Oracle® Health Sciences Clinical Development Analytics

Installation and Configuration Guide for Informatica Release 3.2.1

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Oracle Health Sciences Clinical Development Analytics Installation and Configuration Guide for Informatica, Release 3.2.1

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Preface

This guide provides information about how to install Oracle Health Sciences Clinical Development Analytics (OHSCDA).

This preface contains the following topics:

- Audience on page v
- Documentation Accessibility on page v
- Finding Certification Information on page vi
- Finding Information and Patches on My Oracle Support on page vi
- Finding Documentation on Oracle Technology Network on page vii
- Related Documents on page viii
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Audience

This installation guide is intended for users who are responsible for installing Oracle Health Sciences Clinical Development Analytics. You must be familiar with:

- Oracle Database
- Oracle Business Intelligence Enterprise Edition (OBIEE) application
- Oracle Business Intelligence Data Warehouse Administration Console (DAC) application
- Informatica PowerCenter application

Documentation Accessibility

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

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

Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

Finding Certification Information

Certifications provide access to product certification information for Oracle and third party products. A product is certified for support on a specific release of an operating system on a particular hardware platform, for example, Oracle Database 10g Release 2 (10.2.0.1.0) on Sun Solaris 10 (SPARC). To find certification information:

- 1. Sign in to My Oracle Support at http://support.oracle.com.
- **2.** Click the **Certifications** tab. The Certifications page opens and displays the Find Certifications region.
- 3. In Select Product, enter Oracle Health Sciences Clinical Development Analytics.
- **4.** Click the Go to Certifications icon.
 - The right pane displays the certification information.
- **5.** Select a certification to view the certification details.

Finding Information and Patches on My Oracle Support

Your source for the latest information about Oracle Health Sciences 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 Business Intelligence Data Warehouse Administration Console, Oracle Business Intelligence Enterprise Edition Release, Oracle Clinical, Siebel Clinical, and Oracle Health Sciences InForm documentation sets.

Oracle Business Intelligence Data Warehouse Administration Console (DAC) Documentation

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

- Oracle® Fusion Middleware User's Guide for Oracle Business Intelligence Data Warehouse Administration Console
- Oracle Business Intelligence Data Warehouse Administration Console Installation, Configuration, and Upgrade Guide

Oracle Business Intelligence Enterprise Edition (OBIEE) Documentation

The *Oracle Business Intelligence Suite Enterprise Edition Online Documentation Library* documentation set includes:

- Oracle® Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware Metadata Repository Builder's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware System Administrator's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware Scheduling Jobs Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware Security Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware Developer's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware Integrator's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)

Oracle Clinical Documentation

The Oracle Clinical documentation set includes:

Oracle Clinical Administrator's Guide

- Oracle Clinical Getting Started
- Interfacing from Oracle Clinical
- Oracle Clinical Conducting a Study
- Oracle Clinical Creating a Study
- Oracle Clinical Installation Guide

Siebel Clinical Documentation

The Siebel Clinical documentation set includes:

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

Oracle Health Sciences InForm Documentation

The Oracle Health Sciences InForm documentation set includes:

- Oracle Health Sciences InForm Upgrade and Migration Guide
- Oracle Health Sciences InForm Installation Guide
- Oracle Health Sciences InForm Study and Reporting Setup Guide
- Oracle Health Sciences InForm User Guide
- Oracle Health Sciences InForm Reporting and Analysis
- Oracle Health Sciences InForm Utilities Guide
- Oracle Health Sciences InForm Clinical Data API Guide
- Oracle Health Sciences InForm Reporting Database Schema
- Oracle Health Sciences InForm Secure Configuration Guide
- Oracle Health Sciences InForm Third Party Licenses and Notices

Conventions

The following text conventions are used in this document:

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

Before You Begin

This section presents an overview of the Oracle Health Sciences Clinical Development Analytics (OHSCDA) requirements. It also describes the tasks that you must complete before you can install the application.

This chapter includes the following sections:

- Section 1.1, "Checking for the Most Recent Information"
- Section 1.2, "Technology Stack and System Requirements"
- Section 1.3, "Installing the Prerequisite Software"

1.1 Checking for the Most Recent Information

OHSCDA documentation is updated periodically. Therefore, it is critical that you check that you have the most current information before you begin the installation process.

To ensure that you have the most recent version of this Installation and Configuration Guide, and all other OHSCDA user documentation, see Finding Documentation on Oracle Technology Network.

1.2 Technology Stack and System Requirements

The requisite technology stack for OHSCDA configuration consists of the following products:

- Oracle Database 12.1.0.2.0 with patch 19509982
- Oracle WebLogic Server 10.3.6
- Oracle Business Intelligence Enterprise Edition (OBIEE) 11.1.1.9.0
- Oracle Business Intelligence Data Warehouse Administration Console 11.1.1.6.4
- Informatica PowerCenter 9.5.0, 9.6.1, and 10.1.1

Note: Technology stack components are not part of the media pack. You must acquire their license separately.

All references to *media pack server* in this document refer to the system onto which you download the media pack for Oracle Health Sciences Clinical Development Analytics.

Make sure that the domain information of the Informatica repository, where you plan to import OHSCDA related Informatica mappings, is added to domains.infa file of the Informatica client.

Table 1–1 System Requirements References

Product	Reference		
Oracle Database 12.1.0.2.0 with patch 19509982	Database Installation Guide for <platform></platform>		
Oracle WebLogic Server 10.3.6	Oracle WebLogic Server Documentation Library		
Oracle Business Intelligence Enterprise Edition (OBIEE) 11.1.1.9.0	System Requirements and Supported Platforms for Oracle Business Intelligence Suite Enterprise Edition		
	Oracle Business Intelligence Infrastructure Installation and Configuration Guide		
Oracle Business Intelligence Data Warehouse Administration Console 11.1.1.6.4	Oracle Business Intelligence Data Warehouse Administration Console Installation, Configuration, and Upgrade Guide		
	Data Warehouse Administration Console User's Guide		
Informatica PowerCenter 9.5.0, 9.6.1, and 10.1.1	Informatica PowerCenter Installation Guide		

Note: It is important to get the technology stack products from the OHSCDA media pack because newer versions of the technology stack products may have become available but may not be compatible with OHSCDA.

Installation Considerations

- Determine the computer on which you will install each component of OHSCDA.
- You may select to install each product on a different server, if required. The OHSCDA media pack server does not have to act as server for any of the products, though it may. You may consult Figure 1–1, and the documentation listed in Table 1–1 for information on installing each product.
- Determine the databases you need to create.
- You must create a database schema to serve as the warehouse for OHSCDA.
- It is a good practice to create the schema for the OHSCDA warehouse in a new database.
- You may select to create schemas for repositories for the other OHSCDA components in the same database that will be used for the OHSCDA warehouse. It minimizes the number of databases that you need to maintain for OHSCDA. However, if you will be using the component applications for purposes other than OHSCDA, Oracle recommends that you create their repositories in instances other than the one holding the OHSCDA warehouse.

Supported Platforms Oracle Health Sciences Clinical Development Analytics Oracle Business Intelligence Data Warehouse Administration Microsoft Windows, Unix Console (DAC) 11.1.1.6.4 Oracle Business Intelligence Enterprise Edition 11.1.1.9 Oracle Business Intelligence (BI) Server Microsoft Windows, Unix Microsoft Windows, Linux Oracle Business Intelligence Presentation Services x86, and Sun SPARC Solaris Microsoft Windows Oracle Business Intelligence Client Tools Microsoft Windows, Linux Oracle WebLogic Server 10.3.6 x86, and Sun SPARC Solaris Linux x86, and Sun SPARC Informatica PowerCenter 9.5.0, 9.6.1, and 10.1.1 Solaris Linux x86/x86-64, and Sun Oracle Database 12.1.0.2 with patch 19509982 SPARC Solaris

Figure 1–1 Oracle Health Sciences Clinical Development Analytics Technology

For more information about certifications, see Finding Certification Information.

1.2.1 Supported Web Browsers

OHSCDA supports web browsers that are supported by OBIEE. For the list of the browsers supported by OBIEE, refer to Oracle Fusion Middleware System Administrator's *Guide for Oracle Business Intelligence Enterprise Edition 11g.*

Note: For information on Oracle Software Web Browser Support Policy, see Doc ID 2092205.1 on My Oracle Support (https://support.oracle.com).

1.2.2 Source Systems

OHSCDA is designed to extract data from the following three systems:

- Oracle Clinical (OC) 4.6 or 5.1
- Siebel Clinical Trial Management System (SC) 8.1.1.16
- Oracle Health Sciences InForm 4.6, 5.5, 6.0, or 6.1.0

1.3 Installing the Prerequisite Software

Figure 1–2 displays a sample topology of the technology components for OHSCDA.

DAC Server OHSCDA 3.2 for Informatica: DAC Repository Components and Servers Contains metadata to schedule and coordinate execution of Informatica mappings Database Server Source Database se Serve Client software: DAC Informatica Oracle client Oracle Database nections to esponding servers) OHSCDA Warehouse Contains tables structured to optimize query respons Informatica Repository tains workflo direct ETL deduplicatio OBIEE Server

OBIEE Bl Serve

BI Server Repository Maps warehouse to

Web Catalog Contains reports and dashboards

Figure 1-2 Sample Topology

Before you can install the OHSCDA application, you must complete the following pre-installation tasks:

■ Install Oracle Database 12.1.0.2.0 with patch 19509982. You can download the patch set from My Oracle Support (https://support.oracle.com).

Note: You must set the init parameter *processes* for the database to a minimum of 500.

Follow the instructions in *Oracle Database Installation Guide for <platform>*.

Also, install Oracle Database Client for 12.1.0.2.0 on the system where you are running the OHSCDA installer. Follow the instructions in *Oracle Database Client Installation Guide for <platform>*.

■ Install Oracle WebLogic Server 10.3.6

OBI EE session

- Follow the instructions in *Oracle WebLogic Server Documentation Library*.
- Install Oracle Business Intelligence Enterprise Edition (OBIEE) 11.1.1.9.0 with the following components:
 - Oracle Business Intelligence Server (Supported on Windows and Unix)
 - Oracle Business Intelligence Presentation Services (Supported on Windows and Unix)
 - Oracle Business Intelligence Client Tools (Supported only on Windows)

Follow the instructions in *Oracle Business Intelligence Infrastructure Installation and Configuration Guide*.

 Install Oracle Business Intelligence Data Warehouse Administration Console (DAC) 11.1.1.6.4

Follow the instructions in *Oracle Business Intelligence Data Warehouse Administration Console Installation, Configuration, and Upgrade Guide.*

Install Informatica PowerCenter 9.5.0, 9.6.1, or 10.1.1

Oracle recommends that you create Informatica repository for OHSCDA with the following settings:

Table 1–2 Informatica Repository Settings

Settings	Value
Character Set	UTF8
Versioning	True
Global Repository	False
Security Audit Trail	No
Operating Mode	Normal

You must add the AggSupprtWithNoPartLic property in Informatica PowerCenter Administration Console, to use the sorted Aggregator transformation set in Informatica PowerCenter.

Perform the following steps to add the *AggSupprtWithNoPartLic* property:

- Log on to Informatica PowerCenter Administration Console.
- Select the PowerCenter Integration Service.
- In Custom Properties, click **Edit**.
- Click Add. 4.
- Enter AggSupprtWithNoPartLic in the Name field.
- Enter Yes in the **Value** field.
- Click **OK** to add the property.

For more information, see Informatica PowerCenter Installation Guide.

- If you implement multi-byte character support for OHSCDA, set the following:
 - Operating System Level: Ensure that the system that hosts Informatica and Database have the following parameters set:
 - NLS_LANG=AMERICAN_AMERICA.AL32UTF8
 - LANG=en_US.UTF-8
 - **Database Level**: Ensure that the following parameters are set while creating database:
 - NLS_CHARACTERSET = AL32UTF8
 - NLS_NCHAR_CHARACTER= AL16UTF16
 - Informatica Level: Oracle recommends that you create Informatica integration service for OHSCDA with the following settings:

Table 1–3 Informatica Integration Service

Settings	Value
Character Set	UTF8
Versioning	True
Global Repository	False

Table 1–3 (Cont.) Informatica Integration Service

Settings	Value
Security Audit Trail	No
Operating Mode	Normal
DataMovementMode	Unicode
Code Page	UTF8

- Informatica Workflow Relational Connection: For all relational connection in Informatica (Datawarehouse, Inform_Source, Oracle_Clinical, and Siebel_Clinical), set:
 - Connection Environment SQL to "alter session set NLS_LENGTH_SEMANTICS = 'CHAR';
 - Code Page to UTF-8 encoding of Unicode

Installing Oracle Health Sciences Clinical Development Analytics

This chapter describes the OHSCDA installation tasks that you must complete. OHSCDA application installation consists of the following components:

- Adding InForm Studies to the OHSCDA Warehouse
- Running the OHSCDA Installer
- Source-specific Procedures
- Setting Up Relational Connections in the Informatica Workflow for OHSCDA
- Preparing a DAC Repository for OHSCDA
- Emplacing the OHSCDA Help and Image Files
- Preparing the OBIEE Web Catalog and Repository for OHSCDA
- Configuring HTML 5
- Configuring Maps
- Creating Security Groups and Application Roles for OHSCDA

2.1 Adding InForm Studies to the OHSCDA Warehouse

Note: You must perform the tasks in this section only if:

- You have InForm as a source
- It is a fresh installation of OHSCDA

Figure 2–1 displays the OHSCDA InForm consolidation installation scenarios.

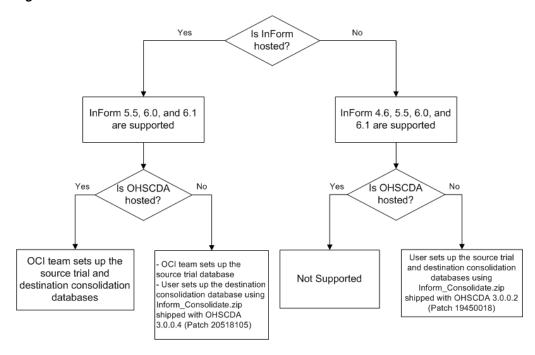


Figure 2–1 OHSCDA InForm Consolidation Installation Scenarios

Note: You can download the OHSCDA patch from My Oracle Support (https://support.oracle.com)

2.1.1 OHSCDA InForm Consolidation Schema

This section describes how OHSCDA extracts InForm's operational data and loads it into the OHSCDA warehouse. All of the data for each InForm study is maintained in a transactional database (actually a database schema). InForm maintains one or more InForm databases per Oracle database instance. Each study also has a Reporting and Analysis database (again, a set of objects in a schema, not necessarily an exclusive database instance) which contains data in views designed for query, as opposed to transactional activity.

Inform maintains the Reporting and Analysis database for each study in a study-specific schema. For efficiency and maintainability, OHSCDA has created a program that extracts data from a number of InForm Reporting and Analysis databases and places that data into a single consolidated database. Then, OHSCDA's source-dependent extract code reads from the consolidated database, and writes to the OHSCDA warehouse.

For the remainder of this section, refer to any given InForm Reporting and Analysis database as a source schema and the schema in which OHSCDA consolidates InForm data as the consolidation schema.

OHSCDA consolidates data from selected InForm source schema views, the selected ones being the ones that have data corresponding to columns in the OHSCDA data model. The following are the InForm source views that are consolidated for OHSCDA:

- IRV_AF_SUBJECT_FORMS
- IRV_CUR_QUERY
- IRV_CUR_RULE
- IRV_CUR_SITE

- IRV_CUR_SPONSOR
- IRV_CUR_SUBJECT
- IRV CUR USER
- IRV FORM REVS
- IRV_ITEMSET_REVS
- IRV_ITEM_REVS
- IRV_QUERY_STATE_CHANGES
- IRV SECTION REVS
- IRV STUDYVERSIONS
- IRV_STUDYVERSION_FORMS
- IRV STUDYVERSION VISITS
- IRV_SUBJECT_STATE_CHANGES
- IRV_SV_SUBJECTVISITS
- IRV USERS SITES

For each of these source views, the consolidation schema contains a consolidation table. Each consolidation table has the same columns as its source view, except that the consolidation table has three additional columns:

- **STUDYGUID**
- CONSOLIDATION DATETIME
- **MODIFIEDDATETIME**

STUDYGUID is needed to retain the association of each record with its InForm study. CONSOLIDATION_DATETIME and MODIFIEDDATETIME allows OHSCDA ETL to detect which consolidated records have been added or updated since the prior ETL execution.

The names of tables in the consolidation schema match the names of their source views, with the following change:

IRV in the source view name is replaced with *RXI* in the consolidation table name.

Consolidation is the process of getting new or modified records from a source schema and updating the consolidation schema with those records. Consolidation is carried out by periodic execution of a scheduled job in each InForm schema that contributes to the consolidation schema. Execution is done through the DBMS_JOB facility. Each source schema is consolidated on its own schedule.

There is no master job that oversees or coordinates the consolidation of all the source InForm schemas. You can choose to consolidate different InForm schemas at different times, and with different intervals between consolidations. However, the more spread out consolidations are, the wider the time period represented by the records in the consolidation schema. So it is recommended that you schedule consolidation jobs to fall within a small time window. For details on scheduling, see Section 2.1.5, "Adjusting Scheduling of Consolidation Jobs".

When the Consolidation job executes for a particular source schema, it does the following:

For each source table from which OHSCDA extracts data,

- Identify what records have been created or modified in this table since the previous consolidation
- For each modified source record, drop the corresponding record in the consolidation table
- Insert all new and modified records in the Consolidation schema table, setting their StudyGUID, and modification timestamps

The procedures that does this work reside in each InForm Reporting and Analysis Schema, they are placed there as part of the process of preparing that schema for consolidation.

Preparation for consolidation also creates an access account in the database holding the source schema. This account is the one that reads the Reporting views, and writes to the consolidation tables. This access account is named CDAxxx, where xxx is the Study name.

All movement of data is done by a pull from the Reporting and Analysis Database to the Consolidation database. This ensures that there is no path by which someone who can connect to the consolidation schema is able to modify the InForm database.

The instructions that follow tell how to do the initial setup of the consolidation schema (this also enrolls the first Study to be consolidated as part of the process) and then how to set up each additional InForm study so that it becomes a contributor to the Consolidation schema.

2.1.2 Prerequisites

- 1. Download the OHSCDA patch (as required) from My Oracle Support (https://support.oracle.com). For information on the required patch, see Figure 2–1.
- **2.** Unzip the downloaded patch.
- **3.** Copy and unzip the Inform Consolidate.zip file to a server from which it is possible to access all InForm source database that contain studies that are to be consolidated and also to access the database in which the consolidation schema is located.

2.1.3 Setting up Consolidation Schema

This section describes the steps to create the Consolidation Schema. As part of the process, it enrolls an initial InForm study as a source to be consolidated.

Note:

- If you are using the OHSCDA 3.0.0.2 patch, you must set up both the source trial and destination consolidation databases.
- If you are using the OHSCDA 3.0.0.4 patch, you must only set up the destination consolidation database.

2.1.3.1 Preparing TNSNAMES Files on Source Trial and Destination Consolidation **Database Servers**

If one does not already exist, create a TNSNAMES.ORA entry for the Consolidation database instance on each InForm database server that contains a study that is to be consolidated.

Note: This is not essential. If you prefer not to create the TNSNAMES entries, you can provide the complete connection string instead of the TNS name when specifying remote databases below.

On the consolidation schema database server, add a TNSNAMES.ORA entry for each source schema database.

2.1.3.2 Creating a Consolidation Management Root Directory

On consolidation schema database server, create a root directory for managing the files needed to configure and log consolidation of the source schemas.

We will refer to this directory as <\$ConsolidationMgmtRoot>.

If source trial and destination consolidation databases are in the same network, then a single <\$ConsolidationMgmtRoot> is sufficient. Else, replicate the directory in both the servers.

During the setup of the source trial database, use TrialCDA and logs folders. And, during the setup of the destination consolidation database, use DestCDA and logs folder.

2.1.4 Initiating Consolidation of InForm Studies

This section describes the steps you must follow to prepare a source schema for consolidation and perform the initial execution of consolidation of that schema. Subsequent consolidations occurs automatically at an interval you define as part of the preparation described here.

The setup and configuration is performed in the following two phases for each study trial:

- Section 2.1.4.1, "Source Trial Database Configuration"
- Section 2.1.4.2, "Destination Consolidation Database Configuration"

2.1.4.1 Source Trial Database Configuration

Follow the instructions in this section for each InForm study that is to be consolidated for consumption by OHSCDA.

- On either source trial or destination consolidation schema database server, based on the network architecture as described in Section 2.1.3.2, "Creating a Consolidation Management Root Directory", create the <Study-name> folder within <\$ConsolidationMgmtRoot>/ to hold the files for consolidation of this study.
- 2. Copy the following folders from Inform_Consolidate.zip into <\$ConsolidationMgmtRoot>/<Study-name>/:
 - TrialCDA
 - Logs

- **3.** Set your current directory to the <\$ConsolidationMgmtRoot>/<Study-name>/TrialCDA/ directory.
- 4. Edit CONFIGTRIALCDA.sql to set specific values of configuration parameters for this study. Make the following changes:

Table 2–1 Source Trial Configuration Parameters

Parameter	Set value to
Slash	Use \ for Windows or / for Linux
trial_name	The name of the study.
inform_release	For InForm 4.6, enter R46. For later releases, enter R55.
trial_tnsname	Name in the local TNSNAMES file of the source database for the study. Can also supply entire TNS entry for the source database as a string.
trial_schema_user	Username of the InForm source schema.
trial_schema_password	Password of the InForm source schema.
trial_ro_user	This is OHSCDA reporting object schema user name and is defaulted to trail_name prefixed with 'cda'.
trial_ro_password	This is OHSCDA reporting object schema password and is defaulted to trail_name prefixed with 'cda'. You can change this password.
DDS_SCHEMA_OWNER	This is OHSCDA reporting object schema user name. This value must be same as the value you have entered for trial_ro_user.
trial_dba_user	Database username who has the dba privileges.
trial_dba_password	Password for database username.
trial_ts	Name of a tablespace in the source schema database to which the access account for this study will be given access.
trial_ts_temp	Name of a temporary tablespace in the source schema database to which the access account for this study will be given access.

- **5.** Save the file.
- **6.** From the SQLPlus prompt, execute the following:

@Setup_Trial_CDA.sql

7. Navigate to the <\$ConsolidationMgmtRoot>/<Study-name>/Logs directory to review the log.

If any errors are found, make necessary corrections and re-execute Setup_Trial_ CDA.sql.

2.1.4.2 Destination Consolidation Database Configuration

Follow the instructions in this section for each InForm study that is to be consolidated for consumption by OHSCDA.

On the consolidation schema database server, based on the network architecture as described in Section 2.1.3.2, "Creating a Consolidation Management Root Directory", create the <Study-name> folder within <\$ConsolidationMgmtRoot>/

if the destination consolidation database is not in the same network as the source trial database.

The <Study-name> folder holds the files for consolidation of this study.

2. Copy the following folders from Inform_Consolidate.zip into <\$ConsolidationMgmtRoot>/<Study-name>/:

> **Note:** Do not copy the Logs folder if the destination consolidation database is in the same network as the source trial database.

- **DestCDA**
- Logs
- Set your current directory to the <\$ConsolidationMgmtRoot>/<Study-name>/DestCDA directory.
- 4. Edit CONFIGDESTCDA.sql to set specific values of configuration parameters for this study. Make the following changes:

Note: If you prefer not to create the TNSNAMES entries, you can provide the complete connection string instead of the TNS name when specifying the remote databases below.

The trial parameters mentioned in Table 2–2 must match with the ones defined in Table 2–1.

Table 2–2 Destination Configuration Parameters

Parameter	Set value to		
Slash	Use \ for Windows or / for Linux		
Parameters for configuring the source	schema and database		
trial_name	The name of the study.		
inform_release	For InForm 4.6, enter R46. For later releases, enter R55.		
trial_tnsname	Name in the local TNSNAMES file of the source database for the study. Can also supply entire TNS entry for the source database as a string.		
trial_schema_user	Username of the InForm source schema.		
trial_global_name	Global name of the source schema database. You can get this by connecting to the source schema and running the following query:		
	SELECT * FROM GLOBAL_NAME		
trial_ro_user	This is OHSCDA reporting object schema user name and is defaulted to trail_name prefixed with 'cda'.		
trial_ro_password	This is OHSCDA reporting object schema password and is defaulted to trail_name prefixed with 'cda'. You can change this password.		

Parameters for configuring the target schema and database

Table 2–2 (Cont.) Destination Configuration Parameters

Parameter	Set value to		
dest_tnsname	Name of the target database in the TNSNAMES file on the source database server for the study. Can also supply entire TNS entry for the target database as a string.		
dest_schema_owner	This defaults to and is same as trial_ro_user parameter.		
dest_schema_password	This defaults to and is same trial_ro_password parameter.		
dest_consolidated_user	This is the consolidation schema username. Default is RXI_INFORM.		
dest_consolidated_password	This is the consolidation schema password. Defaults is RXI_INFORM. You can change this password.		
dest_dba_user	Database username who has dba privileges on the consolidation database.		
dest_dba_password	Password for the database username on the consolidation database.		
dest_ts	Name of a tablespace in the target schema database to which the consolidation and access account will be given access.		
dest_ts_temp	Name of a temporary tablespace in the target schema database to which the consolidation and access account will be given access.		
consolidate_job_interval	The interval between executions of the program to consolidate new and modified data from this study. A value of 1 results in an interval of one day. A value of $1/24$ results in an interval of one hour.		

- **5.** Save the file.
- **6.** From the SQLPlus prompt, execute the following:

@Setup_Dest_CDA.sql

7. Navigate to the <\$ConsolidationMgmtRoot>/<Study-name>/Logs directory to review the log.

If any errors are found, make necessary corrections and re-execute Setup_Dest_ CDA.sql.

2.1.5 Adjusting Scheduling of Consolidation Jobs

As mentioned earlier, initial consolidations, especially of large source schemas, should be done in isolation to avoid contention for resources. But once the initial consolidation of a schema is done, subsequent consolidations of that schema are incremental and involve smaller numbers of records (incremental consolidations are limited to new or modified Subjects, CRFs, and Queries accumulated since the previous consolidation).

Once initial consolidation of an InForm trial source schema is complete, it is useful to adjust the scheduling of its incremental consolidations so that they start near to the time of other incremental consolidation of other source schemas. The closer in time consolidations start across studies, the smaller the time period represented in the consolidation schema.

To adjust the time when a study's consolidation job executes, perform the following steps:

- Connect as the InForm trial source schema owner.
- Determine the consolidation job ID using the following query for InForm 4.6:

```
select job
from user_jobs
where what like 'REFRESH_PROCS.REFRESH_WITH_STREAMS_DELAY%';
```

or the following query for InForm 5.5, 6.0, and 6.1:

```
select job
from user_jobs
where what = 'CDA_PROCS.CONSOLIDATE';
```

3. Change the time for the next execution of the job by using the dbms_job.next_date procedure.

Note: The next_date parameter is an Oracle date-time in which you can specify both the date and time for the next execution.

Remember to follow the call with a commit. For example,

```
begin
dbms_job.next_date (
 job => 12345,
 next_date => to_date('21-AUG-2013@01:01:00','DD-MON-YYYY@HH24:MI:SS')
end;
commit;
```

This causes job 12345 to next be executed at 1:01 AM on 21-AUG-2013.

You can also change the interval between subsequent executions of the job using the dbms_job.interval procedure. Set the interval parameter to the string 'SYSDATE + <desired-interval>', replacing <desired-interval> with the number of days, or the fraction of a day to elapse before the next execution.

```
begin
dbms_job.interval(
 job => 12345,
 interval => 'SYSDATE + 1/2'
);
end;
commit:
```

This sets the interval between executions of job 12345 to half a day or every 12 hours.

2.2 Running the OHSCDA Installer

The basic OHSCDA components are installed using the Oracle Universal Installer. The installer gathers all the information about the database connectivity, data mart, Informatica repository by presenting a sequence of prompt screens and then installs the components accordingly.

Note: Same installer can be used for both install modes - fresh installation or upgrading from previous version.

Important: Make sure that both the Oracle Database client and the Informatica client are available on the same system where you plan to execute the installer.

Perform the following steps to install the OHSCDA application on Windows:

- 1. Extract the contents of the media pack into a temporary directory (For example, C:\ocda_temp).
- **2.** Navigate to the \install directory under the extracted temporary folder.
- 3. Double-click the setup exe file to launch the Oracle Universal Installer with the Welcome screen.

The installer will take you through a series of screens having fields. Attend to the Installer's prompts. The following sections describe each Installer screen, and the required action.

The Welcome screen provides information about the Oracle Universal Installer.

4. Click Next.

The Specify Home Details screen appears.

5. Enter the name of the installation and path where all the staged files from the Installer get copied to the local system. This is also the location from where Installer executes the database script.

Example Name: OCDAHome1

Path: C:\OCDA

6. Click Next.

The Install or Upgrade OHSCDA screen appears.

- **7.** Select one of the following options:
 - **Install**: If you want to make a fresh installation of OHSCDA.
 - **Upgrade**: If you want to upgrade an existing OHSCDA 3.2 instance.
- **8.** Click **Next**.

The OCDA Data Warehouse Details screen appears.

- **9.** Enter values in the following fields:
 - **Database Host Name**
 - **Database Port No**
 - **Database Service Name**
 - System Password
 - **Default Tablespace Name**
 - **Temporary Tablespace Name**
 - **Enable National Language Support (NLS)**

- 10. Click Next.
- **11.** Enter values in the following fields:

Note: The password must be alphanumeric and can contain only "_" or "#" special character.

- OCDA Warehouse Schema (RXI) Password
- OCDA Warehouse Schema (RXI) Confirm Password (Not applicable for Upgrade)
- OCDA RPD (RXI_RPD) Password
- OCDA RPD (RXI_RPD) Confirm Password (Not applicable for Upgrade)
- 12. Click Next.

The Informatica PowerCenter Details screen appears.

- **13.** Enter values in the following fields:
 - **Informatica Repository Name**
 - Informatica Domain Name
 - **Informatica Host Name**
 - **Informatica Repository Port Number**
 - Informatica Username with Admin Privileges
 - Informatica Password for Admin User
 - Confirm Informatica Password for Admin User
- 14. Click Next.

The Informatica PowerCenter Client Home Directory screen appears.

- 15. Specify Informatica PowerCenter client Home directory. For example: C:\Informatica\9.6.1\clients\PowerCenterClient\client
- 16. Click Next.
- 17. Verify the details provided in the Summary screen.
- 18. Click Install.

Note: You must record the log file path that appears on the bottom of the screen for future reference.

2.3 Source-specific Procedures

This section describes procedures you must perform for certain OHSCDA sources. Please review each section and determine if it applies to the source(s) you are using for OHSCDA. If the section does apply, carry out the procedure. If the section is optional, decide whether it is appropriate for your requirements and act accordingly.

2.3.1 Handling Deletions of Source Records

Different source applications handle the deletion of records in different ways. Oracle Clinical allows deletions of records in a way that avoids orphans, and has built-in

auditing of these deletions. Siebel Clinical also allows deletions, properly cascading to maintain referential integrity, but does not have built-in auditing of deletions. InForm does not provide any means to hard-delete records in its transactional database. So, it does not need to be concerned neither with maintaining integrity in the face of deletions nor with auditing deletions.

2.3.1.1 Handling Deletions in Oracle Clinical

OHSCDA's ETL consults the audit trails to determine if source records have been deleted, and then soft-deletes those records in the warehouse.

2.3.1.2 Handling Deletions in Siebel Clinical

OHSCDA provides a feature to manage hard deletion of records in Siebel Clinical. Create triggers in the source system to handle deletion of records.

- 1. Navigate to the following temporary staging location where the OHSCDA installer copies the installation files:
 - <OCDA_HOME>\OCDA_Common\OCDA_Common_Scripts\Delete_Script
- **2.** Connect to the Siebel Clinical schema and run the ocda_sc_del_trigger.sql script delivered with OHSCDA. This script creates the triggers on tables provided as input. The following are the tables in Siebel Clinical for which OHSCDA 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
 - S ORG EXT
 - S_PTCL_VER_LS
 - S_ASSESS

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, and S_CL_SUBJ_LS. The tables names that you provide can only be a subset of the tables listed above.

Note: When you delete 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. Set the values of the OHSCDA.DELETE_FLOW and DELETE_FLOW variables to **Y** while executing the load plan in ODI.
- **4.** Execute the ETLs. For information, see *Oracle Clinical Development Analytics* Administrator's Guide.

The Siebel Clinical related SDE mappings read 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.

2.3.1.3 Handling Deletions in InForm

Since no deletions are supported through the InForm UI, OHSCDA makes no provision for detecting them. If you need to delete records from an InForm transactional table at the backend and want the OHSCDA warehouse to be consistent with that change, you must identify the warehouse records that arose from the InForm records that are to be deleted. Also, you must remove them from the consolidation schema and the warehouse.

2.3.2 (Optional) Handling Deletion or Deactivation of a Study

Depending on how you use OHSCDA, you may prefer to have reports that give information only on currently active studies. If so, and if source studies are completed or possibly deleted, the recommended approach for removing such a study from OHSCDA is to use OHSCDA's access control capability. That is, enable Study and Study-site access controls, and then exclude the study and its sites from the list of studies (and sites) available to OHSCDA users. Aside from being simpler than identifying and deleting records from the warehouse, this approach has the advantage of being reversible if the decision to remove the study from the warehouse is reconsidered.

If you do not wish to use access control to avoid display of deactivated or deleted studies, there is an alternative solution. In the OHSCDA warehouse, every dimension table, and every base fact table, has a column named DELETE_FLG. OHSCDA's OBIEE repository is designed to treat records where DELETE_FLG equals 'Y' as if they were not present in the warehouse. OHSCDA's SIL also disregards records with DELETE_FLG = 'Y' when calculating values for aggregate tables (those with names ending with _A). So you can cause records to be effectively removed from the warehouse by setting their DELETE_FLG to 'Y'. Thus, if a study has been removed from a source database, you could identify all dimension and fact records for that study, and set their DELETE_FLG to 'Y'. This causes them to be forever invisible to OHSCDA's analytics.

This solution could be used, but only with great caution, for a study that is considered to be deactivated, but still remains in the source. Once marked as deleted, warehouse records for a study will not get their DELETE_FLG set back to 'N', but OHSCDA creates new warehouse records if there are changes or additions in the source for that study. So, if the study is truly inactive in the source, soft-deleting warehouse records for the study by setting DELETE_FLG to 'Y' will work. But any changes or additions to the study would cause new records to be loaded into the warehouse for the study, and it would re-appear in analyses.

2.3.3 (Optional) Fine-tuning of Oracle Clinical Settings

To optimize source system integration with OHSCDA, perform the following steps:

- For OC 4.6, navigate to Informatica Relational Connections > OC Connection **Object** > **Attribute** in Informatica Workflow Manager.
- **2.** Set Connection Environment SQL value as:

For Oracle Database 11.2.0.2:

alter session set optimizer_features_enable='11.2.0.2'

For Oracle Database 11.2.0.3:

alter session set optimizer_features_enable='11.2.0.3'

For Oracle Database 11.1.0.7:

```
alter session set optimizer_features_enable='11.1.0.7'
```

- **3.** Create the following indexes on their respective Oracle Clinical tables:
 - Function based index on DISCREPANCY_ENTRIES NVL ("MODIFICATION_TS", "CREATION_TS")
 - Function based index on DISCREPANCY ENTRY REVIEW HIST NVL ("NEXT_STATUS_TS", "CREATION_TS")
 - Function based index on RECEIVED_DCIS NVL ("MODIFICATION_TS", "RECEIVED_DCI_ENTRY_TS")
 - Function based index on RECEIVED_DCMS NVL ("MODIFICATION_TS", "RECEIVED_DCM_ENTRY_TS")

2.4 Setting Up Relational Connections in the Informatica Workflow for **OHSCDA**

For each database that will be a source for extracting data into the OHSCDA warehouse, perform the following steps to create a Relational Connection in the Informatica Workflow Manager:

- 1. Launch the Informatica PowerCenter Workflow Manager.
- 2. Connect to the repository where OHSCDA Informatica mappings are imported.
- **3.** Select **Connections**, and then select **Relational** to display the Relational Connection Browser.
- **4.** Click **New** to display the Select Subtype dialog.
- Select **Oracle** as database type, and then click **OK**. The Connection Object Definition dialog box is displayed with options for the selected database platform.
- **6.** Enter values in the following fields according to the Source database connection:
 - **Connection Name**: Enter the logical connection name.
 - User Name: Enter the user name that can access source data (For example, rxa_des for Oracle Clinical.)
 - **Password**: Enter the database password.
 - **Connection String**: Enter the Connect string for connecting to the database.
 - **Code Page**: Enter UTF-8 encoding of Unicode.

Note: These values will also be required in setting up DAC. Make note of them to ensure that you enter the same during DAC setup.

The TNS entry for all your source and target databases must be added on Informatica Server.

Note: You must repeat steps 1 through 4 for each required source connection.

2.5 Preparing a DAC Repository for OHSCDA

- Create a new DAC repository, as an Administrator.
- Unzip OCDA_HOME\oracle.pharma.ocda.standard\DAC_Code\CDA_ Warehouse.zip onto the computer where you will run DAC client.
- Import the OHSCDA Warehouse Application metadata.
 - Start the Data Warehouse Administration Console (DAC) client.
 - b. From the Tools menu select DAC Repository Management, and then select Import.
 - **c.** Click **Change import/export folder** to navigate to the folder where you unzipped CDA_Warehouse.zip in step 2 of Section 2.5, "Preparing a DAC Repository for OHSCDA".
 - **d.** Click **OK** to display the Import dialog box.
 - Select the following categories of metadata you want to import: **Logical**, Overwrite log file, and User Data. Deselect the User and System check boxes.
 - Select **CDA_Warehouse** application in the ApplicationList.
 - Click **OK**.
 - Enter the verification code and click **Yes** in the secondary window that is displayed after the import.
 - You can inspect the import log in \${DAC_INSTALL_DIR}\log\import.log to verify if import is successful.
- Configure Informatica Repository Service in DAC.
 - Navigate to the **Setup** view, and then select the **Informatica Servers** tab.
 - **b.** Click **New** to display the Edit tab below or select an existing Informatica server from the list.
 - If you are configuring a new installation, the Informatica Servers tab will be empty. If you are upgrading an existing installation, the Informatica Servers tab might contain existing Informatica servers.
 - Enter values in the following fields:
 - Name: Enter the Logical name for the Informatica server (for example, INFA_REP_SERVER).
 - Type: Select Repository.
 - **Hostname**: Enter the host system name where Informatica Server is installed.
 - Server Port: Enter the port number of the Informatica Server or Informatica Repository Server used to listen to requests.
 - **Login**: Enter the Informatica user login for the Admin user.
 - **Password**: Enter the Informatica Repository password.
 - Repository Name: Enter the Informatica Repository Name.

- **d.** Test the connection to verify the settings.
- **e.** Click **Save** to save the details.
- Configure Informatica Integration Service in DAC.

Note: Make sure that you use the same Login and Password that you have used in setting up Informatica.

Click New to display the Edit tab below or select an existing Informatica server from the list.

If you are configuring a new installation, the Informatica Servers tab will be empty. If you are upgrading an existing installation, the Informatica Servers tab might contain existing Informatica servers.

- Enter values in the following fields:
 - Name: Enter the Logical name for the Informatica server (for example, INFA_SERVER).
 - Type: Select Informatica.
 - Service Name: Enter the Informatica Integration service name associated with the Informatica repository added in Step 5.
 - **Domain**: Enter the Informatica domain name.
 - Login: Enter the Informatica Repository user login (Admin User).
 - **Password**: Enter the Informatica Repository password.
 - **Repository Name**: Enter the Informatica Repository Name.
- Test the connection to verify the settings.
- **d.** Click **Save** to save the details.
- Configure source databases (Oracle Clinical, Siebel Clinical, and InForm) and the target database (the OHSCDA warehouse). For each database with which DAC will interact for OHSCDA, perform the following steps:
 - Navigate to the **Setup** view, and then select the **Physical Data Sources** tab.
 - Click **New** to display the Edit tab below or select an existing database connection from the list.
 - Enter values in the following fields:
 - Name: Enter the logical name for the database connection.
 - Type: Select Source when you create the database connection for a transactional (OLTP) database. Select Warehouse when you create the database connection for a data warehouse (OLAP) database.
 - **Connection Type**: Select a connection type for the database connection.
 - Service Name: Enter the Data Mart database service name.
 - Table Owner: Enter the Data Mart schema name.
 - **Table Owner Password**: Enter the Data Mart schema password.
 - DB Host: Enter the Data Mart host name.
 - Port: Enter the Data Mart host port.

- **Dependency Priority**: Enter the user-defined priority of the data source.
- Data Source Number: Enter the user-defined number of the data source. Make sure the number is less than 100.
- Num Parallel Indexes Per Table: Enter a number to specify how many indexes are to be created in parallel.
- **d.** Test the connection to verify the settings.
- **e.** Click **Save** to save the details.

Note: By Default, Oracle supports Data Source Number 1, 2, and 3 for Oracle Clinical, Siebel Clinical, and InForm respectively.

The logical Names of the connections in DAC must be same as the connection names created in Informatica Workflow Manager.

OHSCDA Warehouse connection must be the same as provided during OHSCDA installation.

Table 2–3 Sample of Data Source Table W_RXI_DATASOURCE
--

ROW_ WID	DATASOURCE _NUM_ID	DATASOURCE_ NAME	DELETE_ FLG	INTEGRATION_ID	ENTERPRISE _ID	INFORM_STUDY_GUID
1	1	ORACLE_ CLINICAL	N	ORACLE_ CLINICAL	0	-
2	2	SIEBEL_ CLINICAL	N	SIEBEL_CLINICAL	0	-
3	3	INFORM	N	INFORM	0	{FA5BCD87-B858-4F08-8BF 8-1914B61C9DDF}
4	101	INFORM_1	N	INFORM_1	0	{CC0DBD73-FA40-4943-BD B3-60752C1A2732}

Note: If InForm is one of your sources and auto merge feature is not used, then the column INFORM_STUDY_GUID must be populated with studyguid for the corresponding InForm study.

You can find the distinct studyguid from table RXI_STUDYVERSIONS in the consolidation database.

From DAC, the value passed for the data source parameter is always 3. Since we have one consolidation DB which holds all study data, the guid, when auto merge is set to N, helps resolving individual data source numbers.

If auto merge is set to Y, then a single entry for data source 3 for INFORM is sufficient and INFORM_STUDY_GUID need not be populated. In this case, the consolidation DB is considered as single source and duplicates are handled by auto merge.

- **7.** Perform the following steps to modify the value for data sources:
 - Navigate to the **Execute** view, and then select the **Execution Plans** tab.
 - b. If Oracle Clinical, Siebel Clinical, and InForm are your source systems, select **CDA - Complete Warehouse** from the list.

If Oracle Clinical is your only source system, select CDA - Oracle Clinical Warehouse from the list.

If Siebel Clinical is your only source system, select CDA - Siebel Clinical Warehouse from the list.

If InForm is your only source system, select CDA - InForm Warehouse from the list.

- **c.** Click **Connectivity Parameters** subtab in the bottom pane.
- **d.** For each row with TYPE equal to DATASOURCE, in the **Value** field, select the appropriate Physical Data Source Name from the drop-down list for the field.
- **e.** Select a relevant value from the list for each of the data sources.
- f. Click Save.

Note: If Oracle Clinical, Siebel Clinical, and InForm are your source systems, use CDA - Complete Warehouse.

- If Oracle Clinical is your only source system, use CDA Oracle Clinical Warehouse.
- If Siebel Clinical is your only source system, use CDA Siebel Clinical Warehouse.
- If InForm is your only source system, use CDA InForm Warehouse.

2.5.1 DAC Configurable Parameters

Navigate to Design View and select CDA_Warehouse container from drop down. On Source System Parameters tab set values as mentioned in Table 2-4.

Table 2–4 lists the DAC configurable parameters.

Table 2–4 DAC Configurable Parameters

Parameter	Description
START_TS	This is the last refresh time of the source tables minus prune days. (@DAC_SOURCE_PRUNED_REFRESH_TIMESTAMP)
END_TS	Current Execution Plan's actual start time adjusted to source database time zone minus prune days. (@DAC_ETL_START_TIME_FOR_SOURCE)
DATASOURCE_NUM_ID	The ID associated with every source system. The default ID is 1 for Oracle Clinical, 2 for Siebel Clinical, and 3 for InForm.
ENTERPRISE_ID	The ID associated for every tenant. The default value is 0.
DELETE_FLOW	The default value is N and set it to Y if Deletes have to be captured in the data warehouse.
EMAIL_SUFFIX	You can provide domain name as a suffix to username. For example: oracle.com
Prune Days	This is used for setting the END_TS for incremental load.
MPI_AUTHFILE	Currently, not in use.
MPI_USER	Currently, not in use.

Table 2–4 (Cont.) DAC Configurable Parameters

Parameter	Description
AUTO_MERGE_FLG	This is used to enable or disable auto-merge.
	Y: Enables auto-merge
	■ N: Disables auto-merge
\$OutputFile_OCDA	Currently, not in use.
\$DBConnection_SP_OLAP	Currently, not in use.
\$DBConnection_OLAP	Currently, not in use.

2.6 Emplacing the OHSCDA Help and Image Files

You will be using help.zip and images.zip files in this section.

2.6.1 Placement of Files for Oracle WebLogic Managed Server

You need to manually deploy OHSCDA's help and images files on Oracle WebLogic Managed Server. Perform the following steps:

- **1.** Navigate to <MIDDLEWARE_ HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1\analyticsRes\ in Oracle WebLogic Server and create the *s_ocda* folder.
- **2.** Copy the help.zip file from <OCDA_HOME>\OCDA_Common\Reporting\Help to <MIDDLEWARE HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1\analyticsRes\s_ocda\.
- 3. Unzip the help.zip file such that the contents of help.zip (all htm files and folders) are placed under the <MIDDLEWARE_ HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1\analyticsRes\s_ocda\help\ folder.
- 4. Move customMessages and sk_ocda folders from <MIDDLEWARE_ HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1\analyticsRes\s_ocda\help\ to <MIDDLEWARE
 - HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1\analyticsRes\.
- **5.** Replace the tags within the UI tag with the following tags in instanceconfig.xml, present in <MIDDLEWARE_
 - HOME>\instances\instance1\config\OracleBIPresentationServicesComponent\c oreapplication_obips1:

<DefaultSkin>ocda</DefaultSkin> <DefaultStyle>ocda</DefaultStyle>

- **6.** Copy the Images.zip file from <OCDA HOME>\OCDA Common\Reporting\Images to <MIDDLEWARE_ HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1\analyticsRes\s_ocda.
- 7. Unzip the Images.zip file such that the contents of Images.zip (all image files and folders) are placed under the <MIDDLEWARE HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices

Component\coreapplication_obips1\analyticsRes\s_ocda\images\ folder.

8. Launch Oracle WebLogic Administration Server Console. The following shows the format of the URL:

https://<hostname>.<domain>:<port>/console

The Oracle WebLogic Server Administration Console screen appears.

- **9.** Log on to Oracle WebLogic Server Administration Console as an Administrator.
- **10.** In the left pane of the Administration Console, select **Deployments**.
- 11. In the left pane, click Lock & Edit.
- **12.** In the right pane, click **Install**.

This opens the Install Application Assistant.

- **13.** In the **Path** field, browse to <MIDDLEWARE HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1.
- **14.** Select **analyticsRes** and click **Next**.
- **15.** Select **Install this deployment as an application** and click **Next**.
- 16. In Available targets for analyticsRes, under Clusters, select bi servers on which you want to deploy OHSCDA.
- **17.** Click **Next**.
- 18. Select I will make the deployment accessible from the following location option for <MIDDLEWARE

HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1\analyticsRes\ in the Source accessibility section.

19. Click Finish.

analyticsRes appears in the Deployment section.

- **20.** Click **Activate Changes**.
- **21.** Select **analyticsRes** in the Deployment section.
- 22. Click Start to view the list and select Servicing all requests. The Start Application Assistant page is displayed.
- **23.** In the content pane of the new page, click **Yes** to start the selected deployment.
 - State of analyticsRes should be Active after this deployment. You may confirm the same on Deployments page.
- **24.** Log out from Oracle WebLogic Server Administration Console.
- 25. Log on to Oracle Enterprise Manager Fusion Middleware Control. The following shows the format of the URL:

https://<hostname>.<domain>:<port>/em

- **26.** Restart the BI components.
- **27.** Log on to OBIEE and verify the branding and help links on the dashboards.

See Also:

Oracle WebLogic Server Documentation Library

2.7 Preparing the OBIEE Web Catalog and Repository for OHSCDA

- Copy the OCDA.zip file from <OCDA_HOME>\OCDA_ Common\Reporting\Webcat to the OBIEE server.
- 2. Copy the OCDA.rpd file from <OCDA HOME>\OCDA Common\Reporting\RPD to the OBIEE server.
- **3.** Unzip the OCDA.zip file in the <MIDDLEWARE_ HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1\catalog directory.
- 4. In the Oracle BI Administration Tool, select **File**, then **Open**, and then **Offline**.
- Navigate to the OCDA.rpd file, and then click **Open**.

Password: Admin123

- 6. Click OK.
- 7. In the Oracle BI Administration Tool, select File, and then select Change Password.
- **8.** Enter the current (old) password.
- Enter the new password and confirm it.
- **10.** Confirm the new password.
- **11.** Click **OK**.
- **12.** Modify the connection pools in the RPD as following:
 - In the physical layer, expand the OCDA Data Warehouse node and double-click the **Connection Pool** object.
 - The Connection Pool dialog box appears.
 - **b.** In the following string under the **Data source name** field, replace <hostname>, <port_number>, and <SID_NAME> with the host name, port number, and SID name of the database:

```
(DESCRIPTION=(ADDRESS=(PROTOCOL=tcp)(HOST=<hostname>)(PORT=<port_
number>))(CONNECT_DATA=(SID=<SID_NAME>)))
```

- **c.** Change the username to the username of the OHSCDA read-only DW RPD schema name.
- **d.** Change the password to the password of the OHSCDA read-only DW RPD schema password.
- e. Click **OK**.
- Reconfirm the password.
- Click **OK**.
- **h.** In the physical layer, expand the OCDA Data Warehouse node and double-click the **OCDA_CP_InitBlocks** object.
- Repeat steps b through h.
- **13.** From the File menu, select **Save** to save the rpd.
- **14.** Click **Yes** for Do you wish to check global consistency?
- **15.** Click **Close** in the Consistency Check Manager.

- 16. Click Save.
- **17.** Click **File** and then click **Close**.
- 18. Click File and then click Exit.
- **19.** Open NQSConfig.INI found at <MIDDLEWARE HOME>instances\<instancename>\config\OracleBIServerComponent\coreappli cation obis1.
- **20.** Set EVALUATE_SUPPORT_LEVEL =2.
- **21.** Restart the Oracle WebLogic Server and BI components.
- 22. Open the Fusion Middleware Control URL from the system where you saved the OCDA.rpd in step 13. The URL includes the name of the host and the port number assigned during the installation. The following shows the format of the URL:

https://<hostname>.<domain>:<port>/em

The login page appears.

Note: Oracle recommends that you enable HTTPS on middle-tier computers that are hosting the Web services, since otherwise the trusted user name and password that are passed can be intercepted.

- 23. Enter the Oracle Fusion Middleware administrator user name and password and click **Login**.
- **24.** Expand the **Business Intelligence** folder and select the **coreapplication** node.

The Overview page displays the current status of the system, by providing information about current availability, performance, and issues identified within the BI domain. The Overview page also enables you to start and stop Oracle Business Intelligence.

- **25.** Navigate to the Repository tab of the Deployment page.
- 26. Click Lock and Edit Configuration.
- 27. Click Close.
- 28. In the Upload BI Server Repository section, click Browse and navigate to select the RPD.
- 29. Enter the RPD password in the Repository Password and Confirm Password fields.
- **30.** In the BI Presentation Catalog section, enter the following (as applicable) in the **Catalog Location** field:

<MIDDLEWARE

HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServices Component\coreapplication_obips1\catalog\OCDA

- **31.** Click **Apply**, and then click **Activate Changes**.
- **32.** Return to the Business Intelligence Overview page and click **Restart**.
- **33.** Log on to OBIEE Analytics. The following shows the format of the URL:

https://<hostname>.<domain>:<port>/analytics

If you get an authentication error, perform the following steps:

a. Stop all opmn processes. Execute the following command from <MIDDLEWARE HOME>\instances\<instancename>\bin:

opmnctl stopall

b. Update the NQSConfig.INI file found at <MIDDLEWARE_ HOME>instances\<instancename>\config\OracleBIServerComponent\corea pplication_obis1.

FMW_UPDATE_ROLE_AND_USER_REF_GUIDS = YES;

By default, the value of FMW_UPDATE_ROLE_AND_USER_REF_GUIDS is No.

c. Add the following tag within the catalog tag in the instanceconfig.xml file found at <MIDDLEWARE_

HOME>\instances\instance1\config\OracleBIPresentationServicesCompone nt\coreapplication_obips1:

<UpdateAccountGUIDs>UpdateAndExit/UpdateAccountGUIDs>

d. Start all opmn processes. Execute the following command from <MIDDLEWARE HOME>\instances\<instancename>\bin:

opmnctl startall

e. Stop all opmn processes. Execute the following command from <MIDDLEWARE_HOME>\instances\<instancename>\bin:

opmnctl stopall

Update the NQSConfig.INI file found at <MIDDLEWARE_ HOME>instances\<instancename>\config\OracleBIServerComponent\corea pplication_obis1.

FMW_UPDATE_ROLE_AND_USER_REF_GUIDS = NO;

g. Delete the following tag within the catalog tag in the instanceconfig.xml file found at <MIDDLEWARE_

HOME>\instances\instance1\config\OracleBIPresentationServicesCompone nt\coreapplication_obips1:

<UpdateAccountGUIDs>UpdateAndExit/UpdateAccountGUIDs>

h. Start all opmn processes. Execute the following command from <MIDDLEWARE_HOME>\instances\<instancename>\bin:

opmnctl startall

2.8 Configuring HTML 5

- 1. Navigate to <MIDDLEWARE HOME>\instances\<instancename>\config\OracleBIPresentationServicesCompo nent\coreapplication_obips1.
- **2.** Open instanceconfig.xml.
- **3.** Within the <Views> tag, add the following:

<Charts>

<DefaultWebImageType>html5</DefaultWebImageType> </Charts>

4. Restart the presentation services.

2.9 Configuring Maps

To configure maps:

1. Go to

http://www.oracle.com/technetwork/middleware/bi-foundation/obieesamples archive-2026956.html.

- 2. Navigate to **OBIEE 11.1.1.3 Sample Application**.
- 3. Click Documentation Downloads.
- Click Save.
- Unzip the folder.
- **6.** Open SampleApp_Deploy_Instructions_825.pdf and see section 6 *Deploying* SampleApp Mapviewer Content for instructions on how to configure maps.

2.10 Creating Security Groups and Application Roles for OHSCDA

2.10.1 Creating Groups

Perform the following steps to create groups:

- Launch Oracle WebLogic Server Administration Console.
- In Oracle WebLogic Server Administration Console, select Security Realms from the left pane and click the realm you are configuring. For example, **myrealm**.
- **3.** Select **Users and Groups** tab, then **Groups**.
- 4. Click New.
- **5.** In the **Create a New Group** page, provide the following information:
 - Name: Enter the name of the group. Group names are case insensitive but must be unique. See online help for a list of invalid characters.
 - (Optional) **Description**: Enter a description.
 - **Provider**: Select the authentication provider from the list that corresponds to the identity store where the group information is contained. DefaultAuthenticator is the name for the default authentication provider.
- 6. Click OK.

The group name is added to the Groups table.

7. Repeat step 4 through 6 with the following values:

Table 2-5 Security Group Parameters

Name	Description	Provider
OCDA-CRA	(Optional)	DefaultAuthenticator
OCDA-DataManager	(Optional)	DefaultAuthenticator
OCDA-ExecutiveManager	(Optional)	DefaultAuthenticator
OCDA-RegionManager	(Optional)	DefaultAuthenticator
OCDA-StudyManager	(Optional)	DefaultAuthenticator
OCDA-WebcatAdim	(Optional)	DefaultAuthenticator

2.10.2 Creating Application Roles

Perform the following steps to create groups:

Log on to Oracle Enterprise Manager Fusion Middleware Control. The following shows the format of the URL:

https://<hostname>.<domain>:<port>/em

- 2. From the target navigation pane, open Business Intelligence.
- Right-click **coreapplication**, then select **Security** > **Application Roles**.

The Application Roles page is displayed.

Click Create to display the Create Application Role page. Complete the fields as follows:

In the **General** section:

- **Role Name** Enter the name of the Application Role.
- (Optional) Display Name Enter the display name for the Application Role.
- (Optional) **Description** Enter a description for the Application Role.
- In the **Members** section, click **Add**.
 - In the dialog box that appears, click the blue button to search. The list containing all groups is displayed.
 - **b.** Select a group from the list.
 - c. Click OK.
- Repeat steps 4 and 5 for all the Roles listed in the following table:

Application Roles and Groups Table 2–6

Role Name	Description	Groups
OCDA-CRA	(Optional)	OCDA-CRA
OCDA-DataManager	(Optional)	OCDA-DataManager
OCDA-ExecutiveManager	(Optional)	OCDA-ExecutiveManager
OCDA-RegionManager	(Optional)	OCDA-RegionManager
OCDA-StudyManager	(Optional)	OCDA-StudyManager
OCDA-WebcatAdim	(Optional)	OCDA-WebcatAdim

7. Click OK.

Creating Securit	v Groups	and Apr	olication	Roles fo	r OHSCDA

Upgrading Oracle Health Sciences Clinical Development Analytics

This chapter provides procedures that explain how to upgrade OHSCDA. It includes the following section:

Section 3.1, "Upgrading from OHSCDA 3.2 to OHSCDA 3.2.1"

3.1 Upgrading from OHSCDA 3.2 to OHSCDA 3.2.1

The Installer automates the upgrade of the warehouse and the Informatica mappings. After running the Installer, to complete the upgrade from OHSCDA 3.2 to OHSCDA 3.2.1, perform the steps mentioned in Section 3.1.3, "Performing Next Steps" through Section 3.1.5, "Executing the ETL Load Plan".

Note: OHSCDA 3.2 is certified on Oracle Database 12.1.0.2.0. For detailed certification information, see Finding Certification Information.

3.1.1 Prerequisites

For information, see Section 1.2, "Technology Stack and System Requirements".

3.1.2 Running the Installer in Upgrade Mode

1. Run the OHSCDA Installer as described in Section 2.2, "Running the OHSCDA Installer".

3.1.3 Performing Next Steps

After running the installer, perform the following steps:

- To enable multi-byte character support, execute the Database Migration Assistant for Unicode (DMU) on the CDA warehouse schema.
 - For information, see Oracle Database Migration Assistant for Unicode Guide.
- 2. Merging your RPD and Webcatlog Changes into the 3.2.1 Oracle-supplied OBIEE RPD and Webcatlog.

If you are upgrading from OHSCDA 3.2 and have modified the OBIEE repository or Web Catalog, merge your changed objects into the 3.2.1 Oracle-supplied OBIEE RPD and Webcatlog.

For more information, refer to Oracle® Fusion Middleware Metadata Repository Builder's Guide for Oracle Business Intelligence Enterprise Edition 11g.

- **3.** Perform the steps listed in the following sections:
 - Section 2.6, "Emplacing the OHSCDA Help and Image Files"
 - Section 2.7, "Preparing the OBIEE Web Catalog and Repository for OHSCDA"

Note: If you are upgrading from OHSCDA 3.2 and have modified the OBIEE repository or Web Catalog, merge these objects. For more information, refer to Oracle® Fusion Middleware Metadata Repository Builder's Guide for Oracle Business Intelligence Enterprise Edition 11g.

3.1.4 Importing the OHSCDA Warehouse Application Metadata into the DAC Repository

- Unzip <ocda_home>\ oracle.pharma.ocda.standard\DAC_Code\CDA_ Warehouse.zip into a local folder.
- Start the Data Warehouse Administration Console (DAC) client.
- 3. From the Tools menu, select DAC Repository Management, and then select Import.
- 4. Click Change import/export folder to navigate to the folder where you unzipped CDA_Warehouse.zip.
- Click **OK** to display the Import dialog box.
- 6. Select the following categories of metadata you want to import: **Update existing** records, Logical, Overwrite log file, and User Data.
- **7.** Deselect the **System** check box.
- **8.** Click **OK**.
- **9.** Enter the verification code and **OK** in the secondary window that is displayed after the import.
- **10.** Select one of the following execution plan and click **Build**.
 - CDA Complete Warehouse

Note: Complete warehouse has InForm source extractions ETL added.

- CDA Siebel Clinical Warehouse
- CDA Oracle Clinical Warehouse
- CDA InForm Warehouse
- **11.** Execute the execution plan which you built in the earlier step.

Note: The execution plan must be same as what you had executed in OHSCDA 3.2.

3.1.5 Executing the ETL Load Plan

For information, see Oracle Health Sciences Clinical Development Analytics Administrator's Guide.

Upgrading from OHSCDA 3.2 to OHSCDA 3.2.	2 to OHSCDA	3.2 t	OHSCDA	from	Jparadina	l
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