST_LS.STATUS_ID =<br>"Re-Screened"                                               | -                                                                  |
| M-SST33C     | Count of S_CL_SUBJ_LS.ROW_ID<br>Where S_CL_SUBJ_LS.PR_STATUS_<br>ID = S_CL_SUBJ_ST_LS.ROW_ID<br>and S_CL_SUBJ_ST_LS.STATUS_<br>CD='Re-Screened'    | -                                                                  |
| M-SST34      | Count Distinct S_CL_SUBJ_ST_<br>LS.PAR_ROW_ID where S_CL_<br>SUBJ_ST_LS.STATUS_ID = "Screen<br>Failure"                                            | -                                                                  |
| M-SST34C     | Count of S_CL_SUBJ_LS.ROW_ID<br>Where S_CL_SUBJ_LS.PR_STATUS_<br>ID = S_CL_SUBJ_ST_LS.ROW_ID<br>and S_CL_SUBJ_ST_LS.STATUS_<br>CD='Screen Failure' | -                                                                  |
| M-SST35      | Count Distinct S_CL_SUBJ_ST_<br>LS.PAR_ROW_ID<br><br>where S_CL_SUBJ_ST_LS.STATUS_<br>ID = "Screened"                                              | -                                                                  |
| M-SST35C     | Count of S_CL_SUBJ_LS.ROW_ID<br>Where S_CL_SUBJ_LS.PR_STATUS_<br>ID = S_CL_SUBJ_ST_LS.ROW_ID<br>and S_CL_SUBJ_ST_LS.STATUS_<br>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_<br>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_<br>STATUS' and NAME='Completed'  |
| M-SST42      | S_CL_SUBJ_ST_LS.STATUS_DATE                                                                                                                        | S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_<br>STATUS' and NAME='Enrolled'   |
| M-SST43      | S_CL_SUBJ_ST_LS.STATUS_DATE                                                                                                                        | S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_<br>STATUS' and NAME='Randomized' |
| M-SST44      | S_CL_SUBJ_ST_LS.STATUS_DATE                                                                                                                        | S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_<br>STATUS' and NAME='Screened'   |
| M-SST45      | S_CL_SUBJ_ST_LS.STATUS_DATE                                                                                                                        | S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_<br>STATUS' and NAME='Completed'  |
| M-SST46      | S_CL_SUBJ_ST_LS.STATUS_DATE                                                                                                                        | S_LST_OF_VAL,TYPE='CLNCL_SUBJECT_<br>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<br>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         | -                                                                    |

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## Troubleshooting

This appendix contains the following topics:

- [Sorting and Displaying of Null Values in Reports](#) on page C-1
- [Aborting a Workflow](#) on page C-2

### 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.

## Aborting a Workflow

A workflow can be aborted by the following two methods:

### Method 1

Perform the following steps in DAC to abort a workflow:

1. Navigate to Execute > Execution Plan sub tab.
2. Click the Execution Plan you want to abort.
3. Click **Abort**.

### Method 2

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.
3. In the Workflow Run pane, select and right-click the workflow, and click **Abort**.

**See Also:**

*Informatica PowerCenter Online Help*

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# 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 Pharm 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 [investigators](#) 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](#)



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# Index

## A

---

### about

- Oracle BI Answers, 3-4
- presentation variables, 3-15
- repository variables, 3-15
- security in OCDA, 6-1
- session variables, 3-15
- variables, 3-15

### accessing

- OCDA, 2-2
- requests, 3-6
- subject areas, 3-6
- tabs in workspace, 3-8

### action links, 3-4

### adding, new data source, 5-4

### Approval & Verification Rates - Worst 25

- reports, A-12

### architecture

- ETL programs, 5-1
- OCDA, 1-2

### Average Days from Complete to Initially Approved - Top 25 report, A-13

### Average Days from Complete to Initially Verified - Top 25 report, A-14

### Average Duration in Categorized Discrepancy Review Status report, A-15, A-17

### Average Duration of Currently Open Discrepancies, by Site report, A-16

## B

---

### bulk and normal load

- about, 5-2

### bulk load, 5-2

## C

---

### cache, definition, 2-8

### changing criteria, 3-10

### CO - Document Management

- dashboard, A-1

- dashboard pages, A-2

- Document Collection Cycle Times, A-2

- Document List, A-2

### CO - Site and Recruitment

- dashboard pages, A-3

### CO - Site and Recruitment Overview

- dashboard, A-3

- dashboard pages

- Comparative Site Enrollment, A-3
  - Enrollment Overview, A-4
  - Randomization Overview, A-4
  - Screen Failure Overview, A-3
  - Screening Overview, A-3
  - Site Status Overview, A-3
  - Subject Recruitment Over Time, A-4

### CO - Study and Region Overview

- dashboard, A-4

### CO - Subject Retention

- dashboard, A-5

- dashboard pages, A-5

- Early Termination Overview, A-5
  - Subject Retention Over Time, A-5
  - Subject Retention Overview, A-5

### Comparative Site Enrollment

- CO - Site and Recruitment Overview, A-3

### Comparative Site Enrollment Status Table, A-18

### Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank report, A-20

### Counts of Categorized Open Discrepancies, by Review Status report, A-21

### Counts of Discrepancies, by State and Review Status report, A-22

### Counts of Open Multivariate Discrepancies, by Procedure report, A-23

### CRA EDC

- dashboard, A-6

- dashboard pages, A-4, A-6

- Discrepancy Workload, A-7
  - eCRF Workload, A-4, A-6
  - Home, A-4, A-6
  - Key Rates, A-6
  - Performance, A-6

### creating

- ETL programs, 5-7
- requests, 3-6, 3-10

### custom reports in OCDA, 3-3

### customizing ETL programs, 5-7

## D

---

### dashboard pages

- CO - Document Management, A-2
  - Document Collection Cycle Times, A-2
  - Document List, A-2
- CO - Site and Recruitment, A-3
- CO - Site and Recruitment Overview
  - Comparative Site Enrollment, A-3
  - Enrollment Overview, A-4
  - Randomization Overview, A-4
  - Screen Failure Overview, A-3
  - Screening Overview, A-3
  - Site Status Overview, A-3
  - Subject Recruitment Over Time, A-4
- CO - Subject Retention, A-5
  - Early Termination Overview, A-5
  - Subject Retention Over Time, A-5
  - Subject Retention Overview, A-5
- CRA EDC, A-4, A-6
  - Discrepancy Workload, A-7
  - eCRF Workload, A-4, A-6
  - Home, A-4, A-6
  - Key Rates, A-6
  - Performance, A-6
- definition, 2-1
- DM EDC, A-7
  - Discrepancy Workload, A-7
  - eCRF Workload, A-7
  - Home, A-7
  - Key Rates, A-8
  - Performance, A-8
  - Quality, A-8
  - Study Discrepancies, A-8
  - Study Processing Detail, A-8
  - Study Processing Summary Page, A-8
- DM Paper, A-9
  - Home, A-9
  - Page Workload, A-9
  - Performance, A-10
  - Quality, A-10
  - Study Processing Detail, A-10
  - Study Processing Summary, A-10
- emailing, 2-7

### dashboards

- about, A-1
- CO - Document Management, A-1
- CO - Site and Recruitment Overview, A-3
- CO - Study and Region Overview, A-4
- CO - Subject Retention, A-5
- CRA EDC, A-6
- definition, 2-1
- display values using variables, 3-15
- DM EDC, A-7
- DM Paper, A-9
- embedding requests, 3-15
- printing, 2-6
- refreshing, 2-8
- viewing, 2-3
- viewing descriptions, 2-5

### data tracking

See tracking data

- data warehouse
  - maintaining, 4-3
- data warehouse tables, modifying, 4-6
- derivations
  - about, 4-3
  - definition, 4-3
- descriptions of dashboards and requests,
  - viewing, 2-5
- dimensions in the presentation catalog, B-1
- Discrepancies per Pages Entered - 25 highest rates, A-24
- Discrepancies per Subjects Enrolled - Top 25 report, A-25
- Discrepancy Overview with Ratios report, A-25
- Discrepancy Workload
  - CRA EDC dashboard page, A-7
  - DM EDC dashboard page, A-7
- displaying values in results and dashboards, 3-15
- DM EDC
  - dashboard, A-7
  - dashboard pages, A-7
    - Discrepancy Workload, A-7
    - eCRF Workload, A-7
    - Home, A-7
    - Key Rates, A-8
    - Performance, A-8
    - Quality, A-8
    - Study Discrepancies, A-8
    - Study Processing Detail, A-8
    - Study Processing Summary, A-8
- DM Paper
  - dashboard, A-9
  - dashboard pages, A-9
    - Home, A-9
    - Page Workload, A-9
    - Performance, A-10
    - Quality, A-10
    - Study Processing Detail, A-10
    - Study Processing Summary, A-10
- Document Collection Cycle Times
  - CO - Document Management dashboard page, A-2
- Document Collection Cycle Times - Days Outstanding by Type, A-27
- Document Collection Cycle Times Table, A-28
- Document Collection Cycle Times -Turn Around Time by Type, A-29
- Document List
  - CO - Document Management dashboard page, A-2
- Documents List, A-30
- domain hierarchy, OCDA, 5-5
- drilling down results, 2-11

## E

---

### Early Termination Overview

- CO - Subject Retention dashboard page, A-5
- ### eCRF Workload

- CRA EDC dashboard page, A-4, A-6
- DM EDC dashboard page, A-7
- emailing dashboard page and request, 2-7
- embedding
  - requests in a dashboard, 3-15
- Enrollment Overview
  - CO - Site and Recruitment Overview, A-4
- Enrollment Overview By Region Chart, A-32
- Enrollment Overview By Site, A-33
- Enrollment Progress Over Time, A-34
- ETL programs
  - architecture, 5-1
  - creating, 5-7
  - customizing, 5-7
  - definition, 5-1
  - executing, 5-6
  - modifying
    - one or more tables, 5-8
    - without changes to the associated tables or columns, 5-8
  - scheduling, 5-9
  - source-dependent extract (SDE)
    - definition, 5-2
  - source-independent loads (SIL)
    - definition, 5-2
  - version management, 1-4
- executing ETL programs, 5-6
- exiting, Oracle BI, 2-5
- extensions
  - about, 4-3
  - definition, 4-3

## F

---

- facts in the presentation catalog, B-8
- filters, definition, 2-2

## H

---

- Home
  - CRA EDC dashboard page, A-4, A-6
  - DM EDC dashboard page, A-7
  - DM Paper dashboard page, A-9

## I

---

- incremental load, 5-2
- indexes, managing, 4-6
- introducing, OCDA, 1-1

## K

---

- Key Cycle Times for Paper Studies report, A-36
- Key EDC Cycle Times report, A-37
- Key EDC processing volumes report, A-38
- Key Paper processing volumes reports, A-40
- Key Rates
  - CRA EDC dashboard page, A-6
  - DM EDC dashboard page, A-8

## L

---

- List Discrepancy Details report, A-41
- Listing of Subject-Pages, Awaiting EDC Processing report, A-43
- Listing of Subject-Pages, Awaiting Paper Processing report, A-44
- load
  - bulk, 5-2
  - incremental, 5-2
  - normal, 5-2
- logging in, OCDA, 2-3
- logging out, Oracle BI *See* exiting, Oracle BI
- Low Approved to Entered Rate - Worst 25 report, A-45
- Low Verified to Entered Rate - Worst 25 report, A-46

## M

---

- maintaining
  - data warehouse, 4-3
  - repository, 4-1
- managing ETL versions, 1-4
- managing indexes, 4-6
- modifying
  - criteria *See* changing criteria
  - data warehouse tables, 4-6
  - ETL programs
    - one or more tables without changes to the associated ETL programs, 5-8
    - without changes to the associated tables or columns, 5-8
  - requests, 3-6
- My Account page, using, 2-11

## N

---

- navigation in Oracle BI, 2-9
- normal load, 5-2

## O

---

- OCDA
  - about security, 6-1
  - accessing, 2-2
  - architecture, 1-2
  - custom reports, 3-3
  - domain hierarchy, 5-5
  - logging in, 2-3
  - overview, 1-1
  - predefined reports, 3-1
- online help, using, 2-5
- Oracle BI
  - drilling down, 2-11
  - exiting, 2-5
  - navigating, 2-9
  - setting preferences, 2-12
  - setting time zone, 2-12
  - sorting table columns, 2-11
  - using, 2-4

- Oracle BI Answers, 2-4
  - about, 3-4
  - accessing requests, 3-6
  - accessing subject areas, 3-6
  - accessing tabs in workspace, 3-8
  - refreshing selection pane, 3-13
  - start page, 3-5
  - using, 3-6
  - viewing results, 3-14
- Oracle BI Delivers, 2-4
- Oracle BI features links, using, 2-10
- Oracle BI interactive dashboards, 2-4
- Oracle BI pages, working, 2-11
- Oracle BI Presentation Services, 2-4
  - Oracle BI Answers, 2-4
  - Oracle BI Delivers, 2-4
  - Oracle BI interactive dashboards, 2-4
- Outstanding Documents by Category, Type, A-47
- Overview
  - Randomization Overview
    - CO - Site and Recruitment Overview, A-4
    - Subject Recruitment Over Time
      - CO - Site and Recruitment Overview, A-4
- overview, OCDA, 1-1
- overview, using OCDA, 2-1

## P

- Page Workload, DM Paper dashboard page, A-9
- pages
  - See* dashboard pages, definition
- Pages Awaiting Entry Completion report, A-48
- panes, definition, 2-11
- Paper Processing Cycle Times - 25 Longest report, A-49
- parameters, definition, 2-2
- patches, xxi
- Patient Retention Table, A-50
- Performance
  - CRA EDC dashboard page, A-6
  - DM EDC dashboard page, A-8
  - DM Paper dashboard page, A-10
- Planned Sites vs. Sites Screening & Enrolling Chart (Bottom 10), A-51
- Planned Sites vs. Sites Screening & Enrolling Chart (Top 10), A-52
- predefined
  - reports, 3-1
  - variables, 3-17
- predefined variables, referencing, 3-17
- presentation catalog
  - dimensions, B-1
  - facts, B-8
  - oracle clinical sources, B-21
  - siebel clinical sources, B-35
- presentation variables
  - syntax, 3-16
- printing dashboards and requests, 2-6
- prompts, definition, 3-1

## Q

- Quality
  - DM EDC dashboard page, A-8
  - DM Paper dashboard page, A-10

## R

- Randomization Overview By Region Chart, A-53
- Randomization Overview By Site Table, A-54
- referencing
  - predefined variables, 3-17
  - session variables, 3-16
- refreshing
  - dashboards and requests, 2-8
  - information in selection pane, 2-9, 3-13
- regulatory compliance, 1-3
  - data tracking, 1-3
  - ETL version management, 1-4
  - security, 1-4
- reporting, using OCDA, 1-3
- reports
  - Approval & Verification Rates - Worst 25, A-12
  - Average Days from Complete to Initially Approved - Top 25, A-13
  - Average Days from Complete to Initially Verified - Top 25, A-14
  - Average Duration in Categorized Discrepancy Review Status, A-15
  - Average Duration of Currently Open Discrepancies, by Site, A-16
  - Average Duration of Open Discrepancies in Review Statuses, A-17
  - Comparative Site Enrollment Status Table, A-18
  - Count of Currently Open Discrepancies by CRF and Type - Top 10 by Rank, A-20
  - Counts of Categorized Open Discrepancies, by Review Status, A-21
  - Counts of Discrepancies, by State and Review Status, A-22
  - Counts of Open Multivariate Discrepancies, by Procedure, A-23
  - custom, 3-3
  - defined, 2-1, 3-1
  - Discrepancies per Pages Entered - 25 highest rates, A-24
  - Discrepancies per Subjects Enrolled - Top 25, A-25
  - Discrepancy Overview with Ratios, A-25
  - Document Collection Cycle Times - Days Outstanding by Type, A-27
  - Document Collection Cycle Times Table, A-28
  - Document Collection Cycle Times - Turn Around Time by Type, A-29
  - Documents List, A-30
  - Enrollment Overview By Region Chart, A-32
  - Enrollment Overview By Site, A-33
  - Enrollment Progress Over Time, A-34
  - Key Cycle Times for Paper Studies, A-36
  - Key EDC Cycle Times, A-37
  - Key EDC processing volumes, A-38

- Key Paper processing volumes, A-40
  - List Discrepancy Details, A-41
  - Listing of Subject-Pages, Awaiting EDC Processing, A-43
  - Listing of Subject-Pages, Awaiting Paper Processing, A-44
  - Low Approved to Entered Rate - Worst 25, A-45
  - Low Verified to Entered Rate - Worst 25, A-46
  - Outstanding Documents by Category, Type, A-47
  - Pages Awaiting Entry Completion, A-48
  - Paper Processing Cycle Times - 25 Longest, A-49
    - parameters, 2-2
  - Patient Retention Table, A-50
  - Planned Sites vs. Sites Screening & Enrolling Chart (Bottom 10), A-51
  - Planned Sites vs. Sites Screening & Enrolling Chart (Top 10), A-52
  - predefined, 3-1
  - Randomization Overview By Region Chart, A-53
  - Randomization Overview By Site Table, A-54
  - request, 2-1
  - Screen Failure Reason by Site Chart, A-56
  - Screen Failure Reason Chart, A-57
  - Screen Failure Reason Counts by Site Table, A-58
  - Screening Overview By Region Chart, A-59
  - Site Detail Table, A-60
  - Site Status by Region Chart, A-62
  - Subject Retention Over Time, A-63
  - Subjects who Failed Screening Table, A-64
  - Subjects Withdrawn List Table, A-66
  - Summary of Subjects Awaiting EDC Processing, A-67
  - Summary of Subjects Awaiting Paper Processing, A-68
  - view, 3-2
  - view on Apple iPhone, 3-4
  - Withdrawn Reason Chart, A-69
  - Withdrawn Reason Counts by Site Table, A-70
  - Withdrawn Reason Overview Chart (Top 10 # Early Terms), A-71
  - repository variables
    - about, 3-15
    - syntax, 3-16
  - repository, maintaining, 4-1
  - request
    - emailing, 2-7
    - searching, 3-7
  - requests
    - creating, 3-6, 3-10
    - embedding in a dashboard, 3-15
    - modifying, 3-6
    - printing, 2-6
    - refreshing, 2-8
    - running, 3-10
    - saving, 3-6
    - saving to personal or shared folder, 3-14
    - sort order, 3-13
    - viewing descriptions, 2-5
  - results
    - display values using variables, 3-15
    - downloading, downloading results, 2-8
    - viewing, 3-14
  - running, requests, 3-10
- ## S
- 
- saving
    - requests, 3-6, 3-14
  - scheduling
    - ETL programs, 5-9
  - Screen Failure Overview
    - CO - Site and Recruitment Overview, A-3
  - Screen Failure Reason by Site Chart, A-56
  - Screen Failure Reason Chart, A-57
  - Screen Failure Reason Counts by Site Table, A-58
  - Screening Overview
    - CO - Site and Recruitment Overview, A-3
  - Screening Overview By Region Chart, A-59
  - searching, request, 3-7
  - security, 1-4
  - selection pane
    - refreshing, 3-13
  - selection pane, definition, 2-11, 3-7
  - session variables
    - about, 3-15
    - referencing, 3-16
    - syntax, 3-16
  - setting preferences, Oracle BI, 2-12
  - setting time zone, Oracle BI, 2-12
  - Site Detail Table, A-60
  - Site Status by Region Chart, A-62
  - Site Status Overview
    - CO - Site and Recruitment Overview dashboard page, A-3
  - sorting table columns in Oracle BI, 2-11
  - source-dependent extract (SDE)
    - definition, 5-2
    - features, 5-2
  - source-independent load (SIL)
    - features, 5-3
  - source-independent loads (SIL)
    - definition, 5-2
  - specifying sort order, 3-13
  - start page, Oracle BI answers, 3-5
  - Study Discrepancies
    - DM EDC dashboard page, A-8
  - Study Processing Detail
    - DM EDC dashboard page, A-8
    - DM Paper dashboard page, A-10
  - Study Processing Summary
    - DM EDC dashboard page, A-8
    - DM Paper dashboard page, A-10
  - Subject Retention Over Time, A-63
    - CO - Subject Retention dashboard page, A-5
  - Subject Retention Overview
    - CO - Subject Retention dashboard page, A-5
  - Subjects who Failed Screening Table, A-64
  - Subjects Withdrawn List Table, A-66
  - substitutions
    - about, 4-5

- definition, 4-3
- Summary of Subjects Awaiting EDC Processing
  - report, A-67
- Summary of Subjects Awaiting Paper Processing
  - report, A-68
- syntax
  - presentation variables, 3-16
  - repository variables, 3-16
  - session variables, 3-16

## **T**

---

- tracking data, 1-3

## **U**

---

- using
  - My Account Page, 2-11
  - Oracle BI, 2-4
  - Oracle BI Answers, 3-6
  - variables, 3-15
- using OCDA, 2-1
- using online help, 2-5
- using Oracle BI features links, 2-10

## **V**

---

- variables
  - display values, 3-15
  - presentation, 3-15
  - repository, 3-15
  - session, 3-15
  - using, 3-15
- viewing
  - dashboards, 2-3
  - descriptions of dashboards and requests, 2-5
  - predefined reports, 3-2
  - reports on Apple iPhone, 3-4
  - results, 3-14
  - saved requests, 3-7

## **W**

---

- what can i do using Oracle Clinical Development Analytics, 1-2
- what is available to you after accessing Oracle BI, 2-9
- Withdrawn Reason Chart, A-69
- Withdrawn Reason Counts by Site Table, A-70
- Withdrawn Reason Overview Chart (Top 10 # Early Terms), A-71
- working
  - Oracle BI pages, 2-11