Oracle® Health Sciences Data Management Workbench Installation Guide



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Oracle Health Sciences Data Management Workbench Installation Guide, Release 3.2

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Preface

The Oracle Health Sciences Data Management Workbench Installation Guide describes how to install and configure the (Oracle DMW) application for use in clinical trials.

- Documentation accessibility
- Related resources
- Access to Oracle Support

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.

Related resources

All documentation and other supporting materials are available on the Oracle Help Center.

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.



1 System Requirements and Technology Stack

This section includes the following topics:

- System Requirements
- Technology Stack

System Requirements

This section includes system requirements for your Oracle Health Sciences Data Management Workbench (Oracle DMW) 3.2 installation. Oracle DMW is built on Oracle Life Sciences Data Hub (Oracle LSH). It contains the following topics:

Operating Systems

Operating Systems

To get the most current information on the technology stack, see My Oracle Support article 180430.1, *Oracle Health Sciences Applications Supported Technology Stack*.

For details on the database and middle tier, see these topics:

- Database Tier
- Middle Tier

Database Tier

The requirements are the same as for the Oracle LSH database tier:

- Linux x86-64 (64-Bit)
 - Oracle Enterprise Linux 7.4 or later, and 8.x
 - Red Hat Enterprise Linux 7.4 or later, and 8.x
- AIX 7.1 and 7.2 (64-Bit)
- Oracle Solaris 11 on SPARC (64-Bit)

Middle Tier

Oracle DMW requires both an Oracle LSH middle tier and a Oracle DMW middle tier.

Oracle LSH Middle Tier

- Linux x86-64 (64-Bit)
 - Oracle Enterprise Linux 6 or later
 - Red Hat Enterprise AS/ES 5
 - Red Hat Enterprise AS/ES 6



- HP Itanium 11i v3 (11.31) (64-bit)
- AIX 6.1 (64-Bit)
- Oracle Solaris 10 on SPARC (64-Bit)
- Oracle Solaris 11 on SPARC (64-Bit)

Oracle DMW Middle Tier

- Linux x86-64 (64-Bit)
 - Oracle Enterprise Linux 7
 - Oracle Enterprise Linux 8
 - Red Hat Enterprise Linux 6
 - Red Hat Enterprise Linux 7
 - Red Hat Enterprise Linux 8
- Oracle Solaris 10 on SPARC (64-Bit)
- Oracle Solaris 11 on SPARC (64-Bit)

Technology Stack

To get the most current information on the Oracle DMW technology stack, see My Oracle Support article 180430.1.

In addition to the Oracle Life Sciences Data Hub technology stack, Oracle DMW has the following requirements:

- Oracle Life Sciences Data Hub 3.2 and its technology stack
- Oracle WebLogic Server 12.2.1.4
- Java Development Kit (JDK) 1.8.0_211
- Oracle Application Developer 12.2.1.4
- One of the following:
 - Oracle InForm Adapter 1.3.8, 1.3.8.1, or 1.3.9* with Oracle InForm 6.1.x.

*Oracle InForm Adapter 1.3.9 is compatible only with Oracle InForm 6.1.1.5 (earlier Oracle InForm Adapter versions are not supported with Oracle InForm 6.1.1.5).

- Oracle InForm Adapter 6.2.x with Oracle InForm 6.2.x
- Oracle InForm Adapter 6.3 with Oracle InForm 6.3

For details on browsers, see the following topic:

• Supported Browsers

Supported Browsers

Oracle DMW supports the following browsers on Microsoft Windows operating systems:

- Google Chrome Version 99.0.4844.84 (Official Build) (64-bit)
- Mozilla Firefox Quantum Extended Support Release 91.7.1esr (64-bit)



- Mozilla Firefox Version 98.0.2 (64-bit)
- Microsoft Edge Chromium Version 99.0.1150.36 (Official build) (64-bit)

Note:

For the best performance, use a minimum screen resolution of 1024×768 .

2 Install Oracle Life Sciences Data Hub

Oracle Health Sciences Data Management Workbench (Oracle DMW) is built on top of Oracle Life Sciences Data Hub (Oracle LSH). It uses the Oracle LSH database, processing engine, Distributed Processing (DP) Server, security system, defined objects, and adapters. The Oracle LSH installation includes everything required to support Oracle DMW's database.

Install Oracle LSH and its technology stack, including Oracle eBusiness Suite and Oracle Database, following instructions in the *Oracle Life Sciences Data Hub Installation Guide*. The original version is on the Oracle Health Sciences Life Sciences Warehouse media pack, but always check the Oracle Help Center website to see if a revised version is available: https://docs.oracle.com.

Also check My Oracle Support article 1138053.1 Oracle Life Sciences Data Hub and Oracle Clinical Development Analytics Known Install and Configuration Issues for the latest information.

The Oracle Life Sciences Data Hub Installation Guide gives instructions for downloading the software from Oracle Software Delivery Cloud and My Oracle Support into a staging area.

Note:

If you only install Oracle LSH to support DMW, you do not need to follow instructions listed in the "What's Next" chapter of the *Oracle Life Sciences Data Hub Installation Guide*. See the What's Next section in this document instead.

Deploy Oracle DMW on the WebLogic Server

Before you deploy Oracle DMW, make sure the WebLogic Server clock is synchronized with the InForm Adapter server clock by modifying the setDomainEnv.sh file.

This section contains the following topics:

- Download the Oracle DMW Folder
- Deploy Oracle DMW with Default Support for HTTPS
- Deploy Oracle DMW and Disable HTTPS Support
- Check for and Install Any Oracle DMW 3.2.x Patches
- Run the Health Check Scripts

Download the Oracle DMW Folder

Follow these steps to download the Oracle DMW folder from Oracle Software Delivery Cloud:

- 1. Go to Oracle Software Delivery Cloud, http://edelivery.oracle.com, click Sign In, and log in with your user ID.
- Select Download Package from the All Categories drop-down list (or leave All Categories selected). Enter Oracle Health Sciences Data Management Workbench in the Search field and click Search.
- 3. Select DLP: Oracle Health Sciences Data Management Workbench 3.2.0.0.0 and click Add to Cart.
- 4. Click Checkout. You see a list of the selected software:
 - Oracle Health Sciences Data Management Workbench 3.2.0.0.0 (Oracle Standard Terms and Conditions)
 - Oracle Life Sciences Data Hub 3.2.0.0.0
 - Oracle Health Sciences Data Management Workbench 3.2.0.0.0
- 5. From the **Platform** drop-down list, select the appropriate operating system.
- 6. Click Continue.
- 7. Review the Terms and Restrictions and select I accept the terms in the license agreement to continue. (Click Print from the top-right corner of the screen to print the agreement.) Click Continue. You see a list of zipped files for the Oracle Life Sciences Data Hub <*your operating system*> 3.2 release and Oracle Health Sciences Data Management Workbench <*your operating system*> 3.2 release:
 - Oracle Life Sciences Data Hub 3.2.0
 - Oracle Health Sciences Data Management Workbench 3.2.0
- 8. Leave the list of zipped files selected to download the package of Oracle Health Sciences Data Management Workbench 3.2.0.0.0 files or only select the files you need.



- 9. Click **Download**. Then browse to the location where you want to save the Oracle executable.
- **10.** Double-click the Oracle executable. Leave the default destination or click **Browse** to select another one. Click **Next**. Oracle downloads the zipped files.
- Move the zipped files to a staging area and unzip them. The full release contains a software folder for Oracle DMW (p33460037_32000_Generic.zip) and Oracle LSH (p33345421_R12_GENERIC.zip, p6114439_R12_GENERIC.zip, p18551089_R12_GENERIC.zip).
- 12. Unzip the Oracle DMW 3.2 ZIP file (**p33460037_32000_Generic.zip**) to a temporary directory on the WebLogic Server, creating the software directory containing the dmwapp.ear and plan.xml files.

Note:

For details on installing Oracle LSH and Oracle TMS, see the Oracle Life Sciences Data Hub Installation Guide.

- **13.** Deploy the patch, which contains the entire application. Depending if you use HTTPS or HTTP, following one of the following procedures:
 - To use HTTPS, follow the steps in Deploy Oracle DMW with Default Support for HTTPS. By default, Oracle DMW supports and requires HTTPS.
 - To use HTTP, follow the steps in Deploy Oracle DMW and Disable HTTPS Support

Deploy Oracle DMW with Default Support for HTTPS

Deploy the Oracle DMW application tier on the WebLogic Server.

 After you perform the steps listed in Deploy Oracle DMW on the WebLogic Server, log in as the admin user to the WebLogic Administration Console. The URL is: http(s)://host_name.company_domain.com:port/console/

for example:

http(s)://machine.example.com:1234/console

Note:

If you have an earlier version of Oracle DMW deployed, stop it and delete it before deploying the new version.

In the Weblogic Administration Console, select **Deployments** from **Domain Structure**. A list of all deployed applications appears.

If dmwapp is included in the list, select its check box and:

- a. Stop it by selecting Force Stop Now from the Stop drop-down list.
- b. Delete it by clicking **Delete**. It no longer appears in the list.
- 2. Click Install. The Install Application Assistant opens.



- 3. In the paragraph beginning with Locate deployment to install and prepare for deployment, click upload your file(s).
- 4. In the Deployment Archive line, click **Browse** and select dmwapp.ear from your local computer and click **Open**. The system returns to Install Application Assistant.
- 5. In the Install Application Assistant, click **Next**. This uploads dmwapp.ear to a server directory. This may take some time. When the process completes, the system displays the path to the server directory.
- 6. In Install Application Assistant, click Next.
- 7. Select Install this deployment as an application and click Next. The system displays a list of servers.
- 8. Select the managed server where you want to install the application (DMWServer) and click **Next**. Optional settings appear.
- 9. Under General, in the Name field, enter dmwapp and click **Finish**. The system displays a summary of your selections.
- **10.** Click **Finish**. The system deploys the Oracle DMW middle tier on the managed server. After a successful deployment ta new page called **Settings for dmwapp** appears with the Overview tab displayed.
- **11.** Click **Deployments** under **Domain Structure** to verify that dmwapp is included in the Deployments list and its state is Active.
- **12.** Go to the login screen to check that the application is running. The URL is: http://host_name.company_domain.com:port/lsw/dme/faces/DmeLogin.jsf

For example:

http://srv123.example.com:1234/lsw/dme/faces/DmeLogin.jsf

Deploy Oracle DMW and Disable HTTPS Support

By default, Oracle DMW uses HTTPS. If you intend to use HTTP, you can deploy Oracle DMW using the deployment plan (Plan.xml) that disables HTTPS for Oracle DMW. For further information, see the Oracle® Fusion Middleware Deploying Applications to Oracle WebLogic Server 12c (12.2.1.4) at https://docs.oracle.com/en/middleware/fusion-middleware/weblogic-server/12.2.1.4/depgd/index.html.

- 1. After you perform the steps listed in Deploy Oracle DMW on the WebLogic Server, log in to the WebLogic Server.
- 2. Open the software directory.
- 3. Copy the dmwapp.ear file and the plan.xml file to the tmp directory and delete the software directory. The tmp directory now contains only the dmwapp.ear and plan.xml files.
- 4. Open a shell window and set up the environment: source WL HOME/server/bin/setWLSEnv.sh

for example:

source app/oracle/middleware/Oracle_Home/wlserver/server/bin/setWLSEnv.sh

- 5. Change directory to the tmp directory.
- 6. If you have an earlier version of Oracle DMW deployed, stop it and delete it before deploying the new version by entering the following commands.



Note:

If you want to store the username and password in a WebLogic configuration file, omit the username and password parameters in the following commands. For more information, see the WebLogic Scripting Tool Command-Line Reference in the Oracle® Fusion Middleware Deploying Applications to Oracle WebLogic Server 12c (12.2.1.4) at https://docs.oracle.com/en/middleware/fusion-middleware/12.2.1.4/use-weblogic-scripting-tool-tasks.html

```
java weblogic.Deployer -adminurl t3://
host_name.your_company_domain.com:port_number -username WLS_USER -password
WLS_PASSWORD -stop -targets DMW_SERVER_NAME -name dmwapp
```

```
java weblogic.Deployer -adminurl t3://
host_name.your_company_domain.com:port_number -username WLS_USER -password
WLS_PASSWORD -undeploy -targets DMW_SERVER_NAME -name dmwapp
```

 Deploy the new Oracle DMW release by entering the following command. If you stored the username and password in a configuration file, omit the username and password parameters.

```
java weblogic.Deployer -adminurl t3://
host_name.your_company_domain.com:port_number -username WLS_USER -password
WLS_PASSWORD -targets DMW_SERVER_NAME -deploy dmwapp.ear -name dmwapp -
upload -plan Plan.xml
```

8. Exit the shell by entering:

exit

 Go to the login screen to check that the application is running. The URL is: http://host_name.company_domain.com:port/lsw/dme/faces/DmeLogin.jsf

For example:

http://srv123.example.com:1234/lsw/dme/faces/DmeLogin.jsf

Check for and Install Any Oracle DMW 3.2.x Patches

Oracle strongly advises that you immediately install any patches that have been released since the full release (if available).

For example, if you installed 3.2 and there are two 3.2 patches (3.2.1 and 3.2.2), install 3.2.1 first and then 3.2.2 by following instructions in their release notes.

- Check My Oracle Support article 1558745.1, Oracle Health Sciences Data Management Workbench (DMW) Summary of Patches Available at https:// support.oracle.com.
- 2. If any patches have been released on top of the release you installed, download and install all of them, in order, following instructions in their Release Notes.



Run the Health Check Scripts

Run the Health Check scripts for Oracle LSH and Oracle DMW as described in My Oracle Support Article 2733714.1 (https://support.oracle.com).



Install Oracle Thesaurus Management System (Optional)

Oracle Thesaurus Management System (TMS) can be integrated with Oracle Health Sciences Data Management Workbench for use in coding clinical patient data to standard dictionary terms.

See the following topics for details to:

Install Oracle Thesaurus Management System

Install Oracle Thesaurus Management System

Oracle DMW supports Oracle Thesaurus Management System (TMS) 5.4. To install TMS 5.4, see Oracle Thesaurus Management System Installation Guide at https://docs.oracle.com/en/industries/health-sciences/thesaurus-system/5.4/index.html.



4

5 Upgrade to Release 3.2

For upgrading to Oracle DMW release 3.2:

- 1. If you have not already done so, upgrade to Oracle DMW release 3.1.1. Follow instructions in Oracle Life Sciences Data Hub and Oracle Health Sciences Data Management Workbench Installation Instructions.
- 2. Upgrade to Oracle DMW release 3.2 by follow instructions in the following topics:
- Upgrade Oracle Life Sciences Data Hub
- Deploy Oracle DMW to the WebLogic Server
- Upgrade File Watcher to Support Archiving Files (Optional)
- Install Oracle Thesaurus Management System (Optional)

Upgrade Oracle Life Sciences Data Hub

Follow instructions in the *Oracle Life Sciences Data Hub Installation Guide* chapter on upgrading to Release 3.2. The process includes upgrading Oracle Database.

Deploy Oracle DMW to the WebLogic Server

You must deploy the new version of Oracle DMW to the WebLogic Server. Follow instructions in Deploy Oracle DMW on the WebLogic Server, including instructions for applying the latest patch set and patches.

Upgrade File Watcher to Support Archiving Files (Optional)

File Watcher now supports automatically archiving loaded data files. To archive loaded files, you must set up the folders in which to store them the same way you do the folders where you put files to be loaded: create a specified directory structure and register the path for each as Oracle LSH profile values.

To archive files in an existing, pre-Release 3.2 study, edit the study File Watcher and click the **Regenerate** button to enable archiving for the study.

See the Oracle Health Sciences Data Management Workbench Administration Guide for more information.

Install Oracle Thesaurus Management System (Optional)

If you plan to use Oracle Thesaurus Management System (TMS) as a coding tool integrated with Oracle DMW, follow instructions in Install Oracle Thesaurus Management System (Optional).



6 What's Next

After you have finished all the installation tasks in this book, you must do the following tasks before you can begin to use the Oracle Health Sciences Data Management Workbench (Oracle DMW).

You perform most of the following tasks in Oracle Life Sciences Data Hub (Oracle LSH):

- Set Up System Security
- Set Up User Security
- Set Up Oracle LSH Services
- Assign User Group to InForm Family Adapter
- Set Required Profile and Lookup Settings
- Create Study and Library Categories in Oracle LSH
- Set Up File Watcher
- Set Up Logging
- Integrate Other Applications (Optional)

Set Up System Security

For information on securing your system, see Oracle Health Sciences Life Sciences Warehouse Security Guide and the Secure Configuration Guide for Oracle E-Business Suite Release 12 (My Oracle Support document 403537.1.)

Set Up User Security

Oracle DMW uses the Oracle LSH security system, which uses the user security features of the Oracle E-Business Suite. See the Oracle Health Sciences Data Management Workbench Administration Guide.

Set Up Oracle LSH Services

Define Oracle LSH service locations and service instances to support Oracle DMW features as follows, following instructions in the Oracle Life Sciences Data Hub System Administrator's *Guide*.

This section contains details to do the following:

- Distributed Processing Services for File Watcher
- PLSQL Service Instances

Distributed Processing Services for File Watcher

You need the following service types to support Oracle DMW File Watcher:



- **Text for SQL Loader** if you are loading text files from labs or elsewhere.
- **SAS** if you are loading SAS files from labs or elsewhere.

PLSQL Service Instances

InForm and Clinical One metadata and data loading use the PLSQL service. Oracle LSH installation automatically creates a service location with the database SID as its name and creates the PLSQL service under it in the Oracle LSH user interface with three service instances, which allows concurrent processing of three PL/SQL jobs.

In Oracle DMW, these jobs include:

- Loading metadata and data for InForm and Clinical One studies
- Executing a PL/SQL custom program for a transformation
- Executing a generated transformation
- Executing a validation check batch

Increase the number of PLSQL service instances to support the number of PL/SQL jobs you are likely to run concurrently. Oracle recommends a setting of 100.

Assign User Group to InForm Family Adapter

Assign appropriate user group(s) to the InForm Adapter family as described in the Oracle Life Sciences Data Hub System Administrator's Guide.

Set Required Profile and Lookup Settings

Oracle DMW uses Oracle Applications profiles and lookups to determine some aspects of system behavior. See the *Oracle Health Sciences Data Management Workbench Administration Guide* for information.

Create Study and Library Categories in Oracle LSH

After finishing the installation, create subdomains within the shipped Oracle DMW domain to organize your company's studies and libraries. See the *Oracle Health Sciences Data Management Workbench Administration Guide* for information.

Set Up File Watcher

For details on setting up File Watcher, see the Oracle Health Sciences Data Management Workbench Administration Guide.

Set Up Logging

After you deploy the Oracle DMW application (dmwapp) as described in Deploy Oracle DMW on the WebLogic Server, follow these steps to enable logging for dmwapp at the INFO level.



Note:

Check that you perform these steps whenever you need to restart the managed server. The system you use depends on where you deployed Oracle DMW (for example, WebLogic Server or Oracle Enterprise Manager). This procedure uses Oracle Enterprise Manager (OEM).

- 1. Log in to the managed server where you deployed Oracle DMW (for example, OEM).
- 2. From the Server section, select the managed server where you deployed Oracle DMW.
- 3. From the WebLogic Server menu, select Logs > Log Configuration.
- Expand Root Logger, locate dmwapp, and select Notification: <#> (INFO) from the Oracle Diagnostic Logging Level (Java Level) column.
- 5. Click Apply.

If you deployed Oracle DMW to more managed servers, repeat steps 2 through 4 for each server.

Integrate Other Applications (Optional)

If you plan to use Oracle or third-party applications with Oracle DMW, follow instructions in the *Oracle Life Sciences Data Hub Installation Guide* and *Oracle Life Sciences Data Hub System Administrator's Guide* to integrate them with Oracle LSH, including defining Distributed Processing Services for them. Applications must be purchased and licensed separately.

You can use Oracle Business Intelligence Enterprise Edition (OBIEE) for data visualizations

If you plan to integrate with Oracle Identity Cloud Services (IDCS) for the single sign-on solution, follow instructions in Doc ID 2862928.1 on My Oracle Support.



7 Architecture

The following figure shows the architecture described in this section.



Figure 7-1 Oracle Health Sciences Data Management Workbench Architecture

This section contains the following topics:

- Client Tier
- Application Tier
- Database Tier

Client Tier

There are two ways to set up a client, depending on the type of user:

Most Users Oracle DMW who do not write custom programs for transformations and validation checks, require the following on their personal computers:



- A web browser
- Java Virtual Machine (JVM)

Administrators require JVM to use any of the Oracle Forms screens related to security, including setting up user accounts, and to run the post-installation jobs.

Programmers Users who write custom programs in an integrated development environment from Oracle LSH require additional software:

- One or more integrated development environments such as PC SAS, SQL*Plus, or SQL Developer.
- Oracle LSH plug-in for launching Integrated Development Environments (IDEs)
- WinZip
- Web browser

Application Tier

Oracle DMW has two distinct application tiers:

- Oracle Life Sciences Data Hub Application Tier
- Oracle Health Sciences Data Management Workbench Application Tier

Oracle Life Sciences Data Hub Application Tier

In addition to standard Oracle Applications components, the Oracle LSH application tier includes the following:

Oracle LSH Application Server: The Oracle LSH Application Server renders the user interface using the Oracle Applications Framework and handles the communication between the user interface and the database using the Java Runtime Environment.

Oracle LSH Distributed Processing (DP) Server: The Oracle LSH DP Server handles the communication between Oracle LSH and the external processing systems required to support the IDEs.

Processing Systems: XML Publisher is required for internal Oracle LSH processing. The other systems are required only if you are developing Oracle LSH Programs in those technologies:

• SAS executes user-developed SAS Programs.

Oracle Health Sciences Data Management Workbench Application Tier

The Oracle DMW-specific application tier requires Oracle WebLogic Server and Oracle Applications Developer.

Database Tier

Oracle DMW uses the Oracle LSH database tier that includes:

Oracle Enterprise Edition RDBMS: All of Oracle LSH's database tier components use the Oracle Enterprise Edition database server and database.



Oracle Applications Schema: The Oracle Applications Schema is the schema installed as part of the Oracle Applications installation. It contains the Oracle LSH schema.

Oracle LSH Database Server and Schema: These include Oracle LSH's business logic in PL/SQL packages, internal Oracle LSH tables and views, security, adapters, and APIs; as well as Oracle LSH user-developed metadata tables and packages.

Oracle Thesaurus Management System (TMS) : Oracle LSH classification system is based on TMS.

