Oracle® Health Sciences Clinical Development Analytics

Installation and Configuration Guide for Oracle Data Integrator Release 4.0 E89763-05

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Oracle Health Sciences Clinical Development Analytics Installation and Configuration Guide for Oracle Data Integrator, Release 4.0

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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 v
- Change Record on page vi
- Related Documents on page vi
- Conventions on page vii

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

Finding Certification Information

Certifications provide access to product certification information for Oracle and third party products. A product is certified for support on a specific release of an operating system on a particular hardware platform. For certification information, see *Oracle*

Health Sciences Applications Supported Technology Stack (Doc ID 180430.1) on My Oracle Support (https://support.oracle.com).

Change Record

July 2019: First version of the guide.

- Oracle Database version 19c (19.3.0.0.0) has been certified.
- Added instructions to grant "CREATE JOB" to "dest_schema_owner" has been added in Section 2.1.4.2, "Destination Consolidation Database Configuration".
- Removed information on applying OBIEE patches 26725930 and 27311972

March 2020: Second version of the guide. In this version:

October 2022: Third version of the guide. In this version:

- Oracle Database version 19c (19.15.0.0.0) has been certified.
- Oracle Data Integrator version 12.2.1.4.0 has been certified.
- Oracle Analytics Server version 5.9 has been certified.

January 2023: Fourth version of the guide. In this version, fixed a typo in Section 2.9

Preparing the OAS Web Catalog and Repository for OHSCDA.

October 2023: Fifth version of the guide. In this version:

- Oracle Database version 19c (19.20.0.0.0) has been certified.
- Oracle Analytics Server version 7.0 has been certified.

Related Documents

For more information, see the following documents in the Oracle Analytics Server, Oracle Clinical, Siebel Clinical, Oracle Health Sciences InForm, and Oracle Data Integrator documentation sets:

Oracle Analytics Server Documentation

The Oracle Analytics Server (OAS) documentation set includes:

- Oracle Analytics Designing and Publishing Pixel-Perfect Reports in Oracle Analytics Server
- Oracle Analytics Using Oracle Analytics Publisher in Oracle Analytics Server
- Oracle Analytics Migrating and Upgrading to Oracle Analytics Server
- Oracle Analytics Administering Oracle Analytics Server
- Oracle Analytics Managing Metadata Repositories for Oracle Analytics Server
- Oracle Analytics Managing Security for Oracle Analytics Server
- Oracle Analytics Installing and Configuring Oracle Analytics Server

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

1

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 https://docs.oracle.com/cd/F19319_01/index.htm.

1.2 Technology Stack and System Requirements

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

- Oracle Database 19.20.0.0.0
- Oracle Analytics Server (OAS) 7.0
- Oracle Fusion Middleware 12c (12.2.1.4.0) Infrastructure
- Oracle Data Integrator (ODI) 12.2.1.4.0
- Oracle WebLogic Server 12.2.1.4.0

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 19.20.0.0.0	Database Installation Guide for <platform></platform>
Oracle WebLogic Server 12.2.1.4.0	Oracle WebLogic Server Documentation Library
Oracle Analytics Server (OAS) 7.0	Oracle Analytics Installing and Configuring Oracle Analytics Server
	System Requirements and Supported Platforms for Oracle
Oracle Fusion Middleware 12c (12.2.1.4.0) Infrastructure	Oracle Fusion Middleware Documentation Library
Oracle Data Integrator 12.2.1.4.0	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

1.2.1 Supported Web Browsers

OHSCDA supports web browsers that are supported by OAS. For the list of the browsers supported by OAS, refer to *Administering Oracle Analytics Server for Oracle analytics server Edition 7.0.*

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) 5.2 and 5.4
- Siebel Clinical Trial Management System (SC) 8.1.1.17, 8.1.1.18, and 22.4
- Oracle Health Sciences InForm 4.6, 5.5, 6.0, 6.1.0, 6.1.1, 6.2.0, 6.3.0, 6.3.1, and 6.3.1.1. Version 7.0 and 7.0.1 are for Cloud only.

1.3 Installing the Prerequisite Software

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





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

Install Oracle Database 19.20.0.0.0

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

- Install Oracle Analytics Sever (OAS) 7.0 with the following components:
 - Oracle Fusion Middleware 12c (12.2.1.4.0) Infrastructure (Supported on Windows and Unix)
 - Oracle Analytics Server 7.0 (Supported on Windows and Unix)
 - Oracle Analytics Client Tools (Supported only on Windows)

Follow the instructions in Installing and Configuring Oracle Analytics Server.

Install Oracle Data Integrator 12.2.1.4.0

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
- Set Up Siebel Clinical Replication Schema
- 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 Files
- Preparing the OAS Web Catalog and Repository for OHSCDA
- OAS Post-deployment Configuration
- Configuring Maps
- Creating Security Groups for OHSCDA
- Adding a Source System to an Existing OHSCDA Setup

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
- Inform_Consolidate.zip and Inform_Consolidate_on_prem.zip files are part of the OHSCDA installer. Run installer for target data warehouse to get access to the files from installer home.

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

- Copy Inform_Consolidate.zip for InForm cloud or Inform_Consolidate_on_ prem.zip for InForm on premise from <OCDA_HOME>\OCDA_ ODI\Database\DWH_Scripts\OCDA_Common_Scripts directory.
- **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.

2.1.3 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.

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.
- 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.
- Edit CONFIGTRIALCDA.sql to set specific values of configuration parameters for this study. Make the following changes:

Parameter	Set value to
Slash	Use \setminus for Windows or / for Linux
trial_name	The name of the study.

 Table 2–1
 Source Trial Configuration Parameters

Parameter	Set value to
inform_release	For InForm release 4.6, enter R46.
	For InForm releases 5.5 to 6.2.x, enter R55.
	For InForm release 6.3 onward, enter R63.
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.

 Table 2–1 (Cont.) Source Trial Configuration Parameters

- **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
- **3.** Set your current directory to the <\$ConsolidationMgmtRoot>/<Study-name>/DestCDA directory.
- **4.** If you use Oracle Database 19c as the destination consolidation database, provide additional grant "CREATE JOB" to "dest_schema_owner":
 - **a.** Open the Setup_Dest_CDA.sql file.
 - **b.** Navigate to the section "Prompt Creating the trial schema user account in the Destination database.."
 - **c.** Replace execute immediate ' grant CREATE VIEW, CREATE TABLE ,ALTER SESSION , CREATE SESSION '

with

```
execute immediate ' grant CREATE JOB,CREATE VIEW, CREATE TABLE ,ALTER SESSION ,CREATE SESSION '
```

- **d.** Save the file.
- **5.** 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.

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 release 4.6, enter R46.
	For InForm releases 5.5 to 6.2.x, enter R55.
	For InForm release 6.3 onward, enter R63.
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.

Table 2–2 Destination Configuration Parameters

Parameter	Set value to
trial_global_name	Global name of the source schema database. You can get this by connecting to the source schema and running the following query:
	SELECT * FROM GLOBAL_NAME
trial_ro_user	This is OHSCDA reporting object schema user name and is defaulted to trail_name prefixed with 'cda'.
trial_ro_password	This is OHSCDA reporting object schema password and is defaulted to trail_name prefixed with 'cda'. You can change this password.
Parameters for configuring the destinat	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.

Table 2–2 (Cont.) Destination Configuration Parameters

6. Save the file.

7. Connect to SQLPlus. Execute the following command:

sqlplus /nolog

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

@Setup_Dest_CDA.sql

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

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

2.1.5 Adjusting Scheduling of Consolidation Jobs

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

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

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

- 1. Connect as the InForm trial 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 release 5.5 and later:

```
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 Set Up Siebel Clinical Replication Schema

If you have Siebel Clinical on cloud and OHSCDA on premise, replicate the Siebel Clinical tables on premise. To do so, replicate the OHSCDA Siebel Clinical source by performing the following steps:

- 1. Copy the CDA_Source_Replication.zip from <OCDA_HOME>\OCDA_ ODI\Database\DWH_Scripts\CDA_Source_Replication directory to your folder.
- 2. Unzip CDA_Source_Replication.zip.
- 3. Navigate to DestCDA folder.
- **4.** Open CONFIGDESTCDA.sql, and set value for parameters mentioned in Table 2–3.

Table 2–3 Parameters in CONFIGDESTCDA.sql

Parameter	Set value to
Slash	Use \ for Windows or / for Linux.
Parameters related to source scher	na and database
trial_name	Name of the study or source type. For example, SIEBEL.
application_release	The source application release version.
instance_guid	Numeric unique ID for the source instance that will be replicated.
	This is added as a record qualifier for each record that is replicated in the target schema.
incr_date_col	The date column on source tables that are used to identify incremental data load.
	For example:
	For Siebel Clinical, the date column is "DB_LAST_UPD".
trial_tnsname	Name in the local TNSNAMES file of the source database for the study/source. You can also provide the entire TNS entry for the source database as a string.
trial_global_name	The global name of the source schema database. You can get this name by connecting to the source schema and running the following query:
	SELECT * FROM GLOBAL_NAME
trial_schema_user	Username of the source schema that holds the actual transactional tables.
trial_ro_user	The source read only user name that is created on the trial schema user to provide read only access.
	If your source is not protected by Read Only user, provide the actual source schema name (trial_schema_user) and its password.
Parameters for configuring the target schema and database	
dest_tnsname	Name of the target database for the study in the TNSNAMES file located on the source database server. You can also provide the entire TNS entry for the target database as a string.
dest_schema_owner	The stage user where the data is processed.
dest_consolidated_user	The consolidation schema username. For example, RXI_SC.

Parameter	Set value to
dest_dba_user	The database username who has database administrator privileges 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 the source system. A value of 'freq=hourly; INTERVAL=1' results in an interval of one hour.
	This parameter is similar to DBMS_SCHEDULER parameter repeat_ interval. You can provide input as per the standards of the package. For more information, see https://docs.oracle.com/database/121/ARPLS/d_ sched.htm#ARPLS72261.

Table 2–3 (Cont.) Parameters in CONFIGDESTCDA.sql

- **5.** Open command prompt and navigate to CDA_Source_Replication\DestCDA.
- **6.** Connect to SQL*Plus.

sqlplus /nolog

7. Execute the script:

@Setup_Dest_CDA.sql

8. Enter passwords in the prompts that appear.

This will setup the infrastructure for the data replication schemas.

- 9. If you want to replicate additional tables:
 - **a.** Connect to dest_schema_owner.
 - **b.** Create an entry for the additional table in the "CDA_CONSOLIDATED_ TABLES" table.
 - c. Commit the changes.
- **10.** In SQL*Plus, execute the script:

@Setup_Dest_CDA_Load.sql

11. Enter passwords in the prompts that appear.

The execution log is created in the CDA_Source_Replication\Logs directory.

2.3 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 media pack folder.
- **3.** Double-click the setup.exe file.

The Oracle Universal Installer: Welcome screen appears.

The Welcome screen provides information about the Oracle Universal Installer.

4. Click Next.

The Select a Product to Install screen appears.

- **5.** Perform the following steps:
 - **a.** Set up the OHSCDA data warehouse. For information on how to do so, see Section 2.3.1, "Setting Up the Data Warehouse".
 - **b.** Set up the source system for OHSCDA. For information on how to do so, see Section 2.3.2, "Setting Up the Source System".

2.3.1 Setting Up the Data Warehouse

- **1.** Select the **Oracle Clinical Development Analytics Standard 4.0.0.0** 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 Specify OCDA Data Warehouse Details screen appears.

- 5. Enter values in the following fields:
 - Database Host Name
 - Database Port No
 - Database Service Name
 - System Password
- 6. Click Next.

The OCDA Data Warehouse Details screen appears.

- **7.** Enter values in the following fields:
 - Data Warehouse Schema Name
 - Data Warehouse Schema Password
 - Data Warehouse Schema Confirm Password
 - Default Tablespace Name
 - Temporary Tablespace Name
 - Default Tablespace Name For Stage

- Enable National Language Support (NLS)?
- 8. Click Next.

The OCDA ODI Data Warehouse RPD Details screen appears.

- **9.** Enter values in the following fields:
 - DW RPD Schema Name
 - DW RPD Schema Password
 - DW RPD Schema Confirm Password
 - Default Tablespace Name
 - Temporary Tablespace Name
- 10. Click Next.

The OCDA ODI Data Warehouse Work Details screen appears.

- **11.** Enter values in the following fields:
 - DW Work Schema Name
 - DW Work Schema Password
 - DW Work Schema Confirm Password
 - Default Tablespace Name
 - Temporary Tablespace Name
- 12. Click Next.

The Do you wish to install ODI source system screen appears.

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

The ODI Source System screen appears. Perform steps through step 7 in Section 2.3.2, "Setting Up the Source System".

Else, select the No option and click Next.

The Summary screen appears.

14. 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.

15. Click Exit.

2.3.2 Setting Up the Source System

- 1. Select the **ODI Source System 4.0.0.0** 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

4. Click Next.

The Select the Source System to install screen appears.

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

The selected source systems appear.

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:
 - OC Source Server Host Name
 - OC Source Server Port No
 - OC Source Server Service Name
 - OC Source System Password
- 9. Click Next.
- **10.** Enter values in the following fields:
 - OC Source Schema Name
 - OC Source Schema Password
- 11. Click Next.

The OCDA Oracle Clinical Source System Details screen appears.

- **12.** Enter values in the following fields:
 - OCDA OC Source Schema Name
 - OCDA OC Source Schema Password
 - OCDA OC Source Schema Confirm Password
 - OCDA OC Default Tablespace Name
 - OCDA OC Temporary Tablespace Name
- 13. Click Next.

The OCDA Oracle Clinical Work Schema Details screen appears.

- 14. Enter values in the following fields:
 - OCDA OC Work Schema Name
 - OCDA OC Work Schema Password
 - OCDA OC Work Schema Confirm Password
 - OCDA OC Work Default Tablespace Name
 - OCDA OC Work Temporary Tablespace Name
- 15. Click Next.

The Summary screen appears.

16. Click **Install**.

Note: Similar set of screens are displayed for other selected source systems. Perform steps through 10 for Siebel Clinical and/or InForm source systems.

2.4 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.

2.4.1 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.

2.4.1.1 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.

2.4.1.2 Handling Deletions in Siebel Clinical

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

1. Navigate to the following temporary staging location where the OHSCDA installer copies the installation files:

<OCDA_HOME>\OCDA_Common\OCDA_Common_Scripts\Delete_Script

- 2. Connect to the Siebel Clinical schema and run the ocda_sc_del_trigger.sql script delivered with OHSCDA. This script creates the triggers on tables provided as input. The following are the tables in Siebel Clinical for which OHSCDA supports creating triggers:
 - S_CL_PTCL_LS

- S_PROD_INT
- S_CL_SUBJ_LS
- S_CONTACT
- S_CL_PGM_LS
- S_PTCL_SITE_LS
- S_EVT_ACT
- S_ORG_EXT
- S_PTCL_VER_LS
- S_ASSESS

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

Note: When you delete a record in the table, the primary key of the deleted record is inserted in the RXI_DELETE_LOG_S table on the Siebel source system.

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

The Siebel Clinical related SDE mappings read the above instance of the RXI_ DELETE_LOG_S table.

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

2.4.1.3 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.

2.4.2 (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 OAS 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.

2.4.3 (Optional) Fine-tuning of Oracle Clinical Settings

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

- 1. Create the following indexes on their respective Oracle Clinical tables:
 - Function based index on DISCREPANCY_ENTRIES NVL ("MODIFICATION_TS", "CREATION_TS")
 - Function based index on DISCREPANCY_ENTRY_REVIEW_HIST NVL ("NEXT_STATUS_TS", "CREATION_TS")
 - Function based index on RECEIVED_DCIS NVL ("MODIFICATION_TS", "RECEIVED_DCI_ENTRY_TS")
 - Function based index on RECEIVED_DCMS NVL ("MODIFICATION_TS", "RECEIVED_DCM_ENTRY_TS")

2.5 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 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.
- 3. Click Yes.
- 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.** 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.
- 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.** Go to Agents under Logical Architecture.
- **30.** Double-click on OCDA_LA logical agent.
- 31. Set all context to physical agent "OracleDIAgent".
- **32.** Save and close.
- **33.** 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 (Data Server)** 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**, 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.
 - j. In **Definition**, update **Schema (Schema)** to the OHSCDA DWH schema and **Schema (Work Schema)** to the work schema name.
 - **k.** Save the configuration.
 - I. 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 (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.
- **p.** In **JDBC**, select the **Oracle JDBC Driver** as the **JDBC Driver** and change **JDBC URL** to point to the Oracle Clinical work schema.
- q. Expand the data server DS_OCDA_OracleClinical.
- r. Right-click the DS_OCDA_OracleClinical.<OCDA_OC_SRC_SCHEMA> physical schema and select Open.
- **s.** In **Definition**, update **Schema (Schema)** to the OHSCDA Oracle Clinical source schema and **Schema (Work Schema)** to the work schema name.
- t. Save the configuration.

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

- 1. Expand the data server DS_OCDA_InForm.
- 2. Right-click the DS_OCDA_InForm.<INFORM_CONSOLICATION_ SCHEMA> physical schema and select Open.
- **3.** In **Definition**, update **Schema (Schema)** to the InForm consolidation schema and **Schema (Work Schema)** to the work schema name.
- 34. Log on to the WebLogic console where ODI Agent is configured.
- 35. Expand Services and click Data Sources.
- **36.** Under the Configuration tab, click odiMasterRepository to open.
- 37. Click the Connection Pool tab
- **38.** Set value for the following properties:
 - Initial Capacity =100
 - Maximum Capacity=3600
 - Minimum Capacity =100
- 39. Click Save.

Note: Perform the same changes to the odiWorkRepository datasource.

2.6 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	Ν	ORACLE_ CLINICAL	0	-
2	2	SIEBEL_ CLINICAL	Ν	SIEBEL_CLINICAL	0	-
3	3	INFORM	Ν	INFORM	0	{FA5BCD87-B858-4F08-8BF 8-1914B61C9DDF}
4	101	INFORM_1	N	INFORM_1	0	{CC0DBD73-FA40-4943-BD B3-60752C1A2732}

Table 2–4 Sample of Data Source Table W_RXI_DATASOURCE_S

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.

2.7 Executing the ETL Load Plans

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

- **CDA Complete Warehouse**: 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*.

2.8 Emplacing the OHSCDA Help Files

You will be using the help.zip file in this section.

2.8.1 Placement of Files for Oracle WebLogic Managed Server

If the OAS Server is not the same machine where the installer is run, copy the help.zip file to the machine where OAS server is installed. The help.zip file is located in the <OCDA_HOME>\Reporting directory.

- Extract the help.zip file at any location on the OAS Server. For example, /scratch/stage/help.
 The extracted help folder contains the analyticsRes folder.
- 2. 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.

- 3. Log on to Oracle WebLogic Server Administration Console as an administrator.
- 4. In the left pane of the Administration Console, select Deployments.
- 5. In the left pane, click Lock & Edit.
- **6.** In the right pane, click **Install**, and navigate to the location where help.zip was extracted in step 1.
- 7. Select analyticsRes and click Next.
- 8. Select Install this deployment as an application and click Next.
- **9.** In the Available targets for analyticsRes section, under Clusters, select **bi_server1** on which you want to deploy OHSCDA.
- 10. Click Next.
- Select the I will make the deployment accessible from the following location option, and select the path for analyticsRes. For example, /scratch/stage/help/analyticsRes.
- 12. Click Finish.

The analyticsRes appears in the Deployment table.

- **13.** Click Activate Changes.
- **14.** Click the **Control** tab.
- 15. Select analyticsRes in the Deployment section.
- 16. Click Start, and select Servicing all requests.

The Start Application Assistant page appears.

- 17. Click Yes to start the selected deployment. The analyticsRes state becomes active after this deployment. You may confirm the same on Deployments page.
- 18. Log out from Oracle WebLogic Server Administration Console.
- 19. Log on to Oracle Enterprise Manager Fusion Middleware Control. The following shows the format of the URL: https://<hostname>.<domain>:<port>/em
- **20.** Restart the BI components.
- **21.** Log on to OAS and verify the help links on the dashboards.

2.9 Preparing the OAS Web Catalog and Repository for OHSCDA

- **1.** Stop the BI services.
- 2. To import the ssi.bar file, run the following command in [DOMAIN_HOME]/bi/bitools/bin: Importarchive.sh ssi <Location of the Bar file> encryptionpassword=<RPD Password>

Where, encryptionpassword is the password used to encrypt the database connection credentials in the RPD. If not provided the connection credentials will not be imported.For example:

importarchive.sh ssi /scratch/Software/OCDA/
ssi.bar encryptionpassword=Admin123 for linux

importarchive.cmd ssi C:\scratch\Software\OCDA\ssi.bar encryptionpassword=Admin123 for windows

- **3.** Start the BI services.
- **4.** Copy the OCDA.rpd file from <OCDA_HOME>\Reporting to the location where the BI Administration tool is available.
- 5. In the Oracle BI Administration Tool, select File, then Open, and then Offline.
- 6. Navigate to the OCDA.rpd file, and then click **Open**.

Password: Admin123

- 7. Click OK.
- 8. In the Oracle BI Administration Tool, select File, then Change Password.
- **9.** Enter the current (old) password.

- **10.** Enter the new password and confirm it.
- 11. Click OK.
- **12.** Modify the connection pools in the RPD as following:
 - a. 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.
 - f. Reconfirm the password.
 - g. Click OK.
 - **h.** In the physical layer, expand the OCDA Data Warehouse node and double-click the **OCDA_CP_InitBlocks** object.
 - i. Repeat steps b through g.
- **13.** From the File menu, select **Save**.
- 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.
- 20. 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.

2.10 OAS Post-deployment Configuration

- 1. Log in to EM (https://<hostname>.<domain>:<port>/em).
- 2. Navigate to Security > Application Policies.
- **3.** Select Application Stripe as "obi", Principal Type as "Application role", and click on the right turned triangle icon.
- 4. Select BIAdministrator in the Principal pane and click on the Edit icon.
- 5. Under Permissions, click on the Add icon.
- 6. Click Resource Types.
- 7. Select Resource Type as "oracle.bi.tech.visualanalyzer.permission".
- 8. Click on right turned triangle icon.
- 9. Select Resource Name as "oracle.bi.tech.visualanalyzer.admin.access" and click Continue.
- 10. Select Permission Actions check box to "All" and click Select.
- 11. Under Permissions, click on the Add icon.
- 12. Click Resource Types.
- 13. Select Resource Type as "oracle.bi.pod.administration.permission".
- 14. Click on right turned triangle icon.
- 15. Select Resource Name as "oracle.bi.pod.admin.properties.edit" and click Continue.
- 16. Select Permission Actions check box to "All" and click Select.
- 17. Click OK and exit the page.
- 18. Restart the entire stack for the changes to take effect.
- 19. Open http://host.domain:port/analytics/systemsettings/
- 20. Search for "EVALUATE SUPPORT LEVEL" and change the value to 2.
- Search for "Show Null Value When Column Is Nullable " and by default, it has "always" selected. Select "never".
- 22. Save the changes.
- 23. Click Restart in the upper right pane.

2.11 Configuring Maps

This section assumes that you installed Oracle BI Enterprise Edition and that Oracle MapViewer was automatically configured and deployed. For information on MapViewer, see *Oracle Fusion Middleware User's Guide for Oracle MapViewer*.

To administer maps using Administration pages:

1. Sign in to OAS.

Make sure you have been granted the Access to Administration and Manage Map Data privileges.

- 2. In the global header, click Administration.
- 3. Click the Manage Map Data link to display the Manage Map Data page.
- 4. Click the Layers tab.
- 5. Click Import Layers to display the Import Layers dialog.
 - **a.** In the dialog box, select ORACLE_MAPS from the Preview Map drop-down list.
 - b. Select OracleMaps from the Look in drop-down list.
 - c. In Available Layers, select World_Cities.
 - d. Click OK.
 - **e.** Repeat steps a to d, but in step c for Available Layers, select World_Countries. This will populate two entries in layers table.
- 6. Highlight and select World_cities in layers, and click Edit.
 - **a.** In Edit layer dialog box, select Layer key as City name from the drop-down list.
 - **b.** In BI Key columns, click on the "+" icon, and select OCDA subject area in select subject area pop-up.
 - c. In selected BI columns pop-up, expand study site folder, and select city.
 - **d.** Use ">" button to select the column, click **OK**, and again click **OK** to close main dialog box.
 - e. Highlight and select World_countries in layers, and click Edit.
 - f. In Edit layer dialog box, select Layer key as Name from the drop-down list.
 - **g.** In BI Key columns, click on the "+" icon, and select OCDA subject area in select subject area pop-up.
 - h. In selected BI columns pop-up, expand study site folder, and select country.
 - i. Use ">" button to select the column, click **OK**, and again click **OK** to close main dialog box.
- **7.** Click **OK** when you have finished selecting layers that are appropriate for the subject area with which you are working.

- **8.** Click the **Background Maps** tab, and click **Import Background Maps** to display the Import Background Map dialog.
- 9. In the dialog, select ORACLE_MAPS for Available Maps.
- **10.** Click **OK** when you have finished selecting main maps.
- **11.** On the Background Maps tab, select a map, and click **Edit Background Map** to display the Edit Background Map dialog in which you name the map and specify the order of layers and their zoom levels preferably 6.
- **12.** Click **OK** when you have finished editing the map.
- **13.** Click **Back** when you have finished working with the Administration page. Your changes are saved automatically.

After you have specified background maps, layers, and zoom levels, MapViewer creates a static image for a map using this information. Then, MapViewer sends that image for rendering in the browser for use by content designers and end users in map views.

Note: This content will be lost if you reimport bar.

2.12 Creating Security Groups for OHSCDA

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 Groups table.

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

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

Table 2–5 Security Group Parameters

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

Table 2–5 (Cont.) Security Group Parameters

2.13 Adding a Source System to an Existing OHSCDA Setup

After you install the OHSCDA application, you can add another source system to the existing OHSCDA setup.

 To add InForm as a source system, see Section 2.1, "Adding InForm Studies to the OHSCDA Warehouse" for the prerequisites.

Perform the following steps to add a source system to an existing OHSCDA setup:

1. Run the OHSCDA installer; see Section 2.3, "Running the OHSCDA Installer".

Note: To add a source system, you need not set up the OHSCDA data warehouse. So, skip instructions in Section 2.3.1, "Setting Up the Data Warehouse".

2. Follow instructions in Section 2.3.2, "Setting Up the Source System".

Note: In step 7 of Section 2.3.2, "Setting Up the Source System", select the source system you want to add.

- 3. Follow instructions in Section 2.4, "Source-specific Procedures".
- **4.** Log on to ODI Studio from the system where OHSCDA is installed and connect to the work repository.
- 5. Update the data source connection for the newly added source.
 - **a.** Click the **Topology** tab.
 - **b.** Expand **Physical Architecture**, and navigate to **Technologies** > **Oracle**.
 - **c.** Perform steps L through T in step 29 in Section 2.5, "Setting Up Oracle Data Integrator".
- 6. Set the variable value for the newly added source system to Y.

Variable for:

- Oracle Clinical is "OHSCDA.VAR_OC"
- Siebel Clinical is "OHSCDA.VAR_SC"
- InForm is "OHSCDA.VAR_IF"

Set the variable value when you:

- Execute the CDA Complete Warehouse load plan. For information, see section "Executing the ETL Load Plans" in the Oracle Health Sciences Clinical Development Analytics Administrator's Guide for Oracle Data Integrator.
- Schedule the CDA Complete Warehouse load plan. For information, see section "Scheduling an ETL Load Plan" in the Oracle Health Sciences Clinical Development Analytics Administrator's Guide for Oracle Data Integrator.

Installing and Configuring Oracle GoldenGate

You should perform the Oracle GoldenGate installation tasks, as described in this chapter, only if you have an on-premise version of Oracle Clinical (OC) and a cloud version of OHSCDA installed.

- Section 3.1, "Prerequisite"
- Section 3.2, "Installing Oracle GoldenGate"
- Section 3.3, "Deploying and Configuring OHSCDA-specific Oracle GoldenGate Code"
- Section 3.4, "Encrypting Oracle GoldenGate Data"
- Section 3.5, "Executing Scripts"
- Section 3.6, "Executing Full Load"
- Section 3.7, "Executing an Incremental Load"

3.1 Prerequisite

The Oracle Clinical database must be on version 19c.

3.2 Installing Oracle GoldenGate

1. Set the environment variables on the source and target database systems.

Variable Name	Value	
export ORACLE_HOME	<oracle directory="" home=""></oracle>	
export PATH	\$ORACLE_HOME/bin:\$PATH	
export TNS_ADMIN	\$ORACLE_HOME/network/admin	
export ORACLE_SID	 If the source database is a pluggable database, set this value the same as the SID value set for the container database. 	
	 If the source database is a standalone database, set the value (as required) for a regular database. 	
export gg_home	<goldengate directory="" install=""></goldengate>	
export LD_LIBRARY_PATH	\${ORACLE_HOME}/lib	

2. On the OC source database SQLPlus prompt, execute the following:

SELECT log_mode FROM v\$database;

- **3.** If log_mode is *NOARCHIVELOG*, execute the following commands sequentially in SQLPlus:
 - a. shutdown immediate
 - **b.** startup mount
 - c. ALTER DATABASE ARCHIVELOG;
 - d. ALTER DATABASE OPEN;
 - e. SELECT log_mode FROM v\$database;

This command ensures that ARCHIVELOG is enabled.

4. Install Oracle GoldenGate on the source and target database systems. For information, see *Oracle Fusion Middleware Installing and Configuring Oracle GoldenGate for Oracle Database* guide.

Note: While installing Oracle GoldenGate, set the source manager port to 7809 and the target manager port to 7909.

3.3 Deploying and Configuring OHSCDA-specific Oracle GoldenGate Code

On the source database system:

- 1. Back up the mgr.prm file located in the \$gg_home\dirprm directory.
- **2.** Navigate to OCDA_ODI_Home\OCDA_Common\cda_goldengate.
- **3.** Open mgr.prm and make sure the manager port number is 7809 (provided during GoldenGate installation).
- **4.** Copy contents of the source_dirprm folder to the source GoldenGate system directory \$gg_home/dirprm.
- 5. Open the fulpinta.prm and pinta.prm files and enter values for the following:
 - rmthost <target host IP address>
 - If the OC source database is a pluggable database, uncomment SOURCECATALOG *<PDB>* and enter the PDB name.
- **6.** Open the einta.prm file, and if the OC source database is a pluggable database, uncomment SOURCECATALOG *<PDB>* and enter the PDB name.

On the target database system:

- 1. Back up the mgr.prm file located in the \$gg_home\dirprm directory.
- 2. Navigate to OCDA_ODI_Home\OCDA_Common\cda_goldengate.
- **3.** Open mgr.prm and make sure the manager port number is 7909 (provided during GoldenGate installation).
- **4.** Copy contents of the target_dirprm folder to the target GoldenGate system directory \$gg_home/dirprm.
- **5.** Open the rinta.prm and fulrinta.prm files, and perform the following for all table entries:

- If the OC source database is a pluggable database, enter value for *<SRC_PDB>* (source PDB from where tables were extracted). If the OC source database is a standalone database, delete *<*SRC_PDB>.
- Change the Target parameter *<PDB>* to the PDB name.
- Change the Target parameter <gg_oc_tgt_user> to the target OC schema name.

```
For example, Map OPA.OPA_LEVEL_PRIVS, Target <PDB>.<gg_oc_tgt_
user>.OPA_LEVEL_PRIVS;
```

3.4 Encrypting Oracle GoldenGate Data

- 1. Navigate to the Oracle GoldenGate home directory on the source database system.
- **2.** From the shell command prompt, execute the following:

./keygen 256 1

This generates a key. For example: 0x08E6F4291BD769739204C50E4A50C93B.

3. From the shell command prompt, execute the followings commands to create an ENCKEYS file and add the key generated in previous step:

vi ENCKEYS cdasecurekey 0x08E6F4291BD769739204C50E4A50C93B

The key alias (cdasecurekey) in the ENCKEYS file will be used in the extract, pump, and replicate files.

- Copy the ENCKEYS file to the Oracle GoldenGate software location on the target database system.
- **5.** From the shell command prompt on the source and target database systems, execute the following command to set permission on the ENCKEYS file:

chmod 640 ENCKEYS

3.5 Executing Scripts

This section describes information on executing scripts on the OC source and target systems.

3.5.1 Executing Scripts on Oracle Clinical Source System

- **1.** From the SQLPlus prompt, perform one of the following:
 - If OC source database is a standalone database, execute the following: cda_gg_oc_source_config.sql
 - If OC source database is a pluggable database, execute the following:

cda_gg_oc_source_config_pdb.sql

2. From the Oracle GoldenGate Software Command Interface (GGSCI) terminal, execute the following commands sequentially:

- a. Create Wallet
- b. Add CredentialStore
- C. Alter CredentialStore Add User <ggadmin_user>@<cdb/dbname> Alias <ogg_user>

At the password prompt, enter a password (*<ggadmin_passwd>*) for the <ggadmin_user>.

Enter the same values in the prompt as provided in step 1.

d. Info CredentialStore

This displays the user added in the wallet.

3. From the GGSCI terminal, execute the following:

dblogin useridalias <ogg_user>

- **4.** Perform one of the following:
 - If the OC source database is a pluggable database:

a. Navigate to the source Oracle GoldenGate home directory/dirprm, and open the ocda_add_trana_data_pdb.oby file.

b. Add the PDB name (*<PDB>*) for all table entries.

c.From the GGSCI terminal, execute the following:

- Obey ./dirprm/ocda_add_trana_data_pdb.oby
- If the OC source database is a standalone database:

a. Navigate to the source Oracle GoldenGate home directory/dirprm, and open the ocda_add_trana_data.oby file.

b. Add the PDB name (*<PDB>*) for all table entries.

c. From the GGSCI terminal, execute the following:

Obey ./dirprm/ocda_add_trana_data.oby

5. From the SQLPlus prompt, execute the following:

```
SELECT first_change#
FROM v$archived_log
WHERE dictionary_begin = 'YES' AND
standby_dest = 'NO' AND
name IS NOT NULL AND
status = 'A';
```

Pick the maximum SCN <SCN_Number_1> (for example, 13910388958710), which will be used for the extract and pump operations.

If the above query does not return any value:

- a. Connect as sys to the OC source database.
- **b.** From the SQLPlus prompt, execute the following:

execute DBMS_LOGMNR_D.BUILD(options => DBMS_LOGMNR_D.STORE_IN_REDO_LOGS);

c. Re-execute the following command to return <SCN_Number_1>:

SELECT first_change# FROM v\$archived_log

```
WHERE dictionary_begin = 'YES' AND
standby_dest = 'NO' AND
name IS NOT NULL AND
status = 'A';
```

6. From the SQLPlus prompt, execute the following:

select to_char(current_scn) from v\$database;

The database returns <SCN_Number_2>, which will be used in replicat.

- **7.** Register the extract.
 - If the OC source database is a pluggable database, execute the following command from the GGSCI terminal:
 - register extract einta database container(<pdb>) SCN <SCN_Number_1>
 - If the OC source database is a standalone database, execute the following command from the GGSCI terminal:

register extract einta database SCN <SCN_Number_1>

- **8**. From the GGSCI terminal, execute the following commands sequentially:
 - a. add extract einta, integrated tranlog, SCN SCN_Number_1>
 - **b.** add exttrail ./dirdat/in, extract einta, megabytes 10
 - c. add extract pinta, exttrailsource ./dirdat/in, SCN <SCN_Number_1>
 - d. add rmttrail ./dirdat/pn, extract pinta, megabytes 10

3.5.2 Executing Scripts on Oracle Clinical Target System

1. From the SQLPlus prompt, execute the following:

@cda_gg_target_config.sql

Enter a value for each prompt.

This creates an admin user on the Oracle GoldenGate target and grants the user the Oracle GoldenGate db config role. This script executes sub-scripts to create user, OC tables, function, view, and grants for the OC tables.

- 2. From the GGSCI terminal, execute the following commands sequentially to add <ggadmin_user> to the wallet and the alias <ogg_user> will be used in the extract files.
 - a. Create Wallet
 - **b.** Add CredentialStore
 - C. Alter CredentialStore Add User <ggadmin_user>@<pdb> Alias <ogg_user>

At the password prompt, enter a password (*<ggadmin_passwd>*) for the <ggadmin_user>.

Enter the same values in the prompt as provided in step 1.

- d. Info CredentialStore
- **3.** From the GGSCI terminal, execute the following commands sequentially:
 - a. dblogin useridalias ogg_user

- **b.** add replicat fulrinta, exttrail ./dirdat/la, nodbCheckPoint
- c. add replicat rinta Integrated exttrail ./dirdat/pn

3.6 Executing Full Load

 From the source Oracle GoldenGate home, execute the following command in a Bash/shell command prompt:

```
./extract paramfile ./dirprm/fulpinta.prm reportfile ./dirrpt/FULPINTA.rpt
```

- **2.** Monitor ggserr.log from the Oracle GoldenGate home in a separate Bash/shell command prompt.
 - On the source system, execute the following:

tail -f ggserr.log

• On the target system, execute the following:

```
tail -f ggserr.log
```

Monitor the following:

- The collector starting on the target system
- The trail files in the dirdat directory on the target system
- The report file in the dirrpt directory on the source system
- 3. From the GGSCI terminal on the source system, execute the following:

tail -f ggserr.log

When extract is complete, the log file shows "EXTRACT FULPINTA stopped normally".

The FULPINTA.rpt file is generated in the \$gg_home/dirrpt directory.

4. From the GGSCI terminal on the target system, execute the following:

start replicat fulrinta

When the execution is complete, both the ggserr.log file and the dirrpt folder under the Oracle GoldenGate home directory will have the fulrinta file with a message that the execution has completed.

- **5.** From the GGSCI terminal, execute the following:
 - On the source system:

stop fulpinta

On the target system:

stop fulrinta

6. Log on to the target database as an OC target user and execute the following command from the SQLPlus prompt:

@ cda_oc_tables_index_constraints_creation.sql

3.7 Executing an Incremental Load

- **1.** On the source system, execute the following commands sequentially from the GGSCI terminal:
 - a. START EXTRACT einta ATCSN <SCN_Number_1>
 - **b.** START EXTRACT pinta ATCSN <SCN_Number_1>
- 2. On the target system, execute the following command from the GGSCI terminal:

```
START REPLICAT rinta, ATCSN <SCN_Number_2>
```

- **3.** Monitor ggserr.log from the Oracle GoldenGate home in a separate Bash/shell command prompt.
 - On the source system, execute the following:

tail -f ggserr.log

• On the target system, execute the following:

tail -f ggserr.log

For specific log files related to the extract or replicat program, the \$gg_ home/dirrpt directory will have the corresponding log files on the source and target systems.

- **4.** From the GGSCI terminal, execute the following commands to get the list of dml operations and the number of rows affected in the source database for each dml operation:
 - On the source system:

stats einta stats pinta

On the target system:

stats rinta

5. On the source system, execute the following command from the GGSCI terminal to get the list of program and their status:

Info all <blank or program name>