

**Oracle® Health Sciences Clinical Development
Analytics**

Installation and Configuration Guide

Release 3.1 for Standard Configuration

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Oracle® Health Sciences Clinical Development Analytics Installation and Configuration Guide, Release 3.1 for Standard Configuration

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Preface

This guide provides information about how to install Oracle Health Sciences Clinical Development Analytics Standard Configuration (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 Standard Configuration. 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 Standard Configuration 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.
<i>italic</i>	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 is provided in the media pack, with the exception of Oracle Data Integrator (ODI). It consists of the following products:

- Oracle Database 12.1.0.1.0
- Oracle WebLogic Server 10.3.6
- Oracle Business Intelligence Enterprise Edition (OBIEE) 11.1.1.7.0
- Oracle Fusion Middleware 12c (12.1.3.0.0) Infrastructure
- Oracle Data Integrator 12.1.3

Note: ODI is not part of the media pack. You need to acquire its license separately.

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

Table 1–1 System Requirements References

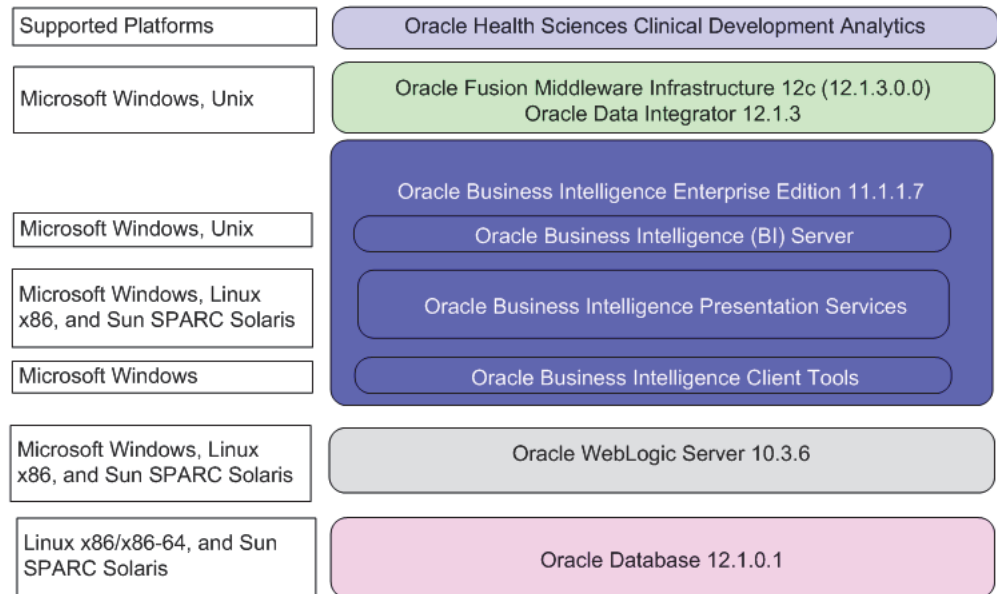
Product	Reference
Oracle Database 12.1.0.1.0	<i>Database Installation Guide for <platform></i>
Oracle WebLogic Server 10.3.6	<i>Oracle WebLogic Server Documentation Library</i>
Oracle Business Intelligence Enterprise Edition (OBIEE) 11.1.1.7.0	<i>System Requirements and Supported Platforms for Oracle Business Intelligence Suite Enterprise Edition</i> <i>Oracle Business Intelligence Infrastructure Installation and Configuration Guide</i>
Oracle Fusion Middleware 12c (12.1.3.0.0) Infrastructure	<i>Oracle Fusion Middleware Documentation Library</i>
Oracle Data Integrator 12.1.3	<i>Oracle Data Integrator Documentation Library</i>
Other Technology Stack Components	My Oracle Support/Certifications

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 (Standard Configuration).
- You may select to install each product on a different server, if required. The OHSCDA (Standard Configuration) 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 Standard Configuration 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.
- If you plan to implement deduplication, you may create the schemas for the OHMPI Master Indexes either in the OHSCDA warehouse database, or in a separate database specific to OHMPI Master Indexes. If you are using OHMPI for purposes in addition to OHSCDA, Oracle recommends that the Master Index schemas be created in a database specific to OHMPI.
- OHMPI Projects need to be deployed on Oracle WebLogic Server. You may select to deploy the OHMPI projects on the same Oracle WebLogic Server used for OBIEE by creating a new WebLogic domain running on different port (which is not used by any other domains) or you may choose to deploy the projects on a different Oracle WebLogic Server instance.

Figure 1–1 Oracle Health Sciences Clinical Development Analytics Technology for Standard Configuration



For more information about certifications, see [Finding Certification Information](#).

1.2.1 Supported Browsers

OHSCDA supports those Internet browsers supported by OBIEE. For a list of the browsers supported by OBIEE, refer to *Oracle Fusion Middleware System Administrator's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)*.

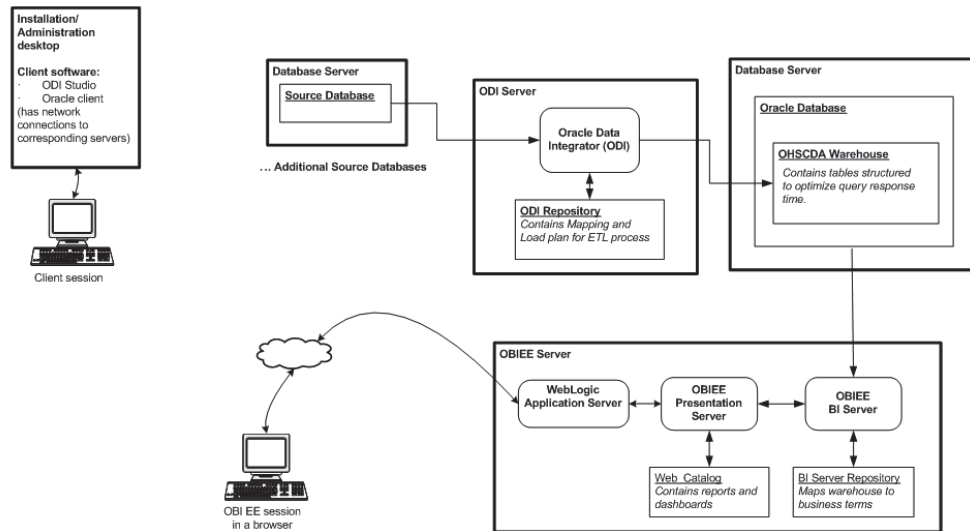
1.2.2 Source Systems

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

- Oracle Clinical (OC) 4.5.3.23 or higher
- Siebel Clinical Trial Management System (SC) 8.0.x or 8.1.1
- Oracle Health Sciences InForm 4.6 and later

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 3.1 (Standard Configuration):
Components and Servers**

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

- Install Oracle Database 12.1.0.1.0.

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

- Install Oracle Business Intelligence Enterprise Edition (OBIEE) 11.1.1.7.0 with the following components:
 - Oracle Business Intelligence Server (Supported only 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

For more information, see *Oracle Data Integrator Installation Guide*.

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.

Installing Oracle Health Sciences Clinical Development Analytics Standard Configuration

This chapter describes the OHSCDA Installation tasks that you must complete and includes the following sections:

- [Section 2.1, "Installing Oracle Health Sciences Clinical Development Analytics Standard Configuration"](#)
- [Section 2.2, "Adding InForm Studies to the OHSCDA Warehouse"](#)
- [Section 2.3, "Source-specific Procedures"](#)

2.1 Installing Oracle Health Sciences Clinical Development Analytics Standard Configuration

This section describes the OHSCDA Installation tasks that you must complete.

OHSCDA application installation consists of the following components:

- [Running the OHSCDA Installer](#)
- [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](#)

2.1.1 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.

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

1. Extract the contents of the media pack into a temporary directory.
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.
4. Review the Oracle Universal Installer Welcome screen and click **Next**.

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

 - **Deinstall Products:** Deinstall individual components or the entire product. This button appears only on the Welcome screen.
 - **About Oracle Universal Installer:** View the version number of the installer in use.
 - **Help:** Access detailed information about the functionality of each screen.
 - **Installed Products:** View currently installed products or deinstall the entire product or components.
 - **Next:** Proceed to the next screen.
 - **Cancel:** Cancel the installation process and exit the installer.
5. Click **Next**.

The Select a Product to Install screen appears.
6. Perform the following steps:
 - a. Set up the OHSCDA data warehouse. For information on how to do so, see [Section 2.1.1.1, "Setting Up the Data Warehouse"](#)
 - b. Set up the source system for OHSCDA. For information on how to do so, see [Section 2.1.1.2, "Setting Up the Source System"](#)

2.1.1.1 Setting Up the Data Warehouse

1. Select the **Oracle Health Sciences Clinical Development Analytics Standard ODI 3.1** option to setup the OHSCDA data warehouse.
2. Click **Next**.

The Specify Home Details screen appears.
3. The OHSCDA Home path is the location 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: <Drive>:\CDA_INSTALL
4. Click **Next**.

The OHSCDA Data Warehouse Details screen appears.
This screen collects all the information regarding the OHSCDA data warehouse.
5. Enter values in the following fields:
 - **Connect String of the Warehouse:** Connection of the database where OHSCDA Data Warehouse will be deployed.

- **Default Tablespace Name**
 - **Temporary Tablespace Name**
 - **Data Warehouse Schema Name**
6. Click **Next**.

The OHSCDA Data Warehouse screen appears.
 7. Enter and confirm the System Password of the database where OHSCDA Data Warehouse will be deployed.
 8. Click **Next**.

The OHSCDA ODI Data Warehouse Schema Details screen appears.
 9. Enter and confirm the **OHSCDA Warehouse Schema Password**.
 10. Click **Next**.

The OHSCDA ODI Data Warehouse RPD Details screen appears.
 11. Enter values in the following fields:
 - **DW RPD Schema Name**
 - **DW RPD Default Tablespace Name**
 - **DW RPD Temporary Tablespace Name**
 12. Click **Next**.

The OHSCDA ODI Data Warehouse RPD Schema Details screen appears.
 13. Enter and confirm the **OHSCDA Data Warehouse RPD Schema Password**.
 14. Click **Next**.

The OHSCDA ODI Data Warehouse Work Details screen appears.
 15. Enter values in the following fields:
 - **Data Warehouse Work Schema Name**
 - **Default Tablespace Name**
 - **Temporary Tablespace Name**
 16. Click **Next**.

The OHSCDA ODI Data Warehouse Work screen appears.
 17. Enter and confirm the **Date Warehouse Work Password for OHSCDA Database**.
 18. Click **Next**.

The Do you wish to install OCDA Source System? screen appears.
 19. Perform one of the following:
 - If you want to setup source systems, select the **Yes** option and click **Next**.

The Select the Source System to install screen appears. Perform step 5 in [Section 2.1.1.2, "Setting Up the Source System"](#)
 - Else, select the **No** option and click **Next**.

The Summary screen appears. Perform steps through step 20.
 20. Verify setting => details provided in the Summary screen.
 21. Click **Install**.

At the completion of the installation, you can inspect the installation as displayed at the end of the installation screen.

2.1.1.2 Setting Up the Source System

1. Select the **ODI Source System 3.1** option to setup the source system for OHSCDA.
2. Click **Next**.

The Specify Home Details screen appears.

3. The OHSCDA Home path is the location 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: <Drive>:\CDA_INSTALL

4. Click **Next**.

The Select the Source System to install screen appears.

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

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

6. Click **Next**.

The selected source systems appears.

7. 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.

8. Enter values in the following fields:

- **Connect String for OC Source Server**
- **Oracle Clinical Source Schema Name**

9. Click **Next**.

10. Enter and confirm the System Password of the database where Oracle Clinical source system is deployed.

11. Click **Next**.

12. Enter and confirm the **Oracle Clinical Source Schema Password**.

13. Click **Next**.

The OCDA Oracle Clinical Source System Details screen appears.

14. 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**
15. Click **Next**.

The Oracle Clinical Source System Details screen appears.
16. Enter and confirm the **OCDA Oracle Clinical Source Schema Password**.
17. Click **Next**.

The OHSCDA Oracle Clinical Work Schema Details screen appears.
18. Enter values in the following fields:
 - **OCDA OC Work Schema Name**
 - **OCDA OC Work Default Tablespace Name**
 - **OCDA OC Work Temporary Tablespace Name**
19. Click **Next**.
20. Enter and confirm the **OHSCDA Oracle Clinical Work Schema Password**.

Note: Similar set of screens are displayed for other selected source systems. Perform steps 5 through 20 for Siebel Clinical and/or InForm source systems.

2.1.2 Setting Up Oracle Data Integrator

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

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

3. Launch ODI Studio and connect to work repository.
4. Click the **Designer** tab.
5. 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.
8. Select **Synonym mode INSERT_UPDATE** from the **Import Mode** drop-down list.
9. Select the **Import From a Zip file** option.
10. Navigate to the OCDA_Topology.zip file in the OHSCDA home directory. For example, <Drive>:\OCDA_HOME\OCDA_ODI\ODI_Code.

11. Click **OK**.

Note: Save the log file after import for future reference.

12. Select **Import** from the **Designer Menu** drop-down list.
The Import Selection dialog box appears.
13. Select **Import the Work Repository**.
14. Click **OK**.
The Import Work Repository dialog box appears.
15. Select **Synonym mode INSERT_UPDATE** from the **Import Mode** drop-down list.
16. Select the **Import From a Zip file** option.
17. Navigate to the OCDA_Work_Repository.zip file in the OHSCDA home directory.
For example, <Drive>:\OCDA_HOME\OCDA_ODI\ODI_Code.
18. Click **OK**.

Note: Save the log file after import for future reference.

19. Click the **Topology** tab.
20. Expand **Agents**.
21. Navigate to the physical agent OracleDIAGENT and double-click to open the physical agent.
The <Physical agent> tab opens.
22. Enter the host name and port to point to an agent of current environment and save the changes.
23. Click **Test** to test the changes.
The OracleDIAGENT Test Successful dialog box must appear.
24. Make changes to the physical data server connections to point to the required source and target schemas. Perform the following steps to do so:
 - a. Click the **Topology** tab.
 - b. Expand **Physical Architecture**.
 - c. Navigate to **Technologies > Oracle**.
 - d. Right click and open the data server DS_OCDA_DWH.
 - e. In **Definition**, change **Instance/dblink** to point to the OHSCDA DWH work schema.
 - f. In **Connection**, change **user** and **password** to the user and password which were specified for the DWH work schema while installation.
 - g. In **JDBC**, change **JDBC URL** to point to the DWH work schema.
 - h. Expand the data server **DS_OCDA_DWH**.
 - i. Open the physical schema **DS_OCDA_DWH.<CDA_DWH_SCHEMA>**.
 - j. In **Definition**, update the OHSCDA DWH schema and work schema names.

- k. Click **Save**.
- l. Steps m through t are to update Oracle Clinical source connection. Similarly, update source connections for other required sources (Siebel Clinical and InForm).
- m. Right click and open the data server **DS_OCDA_OracleClinical**.
- n. In **Definition**, change **Instance/dblink** 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.
- p. In **JDBC**, change **JDBC URL** to point to the Oracle Clinical work schema.
- q. Expand the data server **DS_OCDA_OracleClinical**.
- r. Open the physical schema **DS_OCDA_OracleClinical.<OCDA_OC_SRC_SCHEMA>**.
- s. In **Definition**, update the Oracle Clinical source and work schema names.
- t. Click **Save**.

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

1. Expand the data server **DS_OCDA_InForm**.
 2. Open the physical schema **DS_OCDA_InForm.<INFORM_CONSOLIDATION_SCHEMA>**.
 3. In **Definition**, update the InForm consolidation and InForm work schema names.
-

25. Log into the WebLogic console where ODI Agent is configured.
26. Navigate to the Services data source.
27. Open the master repository data source.
28. Click on the **Connection Pool** tab.
29. Change the Maximum Capacity value to 50 and save the changes.
30. Configure data sources in the OHSCDA source schema.

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

Table 2–1 Sample of Data Source Table W_RXI_DATASOURCE_S

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-B858-4F08-8BF8-1914B61C9DDF}
4	101	INFORM_1	N	INFORM_1	0	{CC0DBD73-FA40-4943-BDB3-60752C1A2732}

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 DB 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*.

31. Execute the ETL load plan.

OHSCDA ships the following two load plans:

- **CDA - Complete Warehouse:** This is used to load warehouse with one or all of the three source systems (Oracle Clinical, Siebel Clinical, and InForm). For information on how to execute the CDA - Complete Warehouse load plan, see [Section 2.1.2.1, "Executing CDA - Complete Warehouse Load Plan"](#).
- **CDA- Inform Automerger:** This is used to load warehouse only from Inform data source and only when automerger feature is needed. For information on how to execute the CDA- Inform Automerger load plan, see [Section 2.1.2.2, "Executing CDA - Inform Automerger Load Plan"](#).

2.1.2.1 Executing CDA - Complete Warehouse Load Plan

To load data from the source to their target tables in the data warehouse, run the CDA - Complete Warehouse load plan packaged with OHSCDA. Perform the following tasks in ODI:

1. Click the **Operator** tab.
2. Select **Load Plans and Scenarios**.
3. Right-click the **CDA - Complete Warehouse** load plan and select **Run**.
The Start Load Plan dialog box appears.
4. Select **CTX_OCDA** from the **Context** drop-down list.
5. Select **OCDA_LA** from the **Logical Agent** drop-down list.
6. Select **<Use Session Task Log Level>** from the **Log Level** drop-down list.
7. Assign startup values for the Load Plan Variables.
 - **OHSCDA.AUTO_MERGE_FLG:** Set value as **N**.
 - **OHSCDA.DELETE_FLOW:** Set value as **Y** to enable the Siebel Clinical deletion flow.
 - **OHSCDA.VAR_IF:** If InForm is your *one of the or only* data source(s), set value as **Y** to run load plan for the InForm source.
 - **OHSCDA.VAR_INT_CONFIG_DAYS:** Set numeric value (this variable is used to determine the extraction end date for the incremental load).
 - **OHSCDA.VAR_OC:** If Oracle Clinical is your *one of the or only* data source(s), set value as **Y** to run load plan for the Oracle Clinical source.

- **OHSCDA.VAR_OCDA_DWH_LOAD_FLAG:** For full load, set value as **1** and for incremental load set value as **0**.
 - **OHSCDA.VAR_OCDA_ERROR_REJECT_LIMIT:** This variable is used to set the number of rows that will be tracked in the respective error tables prior to aborting the ETL in case of errors.

You must enter positive integer for this variable. For example, 0, 10, 100, 1000, and so on.
 - **OHSCDA.VAR_SC:** If Siebel Clinical is your *one of the or only* data source(s), set value as **Y** to run load plan for the Siebel Clinical source.
8. Click **OK**.

2.1.2.2 Executing CDA - Inform Automerge Load Plan

To load data from the source to their target tables in the data warehouse, run the CDA - Inform Automerge load plan packaged with OHSCDA. Perform the following tasks in ODI:

1. Click the **Operator** tab.
2. Select **Load Plans and Scenarios**.
3. Right-click the **CDA - Inform Automerge** load plan and select **Run**.
The Start Load Plan dialog box appears.
4. Select **CTX_OCDA** from the **Context** drop-down list.
5. Select **OCDA_LA** from the **Logical Agent** drop-down list.
6. Select **<Use Session Task Log Level>** from the **Log Level** drop-down list.
7. Assign startup values for the Load Plan Variables.
 - **OHSCDA.AUTO_MERGE_FLG:** Set value as **Y**.
 - **OHSCDA.VAR_INT_CONFIG_DAYS:** Set numeric value (this variable is used to determine the extraction end date for the incremental load).
 - **OHSCDA.VAR_OCDA_DWH_LOAD_FLAG:** For full load, set value as **1** and for incremental load set value as **0**.
 - **OHSCDA.VAR_OCDA_ERROR_REJECT_LIMIT:** This variable is used to set the number of rows that will be tracked in the respective error tables prior to aborting the ETL in case of errors.

You must enter positive integer for this variable. For example, 0, 10, 100, 1000, and so on.
8. Click **OK**.

2.1.3 Emplacing the OHSCDA Help and Image Files

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

2.1.3.1 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.

2. Create the following folders at <MIDDLEWARE_HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServicesComponent\coreapplication_obips1\analyticsRes\
 - s_ocda
3. Unzip help.zip from OCDA_Home\oracle.pharma.ocda.standard\Reporting\Help to <MIDDLEWARE_HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServicesComponent\coreapplication_obips1\analyticsRes\s_ocda\
4. Move customMessages and sk_ocda folders from <MIDDLEWARE_HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServicesComponent\coreapplication_obips1\analyticsRes\s_ocda\ to <MIDDLEWARE_HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServicesComponent\coreapplication_obips1\analyticsRes\
5. Add the following tag in instanceconfig.xml, present in <MIDDLEWARE_HOME>\instances\instance1\config\OracleBIPresentationServicesComponent\coreapplication_obips1:


```
<UI><DefaultSkin>ocda</DefaultSkin>
<DefaultStyle>ocda</DefaultStyle></UI>
```
6. Unzip the Images.zip files from OCDA_Home\oracle.pharma.ocda.standard\Reporting\Images to <MIDDLEWARE_HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServicesComponent\coreapplication_obips1\analyticsRes\s_ocda
7. Launch Oracle WebLogic Administration Server Console.

Example: `https://hostname.domain:port/console`

This opens the Oracle WebLogic Server Administration Console.
8. Log in to Oracle WebLogic Server Administration Console as an Administrator.
9. In the left pane of the Administration Console, select **Deployments**.
10. On the left pane, click **Lock & Edit**.
11. In the right pane, click **Install**.

This opens the Install Application Assistant.
12. In the **Path** field browse to <MIDDLEWARE_HOME>\instances\<instancename>\bifoundation\OracleBIPresentationServicesComponent\coreapplication_obips1\analyticsRes\.
13. Select **analyticsRes** and click **Next**.
14. Select **Install this deployment as an application** and click **Next**.
15. In **Available targets for analytics**, select the servers in the cluster on which you want to deploy OHSCDA.
16. Click **Next**.
17. In the **Deployment targets**, select `bi_server1`.
18. Click **Next**.
19. 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.

20. Click Finish.

analyticsRes appears in the Deployment section.

21. Click Activate Changes.

22. Select analyticsRes in the Deployment section.

23. Click Start to view the list and select Servicing all requests. The Start Application Assistant page is displayed.

24. 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.

25. Log out from Oracle WebLogic Server Administration Console.

26. Log in to Oracle Enterprise Manager Fusion Middleware Control.

27. Restart the BI components.

28. Log in to OBIEE and verify the branding and help links on the dashboards.

See Also:

- *Oracle WebLogic Server Documentation Library*

2.1.4 Preparing the OBIEE Web Catalog and Repository for OHSCDA

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

1. To deploy InForm web catalog, copy OCDA.zip from OCDA_Home\oracle.pharma.ocda.standard\Reporting\Webcat\Inform_Webcat to OBIEE server.

Else, copy OCDA.zip from OCDA_Home\oracle.pharma.ocda.standard\Reporting\Webcat to OBIEE server.

2. Copy OCDA.rpd files from OCDA_Home\oracle.pharma.ocda.standard\Reporting\RPD to OBIEE server.

3. Unzip OCDA.zip in the following folder:

- Windows32 - <DRIVE>:\<MIDDLEWARE_HOME>\instances\instance1\bifoundation\OracleBIPresentationServicesComponent\coreapplication_obips1\catalog
- UNIX - /<MIDDLEWARE_HOME>/instances/instance1/bifoundation/OracleBIPresentationServicesComponent/coreapplication_obips1/catalog

4. For fresh installation, create a TNS entry of OHSCDA database in %ORACLE_BI%\network\admin.

5. Create an ODBC entry (System DSN) to connect to (RXI) using Oracle Database 11g client driver.

6. In the Oracle BI Administration Tool, select **File**, then **Open**, and then **Offline**.

7. Navigate to the OCDA.rpd, and then click **Open**.

Password: Admin123

8. Click **OK**.

9. In the Oracle BI Administration Tool, select **File**, then **Change Password**.
10. Enter the current (old) password.
11. Enter the new password and confirm it.
12. Confirm the new password.
13. Click **OK**.
14. Modify the connection pools in the RPD as following:
 - a. In the physical layer, expand the OHSCDA Data Warehouse node and double-click **Connection Pool** object to open Connection Pool dialog box.
 - b. Set **Data source name** field to the ODBC entry for the warehouse you created in step 3.
 - c. Change the username to the username of the OHSCDA read-only schema. (RXI_RPD)
 - d. Change the password to the password of the OHSCDA read-only schema. (RXI_RPD)
 - e. Click **OK**.
 - f. Reconfirm the password.
 - g. Click **OK**.
15. From the File menu, select **Save** to save the rpd.
16. Click **Yes** for Do you wish to check global consistency?
17. Click **Close** in the Consistency Check Manager.
18. Click **Save**.
19. Click **File** and then click **Close**.
20. Click **File** and then click **Exit**.
21. Open NQSConfig.xml found at <MIDDLEWARE_HOME>instances\instance1\config\OracleBIServerComponent\coreapplication_obis1.
22. Set EVALUATE_SUPPORT_LEVEL =2.
23. Start the Oracle WebLogic Server and BI components.
24. 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 is displayed.

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.

25. Enter the Oracle Fusion Middleware administrator user name and password and click **Login**.
26. 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.

27. Navigate the Repository tab of the Deployment page.
28. Click **Lock and Edit Configuration**.
29. Click **Close**.
30. In the Upload BI Server Repository section, click **Browse** and navigate to select the RPD.
31. Enter the RPD password in **Repository Password** and **Confirm Password** fields.
32. In the BI Presentation Catalog section, enter <ORACLE_INSTANCE>/bifoundation/OracleBIPresentationServicesComponent/<COMPONENT_NAME>/catalog/OCDA in the **Catalog Location** field.
33. Click **Apply**, and then click **Activate Changes**.
34. Return to the Business Intelligence Overview page and click **Restart**.

2.1.5 Configuring Maps

You must have a database with the sample map data set. Perform the following steps to download the sample map data set:

1. Go to <http://www.oracle.com/technetwork/middleware/bi-foundation/obieesamplesarchive-2026956.html>.
2. Navigate to **OBIEE 11.1.1.3 - Sample Application**.
3. Click **NAVTEQ Data Bundle for OBIEE**.
4. Click **Save**.
5. Create a user in the database.
6. Enable either the Spatial or the Locator feature in the Oracle database.
7. Import the map metadata using the Oracle import utility.

Perform the following steps to configure maps:

1. Open the **Map Viewer** console available at <http://<server>:9704/mapviewer>.
2. Click **Admin**.
3. Log in with the user ID and password provided during the installation.
4. Click **Configuration** in the right pane.

This launches the mapViewerConfig.xml file.

5. In the <security_config> property of the file, change the following:
 - a. Change <proxy_enabled_hosts> property to hostname, IP address and port to correct values.

Note: There are 4 entries —2 pointing to hostname and 2 pointing to IP address of BI server. Ensure that all 4 entries point to the correct server.

For example,

```
<proxy_enabled_hosts>
http://localhost:9704/mapviewer,http://localhost:9704/,http://10.10.10.10:9
704/,http://10.10.10.10:9704/mapviewer
</proxy_enabled_hosts>
```

- b.** Update or add the following entries:

```
<disable_direct_info_request> true </disable_direct_info_request>
<disable_info_request> true </disable_info_request>
<disable_csf>true</disable_csf>
<enforce_security_role> true </enforce_security_role>
```

- 6.** In the 'Predefined Data Sources' section, add the following format of the user where you have imported the data dump:

```
<map_data_source name="OBIEE_NAVTEQ_SAMPLE"
jdbc_host="<IP address>"
jdbc_sid="<SID>"
jdbc_port="<Port>"
jdbc_user="<username>"
jdbc_password="!<password>"
jdbc_mode="thin"
number_of_mappers="6"
allow_jdbc_theme_based_foi="false"
/>
```

- 7.** Click **Save and Restart** to save the changes and restart the services.
 - 8.** Click **Create Tile Layer** in the left pane.
 - 9.** Select **Oracle Maps** from the **Select type of map source** drop-down list.
 - 10.** Click **Continue**.
- The Create a map tile layer for external map source screen appears.
- 11.** Enter ELOC_WORLD_MAP in the **Name** field.
 - 12.** Select **OBIEE_NAVTEQ_SAMPLE** from the **Data Source** drop-down list.
 - 13.** Click **Submit**.

2.1.6 Creating Security Groups and Application Roles for OHSCDA

2.1.6.1 Creating Groups

Perform the following steps to create groups:

- 1.** Launch Oracle WebLogic Server Administration Console.
- 2.** 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 Group table.
- 7. Repeat step 4 through 6 with the following values:

Table 2–2 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

2.1.6.2 Creating Application Roles

Perform the following steps to create groups:

1. Log in to Oracle Enterprise Manager Fusion Middleware Control.
2. From the target navigation pane, open **Business Intelligence** and select **coreapplication**.
3. Right-click **coreapplication**, then select **Security** to display a submenu with **Application Policies** and **Application Roles** as options.
4. Select **Application Roles**. The Application Roles page is displayed.
5. 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.
6. In the **Members** section, select **Add Group**. To search in the dialog box that displays:
 - a. Click the blue button to search. It will display a list of all the groups.
 - b. Select from the results returned in the **Available** box.
 - c. Use the shuttle controls to move the desired name to the **Selected** box.
 - d. Click **OK** to return to the **Create Application Role** page.
 - e. Repeat steps 5 and 6 for all the Roles listed in the following table:

Table 2–3 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

2.2 Adding InForm Studies to the OHSCDA Warehouse

2.2.1 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 InForm source views that are consolidated for OHSCDA are these:

```

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 2.2.7, "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.

2.2.2 Prerequisites

Before you begin:

1. Navigate to `OCDA_HOME\oracle.pharma.ocda.standard\OCDA_Common_Scripts\Inform_Consolidate.zip`.
2. 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.

2.2.3 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.

2.2.3.1 Preparing TNSNAMES Files on Source and Target 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.

2.2.3.2 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 trial source and target consolidation DB 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 DB, use `TrialCDA` and `logs` folders. And, during the setup of the destination consolidation DB, use `DestCDA` and `logs` folder.

2.2.4 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 2.2.4.1, "Source Trial Database Configuration"](#)

- [Section 2.2.4.2, "Destination Consolidation Database Configuration"](#)

2.2.4.1 Source Trial Database Configuration

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

1. On either source or consolidation schema database server, based on the network architecture as described in [Section 2.2.3.2](#), create a directory within `<$ConsolidationMgmtRoot> /<Study-name>` to hold the files for consolidation of this study.
2. Copy the contents of `InForm_consolidate.zip` into the `<$ConsolidationMgmtRoot>/<Study-name>/TrialCDA` directory.
3. Set your current directory to the `<$ConsolidationMgmtRoot>/<Study-name>` directory.
4. Edit `CONFIGTRIALCDA.sql` to set specific values of configuration parameters for this study. Make the following changes:

Table 2–4 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 or earlier, 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 <code>trial_name</code> prefixed with 'cda'.
trial_ro_password	This is OHSCDA reporting object schema password and is defaulted to <code>trial_name</code> prefixed with 'cda'. You can change this password.
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.

2.2.4.2 Destination Consolidation Database Configuration

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

1. On the consolidation schema database server, based on the network architecture as described in [Section 2.2.3.2](#), create or reuse a directory within <\$ConsolidationMgmtRoot> /<Study-name> to hold the files for consolidation of this study.
2. Copy or reuse the contents of InForm_consolidate.zip into the <\$ConsolidationMgmtRoot>/<Study-name> directory.
3. 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 2-5](#) must match with the ones defined in [Table 2-4](#).

Table 2-5 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 or earlier, 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: <code>SELECT * FROM GLOBAL_NAME</code>
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 2–5 (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. 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.

2.2.5 Creating InForm Auto Merge Tables

If InForm is one of the source systems, connect to the InForm Consolidation database and execute the cda_cdb_automerge_ddl.sql script located in the OCDA_HOME/oracle.pharma.ocda.standard/DataModels/ directory.

2.2.6 Creating OCDA_INFORM_VIEWS

After you have initiated at least one consolidation and created Auto Merge tables, perform the following steps before running ETL against the consolidation schema:

1. Connect to the Consolidation schema database as SYSTEM.

2. Execute script OCDA_INFORM_VIEWS.sql located in the OCDA_HOME/oracle.pharma.ocda.standard/DataModels/ directory.

2.2.7 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 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:

1. Connect as the source schema owner.
2. 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 and later:
```

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

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.

2.3 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 (Optional) 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 defines an optional process that you can use to manage hard deletion of records in Siebel Clinical. You create triggers in the source system to handle deletion of records. For a description of this process, see *Oracle Clinical Development Analytics Administrator's Guide*.

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`")