Oracle® Health Sciences Clinical Development Analytics

Installation and Configuration Guide for Oracle Data Integrator

Release 3.2

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Oracle Health Sciences Clinical Development Analytics Installation and Configuration Guide for Oracle Data Integrator, Release 3.2

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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
- Conventions on page ix

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 Data Integrator 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. 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 Enterprise Edition, Oracle Clinical, Siebel Clinical, Oracle Health Sciences InForm, and Oracle Data Integrator documentation sets:

Oracle Business Intelligence Enterprise Edition Documentation

The Oracle Business Intelligence Suite Enterprise Edition (OBIEE) documentation set includes:

- Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition
- Oracle Fusion Middleware Metadata Repository Builder's Guide for Oracle Business Intelligence Enterprise Edition
- Oracle Fusion Middleware System Administrator's Guide for Oracle Business Intelligence Enterprise Edition
- Oracle Fusion Middleware Scheduling Jobs Guide for Oracle Business Intelligence Enterprise Edition
- Oracle Fusion Middleware Security Guide for Oracle Business Intelligence Enterprise Edition
- Oracle Fusion Middleware Developer's Guide for Oracle Business Intelligence Enterprise Edition
- Oracle Fusion Middleware Integrator's Guide for Oracle Business Intelligence Enterprise Edition

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

Oracle Data Integrator (ODI) Documentation

The Oracle Data Integrator documentation set includes:

- Release Notes for Oracle Data Integrator
- Understanding Oracle Data Integrator
- Administering Oracle Data Integrator
- Installing and Configuring Oracle Data Integrator
- Application Adapters Guide for Oracle Data Integrator
- Developing Knowledge Modules with Oracle Data Integrator
- Connectivity and Knowledge Modules Guide for Oracle Data Integrator
- Oracle Data Integrator Tool Reference
- Java API Reference for Oracle Data Integrator
- Oracle Data Integrator Online Help

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 on page vii.

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 Fusion Middleware 12c (12.1.3.0.0) Infrastructure
- Oracle Data Integrator (ODI) 12.1.3

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.

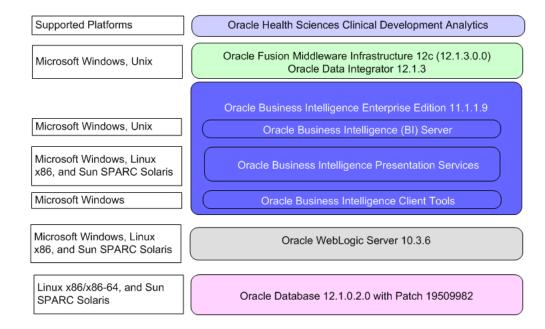
Table 1–1 System Requirements References

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 Fusion Middleware 12c (12.1.3.0.0) Infrastructure	Oracle Fusion Middleware Documentation Library		
Oracle Data Integrator 12.1.3	Oracle Data Integrator Documentation Library		

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.

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:

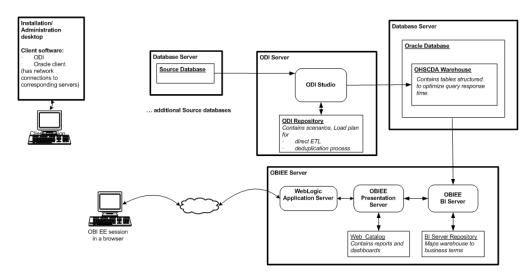
- Oracle Clinical (OC) 4.6 or 5.1
- Siebel Clinical Trial Management System (SC) 8.1.1.15
- Oracle Health Sciences InForm 4.6, 5.5, 6.0, or 6.1

1.3 Installing the Prerequisite Software

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

Figure 1–2 Sample Topology

OHSCDA 3.2 for ODI: Components and Servers



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

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 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 Data Integrator 12.1.3

Note: Oracle recommends that the Java heap size where you install ODI Studio must be minimum of 2 GB.

For more information, see Oracle Data Integrator Installation Guide.

- If you implement multi-byte character support for OHSCDA, set the following:
 - Operating System Level: Ensure that the system that hosts ODI 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

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 Oracle Data Integrator
- Configuring Data Sources for OHSCDA
- **Executing the ETL Load Plans**
- Emplacing the OHSCDA Help and Image Files
- Preparing the OBIEE Web Catalog and Repository for OHSCDA
- 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.

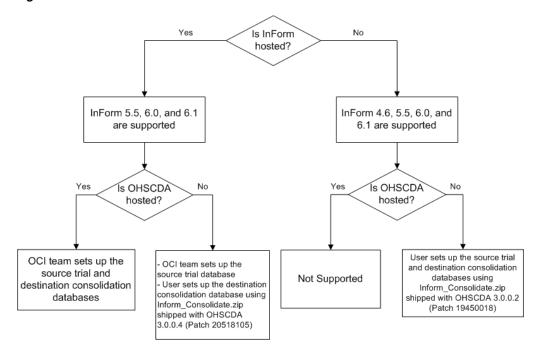


Figure 2–1 OHSCDA InForm Consolidation Installation Scenarios

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 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 destination 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 the destination 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 trial database for the study. Can also supply entire TNS entry for the source trial 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.** Connect to SQLPlus. Execute the following command:

sqlplus /nolog

7. From the command prompt, execute the following command:

@Setup_Trial_CDA.sql

8. 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.

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.
- 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.

Destination Configuration Parameters Table 2–2

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 trial database for the study. Can also supply entire TNS entry for the source trial 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'.		

Table 2–2 (Cont.) Destination Configuration Parameters

Parameter	Set value to		
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 destina	tion schema and database		
dest_tnsname	Name of the destination database in the TNSNAMES file on the source database server for the study. Can also supply entire TNS entry for the destination 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 destination schema database to which the consolidation and access account will be given access.		
dest_ts_temp	Name of a temporary tablespace in the destination 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.** Connect to SQLPlus. Execute the following command:

sqlplus /nolog

7. From the command prompt, execute the following command:

@Setup_Dest_CDA.sql

8. 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 a 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 and data mart by presenting a sequence of prompt screens, and then installs the components accordingly.

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

Note: This note is applicable if you have Oracle Clinical 5.1 as a source.

Oracle Clinical (OC) installer includes a script that can configure OC such that when you log in as <schema_username>, you are able to access tables from other schema.

If you are not able to access tables from other schema when logged in as <schema_username>, then you must search the OC installer for the script and execute it with <schema_username> login.

For OC 5.1, the script is named as *CreateDropPublicSynonym* and you can execute it using the following command:

exec opa_ddl.CreateDropPublicSynonym('PROGRAM_SUBSTANCES','PROGRAM_ SUBSTANCES');

For any other OC version or if you do not find the script in the OC installer, contact the support team.

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

- Extract the contents of the media pack into a temporary directory.
- Navigate to the \install directory under the extracted media pack folder.
- Double-click the setup.exe file.

The Oracle Universal Installer: Welcome screen appears.

The Welcome screen provides information about the Oracle Universal Installer. The following function buttons appear on the installation screens:

- **Deinstall Products**: To view and deinstall the components already installed on the system. This button appears only on the Welcome screen.
- **About Oracle Universal Installer**: To view the version number of the installer you are using.
- **Help**: To access detailed information about the functionality of each screen.
- **Installed Products**: To view components already installed on the system. You can deinstall a component, if necessary.
- **Next**: To proceed to the next screen.
- **Cancel**: To cancel the installation process and exit the installer.
- Click Next.

The Select a Product to Install screen appears.

- **5.** Perform the following steps:
 - Set up the OHSCDA data warehouse. For information on how to do so, see Section 2.2.1, "Setting Up the Data Warehouse".
 - **b.** Set up the source system for OHSCDA. For information on how to do so, see Section 2.2.2, "Setting Up the Source System".

2.2.1 Setting Up the Data Warehouse

- 1. Select the Oracle Health Sciences Clinical Development Analytics Standard **3.2.0.0.0** option to setup the OHSCDA data warehouse.
- 2. Click Next.

The Specify Home Details screen appears.

3. 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: OCDA_HOME

Path: <Drive>:\OCDA HOME

4. Click Next.

The Install or Upgrade OHSCDA screen appears.

- **5.** 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 3.1.1 instance.
- 6. Click Next.

The OHSCDA ODI Data Warehouse Details screen appears.

This screen collects all the information regarding the OHSCDA ODI data warehouse.

- **7.** Enter values in the following fields:
 - Data Warehouse Connect String: Connection of the database where OHSCDA Data Warehouse will be deployed.

Note: Make sure the connect string matches the value in the tnsnames.ora file.

- **Database Host Name**
- **Database Port No**
- **Database Service Name**
- **Default Tablespace Name**
- **Temporary Tablespace Name**
- Data Warehouse Schema Name
- Click Next.

The OHSCDA ODI Data Warehouse screen appears.

9. Enter and confirm the system password of the database where OHSCDA ODI Data Warehouse will be deployed.

10. Click Next.

The OHSCDA ODI Data Warehouse Schema Details screen appears.

- **11.** Enter and confirm the OHSCDA ODI Data Warehouse schema password.
- 12. Click Next.

The OHSCDA ODI Data Warehouse RPD Details screen appears.

- **13.** Enter values in the following fields:
 - DW RPD Schema Name
 - DW RPD Default Tablespace Name
 - DW RPD Temporary Tablespace Name
- 14. Click Next.

The OHSCDA ODI Data Warehouse RPD Schema Details screen appears.

- **15.** Enter and confirm the OHSCDA ODI Data Warehouse RPD schema password.
- Click Next.

The OHSCDA ODI Data Warehouse Work Details screen appears.

- **17.** Enter values in the following fields:
 - Data Warehouse Work Schema Name
 - **Default Tablespace Name**
 - **Temporary Tablespace Name**
- 18. Click Next.

The OHSCDA ODI Data Warehouse Work screen appears.

- 19. Enter and confirm the OHSCDA ODI Data Warehouse work password for OHSCDA database.
- 20. Click Next.

The National Language Support screen appears.

- **21.** Select one the following options:
 - **Yes**: If the source data contains data in English and any other language.
 - **No**: If the source data contains data only in English.
- 22. Click Next.

The Do you wish to install OCDA Source System? screen appears.

- **23.** Perform one of the following:
 - If you want to set up source systems, select the **Yes** option and click **Next**.

The ODI Sources screen appears. Perform steps through step 7 in Section 2.2.2, "Setting Up the Source System".

Else, select the **No** option and click **Next**.

The Summary screen appears.

24. Click Install.

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

The End of Installation screen appears.

25. Click Exit.

2.2.2 Setting Up the Source System

- 1. Select the **ODI Source System 3.2.0.0.0** option to setup the source system for OHSCDA.
- 2. Click Next.

The Specify Home Details screen appears.

3. 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: OCDA_HOME Path: <Drive>:\OCDA HOME

Click Next.

The ODI Sources screen appears.

5. Select the **Yes** option.

Note: The **No** option is for internal purpose.

6. Click **Next**.

The Install or Upgrade screen appears.

- **7.** Select one of the following options:
 - **Install**: If you want to make a fresh installation of source system for OHSCDA.
 - **Upgrade**: If you want to upgrade existing source systems for OHSCDA from 3.1.1 instance.

The Select the Source System to install screen appears.

- Click Next.
- Select one or multiple source system from the following list:
 - Siebel Clinical
 - Oracle Clinical
 - InForm

Note: Hold **CTRL** to select more than one source system.

10. Click Next.

The selected source systems appear.

11. Click OK.

Note: Depending on the selected source system, the installer displays the required screens. For example, if you select Oracle Clinical as the source system, the Oracle Clinical Source System Details screen appears.

- **12.** Enter values in the following fields:
 - Connect String for OC Source Server
 - **OC Source Server Host Name**
 - **OC Source Server Port No**
 - **OC Source Server Service Name**
 - **Oracle Clinical Source Schema Name**
- 13. Click Next.
- 14. Enter and confirm the system password of the database where Oracle Clinical source system is deployed.
- 15. Click Next.
- **16.** Enter and confirm the Oracle Clinical source schema password.
- 17. Click Next.

The OCDA Oracle Clinical Source System Details screen appears.

- **18.** Enter values in the following fields:
 - OCDA OC Source Schema Name: This schema has the read-only grant on the required source tables.
 - **OCDA OC Default Tablespace Name**
 - OCDA OC Temporary Tablespace Name
- Click Next.

The Oracle Clinical Source System Details screen appears.

- **20.** Enter and confirm the OCDA Oracle Clinical source schema password.
- 21. Click Next.

The OHSCDA Oracle Clinical Work Schema Details screen appears.

- **22.** Enter values in the following fields:
 - OCDA OC Work Schema Name
 - OCDA OC Work Default Tablespace Name
 - **OCDA OC Work Temporary Tablespace Name**
- 23. Click Next.
- **24.** Enter and confirm the OHSCDA Oracle Clinical work schema password.
- 25. Click Next.
- 26. Click Install.

Note: Similar set of screens are displayed for other selected source systems. Perform steps through 12 for Siebel Clinical and/or InForm source systems.

2.3 Source-specific Procedures

This section describes procedures you may, or 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.

- 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:

- **1.** Create the following indexes:
 - 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 Oracle Data Integrator

- Create Master and Work repository in ODI.
- Set up Java EE Agent

Note: For information, see *Oracle Data Integrator Installation Guide*.

3. Launch ODI Studio from the system where OHSCDA is installed and connect to work repository.

Note: Before importing the topology, make sure the Global context is not defined.

If the Global context is defined, perform the following steps to delete the Global context:

- 1. Click the **Topology** tab.
- Under the Context section, right-click **Global** and select **Delete**. The Confirmation dialog box appears.
- Click **Yes**.
- **4.** Click the **Designer** tab.
- Select **Import** from the **Designer Menu** drop-down list.

The Import Selection dialog box appears.

- **6.** Select **Import the Topology**.
- 7. Click OK.

The Import Topology dialog box appears.

- Select **Synonym mode INSERT_UPDATE** from the **Import Mode** drop-down list.
- Select the **Import From a Zip File** option.
- 10. Select the OCDA_Topology.zip file in the OCDA home directory. For example, <Drive>:\<OCDA HOME>\OCDA ODI\ODI Code\OCDA Topology.zip.
- **11.** Click **Open**.
- 12. Click OK.

Note: After the import process is complete, you can save the log file for future reference.

- 13. Click Close.
- **14.** Select **Import** from the **Designer Menu** drop-down list.

The Import Selection dialog box appears.

- **15.** Select Import the Work Repository.
- **16.** Click **OK**.

The Import Work Repository dialog box appears.

- 17. Select Synonym mode INSERT_UPDATE from the Import Mode drop-down list.
- **18.** Select the **Import From a Zip File** option.
- 19. Select the OCDA_Work_Repository.zip file in the OCDA home directory. For example, <Drive>:\<OCDA_HOME>\OCDA_ODI\ODI_Code\OCDA_Work_ Repository.zip.
- 20. Click Open.
- 21. Click OK.

Note: After the import process is complete, you can save the log file for future reference.

- 22. Click Close.
- **23.** Click the **Topology** tab.
- **24.** Under the Physical Architecture section, expand **Agents**.
- **25.** Double-click the OracleDIAgent physical agent.

The OracleDIAgent tab opens.

- **26.** Enter the host name and port number to point to an agent of current environment and save the changes.
- **27.** Click **Test** to test the changes.

The OracleDIAgent Test Successful dialog box must appear.

28. Click OK.

- **29.** Make changes to the physical data server connections to point to the required source and target schemas. Perform the following steps to do so:
 - Click the **Topology** tab.
 - Expand **Physical Architecture**.
 - Navigate to **Technologies** > **Oracle**.
 - Right-click and open the data server DS_OCDA_DWH.
 - In **Definition**, change **Instance/dblink** (**Data Server**) to point to the OHSCDA DWH work schema.
 - In **Connection**, change **User** and **Password** to the user and password which were specified for the DWH work schema while installation.
 - In JDBC, select the Oracle JDBC Driver as the JDBC Driver and change **JDBC URL** to point to the DWH work schema.
 - h. Expand the data server **DS_OCDA_DWH**.
 - Right-click the DS_OCDA_DWH.<CDA_DWH_SCHEMA> physical schema and select **Open**.
 - In **Definition**, update **Schema** (**Schema**) to the OHSCDA DWH schema and **Schema (Work Schema)** to the work schema name.
 - Save the configuration.
 - Steps m through t are to update Oracle Clinical source connection. Similarly, update source connections for other required sources (Siebel Clinical and InForm).
 - Right-click and open the data server **DS_OCDA_OracleClinical**.
 - In **Definition**, change **Instance/dblink** (**Data Server**) to point to the Oracle Clinical work schema.
 - **o.** In **Connection**, change **User** and **Password** to the user and password which were specified for the Oracle Clinical work schema while installation.
 - In JDBC, select the Oracle JDBC Driver as the JDBC Driver and change **JDBC URL** to point to the Oracle Clinical work schema.
 - Expand the data server **DS_OCDA_OracleClinical**.
 - Right-click the DS_OCDA_OracleClinical.<OCDA_OC_SRC_SCHEMA> physical schema and select **Open**.
 - In **Definition**, update **Schema** (**Schema**) to the OHSCDA Oracle Clinical source schema and Schema (Work Schema) to the work schema name.
 - Save the configuration.

Note: If InForm is your source and Auto merge is enabled:

- Expand the data server **DS_OCDA_InForm**.
- Right-click the DS_OCDA_InForm.<INFORM_CONSOLICATION_ **SCHEMA>** physical schema and select **Open**.
- In **Definition**, update **Schema** (**Schema**) to the InForm consolidation schema and Schema (Work Schema) to the work schema name.
- **30.** Log on to the WebLogic console where ODI Agent is configured.

- **31.** Expand **Services** and click **Data Sources**.
- **32.** Under the Configuration tab, click odiMasterRepository to open.
- **33.** Click the Connection Pool tab
- **34.** Set value for the following properties:
 - Initial Capacity =100
 - Maximum Capacity=3600
 - Minimum Capacity =100
- 35. Click Save.

Note: Perform the same changes to the odiWorkRepository datasource.

2.5 Configuring Data Sources for OHSCDA

Note: By default, Oracle supports data source number 1, 2, and 3 for Oracle Clinical, Siebel Clinical, and InForm respectively.

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.

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 database is considered as single source and duplicates are handled by auto merge.

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

2.6 Executing the ETL Load Plans

Execute the following ETL load plans (as required) which are shipped with OHSCDA:

- CDA Complete Warehouse with Dedup: This is used to load warehouse with one or all of the three source systems (Oracle Clinical, Siebel Clinical, and InForm).
- **CDA- Inform Automerge:** This is used to load warehouse only from Inform data source and only when automerge feature is needed.

For information on how to execute the load plan, see Oracle Health Sciences Clinical Development Analytics Administrator's Guide.

2.7 Emplacing the OHSCDA Help and Image Files

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

2.7.1 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:

- 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.
- 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>
```

- 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.
- 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. On 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

2.8 Preparing the OBIEE Web Catalog and Repository for OHSCDA

You will be using OCDA.zip and OCDA.rpd files in this section.

 To deploy InForm web catalog, copy OCDA.zip from <OCDA_HOME>\OCDA_ Common\Reporting\Webcat\Inform_Webcat to OBIEE server.

- Else, copy OCDA.zip from <OCDA_HOME>\OCDA_ Common\Reporting\Webcat to OBIEE server.
- 2. Copy OCDA.rpd files from <OCDA_HOME>\OCDA_Common\Reporting\RPD to OBIEE server.
- **3.** Unzip OCDA.zip 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, and then click **Open**.

Password: Admin123

- 6. Click OK.
- 7. In the Oracle BI Administration Tool, select File, then Change Password.
- 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**.
- 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 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
- **29.** Enter the RPD password in **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:

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

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

f. 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

2.9 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.
- 4. Click Save.
- **5.** Unzip the folder.
- Open SampleApp_Deploy_Instructions_825.pdf.

7. For instructions on how to configure maps, see section 6 *Deploying SampleApp* Mapviewer Content.

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.
- Select **Users and Groups** tab, then **Groups**.
- Click New.
- 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.
- Click **OK**.

The group name is added to the Groups table.

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

Table 2-4 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 roles:

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.

4. 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.
- **5.** In the **Members** section, click **Add**.
 - **a.** 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:

Table 2–5 Application Roles and Groups

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 Security	Groups	and Appl	lication	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 3.1.1 Standard to OHSCDA 3.2"

Note: You must upgrade OHSCDA 3.1 to OHSCDA 3.1.1 before upgrading to OHSCDA 3.2.

3.1 Upgrading from OHSCDA 3.1.1 Standard to OHSCDA 3.2

The Installer automates the upgrade of the warehouse. After running the Installer, to complete the upgrade from OHSCDA 3.1.1 to OHSCDA 3.2, perform the steps mentioned in Section 3.1.3, "Performing Next Steps" through Section 3.1.6, "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.
- Perform the steps listed in Section 3.1.4, "Migrating Data from OHSCDA 3.1.1 Standard to OHSCDA 3.2".

- **3.** Perform the steps listed in the following sections:
 - Section 2.7, "Emplacing the OHSCDA Help and Image Files"
 - Section 2.8, "Preparing the OBIEE Web Catalog and Repository for OHSCDA"

Note: If you are upgrading from OHSCDA 3.1.1 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 Release 1.

- Section 2.9, "Configuring Maps"
- Section 2.10, "Creating Security Groups and Application Roles for OHSCDA"

3.1.4 Migrating Data from OHSCDA 3.1.1 Standard to OHSCDA 3.2

Perform the following steps to migrate data from OHSCDA 3.1.1 Standard to OHSCDA 3.2:

1. Log on to the OHSCDA warehouse schema.

```
<warehouse_user>/<warehouse_password>@<SID>
```

- **2.** Create the following database links:
 - oc_dblink for Oracle Clinical source

Example (OC):

```
create database link <oc_dblink>
connect to <oc_username> identified by <oc_password>
using
'(DESCRIPTION=(ADDRESS=(PROTOCOL=tcp) (HOST=<hostname>) (PORT=<portno>)))(CONN
ECT_DATA=(SID=<sidname>)))';
```

sc_dblink for Siebel Clinical source

Example (SC):

```
create database link <sc_dblink>
connect to <sc_username> identified by <sc_password>
using
'(DESCRIPTION=(ADDRESS=(PROTOCOL=tcp) (HOST=<hostname>) (PORT=<portno>)))(CONN
ECT_DATA=(SID=<sidname>)))';
```

if_dblink for InForm source

Example (IF):

```
create database link <if_dblink>
connect to ocda_if_src identified by ocda_if_src
using
'(DESCRIPTION=(ADDRESS=(PROTOCOL=tcp) (HOST=<hostname>) (PORT=<portno>)) (CONN
ECT_DATA=(SID=<sidname>)))';
```

- **3.** Connect to the warehouse schema.
- **4.** Execute the following driver scripts in the sequence as mentioned:

Note: Driver scripts are available in <OCDA_HOME>\OCDA_ ODI\Database\Migration_Scripts3.1.1_to_3.2.zip.

- drv_Migrate_CDA311_to_32_SC_Set1.sql
- drv_Migrate_CDA311_to_32_SC_Set2.sql
- drv_Migrate_CDA311_to_32_IF.sql
- drv_Migrate_CDA311_to_32_OC.sql
- drv_Migrate_CDA311_to_32_Cleanup.sql
- Connect to the Siebel Clinical source schema and execute ocda_sc_del_trigger.sql located at <OCDA_HOME>\OCDA_Common\OCDA_Common_Scripts\Delete_ Script.

3.1.5 Upgrading ODI Topology and Work Repository

Note: Before upgrading the ODI work repository and topology to OHSCDA 3.2, back up the complete topology and work repository.

For information on how to back up, see *Oracle Data Integrator User's* Guide.

1. Perform smart export of customizations you want to apply.

Note: Before exporting the customizations, Oracle recommends that you organize all customizations into a single folder with a unique object name. For example, prefix the object name with *cust*_.

For information on how to smart export, see Oracle Data Integrator User's Guide.

- **2.** Upgrade the topology and work repository to OHSCDA 3.2. To do so, perform steps 3 through 24 in Section 2.4, "Setting Up Oracle Data Integrator".
- **3.** Perform smart import of the customizations which you had exported in earlier
- Update the load plan with required customizations.

3.1.6 Executing the ETL Load Plan

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