

# Oracle® Health Sciences Data Management Workbench Administration Guide



Release 2.4.8  
E96068-03  
October 2019

The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

ORACLE®

Copyright © 2017, 2019, Oracle and/or its affiliates. All rights reserved.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs, including any operating system, integrated software, any programs installed on the hardware, and/or documentation, delivered to U.S. Government end users are "commercial computer software" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, use, duplication, disclosure, modification, and adaptation of the programs, including any operating system, integrated software, any programs installed on the hardware, and/or documentation, shall be subject to license terms and license restrictions applicable to the programs. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Xeon are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Opteron, the AMD logo, and the AMD Opteron logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

# Contents

## Preface

---

Additional copyright information	ix
Documentation Accessibility	ix

## 1 Cross-study setup

---

Set up lab and other file-based data sources	1-1
Select Oracle InForm tables and views for use in Oracle Health Sciences Workbench	1-1
Available InForm tables and views	1-2
Create categories for flags, discrepancies, and validation checks	1-3
Create flags for data	1-5
Create a flag	1-5
Examples of flag use	1-6
Use tags and APIs to create a custom discrepancy workflow	1-7
Discrepancy states and allowed transitions	1-8
Default actions	1-9
Create tags for discrepancies	1-10
Use APIs to create or modify actions	1-11
Compare flags, tags, and categories	1-11
Set up coding in TMS	1-12
Define TMS Sets	1-12
Define TMS Set columns	1-13
Force rederivation	1-14
Set up a data visualization tool	1-15
Configure session timeout (optional)	1-15

## 2 Cross-study setup outside DMW

---

Set up study and library groupings	2-1
Set up custom program and function groupings	2-2
Set lookup values for Reasons for Change and more	2-3
Reasons for change	2-3

Number of studies per partition	2-3
Set profiles to determine system behavior	2-4
Use character semantics	2-5
Increase the maximum number of nested domains	2-5
Append username to discrepancy text	2-5
Change the study grouping user interface label	2-6
Register root folders for File Watcher watched folders	2-6
Register root folders for File Watcher archive folders	2-7
Set blinding behavior for InForm hidden items	2-8
Make discrepancy categories mandatory	2-8
Make discrepancy actions mandatory	2-8
Date format for conversion to text in unpivot transformations	2-9
Hosted environments	2-9
Set the default number of days of job history to display	2-9
Use custom listing name for the custom listing schema	2-10
Set currency behavior for Staging with Audit tables	2-10
Turn debugging on or off	2-11
Enable UI changes for a clinical data system other than InForm	2-11
Set login-related and other profile values	2-11
Enlarge SAS buffer size	2-12

### 3 Study setup

---

Set up the study File Watcher to load data files	3-1
Create study File Watchers	3-1
Select a distributed processing (DP) server for the study File Watcher	3-2
Set up InForm data exchange	3-2
Create users for InForm integration	3-2
Create required Oracle accounts	3-3
Create required InForm users	3-4
Add InForm remote locations	3-4
Add InForm web service locations	3-6
Set up data exchange with a non-InForm clinical data system	3-7
Set up File Watcher	3-7
Add a web service location for a non-InForm clinical data system	3-7
Subscribe users to job status notifications	3-8

### 4 Study monitoring

---

Monitor, suspend, and resume study File Watchers	4-1
View file specifications for study File Watchers	4-1

Monitor validation check discrepancies sent to the source data system	4-2
View, cancel, and suspend scheduled jobs	4-2
View past and current job executions	4-3
Use tracing and logging	4-4
Turn on tracing or logging	4-4
Locate the trace file	4-4
Turn off tracing or logging	4-5
Truncate logging data	4-5
Set up data visualizations	4-5

## 5 User management

---

Create and set up user accounts	5-1
Create user accounts	5-1
Assign application roles to users	5-2
Create database accounts	5-3
Use or create object security roles	5-3
Use predefined object roles	5-4
Create object security roles	5-4
Assign roles to operations	5-5
Create and develop user groups	5-6
Create user groups	5-6
Add users to user groups	5-6
Assign a group administrator	5-7
Add users and assign roles	5-8
Clear the Oracle Applications cache	5-8
Copy user groups with or without users	5-9
Assign user groups to custom programs and study groupings	5-9
Assign user groups to adapters for technology privileges	5-10
List of adapters	5-11
How security works	5-12

## 6 Advanced administration topics

---

Oracle Thesaurus Management System (TMS) integration	6-1
TMS processing	6-1
TMS autoclassification, synchronization, and manual processing	6-1
New and updated data processed in TMS	6-3
System interaction conflicts and discrepancy statuses	6-3
Force rederivation	6-4
DMW context information displayed in TMS	6-4

Database partitioning	6-5
Partitioned tables	6-5
Develop guidelines for setting study size	6-6
Specify the number of similarly sized studies per partition	6-6
Assignment algorithm	6-6
Changing the root folder location for data files	6-7
Updating web service location passwords in bulk	6-7

## 7 Security reference information

---

Application roles for specialized administrators	7-1
DMW Adapter Security Admin	7-1
DMW Data Security Admin	7-1
DMW Checkin Admin	7-1
Application roles for user interface access	7-1
DMW System Administrator	7-2
DMW Study Manager	7-2
DMW Study Consumer	7-2
DMW Study Configurator	7-2
DMW Library Administrator	7-2
DMW Database User	7-2
Data Blinding-related application roles	7-2
DMW Data Blind Break User (Dev, QC, and Prod)	7-3
DMW Data Unblind User (Dev, QC, and Prod)	7-3
Predefined object security roles	7-3
Oracle DMW_STUDY_DEVELOPER	7-4
Clinical Data Models and Query Builder	7-4
Blinding	7-5
Filters	7-6
Data Lineage Tracing	7-6
Transformations and Query Builder	7-6
Discrepancies and Flags	7-7
Validation Checks	7-8
InForm	7-9
File Watcher	7-9
Oracle DMW_STUDY_QC	7-9
Clinical Data Models and Query Builder	7-10
Blinding	7-10
Discrepancies	7-11
Filters	7-11
Flags	7-11

Data Lineage Tracing	7-12
Validation Checks	7-12
InForm	7-12
File Watcher	7-13
Transformations and Query Builder	7-13
Oracle DMW_STUDY_PROD	7-14
Clinical Data Models and Query Builder	7-15
Blinding	7-15
Discrepancies	7-16
Filters	7-16
Flags	7-16
Data Lineage Tracing	7-16
Validation Checks	7-17
InForm	7-17
File Watcher	7-18
Transformations and Query Builder	7-18
Oracle DMW_STUDY_ADMIN	7-19
Clinical Data Models and Query Builder	7-19
Discrepancies	7-21
Flags	7-21
Filters	7-21
Data Lineage Tracing	7-22
Validation Checks	7-22
InForm	7-23
File Watcher	7-23
Transformations and Query Builder	7-23
Oracle DMW_STUDY_INST_ACCESS	7-25
Clinical Data Models and Query Builder	7-25
Blinding	7-25
Discrepancies	7-26
Data Lineage Tracing	7-26
Validation Checks	7-26
Transformations	7-26
Oracle DMW_STUDY_INFORM_CONFIG	7-27
InForm	7-27
Operations	7-27
Operations required to view data and manage discrepancies	7-28
Object ownership	7-28

---

# Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.



# Preface

This preface contains the following sections:

- [Additional copyright information](#)
- [Documentation Accessibility](#)

## Additional copyright information

This documentation may include references to materials, offerings, or products that were previously offered by Phase Forward Inc. Certain materials, offerings, services, or products may no longer be offered or provided. Oracle and its affiliates cannot be held responsible for any such references should they appear in the text provided.

## 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.

# 1


## Cross-study setup

Do the tasks listed in this chapter when you set up DMW. Settings apply to all studies.

- [Set up lab and other file-based data sources](#)
- [Select Oracle InForm tables and views for use in Oracle Health Sciences Workbench](#)
- [Create categories for flags, discrepancies, and validation checks](#)
- [Create flags for data](#)
- [Use tags and APIs to create a custom discrepancy workflow](#)
- [Compare flags, tags, and categories](#)
- [Set up coding in TMS](#)
- [Set up a data visualization tool](#)
- [Configure session timeout \(optional\)](#)

### Set up lab and other file-based data sources

This list populates the list of values for creating file-based input clinical data models. Add each lab and any other entity that sends data files to Oracle Health Sciences Workbench. If you are using a clinical electronic data capture system other than Oracle Health Sciences InForm, enter it here.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Make sure the **Data Sources** tab is selected, then click the **Labs** subtab.
3. Click the **+Add** icon.
4. **Data Source Name:** Enter the name of the data source; for example, `Central Lab`. This value appears in the list of data sources in the File Watcher configuration tab for file-type input clinical data models.

The system uses only the data source name. All other fields are for your own records.

The **Send All Open Discrepancies?** field has no effect in this release.

5. Click **OK**.


### Select Oracle InForm tables and views for use in Oracle Health Sciences Workbench

Select tables and views to be available in all studies by default. The study configurator can override these choices.

Internal InForm metadata and operational tables can be used in DMW studies as source tables in data transformations and viewed in the Default Listings page. Any tables and views used in study templates or standard transformations should be included in studies by default. For example, you may need SUBJECTVISITS metadata for structural reference.

The system stores the tables and views in two internal clinical data models:

- The Metadata model contains tables used by the DMW metadata loading process to create the tables in each InForm input clinical data model.
- The Operational Data model contains tables that store information collected during the course of the study that supports clinical data, including InForm queries, form state flags, comments, and subject visit information.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Make sure the **Data Sources** tab is selected, then click the **InForm Tables and Views** subtab.

The system displays InForm tables and views alphabetically. To sort by the internal data model they are part of if selected, click the heading of the **Internal Data Model** column.

3. Select the tables and views you want to include by default in DMW studies.

 **Tip:**

Some tables are required for internal processing and cannot be deselected.

4. Click the  **Save** icon.
  - [Available InForm tables and views](#)

## Available InForm tables and views

Required tables are marked with an asterisk (\*).

### Metadata

IRV\_CONTROL\_REVS

IRV\_FORM\_REVS

\*IRV\_ITEM\_REVS

IRV\_ITEMSET\_REVS

\*IRV\_MD\_FORMS\_CONTROLS

IRV\_STUDYVERSIONS

IRV\_SECTION\_REVS

\*IRV\_STUDYVERSION\_FORMS

\*IRV\_STUDYVERSION\_REVISIONS

\*IRV\_STUDYVERSION\_VISITS

IRV\_VISIT\_REVS

\*RD\_DATADICTIONARY

In addition, the Metadata model includes the following required DMW tables:

\*DME\_IA\_SRC\_TABLES

\*DME\_IA\_SRC\_COLUMNS

\*DME\_IA\_STANDARD\_COLUMNS

\*DME\_IA\_TABLE\_MAPPING

\*DME\_IA\_COLUMN\_MAPPING

\*DME\_IA\_COLUMN\_MAPPING\_SOURCES

#### **Operational Data**

\*IRV\_COMMENT\_REVS

IRV\_CUR\_COMMENT

IRV\_CUR\_QUERY

IRV\_CUR\_SITE

\*IRV\_CUR\_SUBJECT

IRV\_CUR\_USER

IRV\_DIM\_SUBJECTVISIT

\*IRV\_QUERY\_REVS

IRV\_SV\_SUBJECTVISITS

IRV\_SUBJECT\_REVS

IRV\_USERS\_SITES

\*RT\_ACTIVATED\_FORMS

\*RT\_ITEMSTATE

## Create categories for flags, discrepancies, and validation checks

Categories are used for two purposes:

- **Labeling Discrepancies** Users can filter discrepancies by category.  
Create categories to characterize discrepancies (for example, *Protocol Violation*, *Validation Check Not Working*, *Range or Date Alignment*). Categories can also indicate who should review a discrepancy next (for example, *Medical Review*, *DM Review*) as an alternative to creating custom actions using APIs with these labels as tags.
  - Users can assign a category directly to a discrepancy.

- Users can assign a category to a validation check. The validation check then assigns the category to all discrepancies it creates.
- **Flagging Records** Categories determine which flags are available to assign to which records. You assign categories to clinical data model types. When you create a flag, you assign a category to it. The flag is then available for users to assign to records in model types assigned to the same category.


Users can assign flags to records and then filter records by flag.

 **Tip:**

To simplify flag creation, include the clinical data model type (Input (InForm), Input (File), and Target) in the name of flag categories.

A discrepancy, validation check, or flag can have only one category assigned at a time. Some categories are created and used by the system and cannot be modified. They have IDs under 100.

To create a category:

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **Categories** tab.
3. Click the **Add** icon.
4. Enter values in the following fields:
  - **Category Name:** This label is displayed in the Discrepancies, Listings, Validation Check, and Filter user interfaces.
  - **Description:** (Optional) The description is not displayed anywhere but here.
  - **For Discrepancies?:** If selected, users can assign the category to discrepancies.
  - **For Validation Checks?:** If selected, users can assign the category to validation checks. The validation checks then assign the category to the discrepancies they create.
  - **For Flags?:** If selected, users can assign flags of this category to records in the type(s) of clinical data model you specify. Additional fields appear and you select one or more data model types:
    - **Input (File)** for input models that receive their data from data files, usually from labs.
    - **Input (InForm)** for input models that receive their data from InForm.
    - **Input (EDC System)** for input models that receive their data from an integrated electronic data capture system other than InForm.
    - **Target** for models whose data is populated by a transformation from other model(s).
5. Click **OK**. The system assigns an ID greater than 100 to the category.

## Create flags for data

Flags can help track the data review process or move the process along. See [Examples of flag use](#). Users can apply flags to records (not discrepancies) in the Listings pages and filter records by flag in the Listings and Discrepancies pages.

Each flag can have any number of states, and users must assign a flag state to a record as well as the flag. A record can have multiple flags assigned, but only one state per flag. The system does not enforce any rules concerning the transition of a record from one flag state to another.

Flags created in DMW are assigned to records in DMW. These flag assignments are not sent to InForm. The system imports InForm form and item states as flags with the records they are assigned to in InForm. These flag assignments cannot be changed in DMW.


The system audits changes in flag assignments to records with the timestamp and user name, by category, in the internal table DME\_FLAG\_DATA\_A.

### Tip:

To have a single flag's assignments audited separately, you can create a separate category for it.

- [Create a flag](#)
- [Examples of flag use](#)

## Create a flag

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **Flags** tab.
3. Click the **+Add** icon.
4. Enter values:
  - **Name:** Enter the text you want to appear in the user interface.
  - **Description:** The description is not displayed anywhere but here.
  - **Categories** (Required) Select a category. The flag can then be assigned to records in the data model type the category is assigned to. See [Create categories for flags, discrepancies, and validation checks](#).
  - **Subject Visit Flag** Select this option if the flag is to be applied to records in the Subject Visit table to track subject visit status. Leave it deselected if the flag is to be applied to clinical data records.
  - **User-settable Flag** If selected, users and validation checks can assign this flag to records. If not selected, the flag is imported from InForm and cannot be changed in DMW.

- **States:** Click the **+** **Add** icon to create a flag state.
    - **State Name**
    - **State Description**
    - **State Priority** Select Low, Medium, or High relative to other states of the same flag and other flags, to help data reviewers prioritize their work.

The Listings page displays an icon for the highest priority flag state currently applied to each record.
5. Click **OK**.

## Examples of flag use

Flags can help track the data review process or move the process along:

You can create the following flags and write validation check custom programs that examine data and call the public API `dme_pub_flag_data.setFlag` to set the flag. See the API guide for information about initializing APIs.

- Create a flag called **Needs Review** with states Medical Monitor and Data Manager. These users can then check for data needing their review.
- Create a flag called **Record Complete** with two states: Yes and No. Data managers can use this flag to filter for missing data.

Write a custom program to ascertain that all required fields in a record have a value and apply the flag with the state Yes if they do.

- Create a flag called **Validation Checks** with the states Validation Not Done, Validation Incomplete, and Validation Complete.

Write a custom program that compares the timestamp of the last data update for each unlocked record to the execution timestamp for all validation checks run for that study and sets the **Validation Checks** flag for each record with the appropriate state.

- Create a flag called **Data Readiness** with states: Not Clean, Clean for Medical Review, and Clean for Analysis. Medical reviewers and statisticians can then query for data with the appropriate flag for their review.

Write a custom program that uses the above flags or others to set its values.

- Create a subject visit flag called **Subject Visit Complete** with a single state of On, to be applied only when the subject visit is complete.

Write a custom program that aggregates flag values for the individual clinical record flags in the examples above: loop through each subject/visit combination and set the **Subject Visit Complete** flag to On when every record for the current subject and visit in the Adverse Events, Concomitant Medications, and Vital Signs tables, for example, has the **Record Complete** flag set to On, the **Validation Checks** flag set to Validation Complete, and the **Number of Discrepancies** set to an acceptable number.

A validation check can apply a flag to records if it has a custom program that calls the API `DME_PUB_FLAG_DATA.SetFlag`. The API requires the target table instance object ID and the record's surrogate key value as input. See the *Oracle Health Sciences Data Management Workbench Application Programming Interface Guide* for more information.

## Use tags and APIs to create a custom discrepancy workflow

Data reviewers apply an action to a discrepancy to change its state, send it to an external data source, or mark it for review by someone else. Oracle DMW comes with a set of actions; see [Default actions](#).

If your company needs a more granular workflow such as the ability to send a discrepancy for review by different teams while remaining in an Open state, you can use tags and APIs to create custom actions and disable any default actions you do not need.

Custom actions must conform to allowed state transitions; see [Discrepancy states and allowed transitions](#).

### Tip:

The Discrepancies page allows users to apply only actions that are valid for all selected discrepancies. Valid actions are determined by:

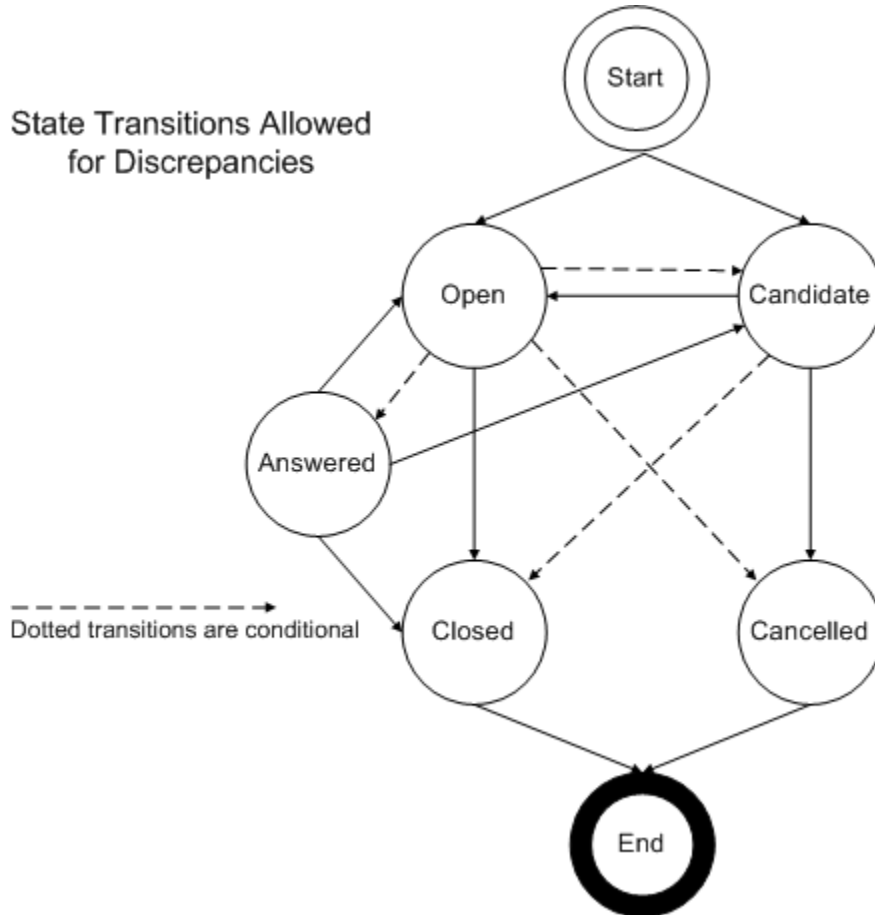
- The discrepancies' **Start State**.
- The discrepancies' **Start Tag**, if any. Default actions do not have Start Tags but custom actions may have them.
- The data source. For example, the **Send to InForm** action is not available for discrepancies on lab data.

1. Create a tag in the DMW user interface. Tags serve as substates. See [Create tags for discrepancies](#) for details.
2. Run an API. See [Use APIs to create or modify actions](#).
  - [Discrepancy states and allowed transitions](#)
  - [Default actions](#)
  - [Create tags for discrepancies](#)
  - [Use APIs to create or modify actions](#)



## Discrepancy states and allowed transitions

Figure 1-1 Discrepancy States and Allowed Transitions for Discrepancies



The diagram shows valid transitions for discrepancies in Oracle DMW integrated with InForm.

 **Note:**

If you are using Oracle DMW with a clinical data system other than InForm, the conditions are configurable. See My Oracle Support article ID 2172786.1, *Using the Generic Connector to Integrate DMW with a Clinical Data System*.

- Candidate and Open are the two valid beginning states for a discrepancy.
- Cancelled and Closed are the two valid end states for a discrepancy.
- Candidate discrepancies can always move to Open.
- Candidate discrepancies can always move to Cancelled.

- Candidate discrepancies can move to Closed if they have not been sent to InForm. Candidate discrepancies that are in InForm (whether they originated in InForm or DMW) can move to Closed if they were previously in the Open state within InForm. This matches InForm rules.
- Open discrepancies can move to Answered if they were created in Oracle DMW and have not been sent to InForm.
- Open discrepancies can always move to Closed.
- Open discrepancies can move to Cancelled only if they were created in Oracle DMW and have not been sent to InForm.
- Open discrepancies can move to Candidate if they were created in Oracle DMW and have not been sent to InForm.
- Answered discrepancies can be reopened in either the Open or Candidate state.
- Discrepancies can be always be closed from the Open or Answered state.

When a discrepancy is sent to InForm, the system limits the actions an Oracle DMW user can take on the discrepancy. The same limited actions are allowed whether the discrepancy originated in InForm or in Oracle DMW.

- While a discrepancy is in InForm, Oracle DMW users can apply comments and categories to it. These are never sent to the source system.
- While a discrepancy is in Oracle DMW, a user can apply an action that changes the state of the discrepancy and must supply a reason for the change. The reason for change is sent to InForm.

## Default actions

**Table 1-1 Default Actions**


Start State	Action Name	Routing Operation	Result State	Result Tag
Candidate	<b>Open</b>	None	Open	None
Candidate	<b>Cancel Discrepancy</b>	None	Cancelled	None
Candidate	<b>Open in InForm</b>	SendToInForm	Open	SentToInForm (This action creates a new Open InForm query.)
Candidate	<b>Send to InForm</b>	SendToInForm	Candidate	SentToInForm (This action creates a new Candidate InForm query.)
Candidate	<b>Close Discrepancy</b>	None	Closed	ClosedAsIs
Candidate	<b>Needs DM Review</b>	None	Candidate	NeedsDMReview
Candidate	<b>Send to Spreadsheet</b>	Send to Spreadsheet	Open	None
Open	<b>Cancel</b>	None	Cancelled	None
Open	<b>Send to InForm</b>	Send To InForm	Open	Sent To InForm (This action creates a new Open InForm query.)

Table 1-1 (Cont.) Default Actions

Start State	Action Name	Routing Operation	Result State	Result Tag
Open	<b>Send to Spreadsheet</b>	Send To Spreadsheet	Open	Sent to Spreadsheet (This action generates a .csv file in the location you specify that includes all selected discrepancies. The file can then be sent to the lab.)
Open	<b>Needs DM Review</b>	None	Open	NeedsDMReview
Open	<b>Answer Discrepancy</b>	None	Answered	Answered By User Response (if a user uses the action Answer) Answered By Data Change (if a data change occurred in the source system)
Open	<b>Reset to Candidate</b>	None	Candidate	None
Open	<b>Close Discrepancy</b>	None	Closed	Closed By Data Change (if a data change occurred in the source system)
Answered	<b>Reopen Discrepancy</b>	None	Open	None
Answered	<b>Reopen to Candidate</b>	None	Candidate	None
Answered	<b>Close Discrepancy</b>	None	Closed	Closed With Answer

## Create tags for discrepancies

A tag is a label that a user can apply to discrepancies by using an *action*. A discrepancy can have only one tag at a time. Tag uses include:

- Users can filter discrepancies by state/tag combination.
  - You can use tags to create substates to direct communication among teams while the discrepancy remains in the same state. For example, two discrepancies might have the state Open but different tags such as DM Review and Med Review.
1. Click the Navigation icon  at the top of any page and then click **Administration**.
  2. Click the **Tags** tab.
  3. Click the **Add** icon.
  4. Enter values in the following fields:
    - **Tag Name:** This text is displayed in the Discrepancies page. Spaces and special characters are allowed.
    - **Description:** (Optional)
    - **Enabled?:** Check to allow the tag to be used.



**Note:**

**System Tag** indicates whether a tag was created by the system or by a user. You cannot modify system tags, but you can disable them.

5. Click **OK**. The system generates an ID.

## Use APIs to create or modify actions

See the API Guide for details on using APIs to create or modify actions. Their attributes include:

- **Start and Result States:** An action is available to a user only for discrepancies that are in the start state. When the user applies an action, the discrepancy's state changes to the result state.

The start and result states must constitute an allowed transition (see [Discrepancy states and allowed transitions](#)) or be the same. If an action does not change the state, it must apply a tag.



**Note:**

No defined action is required to create a discrepancy.

- **Start and Result Tags** (Optional): An action is available to a user only for discrepancies with the start tag. When the user applies an action, the discrepancy's tag changes to the result tag.
- **Enabled:** This attribute determines whether an action is available for use.

## Compare flags, tags, and categories

The following table compares flags, tags, and categories. All are available for use in any study.

**Table 1-2 Flags, Tags, and Categories**

Object	Applied To	Applied By	Used as Filter?	Has Multiple States?	Used for
Flag	Records	User or validation check. InForm flag assignments are imported and can be viewed but not changed.	Yes	Yes	Data management
Tag	Discrepancies	User or validation check, via actions	Yes	No, but can be used to create discrepancy substates	Discrepancy management

Table 1-2 (Cont.) Flags, Tags, and Categories

Object	Applied To	Applied By	Used as Filter?	Has Multiple States?	Used for
Category	Discrepancies, Validation Checks, Flags	Validation check or user	Yes	No	Discrepancy and data management

## Set up coding in TMS

### Prerequisites:

- TMS must be installed.
- TMS must be integrated with DMW as specified in the *DMW Installation Guide*.
- Dictionaries and TMS domains must be defined in TMS. Domains allow you to customize terminologies differently for different studies by creating domain-specific terms and classifications. Domains also determine default TMS system behavior.

### Tip:

DMW displays the domain description, if there is one, for the user to select a TMS domain for use with a particular study. If there is no description, the system displays the TMS domain name.



Video [Show me how!](#)


- [Define TMS Sets](#)
- [Define TMS Set columns](#)
- [Force rederivation](#)

## Define TMS Sets

Specify which information to derive by creating one or more TMS Sets for each dictionary. The study configurator then associates TMS domains and their terminologies to a study and maps TMS Set columns to target data model columns.

The study configurator does not need to map all the columns in the TMS Set. You can either:

- Define a single TMS Set for each dictionary in TMS with the maximum number of columns that might ever be required, and let the study configurator select and map the columns needed in each study.
- Define multiple TMS Sets for each dictionary, each with exactly the columns required in a particular study. The study configurator can then map all TMS Set columns to target table columns in that study.


1. Click the Navigation icon  at the top of any page and then click **Administration**.

2. Click the **TMS** tab.
3. Click the **+Add** icon in the TMS Sets pane.
4. Enter a **Name** and **Description** for the TMS Set. Both are displayed on the Study Configuration page.
5. Select a **Terminology** to code against. All terminologies (*dictionaries*) defined in the local TMS instance are listed.
6. Click **OK**. The system adds a column for the dictionary coding level to the TMS Set columns.

**Next:** [Define TMS Set columns](#)

## Define TMS Set columns

Define a TMS Set column for each piece of information to be derived from TMS to DMW for each coded term.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **TMS** tab.
3. Select a TMS Set.
4. Click the **+Add** icon in the TMS Set Columns pane.
5. **Column Designation:** Enter a descriptive name to enable the study configurator to map this TMS Set column to a table column that will store the derived data.
6. **Column Type:** Select one:
  - **Auxiliary Input:** for mapping to a DMW table column that contains auxiliary information required to code data in WHO-Drug Format C, such as the country where the drug is distributed, its form (for example, tablets or coated tablets), or strength.
  - **Derived:** for mapping to a DMW table column that will hold data derived from TMS.
  - **Indicator:** for mapping to a DMW table column that contains the indication for which a drug was prescribed. This is used to derive a related high-level term, for example in the Anatomical - Therapeutic - Chemical (ATC) level in WHO-Drug Format C, where the value may vary depending on the indication.

Each TMS Set also has one column of type Primary. The primary column must be mapped to the column containing items (*terms*) to be coded.

7. **TMS Level Name:** Select the level from which to derive data into the mapped column. The choices include all of the dictionary's defined levels and Dictionary Informative Notes, which may be defined in TMS and contain the dictionary version.
8. **TMS Field:** The options vary depending on whether you specified a dictionary level or InFormative Notes.

If you specified a **dictionary level**, the TMS Field choices include:

- **TERM:** The dictionary term related to the coded term in the selected level.

- **TERM\_UPPER**: The dictionary term related to the coded term in the selected level, in uppercase.

The choices also include optional, customizable *level details* that your company may have defined for the dictionary level in TMS:

- **CATEGORY**: A category value defined by your company in TMS.
- **DICT\_CONTENT\_ID**: The unique ID generated by TMS for the dictionary level.
- **DICT\_CONTENT\_ALT\_CODE**: An alternate ID for the dictionary level; designed to cross-reference a legacy company dictionary.
- **DICT\_CONTENT\_CODE**: The unique ID of the dictionary level as provided by the vendor. This column is indexed.
- **VALUE\_1 through VALUE\_4**: Four customizable fields can store information about the dictionary level.

If you specified text **Dictionary Informative Notes** for TMS Level Name, select:



- **DICTIONARY VERSION**: The dictionary version as defined in an Informative Note for the base dictionary in TMS.
- **(RDC ACTION TEXT is not used.)**

9. Click **OK**.

## Force rederivation

Normally, transformations process only new or changed data. Use the Force Rederivation job to process all data when you have made structural changes related to TMS in an ongoing study such as:

- Adding columns to target tables to hold derived data.
- Updating a dictionary to a new version with a different structure from the old one.
- Changing domain-related settings in the TMS reference codelist TMS\_CONFIGURATION.

1. Go to the  Home page.
2. Select the study.
3. Click the  Modify icon at the top of the Studies pane.
4. In the Modify Study window, click **TMS**.
5. Click **Force Rederivation**. A confirmation message appears because running the job may take a long time. You can still work while it runs.
6. Click **OK**.

For information about TMS-DMW data processing, forced rederivation, and DMW data displayed in TMS, see [Oracle Thesaurus Management System \(TMS\) integration](#).

## Set up a data visualization tool

You can integrate an external data visualization tool so that users can view data graphically and interactively with the protection of Oracle DMW security and blinding access privileges.

Visualization tools access one clinical data model at a time, along with any custom listings that read from the model. If you are using custom listings, we recommend setting a profile value as detailed in [Use custom listing name for the custom listing schema](#).

You can use:

- Third-party tools that use generic-type business areas to work with Oracle LSH and Oracle DMW.
- Oracle Business Intelligence Enterprise Edition (OBIEE). An adapter is included with Oracle LSH. See the Oracle Life Sciences Data Hub *Installation Guide* and *System Administrator's Guide* for instructions.

### Note:

To use OBIEE, you must create business areas in Oracle LSH. The business areas that are created automatically for a clinical data model in Oracle DMW are "generic," not specialized for OBIEE. See the *Oracle Life Sciences Data Hub Application Developer's Guide* for instructions.

- You can build an integration to a different tool. See the *DMW Data Visualization Integration Guide*, My Oracle Support article 2284413.1. If you are using custom listings, use the API `CDR_PUB_API_GVA.getCustomListingBA`.

To allow users to see data in a particular DMW clinical data model, the study configurator must select the Business Area option for the model.

## Configure session timeout (optional)

By default, a user session times out after 20 minutes of inactivity. To change this setting:

1. Open the `plan.xml` file, which is contained in the software directory on the WebLogic Server, in a text editor.
2. Locate the following code:

```
<variable>  
  <name>SessionTimeout</name>  
  <value>20</value>  
</variable>
```

3. Change the value to the number of minutes you want to use as a timeout value.



 **Note:**

The plan.xml file is replaced for each middle tier DMW patch. You need to repeat this procedure after each patch installation.

4. Redeploy the DMW middle tier, following instructions in the patch release notes or installation guide.
5. Restart the WebLogic Server.

# 2

## Cross-study setup outside DMW

DMW is installed with Oracle Life Sciences Data Hub (LSH) and shares the same database. LSH is installed on the Oracle E-Business Suite, and uses its profiles, lookups, and user management systems.

- [Set up study and library groupings](#)
- [Set up custom program and function groupings](#)
- [Set lookup values for Reasons for Change and more](#)
- [Set profiles to determine system behavior](#)

### Set up study and library groupings

Add a set of study groups to organize studies in a logical way. Codelists and library clinical data models use the same organization. Users select a grouping when they create a study or library object, and when they search for a study template, clinical data model, transformation, or validation check to reuse.

For example, you can organize studies and library objects by project, drug, or therapeutic area. The user interface label for study groupings is Project, but you can change it by resetting a profile. See [Change the study grouping user interface label](#).


When deciding how to organize your studies, consider:



- You can create only one flat list of values. So to organize studies by drug as well as therapeutic area you must create groupings like "Cardiology Drug A" and "Cardiology Drug B."
- If you have clinical data models (sets of tables) generic enough to be used in multiple groupings, create a "Generic" grouping.
- The grouping becomes the namespace for its studies and library objects. This has implications for user security privileges: if you assign a user group to the study grouping, the user group is assigned to all studies and library objects in the grouping. A study configurator can revoke the assignment and assign different user groups to the study.

Study groups are Oracle LSH domains. For information on creating them using APIs, see the *Oracle Health Sciences Life Sciences Warehouse Application Programming Interface Guide*.

When you create a study in the DMW user interface, the system creates it as a subdomain in the selected study group domain.

To create study groups in the LSH user interface:

1. Log in to Oracle LSH. Expand the **Life Sciences Data Hub** node on the left and click **Applications**.
2. In the Applications window, click the  Search icon next to the **Select Domain** field.

3. Select Search By **Domain Name**, enter `DMW_DOMAIN`, then click **Go**.
4. Click the  Quick Select icon for `DMW_DOMAIN`.
5. Click the  Create Child icon for `DMW_DOMAIN`.
6. From the **Select Child** list, select **Domain** and click **OK**.
7. Enter a **name** exactly the way you want it to appear in the user interface. Do not use special characters (except `_`) or reserved words.
8. Click **Apply**.

## Set up custom program and function groupings

To create a custom program or function for use in a transformation from one clinical data model to another or in a validation check, programmers must create a program in the Oracle `DMW_UTILS` domain in Oracle LSH.

You can create application area containers within the Oracle `DMW_UTILS` domain to help users find appropriate custom programs and functions and reuse them, promoting standardization.

The process is similar to creating domains to organize studies and libraries; see [Set up study and library groupings](#).






### Note:

For performance reasons, Oracle recommends creating application areas instead of domains inside `DMW_UTILS` to organize programs and other objects.

For information on creating program and function group application areas using APIs, see the *Oracle Health Sciences Life Sciences Warehouse Application Programming Interface Guide*.

To create grouping application areas in the LSH user interface:

1. Log in to Oracle LSH. Expand the **Life Sciences Data Hub** node on the left and click **Applications**.
2. In the Applications window, click the  Search icon next to the **Select Domain** field.
3. Select Search By **Domain Name**, enter `DMW_UTILS`, then click **Go**.
4. Click the  **Quick Select** icon for `DMW_UTILS`.
5. Click the  **Create Child** icon for `DMW_UTILS`.
6. From the **Select Child** list, select **Application Area** and click **OK**.
7. Enter a **name** as you want it to appear in the user interface. Do not use special characters (except `_`) or reserved words.
8. Click **Apply**.

## Set lookup values for Reasons for Change and more

1. Open your Oracle LSH URL.
2. Log on with the system administrator account. An E-Business Suite screen opens.
3. From the Navigator drop-down, select **LSH Setup Admin**, then **Setups**, then **Lookups**.
4. Press the **F11** key. The window enters Query mode.
5. In the **Type** field, enter the name of the lookup you want to see:
  - `DME_DSC_ACTION_REASON` to create standard Reasons for Change.
  - `DME_PART%` to set the number of small, medium, and large studies in a database partition.
6. Press **Ctrl+F11** to enter the query.
7. Enter values.



### Tip:

The **Meaning** text appears in the UI exactly as entered. Leave the **From** and **To** columns blank to apply the values immediately and with no end date.

- [Reasons for change](#)
- [Number of studies per partition](#)

## Reasons for change

To enable users to select from a list of predefined reasons for change to discrepancies, add values to the lookup `DME_DSC_ACTION_REASON`. The access level is **User**. For each value, add a code and a meaning. The *meaning* text appears in the user interface as the reason for change.

If you define meaning text that is the same as Reason for Change text in InForm, when an InForm user applies a Reason for Change that is then imported to Oracle DMW, Oracle DMW recognizes that the text is the same and stores the code as well as the meaning. Reasons for change are configurable in InForm as well as DMW.

## Number of studies per partition

(`DME_PARTITION_DEVQC` and `DME_PARTITION_PROD`) The access level is **User**.

When users define a study in Oracle DMW they must specify whether they expect the amount of data collected in the study to be small, medium, or large relative to other studies.

These lookups set the maximum number of small, medium, and large studies' data in certain cross-study internal tables that can be stored in a single database partition. Development and QC data are stored in the same partition, while Production data is stored in a separate partition.

The default values are: 1 large study, 5 medium studies, and 20 small studies for both lifecycle partitions.

You can change the default values in the Meaning column. Each value must be different from the others in the same lookup.

See [Database partitioning](#) for more information.

## Set profiles to determine system behavior

1. Open your Oracle LSH URL.
2. Log on with the system administrator account. An E-Business Suite screen opens.

 **Note:**

This user interface requires Java 6 Update 7 (1.6.0.0.7). If you do not have it installed, you can download it from <http://www.oracle.com/technetwork/java/javase/archive-139210.html>. To use this feature, you must accept all warnings.

3. In the Main Menu pane, expand the **System Administrator** (not System Administration) node, then the **Profile** node, and then click **System**.  
A new browser screen opens with several windows open and the Find System Profile Values window on top.

 **Note:**

If you lose the Find System Profiles window at any point, click the **Search** icon in the toolbar or click **System Profiles** in the Top Ten list.

4. In the **Profile** field, enter the name of the profile. See the following tasks for details.
  - [Use character semantics](#)
  - [Increase the maximum number of nested domains](#)
  - [Append username to discrepancy text](#)
  - [Change the study grouping user interface label](#)
  - [Register root folders for File Watcher watched folders](#)
  - [Register root folders for File Watcher archive folders](#)
  - [Set blinding behavior for InForm hidden items](#)
  - [Make discrepancy categories mandatory](#)
  - [Make discrepancy actions mandatory](#)
  - [Date format for conversion to text in unpivot transformations](#)
  - [Hosted environments](#)
  - [Set the default number of days of job history to display](#)
  - [Use custom listing name for the custom listing schema](#)

- [Set currency behavior for Staging with Audit tables](#)
- [Turn debugging on or off](#)
- [Enable UI changes for a clinical data system other than InForm](#)
- [Set login-related and other profile values](#)
- [Enlarge SAS buffer size](#)

## Use character semantics

On each computer where you install Oracle DMW, you must set the Oracle Applications profile **LSH: Use Character Semantics for Workarea Installation** to **Yes**, as instructed in the *Oracle Life Sciences Data Hub Installation Guide*.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter LSH: Use Character Semantics for Workarea Installation.
3. Click **Find**.
4. In the **Site** column, select YES.
5. In the File menu, select **Save and Proceed**.

## Increase the maximum number of nested domains

**LSH: Domain Nesting Levels** should be set to at least 6 because three levels of domains are predefined for Oracle DMW and you will need more to create categories such as Therapeutic Areas.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter LSH: Domain Nesting Levels.
3. Click **Find**.
4. In the **Site** column, enter a number between 6 and 9. Oracle recommends 9.
5. In the File menu, select **Save and Proceed**.

## Append username to discrepancy text

This profile determines the default setting for a checkbox in the Oracle DMW discrepancy creation user interface. Users can override the setting.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter Oracle DMW: Append Username to Discrepancy Text
3. Click **Find**.
4. In the **Site** column, select Yes or No.
  - If set to **No**, the default setting is not to append the username of the person creating the discrepancy to the discrepancy text. Note that the system tracks the username in the database regardless of this setting.
  - If set to **Yes**, the default setting is to append the username of the person creating the discrepancy to the discrepancy text. When discrepancies are sent to InForm, this information is displayed in InForm.

5. In the File menu, select **Save and Proceed**.

## Change the study grouping user interface label

This profile determines the label that appears in the user interface in several places for the category of a study or library. By default, the label is **Project**.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter `Oracle DMW_STUDY_CLASSIFICATION_UI_LABEL`.
3. Click **Find**.
4. In the **Site** column, enter the label exactly as you want it to appear in the user interface, including upper- and lowercase.
5. In the File menu, select **Save and Proceed**.

## Register root folders for File Watcher watched folders

This set of profiles tells the system where to look for SAS and text data files to be loaded into Oracle DMW. There are nine profiles. You enter values for **either**:

- Three folders, one for each lifecycle. Both SAS and text files are placed in the same folder.
- Six folders, one for each lifecycle/file type combination.

You must create the root folders in the locations you specify here. All studies in this Oracle DMW instance must use the same three or six root folders for their input data files. The system creates a study-specific subfolder in each root folder using the name you specify; see [Create study File Watchers](#). The study-specific subfolders become the *watched locations* for the study.

### Note:

If you change these profile values after using them, you must stop and restart the File Watcher service; see [Changing the root folder location for data files](#).

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter `Oracle DMW:FWR_ROOT_FOLDER%`.
3. Click **Find**.
4. In the **Site** column, enter the full path to the subfolder for the profile's file type/ lifecycle combination. Oracle recommends using a naming convention so that it is easy to tell which folder should hold which files. Enter values for **either** the first six profiles **or** the last three.

If you want to use six file type-specific root folders, enter values for these profiles:

- `DME:FWR_ROOT_FOLDER_TEXT_DEV` for text files in the Development lifecycle.
- `DME:FWR_ROOT_FOLDER_TEXT_QC` for text files in the Quality Control lifecycle.
- `DME:FWR_ROOT_FOLDER_TEXT_PROD` for text files in the Production lifecycle.

- DME:FWR\_ROOT\_FOLDER\_SAS\_DEV for SAS files in the Development lifecycle.
- DME:FWR\_ROOT\_FOLDER\_SAS\_QC for SAS files in the Quality Control lifecycle.
- DME:FWR\_ROOT\_FOLDER\_SAS\_PROD for SAS files in the Production lifecycle.

If you want to use three folders for both file types, enter values for these profiles:

- Oracle DMW:FWR\_ROOT\_FOLDER\_ALL\_DEV for SAS and text files in the Development lifecycle.
- Oracle DMW:FWR\_ROOT\_FOLDER\_ALL\_QC for SAS and text files in the Quality Control lifecycle.
- Oracle DMW:FWR\_ROOT\_FOLDER\_ALL\_PROD for SAS and text files in the Production lifecycle.

5. In the File menu, select **Save and Proceed**.

## Register root folders for File Watcher archive folders

To archive data files instead of deleting them after loading their data into Oracle DMW, you must create archive folders and register them using this set of profiles.

There are nine profiles, corresponding to the nine profiles that register root folders for watched folders. You must choose the same setup—three or six root folders—for archive folders that you did for watched folders. The system creates a study-specific folder in each root folder using the name you specify; see [Create study File Watchers](#).

When the system moves a file to an archive folder, it appends the current timestamp to the file name to ensure uniqueness.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter Oracle DMW:FWR\_ARCHIVE%
3. Click **Find**.
4. In the **Site** column, enter the full path to the subfolder for the profile's file type/lifecycle combination. Oracle recommends using a naming convention so that it is easy to tell which folder should hold which files.

If you want to use six file type-specific root folders, enter values for these profiles:

- DME:FWR\_ARCHIVE\_TEXT\_DEV for text files in the Development lifecycle.
- DME:FWR\_ARCHIVE\_TEXT\_QC for text files in the Quality Control lifecycle.
- DME:FWR\_ARCHIVE\_TEXT\_PROD for text files in the Production lifecycle.
- DME:FWR\_ARCHIVE\_SAS\_DEV for SAS files in the Development lifecycle.
- DME:FWR\_ARCHIVE\_SAS\_QC for SAS files in the Quality Control lifecycle.
- DME:FWR\_ARCHIVE\_SAS\_PROD for SAS files in the Production lifecycle.

If you want to use three folders for both file types, enter values for these profiles:

- Oracle DMW:FWR\_ARCHIVE\_ALL\_DEV for all files in the Development lifecycle.
- Oracle DMW:FWR\_ARCHIVE\_ALL\_QC for all files in the Quality Control lifecycle.
- Oracle DMW:FWR\_ARCHIVE\_ALL\_PROD for all files in the Production lifecycle.

In addition, you must set the following profile values:



- Oracle DMW:FWR\_ARCHIVE\_ENABLE Set to Y to enable archiving. The default value is N.
- Oracle DMW:FWR\_ARCHIVE\_SCHEDULE\_DAYS Enter the number of days to elapse between loading the file and moving it to the archive folder. The default value is 7.

 **Note:**

Be sure to set the file deletion time period for individual study File Watchers to a greater number of days.

5. In the File menu, select **Save and Proceed**.

## Set blinding behavior for InForm hidden items

If this profile determines whether data marked as Hidden in InForm is imported to DMW as blinded or not.

1. Log in. See "[Set profiles to determine system behavior](#)".
2. In the **Profile** field, enter Oracle DMW:BLIND\_INFORM\_HIDDEN\_ITEMS
3. Click **Find**.
4. In the **Site** column, enter either:
  - Y so that any tables that contain columns based on InForm hidden items are created with column-level blinding on the hidden items. Blinded columns have a default masking value.
  - N to create all tables with their blinding flag set to N. Users can manually define blinding for tables in the data model in Oracle DMW.
5. In the File menu, select **Save and Proceed**.

## Make discrepancy categories mandatory

Set this profile to Yes to require a manually created discrepancy to have an assigned category. See [Create categories for flags, discrepancies, and validation checks](#).

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter DMW\_DSC\_CATEGORY\_MANDATORY.
3. Click **Find**.
4. In the **Site** column, enter:
  - Yes to require manually created discrepancies to have a category assigned.
  - No to make these categories optional.
5. In the File menu, select **Save and Proceed**.

## Make discrepancy actions mandatory

Set this profile to Yes to require a manually created discrepancy to have an assigned action. The action sets the state and tag of the discrepancy.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter `DMW_DSC_ACTION_MANDATORY`.
3. Click **Find**.
4. In the **Site** column, enter:
  - Yes to require manually created discrepancies to have an action assigned.
  - No to make these actions optional.
5. In the File menu, select **Save and Proceed**.

## Date format for conversion to text in unpivot transformations

This profile determines the date format for use by an unpivot transformation when converting DATE datatypes to VARCHAR2.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter `DMW_XFM_UNPIVOT_DATE_FORMAT`.
3. Click **Find**.
4. In the **Site** column, do one of the following:
  - Leave blank. The system uses the default date format in the database.
  - Enter a valid Oracle date format, for example, DD-MM-YYYY for 22-01-2018 or DD/MON/YYYY for 22/JAN/2018.
5. In the File menu, select **Save and Proceed**.

## Hosted environments

This profile must be set to **Y** if the installation is in an environment hosted by Oracle, to support Single Sign-on functionality. The default value is **N**, which is the required setting for on-premise installations.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter `LSW_SSO_INTEGRATED`
3. Click **Find**.
4. In the **Site** column, enter:
  - Y if the installation is in an environment hosted by Oracle, to support Single Sign-on functionality.
  - N if the installation is maintained by your company.
5. In the File menu, select **Save and Proceed**.

## Set the default number of days of job history to display

In the Home page Data Loads, Transformations, and Validation Checks tabs, the system displays the run history for jobs for the number of days you specify in this profile. The user can toggle between this display and a display of the full history for data loads, transformations or validation check batches.

1. Log in. See [Set profiles to determine system behavior](#).

2. In the **Profile** field, enter `DMW:NUM_DAYS_PAST_RUN_HISTORY`
3. Click **Find**.
4. In the **Site** column, enter the number of days for which you want to display job history by default. The default value is 7.
5. In the File menu, select **Save and Proceed**.

## Use custom listing name for the custom listing schema

If you are using a visualization tool to view data through custom listing schemas, set this profile to **Yes** to generate the secondary schema name with the same name as the custom listing. Using the name makes it easier for users to pick the listing they want to view in the visualization tool. The visualization tool can also query for the custom listing name instead of the ID. For example:

```
select * from BA_INF_CL_DEV.CLTEST;
```

where `BA_INF_CL_DEV` is the custom listing schema and `CLTEST` is the custom listing name, instead of:

```
select * from BA_INF_CL_DEV.QB_3254235_V;
```

where `QB_3254235_V` is the generated ID.

If set to **No**, the secondary schema created for the custom listing is named with the map ID generated by the system and visible only in the LSH work area.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter `DMW : Synch Custom Listing BA synonyms with Primary Datamodel Business Area`
3. Click **Find**.
4. In the **Site** column, enter:
  - Yes to create synonyms in the primary business area schema based on custom listing names.
  - No to name the schemas using a generated ID.
5. In the File menu, select **Save and Proceed**.

## Set currency behavior for Staging with Audit tables

If a job using Staging with Audit processing does not load, modify, or delete any records, by default the currency is soft-deleted, making it appear that the job never ran, and the currency is not available for that table for downstream programs. To change this, set this profile to **Yes**.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter `CDR_SAVE_CURR_STG_TAB: Record currency for Staging table on empty loads`
3. Click **Find**.
4. In the **Site** column, enter:

- **Yes.** The new currency is recorded for Staging with Audit tables even when a job makes no data changes. The currency is then available for that table for downstream programs.
  - **No** (or any other value). No currency is recorded when a job makes no data changes.
5. In the File menu, select **Save and Proceed**.

## Turn debugging on or off

Enable or disable the recording of debugging statements for database processes. The setting applies to all users. The system reads the value of the profile once per user session, so you may need to restart the application tier for a changed setting to take effect.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter `LSH:ENABLE_DEBUGGING`
3. Click **Find**.
4. In the **Site** column, enter:
  - `Y` to enable debugging.
  - `N` to disable debugging.
5. In the File menu, select **Save and Proceed**.

## Enable UI changes for a clinical data system other than InForm

It is possible to integrate a clinical electronic data capture (EDC) system other than InForm with DMW. See *Using the Generic Connector to Integrate DMW with a Clinical Data System*, My Oracle Support article 2172786.1.

This profile makes changes in the UI required for the integration, including a tab for a new input clinical data model type called *External\_System* Configuration, new actions for sending discrepancies to the external system, and a new web service location type.

1. Log in. See [Set profiles to determine system behavior](#).
2. In the **Profile** field, enter `DMW_GC_ON`
3. Click **Find**.
4. In the **Site** column, set to `OUI` to make user interface changes related to the external system integration visible.
5. In the File menu, select **Save and Proceed**.

## Set login-related and other profile values

To control various login and password-related requirements, as well as other system behavior, follow instructions in the *Oracle Life Sciences Data Hub System Administrator's Guide*.

See [How to Log In to Oracle Applications Profile Forms](#)

## Enlarge SAS buffer size

By default, this profile sets the default SAS buffer size option for PROC SQL statements to 262144, which allows loading SAS data files with large "logical record" length. It should not be necessary to change the value of this profile.

# 3

## Study setup

To set up integration with data source systems for each study, you do the following tasks in the Administration page. Then the study configurator creates a clinical data model for each data source.

- [Set up the study File Watcher to load data files](#)
- [Set up InForm data exchange](#)
- [Set up data exchange with a non-InForm clinical data system](#)
- [Subscribe users to job status notifications](#)

### Set up the study File Watcher to load data files

- [Create study File Watchers](#)
- [Select a distributed processing \(DP\) server for the study File Watcher](#)


### Create study File Watchers

For each study, create a study File Watcher. It watches the folder you specify here for uploaded data files and loads the data into Oracle DMW.

#### Prerequisites

Specify the watched folder locations in a system profile. See [Register root folders for File Watcher watched folders](#).

If you want to archive (not delete) loaded data files, specify the archive folder location. See [Register root folders for File Watcher archive folders](#).

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **File Watcher** tab.
3. Click the **+Add** Icon.
4. **Study:** Select the name of the study from the drop-down list. The list includes studies with no existing study File Watcher.
5. **Study Folder Name:** Enter a valid UNIX case-sensitive directory name with **no underscores** ( ) to be used as the final directory of the watched folder path after each root folder. The Study folder name must be **unique within the DMW instance** and you will receive an error if the name you enter is already in use.

If you have enabled archiving and specified locations for archiving files, it creates study-specific archive folders as well as File Watcher folders.

6. **Delete Files After:** To permanently delete a file, enter the number of days after the load date to delete it.

To *archive* the files instead of deleting them, enter a higher number here than in the archiving profile value. (See [Register root folders for File Watcher archive folders.](#))

7. Click **OK**. The system creates actual folders for the study on the file system.



**Next:** [Select a distributed processing \(DP\) server for the study File Watcher.](#)

## Select a distributed processing (DP) server for the study File Watcher

### Prerequisites

These tasks are documented in the *Oracle Health Sciences Data Management Workbench Installation Guide*:

- Set up the Oracle LSH Distributed Processing (DP) Server and, as part of it, the File Watcher service. The File Watcher service detects files to be loaded.
- Define at least one DP Service Location and SAS and Text for SQL\*Loader DP Server services in the Oracle LSH user interface. These services load data from files into the Oracle DMW database. See the *Oracle Life Sciences Data Hub System Administrator's Guide*.
- Security for the folders.
- Compatible time zone configuration on each computer. See the *Oracle Health Sciences Data Management Workbench Installation Guide*.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **File Watcher** tab.
3. Select a Study File Watcher and click the  **DP Servers for File Watchers** icon.
4. Select one DP Server for each type of data file to be loaded in the study.
5. Click **OK**.

## Set up InForm data exchange

The following sections describe how to:

- [Create users for InForm integration](#)
- [Add InForm remote locations](#)
- [Add InForm web service locations](#)

## Create users for InForm integration

To create users for InForm integration, you need to:

- [Create required Oracle accounts](#)
- [Create required InForm users](#)

## Create required Oracle accounts

On each InForm study database, run scripts to create a read-only user account for Oracle DMW to use to access data and metadata in InForm.

The account has Select privileges on all tables and views in study accounts referenced by the InForm Connector, including metadata views, operational data views, and RDE views. This schema also has packages that facilitate the data load process.

Use the credentials of this account when you set up a database connection (remote location) in the Oracle DMW InForm configuration for each study using the InForm database.

- [Create Directory on Each InForm Database](#)
- [Copy Scripts](#)
- [Run the Driver Script](#)

### Create Directory on Each InForm Database

On each InForm database with a study for which you plan to use Oracle DMW, create one OS directory using the `mkdir` command to hold scripts you must copy and run.

You need one directory per database, not per study.

### Copy Scripts

Copy the following files from the directory `$CDR_TOP/patch/115/sql/` on the computer where you have installed Oracle Life Sciences Data Hub to the InForm database directory you created.

- **DMWInFormInstall.sql**—the driver script
- **DMWInFormUser.sql**—creates new users or confirms existing users
- **DMWInFAdms.pls**—installs a package specification into the Oracle DMW administration account
- **DMWInFAdmb.pls**—installs a package body into the Oracle DMW administration account
- **DMWInFormROAccessObjs.sql**—installs a table into the Oracle DMW read-only access account
- **DMWInFroas.pls**—installs a package specification into the Oracle DMW read-only access account
- **DMWInFroab.pls**—installs a package body into the Oracle DMW read-only access account

### Run the Driver Script

The driver prompts for all required input parameter values and calls the other scripts as required.

1. Log into SQL\*Plus with an account with DBA privileges.
2. Go to the directory that contains the downloaded scripts.
3. Execute `DMWInFormInstall.sql`. The script prompts for:



- A name to give the log file.
- TNS name **or** connect string for the InForm database. If you enter the connect string, do not enter any spaces.
- `system` or other DBA username and password.
- Name of the Oracle DMW Admin account to be used or created for the purpose of giving privileges to the Oracle DMW read-only access account. The system creates the account if it does not already exist.
- Name of the Oracle DMW read-only access account to be used or created. The system creates the account if it does not already exist.

 **Tip:**

Do not use spaces or special characters other than underscore ( `_` ) in the username or password.

- Passwords for both accounts. If the accounts are new, the script prompts you to confirm each password. If the accounts already exist, you must enter a password, but the system does not change the existing password. It proceeds to create or update the packages owned by the schema.
- If the read-only access account is new, the script also prompts for a tablespace name. It then creates a tablespace on the InForm database to be used for the integration with Oracle DMW and creates or updates all Oracle DMW objects in this tablespace.

## Create required InForm users

For each InForm study:



1. Log in to the system you use to create InForm user accounts:
  - If your InForm installation is on-premise, use UMT.
  - If your InForm installation is hosted by Oracle, use Single Sign-on.
2. Create a user with a **suggested username DMW\_AUTH** to be used for authentication purposes by the web service connection. This user does not need any privileges. You enter this username and password when creating web service locations.
3. Create a user with the **required username DMW\_QUERY** (in **UPPER CASE**) to be used for sending and updating discrepancies in InForm. Assign this user to a query group. The password for this user is not used in Oracle DMW.
4. Activate both accounts.

## Add InForm remote locations

Database links are used to load data and metadata from InForm to DMW.

When defined here, they are available for use in an InForm clinical data model. Alternatively, study configurators can create and edit them in the clinical data model.

1. Click the Navigation icon  at the top of any page and then click **Administration**.

2. Make sure the **Data Sources** tab is selected, then click the **InForm Remote Locations** subtab.
3. Click the  **Add** icon or  **Modify** icon.
4. Enter:
  - **Name:** A name for the InForm database. It cannot contain spaces, slashes, or special characters other than underscore (`_`). This is displayed for study configurators.

 **Tip:**

Include the study name and lifecycle stage in the name to make it easy for the study configurator to select.

- **ConnectionString:** The text of the Using clause of the Create Database Link SQL statement. This is normally the same as the Description Clause of a TNSNAMES definition—for example:

```
(DESCRIPTION=(ADDRESS=(PROTOCOL=TCP)(HOST=host_name.company_domain.com)
(PORT=1521)))(CONNECT_DATA=(SERVER=DEDICATED)(SERVICE_NAME=trial_name.world))
```

 **Tip:**

It cannot contain spaces.

- **Username:** The name of the DMW read-only access account in the InForm database for this remote location; see [Create required Oracle accounts](#) for details. The system will use this account to connect.
- **Password:** Enter the password of the account. The system changes and encrypts the password after creating the database link.

In the unlikely event that you need to change the password, your InForm database administrator must change the password for the Oracle DMW read-only access account. You can then select **Enable Password Entry?** in the **Edit Remote Location** window and enter the new password. The system then recreates the database link and changes and encrypts the password.

 **Note:**

If you delete the remote location and create a new one with the same username, you must change the password in the InForm database first and then enter it here.




5. Click **Test Connection** to make sure it is set up correctly.
6. Click **OK**.

**Next:** [Add InForm web service locations](#).

## Add InForm web service locations

Web services are used to send discrepancies from DMW to InForm.

When created in the Administration page, they are available for use in the appropriate InForm study clinical data model. Alternatively, they can be created and edited in the clinical data model.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Make sure the **Data Sources** tab is selected, then click the **InForm Web Service Locations** subtab.
3. Click the  **Add** icon or  **Modify** icon.
4. Enter Web Service Location attributes.
  - **Name:** Enter any name for the web service location.

### **Tip:**

Include the study name and lifecycle stage in the name to make it easy for the study configurator to select.

- **Web Service URL:** Enter the URL for the study's InForm website.  
`http://your_InForm_server.your_company.com/your_trial/pfts.dll`
- **Authentication Trial Name:** Enter the study name exactly as it appears in the URL.
- **SSO Organization:** For an on-premise installation, do not enter anything here. Doing so will cause harm.

If your InForm installation, specifically the InForm Adapter, is hosted by Oracle, enter the organization associated with the DMW\_QUERY user as provisioned for Single Sign-On use.

- **Username:** The name of the account set up for authenticating DMW web service transactions. See [Create required InForm users](#) for details.

The suggested name is DMW\_AUTH.

### **Note:**

- The Username and Password fields are not displayed if DMW is installed using HTTP, not HTTPS.
  - Do not use spaces or special characters other than underscore ( `_` ) in the username or password.
- **Password:** Enter the password required for the same user account. The system encrypts the password.

5. Click **Test Connection** to test without saving, or **Test and Save**.

## Set up data exchange with a non-InForm clinical data system


- [Set up File Watcher](#)
- [Add a web service location for a non-InForm clinical data system](#)

### Set up File Watcher

If you are using a clinical data system other than InForm, you must load data from that system in files. Follow instructions in "[Set up the study File Watcher to load data files](#)".

### Add a web service location for a non-InForm clinical data system

If you are using a clinical data system other than Oracle InForm, define a web service location to enable Oracle DMW to send discrepancies to it and to enable data reviewers to open the external system from DMW to view data and discrepancies there.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Make sure the **Data Sources** tab is selected, then click the **External Data Sources** subtab.
3. Click the **+Add** Icon.
4. Enter Web Service Location attributes.
  - **Name:** Enter any name for the web service location.
  - **Data Model Sub Type:**
  - **Username:** The name of the account set up for authenticating DMW web service transactions.

The suggested name is DMW\_AUTH.

#### Note:

- Do not use spaces or special characters other than underscore ( `_` ) in the username or password.
  - The Username and Password fields are not displayed if DMW is installed using HTTP, not HTTPS.
5. Click **OK**.


## Subscribe users to job status notifications

You can specify that certain users receive notifications whenever a particular type of job completes with a particular status in a particular study. Users can also set up their own notifications on the Home page.

User accounts that become inactive or accounts that lose privileges for the target study are automatically unsubscribed from notifications.

### Prerequisite

If you haven't already, follow the instructions in My Oracle Support article 164871.1, "Configuring the Workflow Notification Mailer(s) in Oracle Applications Manager 11i" as directed in the *Oracle Life Sciences Data Hub Installation Guide*.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **Notification Subscription** tab.
3. In the Study Name list, select the study for which you want to set up notifications.


#### **Tip:**

Type a study name in the search box directly above the list and press Enter to find a particular study.

To stop filtering, delete the filter name and click **Refresh**.

4. In the Notification Events list, select one event for which you want the system to send notifications:
  - **Job types:** File loads, InForm loads, Transformations, Validation Checks
  - **Completion statuses:** Success, Warning, Failure

The Subscribed Users list displays the users who currently receive email notifications when a job completes with the selected status for the selected study.

5. Click the **Subscribe/Unsubscribe Users** icon  on the Subscribed Users title bar.
6. Select the checkbox to the left of a user to subscribe them to notifications for the selected study and event.

#### **Tip:**

You can use the search box directly above a column to search in that column or click on the column heading to sort by it.

To unsubscribe users, deselect the checkbox.

7. Click **Save**.




# 4

## Study monitoring

The following tasks describe how to manage ongoing studies. For example, it includes steps to monitor, suspend, and resume study File Watchers. It also describes how to view, cancel, and suspend scheduled jobs. See the following topics for details.

- [Monitor, suspend, and resume study File Watchers](#)
- [View file specifications for study File Watchers](#)
- [Monitor validation check discrepancies sent to the source data system](#)
- [View, cancel, and suspend scheduled jobs](#)
- [View past and current job executions](#)
- [Use tracing and logging](#)
- [Set up data visualizations](#)

### Monitor, suspend, and resume study File Watchers


1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **File Watcher** tab.
3. Select a study file watcher. Each study has one watcher for each lifecycle stage. You can see the lifecycle stage in the File Specifications pane.
4. Check the Watcher Status.
  - If it is Running, you can click the  **Suspend Watcher** icon to suspend it.
  - If the Watcher is Suspended, click the  **Resume** icon to resume it.
5. Check the **DP Server Status**. If it is Offline, the Watcher cannot run, even if its status is Running. To start it, follow instructions in the *LSH Administrator's Guide*.

 **Note:**

The study configurator can also suspend and resume File Watchers.

### View file specifications for study File Watchers

If a data file is not loaded as expected, the problem may be that the file is not named as required by the file specification for the study/clinical data model/lifecycle combination. The study configurator creates file specifications.


1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **File Watcher** tab.
3. Select a study file watcher. Each study has one watcher for each lifecycle stage. You can see the lifecycle stage in the File Specifications pane.
4. Check the file specification in the File Name column against the actual file name in the Home page, Files Not Processed tab.
  - The file specification is case-sensitive.
  - File specifications must use the POSIX standard Extended Regular Expression syntax. An asterisk (\*) in POSIX syntax matches zero or more occurrences of the preceding character. A dot (.) means "any single character."

For example, in the file specification CentralLab\_\*.zip, where the upload date is expected after the underscore (\_), the dot plus asterisk (.\* after the underscore means "any character or no characters."



For more information, see [https://docs.oracle.com/cd/B28359\\_01/server.111/b28286/ap\\_posix001.htm](https://docs.oracle.com/cd/B28359_01/server.111/b28286/ap_posix001.htm).

## Monitor validation check discrepancies sent to the source data system

Validation checks with an Initial Action set to *Send to System* immediately send discrepancies they create to InForm or another source data system as queries. To check the status of this operation:





1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **Validation Checks** tab.
3. Select a study and lifecycle stage.
 

For each source data system, DMW displays counts for the selected study and lifecycle stage:

  - **Processing forSystem** shows the number of validation check discrepancies currently being sent to the system.
  - **Failed Processing forSystem** shows the number of discrepancies that should have been sent to the system but weren't.
4. If any discrepancies failed to be sent, click the  **Reprocess Discrepancies** icon to send them again. Click the  **Refresh** icon to see progress.
 

Reprocessing is also available in the Home page, Validation Checks tab.

## View, cancel, and suspend scheduled jobs

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **Scheduled Jobs** tab.
3. Enter search criteria:
  - **Lifecycle:** (Optional) Select from the drop-down list.
  - **Study Name:** Enter part or all of the study name.
  - **User Name:** Enter part or all of the ID of the user who scheduled the job.
4. Click **Search**. The system displays all pending jobs for data loads, transformations, and validation checks.
5. You can filter by entering values in the blank field above any column. If the blank fields are not displayed, click the  **Query By Example** icon.
6. To cancel or suspend one or more jobs, select the job(s) and:
  - Click the  **Cancel All Jobs** icon. This applies to transformation, validation check batch, and data load jobs.
  - Click the  **Suspend Job(s)** icon. This applies to data load jobs.

 **Note:**

This pane displays currently scheduled jobs. After a job has been canceled or suspended here or elsewhere, it no longer appears.


The exception is that File Watcher Specifications that are current and not explicitly suspended are still displayed even if they are not running because the corresponding Study File Watcher is suspended. If the Study File Watcher is resumed, these File Watcher Specifications resume.

You cannot reschedule jobs in the Administration page. Do so:



- For transformations and validation checks, in the Home page.
- For data loads, in the Clinical Data Models page under Study Configuration.

## View past and current job executions

Use this page to query for jobs that have already run and jobs that are currently running. You can cancel jobs that are in progress.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **Job Execution** tab.
3. To find jobs:
  - Query in the Search Jobs pane. To search by date, job status, or submitting user, click **Advanced**.



- To filter results further, enter a string in the blank field above any column. If the blank fields are not displayed, click the  **Query By Example** icon.
4. To cancel a job, select it and click the  **Cancel** icon. You can only cancel jobs that currently have the status In Progress or Executing.



## Use tracing and logging

Use this page to turn on either logging (debugging) or tracing, either for a particular user or all users. When a user logs in while tracing or logging is running for any user or systemwide, a message appears at the top of every page notifying them that diagnostics are running.

- [Turn on tracing or logging](#)
- [Locate the trace file](#)
- [Turn off tracing or logging](#)
- [Truncate logging data](#)

## Turn on tracing or logging

Logging and tracing begin for each user when he or she logs in after the request has been made. They begin immediately for your own session.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **Tracing and Logging** tab.
3. Click the  **Add Session** icon.
4. **Session Type:** Select either **Logging** or **Tracing**.
5. **Session Scope:** Select either **System** (all users) or **User**.
6. If you selected User, select the user from the **User** drop-down.
7. If you selected Tracing for a particular user, enter a trace file identifier string to help you find the file on the database server.

Logging data is written to the table CDR.CDR\_EXE\_DEBUG.

## Locate the trace file

The trace file is generated on the database server. Its location and name are in the TRACEFILE column of the system view V\$PROCESS. Use the following query to fetch this and other useful information:



```
select s.sid,s.serial#,s.audsid,s.username,s.osuser, s.client_identifier,
s.sql_trace,s.action, p.spid, p.TRACEFILE
from v$session s,v$process p
where s.paddr=p.addr
and s.username is not null;
```

The username for nonbatch jobs is CDRRUN and the client\_identifier is the DMW username of the user whose session is traced. If tracing is running for a particular

user, the trace file identifier is appended to the trace file name just before the .trc extension.

## Turn off tracing or logging

When tracing or logging is turned off, the job is no longer displayed in this page.

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **Tracing and Logging** tab.
3. Select the process you want to stop.
4. Click the  **Cancel Session** icon.
5. For user logging or tracing, the **user must log in again** to end the process.





### Note:

When you stop the process, the record, including the file name, is no longer displayed.

## Truncate logging data

To delete all logging data from the database:

1. Click the Navigation icon  at the top of any page and then click **Administration**.
2. Click the **Tracing and Logging** tab.
3. Make sure no logging processes are currently running.
4. Click the  **Truncate Log Data** icon.

## Set up data visualizations

You can integrate an external data visualization tool so that users can view data graphically and interactively with the protection of DMW security and blinding access privileges, one clinical data model at a time. Requirements:

- The study configurator must select the Business Area option when he or she creates or modifies a clinical data model. The system then generates a *Business Area* object in the database containing views of all tables in the model.
- Users viewing DMW data in a visualization tool must have a database account and must log into the visualization tool using the database account.
- In hosted releases you must install the visualization tool locally and access your hosted data over your VPN.

# 5

## User management

DMW's security system is based on the Oracle Life Sciences Data Hub (LSH) security system.

See also: [How security works](#).

The following tasks are done there.

- [Create and set up user accounts](#)
- [Use or create object security roles](#)
- [Create and develop user groups](#)
- [Assign user groups to custom programs and study groupings](#)
- [Assign user groups to adapters for technology privileges](#)
- [How security works](#)

### Create and set up user accounts

If Oracle DMW is installed at your company, follow these instructions. If it is hosted at Oracle, follow instructions at <https://docs.oracle.com/health-sciences/ohs-iams/admin-guide/toc.htm#IAMS102>.

- [Create user accounts](#)
- [Assign application roles to users](#)
- [Create database accounts](#)

### Create user accounts

1. Log in to Oracle LSH.
2. Select **User Management** from the main menu on the left or from the Navigator drop-down.
3. Click **Users**.
4. In the **Register** drop-down, select **External Organization Contact** and click **Go**.
5. Enter values in the following fields:
  - **Email**. The user's email address.
  - **Name Fields**
  - **Organization**. Enter or search for the Organization to which the user belongs.

 **Note:**

You must set up the list of allowed values as a post-installation step for Oracle Applications, as described in the *Oracle® E-Business Suite System Administrator's Guide - Security*.

See [http://download.oracle.com/docs/cd/B53825\\_08/current/acrobat/121sasg.pdf](http://download.oracle.com/docs/cd/B53825_08/current/acrobat/121sasg.pdf).

- **Phone Number**
- **Account Information--Password.** If you select **Generate Automatically**, the system generates and emails the password to the user's email account.

If you select **Enter Manually** you must type and confirm the password and inform the user what it is. The user must reset the password in either case.

 **Note:**

You can set the minimum length and other requirements for passwords; see [Set login-related and other profile values](#).

6. Click **Submit**.
7. Click **OK**.

## Assign application roles to users

If Oracle DMW is installed at your company, follow these instructions. If it is hosted at Oracle, follow instructions at <https://docs.oracle.com/health-sciences/ohs-iams/admin-guide/toc.htm#IAMS104>.

For an explanation of application roles, see:

- [Application roles for specialized administrators](#)
  - [Application roles for user interface access](#)
  - [Data Blinding-related application roles](#)
1. Log in to Oracle LSH.
  2. Select **User Management** from the main menu on the left or from the Navigator drop-down.
  3. Click **Users**.
  4. In the User Maintenance screen, search for the user to whom you want to assign roles.
  5. Click the user's Update icon. The Update User screen appears.
  6. In the Roles subtab, click **Assign Roles**. The Search and Select screen appears.
  7. Search for all Oracle LSH predefined roles by selecting Search By Role, entering LSH%, and clicking **Go**. The system displays all the predefined Oracle LSH application roles in the lower part of the screen.
  8. Select each role you want to assign.

9. Click **Select**. The system adds the roles to the user and the Update User screen appears.
10. Enter a justification for assigning each role to the user.
11. Click **Apply**.

## Create database accounts

Study configurators need a database account to create and modify studies and study components. People viewing DMW data through a visualization tool also need database accounts.

1. Log in to Oracle LSH.
2. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **Database Account**.

Or, if Oracle LSH is already open, go to the Administration tab and select the **Database Account** subtab.

3. Click **Create**.
4. Enter values in the following fields:
  - **User Name**. Click the Search icon and enter search criteria for the Oracle LSH user for whom you are creating a database account.
  - **Database Account Name**. Enter a username for the database account. The text you enter is stored in uppercase.
  - **Password**. Enter a password of 8 characters or more for the Definer to use with the database account.
  - **Confirm Password**. Reenter the password.

 **Note:**

For security reasons, the user should reset the password in his or her Preferences screen.

5. Click **Apply**. The system returns you to the Database Account screen.

## Use or create object security roles

A role consists of a name, description, and a set of operations allowed on object subtypes. Users in a user group that have access to a particular object will be able to perform the operations on the types of objects specified by the role(s) they have in the user group.

- [Use predefined object roles](#)
- [Create object security roles](#)
- [Assign roles to operations](#)

## Use predefined object roles

Predefined object roles cover most non-administrator users for the lifecycle stage(s) they will be working in:

- **DMW\_STUDY\_DEVELOPER** (Development lifecycle stage) Only this role allows the creation of clinical data models, transformations, and validation checks. These are study configuration tasks.
- **DMW\_STUDY\_QC** (Quality Control lifecycle stage) This role is intended for people who will do formal testing of clinical data models, transformations, and validation checks in a study.
- **DMW\_STUDY\_PROD** (Production lifecycle stage) This role is intended for users who need to view and act on production data. (Users needing only View access should have the **DMW\_STUDY\_INST\_ACCESS** role.)

 **Note:**

These roles are sample roles provided for illustrative purposes only and are not intended to be used for production needs.

The **DMW\_STUDY\_DEVELOPER**, **QC**, and **PROD** roles allow the following privileges in the corresponding lifecycle stage:

- Loading data.
- Reviewing nonblinded and unblinded data and creating and managing discrepancies.
- Half the privileges required to view currently blinded data (blind break) or to unblind data. Application roles are required for the other half.
- Modifying clinical data models, transformations, validation checks, and custom listings.

For a list of all operations included in these roles, see [Predefined object security roles](#).

## Create object security roles

1. Log in to Oracle LSH.
2. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **Roles**.

Or, if Oracle LSH is already open, go to the Security tab and select the **Roles** subtab.

3. Click **Create**.
4. Enter values in the following fields:
  - **Role Name.** Enter a unique name for the role to be displayed in the Oracle LSH user interface.
  - **Code Value.** Enter a unique code for the role to be used internally by Oracle LSH.

- **Description.** Enter a description of the role to help group administrators decide if they want to assign the role to a particular user in their user group.
5. Click **Apply**. The Manage Roles screen appears. You can query for the role by name to check that it was created successfully.
  6. Set it to Active so that it is available for use:
    - a. In the Manage Roles screen, query for the role. The role appears.
    - b. Click the icon in the **Update** column. The Update Role screen appears.
    - c. Select **Is Active** and click **Apply**. You can assign subtype operations only to Active roles.

Next: [Assign roles to operations](#)

## Assign roles to operations

Users assigned to a role within a user group will be able to perform the operations you assign to the role.

To assign roles to operations, go to the Subtype subtab of the Security tab and do the following:

1. Log in to Oracle LSH.
2. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **Subtypes**.

Or, if Oracle LSH is already open, go to the Security tab and select the **Subtypes** subtab.
3. From the **View Subtype By** drop-down, select **Operation**.
4. Expand the node (+) of the object type. All the subtypes appear.
5. Expand the node (+) of the object subtype. All the subtype's operations appear.
6. Click the icon in the Manage column of the operation to which you want to assign or remove a role. The Add Role(s) to Operation screen appears.
7. Double-click on a role in the Available Roles column to move it into the Selected Roles column to assign it to the role. Or move it from Selected Roles to Available Roles to remove the assignment.

### Note:

- Select multiple roles using Shift+Click or Control+Click and move them by clicking the arrows.
  - To promote an input clinical data model to QC or Production, a user must have a role with the "Modify Val Status to QC" or "Modify Val Status to PROD" operation on **load sets** as well as on data models.
8. Click **Apply**. The system assigns the role(s) to the operation on the subtype and the Manage Subtype screen appears.

## Create and develop user groups

A user has access to an object only if he or she belongs to a user group that is assigned to the object, either explicitly or through inheritance.

Plan your user groups based on which objects they will be assigned to and whether the assignment will be for Metadata, Development, QC, or Production.

This section contains the following topics:

- [Create user groups](#)
- [Add users to user groups](#)
- [Assign a group administrator](#)
- [Add users and assign roles](#)
- [Clear the Oracle Applications cache](#)
- [Copy user groups with or without users](#)

### Create user groups

1. Log in to Oracle LSH.
2. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **User Groups**.

Or, if Oracle LSH is already open, go to the Security tab and select the **User Groups** subtab.

3. Click **Create**.
4. Enter values in the following fields:
  - **Group Name**
  - **Description**
  - **Is Active**. If selected, a study configurator can assign the user group to an object.
5. Click **Apply**.

Next: [Add users to user groups](#).

### Add users to user groups

The roles you add to a user group are available for the Group Administrator to assign to users within the group.

1. Log in to Oracle LSH as the system administrator.
2. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **User Groups**.

Or, if Oracle LSH is already open, go to the Security tab and select the **User Groups** subtab.
3. Enter the name of the user group for which you want to add roles in the user group box.



Or, to see all user groups, enter %.

4. Click **Go**.
5. Click the required user group.
6. Click **Add and Remove Role**.
7. Double-click on a role in the Available Roles column to move it into the Selected Roles column.

You can also select multiple Roles by using Shift+Click or Control+Click and use the arrows to move one, a few, or all at once to the column in the shuttle.

You can change the order of the Roles using the Up and Down arrows on the right.

8. Click **Apply**.

Next: [Assign a group administrator](#).

## Assign a group administrator

The Group Administrator is responsible for adding and removing users to a particular user group, and changing users' role assignments within the group.

You must have the LSH Security Admin or LSH Function Security Admin role to assign the LSH Group Admin role to a user.

To assign a Group Administrator to a user group:

1. Log in to Oracle LSH.
2. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **User Groups**.  
Or, if Oracle LSH is already open, go to the Security tab and select the **User Groups** subtab.
3. Enter the name of the user group for which you want to add roles in the user group box.  
Or, to see all user groups, enter %.
4. Click **Go**.
5. Click **Expand All**.
6. Click the **Add User** icon corresponding to the LSH Group Administrator role. The Search and Select Users to Add to Role screen appears.
7. Search for and select the users who need to be LSH Group Administrators for this User Group.
8. Click **Select**. The system assigns the LSH Group Administrator role to the selected users and the Group screen appears.

### Note:

Group Administrators must have the Group Admin application role assigned. See [Assign application roles to users](#).

## Add users and assign roles

The group administrator adds users to a group, at the same time assigning the user to one or more roles within the group.

1. Log in to Oracle LSH.
2. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **User Groups**.

Or, if Oracle LSH is already open, go to the Security tab and select the **User Groups** subtab.

3. In the user group box, type the name of the user group to which you want to assign users.  
If you are not sure of the name, you can use % as a wildcard.
4. Click **Search**. The system displays all the groups you administer that match the search criteria.
5. Click the required user group. The Group screen appears.
6. Click the plus (+) icon to see the roles assigned to the user group.
7. Find the role you want to assign to the user you are adding, and click its Add User icon.
8. Type the user name, first name, and/or last name of the user.  
If you are not sure of the name, you can use % as a wildcard.
9. Click **Search**. All the users matching the search criteria appear.
10. Select one or more users you want to assign to the role.
11. Click **Select**. The system assigns the selected user(s) to this role within this user group and returns to the User Group screen.
12. Repeat until you have added all the users and given each user all the roles he or she needs within the group.
13. When you finish, see [Clear the Oracle Applications cache](#).

## Clear the Oracle Applications cache

Every time you change user assignments to a user group, clear the Oracle Applications cache so that users logging into Oracle LSH see only the appropriate options. (Note that if you do not clear the cache, users may be able to see the wrong options but they cannot actually do them.)

1. Log in as an Oracle LSH user with the Functional Administrator responsibility. See [Assign application roles to users](#) for instructions on granting this responsibility.  
The Security tab's Grants screen appears.

 **Note:**

You can also log in as the `sysadmin` user if you do not want to assign the Functional Administrator responsibility only for the purpose of clearing cache.

2. Click the **Core Services** tab from the Grants screen. The Lookup Types screen appears.
3. Click **Caching Framework** from the list of secondary tabs. The Overview screen opens.
4. Click **Global Configuration** from the left panel. The Global Cache Configuration screen opens.
5. Click **Clear All Cache**. A warning appears.  
Click **Yes**.

## Copy user groups with or without users

You can create copies of a user group in two ways. Either you can duplicate only the user group definition with its supported roles or you can duplicate the definition with its supported roles and also the users assigned to it and their role assignments. When you duplicate a user group, the system appends 'Copy of' to the name of the user group.

1. Log in to Oracle LSH.
2. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **User Groups**.

Or, if Oracle LSH is already open, go to the Security tab and select the **User Groups** subtab.



3. Enter a search string—the name of the user group you want to duplicate in the User Group box or text with the wildcard %, or leave blank to retrieve all user groups.
4. Click **Go**. All the user groups matching the search criteria appear.
5. Click the **Select** checkbox corresponding to the required user group.
6. Click **Duplicate with Roles** or **Duplicate with Roles, Users**.

## Assign user groups to custom programs and study groupings

You can assign user groups to:

- **Custom programs and functions.** If you assign a user group to the `DMW_UTILS` domain, its users have access to all custom programs and functions. If you assign a user group to an application area in the `DMW_UTILS` domain, its users have access to all programs and functions in that application area.


This is the only way to grant access to custom programs and functions. Programmers writing the programs and functions and study configurators using them in transformations and validation checks need access.

- **Study groupings.** If you assign a user group to a study grouping domain, users in the group have access to all studies and library objects, in all lifecycle stages, within the grouping. Study configurators can explicitly remove user groups from studies, objects, and lifecycle stages, and assign other user groups.
1. Navigate to the study grouping or application area:
    - a. Log in to Oracle LSH.
    - b. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **Applications**.  
Or, if Oracle LSH is already open, go to the Applications tab.
    - c. Click the  Search icon next to the **Select Domain** field.
    - d. Select Search By **Domain Name**, enter either:
      - DMW\_DOMAIN for study groupings.
      - DMW\_UTILS for custom programs and functions.
 Click **Go**.
    - e. Click the  Quick Select icon for the domain.
    - f. Click the domain or application area you want.
  2. From the **Actions** drop-down, select **Apply Security** and click **Go**.
  3. Click **Assign User Group**.
  4. To see all user groups, enter % and click **Search**.  
Or, enter part of a user group name and click **Search**.
  5. Select one or more user groups to assign and click **Apply**.

## Assign user groups to adapters for technology privileges

To do certain tasks in DMW that involve an integrated application or technology, users must be in a user group assigned to an *adapter* or *adapter family* (adapters grouped by application/technology).

Users with the **DMW\_STUDY\_DEVELOPER**, **QC**, and **PROD** predefined object security role need to be in a user group assigned to adapters.

1. Log in to Oracle LSH.
2. Expand the Life Sciences Data Hub node in the main menu on the left or from the Navigator drop-down. Select **Adapter Security**.  
Or, if Oracle LSH is already open, go to the Security tab and select the **Adapter Security** subtab.
3. Click the  Apply Security icon for the adapter family or individual adapter to which you want to assign a user group. To see individual adapters, expand the node of the adapter family. See the [List of adapters](#).

 **Tip:**

If you assign a user group to a *family* adapter, it grants access to all the adapters within the family adapter.

4. Click **Assign Group**.
  5. To see all user groups, enter %.  
To find a particular user group, enter part of its name.
  6. Click **Search**.
  7. Select each user group you want to assign to the adapter or adapter family, and click **Apply**.
- [List of adapters](#)

## List of adapters

DMW uses the following adapters. Other adapters appear in the Oracle LSH UI, but they are used only in LSH.

- The **InForm Family Adapter** includes:
  - **InForm Data** is required for users to set up an InForm clinical data model, including loading data from InForm and scheduling data loading.
  - **InForm Metadata** is required for users to set up an InForm clinical data model, including loading InForm metadata.
- **Oracle Export** is required for users to create, modify, or install a clinical data model that is set up for exporting data in an Oracle Export file. It is also required to run the job to create the Oracle Export file.
- The **Oracle Family Adapter** is not required.
  - **Oracle Tables and Views** is not supported in this release.
  - **PLSQL** This adapter is used internally. Users do not need access to it.
- **SAS Export** is required for users to create, modify, or install a clinical data model that is set up for exporting data in a SAS file. It is also required to run the job to create the SAS file.
- The **SAS Family Adapter** includes:
  - **SAS** is required for users who upload SAS files to create table metadata in clinical data models.
  - **SAS Program** is required to upload SAS programs or to run a transformation or validation check that uses a SAS custom program.
- **Text Export** is required for users to create, modify, or install a clinical data model that is set up for exporting data in a text file. It is also required to run the job to create the text file.
- The **Text Family Adapter/Text** is required for users who create an input file clinical data model of type Text.
- The **Visualization Adapter/Generic Visualization** is required to view data using a visualization tool.

## How security works

Studies, clinical data models, transformations, and validation checks are all *objects*. Users are allowed to perform an operation on an object when they:

- Belong to a user group that is assigned to the object either explicitly or by inheritance. For information on inheritance, see [Object ownership](#).
- Are assigned to a role within that user group that allows the operation on the object.
- Have an application role that allows access to the required part of the user interface.
- To either view blinded data or to unblind data, both an object privilege and an application role are required.

# 6

## Advanced administration topics

- [Oracle Thesaurus Management System \(TMS\) integration](#)
- [Database partitioning](#)
- [Changing the root folder location for data files](#)
- [Updating web service location passwords in bulk](#)

### Oracle Thesaurus Management System (TMS) integration

- [TMS processing](#)
- [Force rederivation](#)
- [DMW context information displayed in TMS](#)

#### TMS processing

When DMW is integrated with TMS, transformation jobs have additional steps: they send new and updated source *terms* (data in specified columns) to TMS, run the TMS autoclassification job, and derive TMS data into DMW tables.

Terms that cannot be automatically coded must be manually coded in TMS. TMS then codes all future occurrences of the same term the same way within the same domain.

If a TMS user cannot classify the term because of a problem with the term, for example, it is really multiple terms, like *nausea and headache*, he or she can send a TMS *action* back to DMW as discrepancy text. The discrepancy is then sent to InForm.

- [TMS autoclassification, synchronization, and manual processing](#)
- [New and updated data processed in TMS](#)
- [System interaction conflicts and discrepancy statuses](#)

#### TMS autoclassification, synchronization, and manual processing

1. DMW TMS processing runs the TMS synchronization job, which checks for changes in the TMS dictionary(ies) associated with a study that impact DMW terms in TMS, either coded or not yet coded. It also checks for TMS data that meets the criteria in [New and updated data processed in TMS](#).
2. TMS loops through all records that meet the criteria and calls autoclassification for each one.

Autoclassification looks for exact matches to source terms in the *coding* dictionary level. If there is no exact match, it checks if a TMS user has previously classified the same term to a dictionary term (this is called a *verbatim term assignment*, or VTA), and classifies the current term the same way. It checks first in the current domain and then, if there is no VTA in the domain, globally.

- For terms with a dictionary term or VTA match, TMS sends derived data back to DMW during the same transformation job.
  - For terms that do not have a dictionary term or VTA match, TMS creates a discrepancy in DMW and, if the lifecycle stage is Production, an *omission* in TMS. TMS sets the DMW discrepancy category to TMS in Progress as described in [System interaction conflicts and discrepancy statuses](#).
3. For terms without a match, a TMS user does one of the following:
- Classifies the term manually, creating a new VTA. During the next transformation, autotclassification finds the new VTA and TMS derives data to DMW and answers the discrepancy, setting the DMW discrepancy category to TMS DM Review as described in [System interaction conflicts and discrepancy statuses](#).
  - Applies an action to the omission, requesting review or clarification of the term. This becomes the discrepancy text in DMW and the query text in InForm. TMS sets the DMW discrepancy category to TMS INV, sending the discrepancy to InForm for investigator review.
4. A DMW user can update a discrepancy as follows:
- Add a comment. The user can choose to send the comment to TMS, which changes the category to TMS Evaluation, triggering autotclassification in TMS and making it impossible to make any other updates to the discrepancy until it is acted on in TMS.
  - Change the DMW discrepancy category directly to any of the TMS-related categories.
  - Send the discrepancy to the source system. After a discrepancy has been sent to InForm, any additional changes to the discrepancy in DMW or TMS are automatically sent to InForm.

An InForm user can update a discrepancy as follows:

- Answer the discrepancy by providing text in response to the discrepancy text.
  - Correct the underlying data item.
- In both cases, the category is updated to TMS Evaluation and TMS autotclassification is triggered.

If the data change results in a successful classification, TMS sends derived data to DMW during the next transformation run. If a data change results in declassifying a term that was previously classified, previously derived data is deleted.

If a source term is deleted in InForm, and then DMW, it is deleted in TMS as well.



#### Note:

TMS autotclassification, synchronization, derivation, actions, and DMW discrepancy management are the same in all three lifecycle stages. However, TMS omissions are created only in Production, so TMS users can do manual classification only in Production, and [Force rederivation](#) works only in Production.



## New and updated data processed in TMS

TMS processing includes only target tables that have at least one column associated with a TMS Set primary column **and** meet **at least one** of the following conditions:

- New records in the source table.
- Updates to coded terms (data in the primary column) in the source table.
- Updates made in TMS that affect DMW data.
- Updates in DMW or the source system to TMS-originated discrepancies on data in the source tables.

## System interaction conflicts and discrepancy statuses

The same data passes through three systems—InForm, DMW, and TMS—and conflicts may occur:

- An InForm user may update a TMS-originated discrepancy, changing its text or status, or the underlying data. Those changes are loaded as updates into the DMW discrepancy system, triggering TMS autoclassification and passing any new discrepancy text to TMS.
- State changes in InForm may conflict with the results of autoclassification in TMS. For example, an InForm user might close a discrepancy thinking that the term is a valid one while TMS does not recognize it. In this case, even though the Closed status is loaded into DMW, TMS opens a new discrepancy when autoclassification cannot find a match for the term.
- TMS classification might overwrite status changes made in InForm.

DMW uses four statuses to help coordinate the interaction of the three systems. The first two are set by the system:

- **TMS Evaluation** is set by DMW either when a DMW user adds a comment to a TMS-originated discrepancy (that is not marked as an internal comment) or when an InForm user answers a discrepancy (with or without a data change) and the update is loaded into DMW. The purpose of TMS EVALUATION is to trigger autoclassification on the data again during the next transformation. Without it, autoclassification would run only if there was a data change or if a TMS user had altered the record.
- **TMS in Progress** is set by TMS when autoclassification creates or updates an omission. TMS users can manually classify an omission only when its state is TMS IN PROGRESS.

DMW users cannot update a discrepancy at status TMS IN PROGRESS. If the discrepancy has previously been sent to InForm, InForm users can update it. However, InForm users will not have new data from TMS until the TMS INV Review status is applied.



TMS users can apply the following statuses during omission management or when creating an *action*:

- **TMS DM Review** Prevents TMS users from updating. A DMW user may update with a comment, which sets the discrepancy and omission to TMS EVALUATION so that TMS runs autoclassification on the term during the next transformation.

- **TMS INV Review** Sends the discrepancy to InForm for Investigator review and prevents TMS users from updating.

## Force rederivation

Normally, transformations process only new or changed data. Use the Force Rederivation job to process all data when you have made structural changes related to TMS in an ongoing study such as:

- Adding columns to target tables to hold derived data.
  - Updating a dictionary to a new version with a different structure from the old one.
  - Changing domain-related settings in the TMS reference codelist TMS\_CONFIGURATION.
1. Go to the  Home page.
  2. Select the study.
  3. Click the  Modify icon at the top of the Studies pane.
  4. In the Modify Study window, click **TMS**.
  5. Click **Force Rederivation**. A confirmation message appears because running the job may take a long time. You can still work while it runs.
  6. Click **OK**.

## DMW context information displayed in TMS

For each discrepancy created by TMS, the equivalent TMS omission is displayed in several TMS windows with the following contextual information about the data point (source term) from DMW:

- Study grouping (such as Project or Therapeutic Area)
- Study name
- Clinical data model
- Table name
- Column name
- Subject ID
- Visit name
- DMW discrepancy ID

### Note:

The subject ID and visit name can be displayed only if the Subject ID and Visit Name columns have the corresponding SDTM ID assigned in the DMW table that is mapped to a TMS set.

## Database partitioning

When a user creates a study in Oracle DMW, he or she must specify a study size of either Small, Medium, or Large for the volume of data expected, relative to other studies. The system uses this value, together with lookup values that you can modify, to determine which database partition to use for storing certain types of data in internal cross-study tables.

- [Partitioned tables](#)
- [Develop guidelines for setting study size](#)
- [Specify the number of similarly sized studies per partition](#)
- [Assignment algorithm](#)

## Partitioned tables

The tables that use partitioning do not store clinical patient data, but they do store data that is likely to be created in proportion to the volume of clinical data, especially the discrepancies table.

The system adds a column for the partition ID in all affected tables. The internal SYS\_CONTEXT tracks the partition ID as well as the current study and lifecycle area. All internal queries to affected tables must include the partition ID and call an internal API to get the ID from the SYS\_CONTEXT to run most efficiently.

The tables are:

- **DME\_CTXT\_SKEYS\_MAP**: This table is used to trace the lineage between source and target tables used in transformations. It contains data that maps between specific source and target records. Each record in the target table of a transformation has at least one corresponding record in the DME\_CTXT\_SKEYS\_MAP table, and for some transformations there are multiple records. For example, in a direct map there is one record per target table record; in a join of three tables, there are three record per target table record.
- **DME\_OPOBJ\_CONTEXT\_MAP**: This table is used to highlight discrepancies on the Listings display. The table contains an entry for each primary discrepancy, in the model where it was created, and all of its secondary discrepancies on the same data item in upstream and downstream models. This table is also used to obtain the primary source data item for a discrepancy.
- **DME\_DISCREPANCIES**: This table stores discrepancy-related information such as the table, column, model, study, and lifecycle of the record on which each discrepancy is created. This table also records discrepancy state, comments, and discrepancy ID.
- **DME\_FLAG\_DATA**: This table stores flag assignments to records that that users add and modify in the Listings pages.
- **DME\_DISC\_ACTION\_HISTORY**: This table stores the history of actions performed on specific discrepancies.
- **DME\_DISC\_CSV\_FILES**: This stable stores sets of discrepancies exported as CSV files.

## Develop guidelines for setting study size

Oracle recommends that you develop guidelines to help study configurators categorize studies as small, medium, or large, and to help you in [Specify the number of similarly sized studies per partition](#).

For example, base categories on the number of subjects and the number and size of CRFs in the protocol.

## Specify the number of similarly sized studies per partition

The maximum number of small, medium, and large studies using a single partition is determined by lookups called DME\_PARTITION\_DEVQC and the DME\_PARTITION\_PROD. The default settings for both are:

- Small studies: 20
- Medium studies: 5
- Large studies: 1

You can change these values; see [Number of studies per partition](#) for details.

For example, if you have a relatively small amount of data in your Development and Quality Control lifecycle areas and a huge amount of data in Production, you might change to settings like:

- For the Development/QC partition:
  - Small studies: 20
  - Medium studies: 15
  - Large studies: 11
- For the Production partition:
  - Small studies: 10
  - Medium studies: 4
  - Large studies: 1

There is a limit to the number of partitions that can be created for a database table: 1024k-1. Each partition can hold any number of records for each study; that is, any number of discrepancies or flags for given study.

## Assignment algorithm

Studies are assigned to partitions according to their defined size and in the order they are added.

For example, using the default value of 5 medium studies per partition, the system creates two partitions the first time a medium study is created, one for Development/QC and the other for Production, and assigns that study and the next 4 medium studies to those partitions. When the 6th medium study is created the system creates two new partitions (Development/QC and Production) and assigns the 6th through 10th medium studies to those partitions, and so on.

## Changing the root folder location for data files

Changing the root folder location is disruptive to the flow of work in Oracle DMW and should only be done with caution. However, you can modify the location if necessary:

1. Create new root folders in the new location for both watched and archive folders.
2. Change the value of the LSH profiles to the new location. See [Register root folders for File Watcher watched folders](#) and [Register root folders for File Watcher archive folders](#).
3. Restart the Distributed Processing Server that includes the File Watcher service. Instructions are in the *Oracle Life Sciences Data Hub System Administrator's Guide*.
4. Open each study File Watcher in Edit mode and click **Regenerate** to apply the new settings in the study; see [Create study File Watchers](#).

The system then:

- Migrates all existing Study File Watchers to the new root folders.
- Processes any files already submitted for data load at the time of the change.

The system does **not** move any files. You must:

- Determine which files have not been loaded, if any, and move them to the new location.
- Determine which loaded files have not been archived or deleted, if any, and move or remove them.

## Updating web service location passwords in bulk

When you update the password for one web service location, if there are other DMW web service locations that use the same SSO org (your company's tenant ID) and the same user name as the one you are updating, the password is updated on all of them. So there is no need to perform the same action on other similar web service locations.

# 7

## Security reference information

- [Application roles for specialized administrators](#)
- [Application roles for user interface access](#)
- [Data Blinding-related application roles](#)
- [Predefined object security roles](#)
- [Operations](#)
- [Object ownership](#)

### Application roles for specialized administrators

Give these roles to a few people.

- [DMW Adapter Security Admin](#)
- [DMW Data Security Admin](#)
- [DMW Checkin Admin](#)

#### DMW Adapter Security Admin

This role is intended for administrators who assign user groups to adapters to external systems such as InForm. It provides access to the Adapter Security page.

#### DMW Data Security Admin

This role is intended for administrators who create roles and user groups, and who assign users to roles within user groups. It provides access to the Security page.

#### DMW Checkin Admin

This role is intended for administrators who should be able to check in an object checked out by another user, for example, if the user leaves the company.

### Application roles for user interface access

Each user must have at least one application role to access the DMW user interface. These roles apply across all studies.

- [DMW System Administrator](#)
- [DMW Study Manager](#)
- [DMW Study Consumer](#)
- [DMW Study Configurator](#)
- [DMW Library Administrator](#)

- [DMW Database User](#)

## DMW System Administrator

This role is intended for users who do administrative tasks including setting up data sources and defining objects used across studies, such as categories, flags, and tags. It provides access only to the Administration page. (Home page access may not be needed because the administrator does not work in studies. The Home page is where you select a study.)

## DMW Study Manager

This role is intended for users who run data loads, transformations, and validation checks. It provides access to the Home, Study Configuration, and Data Management pages.

## DMW Study Consumer

This role is intended for users who need to review data and create and manage discrepancies. It provides access to the Home and Data Management pages.

## DMW Study Configurator

This role is intended for users who set up studies by defining models, transformations, and validation checks. It provides access to the Home, Study Configuration, and Data Management pages.



### Note:

There is no functional difference between the application roles DMW\_STUDY\_MANAGER and DMW\_STUDY\_CONFIG.

## DMW Library Administrator

This role is intended for users who create and modify library models and codelists. It provides access only to the Library page.

## DMW Database User

This role allows users to log in to the DMW database through a visualization tool to view data in a data model business area. If you assign this role to a user, be sure to also click the link to send an email to the user with their database account name.

## Data Blinding-related application roles

Some DMW users should have blinding-related privileges in order to view blinded data or to unblind data. This requires both an application role, which applies to the user in any study, and a blinding-related object security privilege through a role in a user group assigned to a particular study or object in a study.

Since the most commonly used predefined object security roles include object-level access to blinded data and the ability to unblind data, it is very important that you assign these application roles **only** to users who require them.

- [DMW Data Blind Break User \(Dev, QC, and Prod\)](#)
- [DMW Data Unblind User \(Dev, QC, and Prod\)](#)

## DMW Data Blind Break User (Dev, QC, and Prod)

Users with this role can do the following in the corresponding lifecycle stage, if they belong to a user group assigned to the object and in that group have a role with the blinding-related object security privilege noted:

- Run a program that reads from currently blinded tables and operates on the real data, not the masked or dummy data (also requires an object security role with the Blind Break operation on Table instances).
- View currently blinded data in the user interface (also requires an object security role with the Blind Break operation on Table instances).
- View currently blinded data through a visualization tool (requires an object security role with the Blind Break operation on Table instances).

## DMW Data Unblind User (Dev, QC, and Prod)

Users with this application role can do the following in the corresponding lifecycle stage, if they belong to a user group assigned to the object and in that group have a role with the blinding-related object security privilege noted:

- Unblind data in Table instances (also requires an object security role with the Unblind operation on Table instances).
- Reblind data in Table instances that was previously unblinded (also requires an object security role with the Unblind operation on Table instances).

### Note:

The DMW Data Unblind User application role is not required in conjunction with the Read Unblind object security operation.

## Predefined object security roles

The roles in this chapter are sample roles provided for illustrative purposes only and are not intended to be used for production needs.

Each role includes all blinding-related privileges. However, in order to perform blinding-related operations users must have blinding-related application roles as well; see [Data Blinding-related application roles](#).

- [Oracle DMW\\_STUDY\\_DEVELOPER](#)
- [Oracle DMW\\_STUDY\\_QC](#)



- [Oracle DMW\\_STUDY\\_PROD](#)
- [Oracle DMW\\_STUDY\\_ADMIN](#)
- [Oracle DMW\\_STUDY\\_INST\\_ACCESS](#)
- [Oracle DMW\\_STUDY\\_INFORM\\_CONFIG](#)

## Oracle DMW\_STUDY\_DEVELOPER

The Oracle DMW\_STUDY\_DEVELOPER object security role is intended for users who configure studies by creating data models and creating and running transformations and validation checks. To test their work, they also need to be able to load data into the development lifecycle area from InForm and files, create custom listings, create and act on discrepancies, assign flags to records, and promote objects from Development to QC and Production. Blinding-related privileges are also included in this role.

Users with this role should have the Oracle DMW\_STUDY\_MANAGER or Oracle DMW\_STUDY\_CONFIG application role. If they need to create library data models they should also have the Oracle DMW\_LIB\_ADMIN application role.

Oracle DMW\_STUDY\_DEVELOPER allows users to perform the following operations on the specified objects.

- [Clinical Data Models and Query Builder](#)
- [Blinding](#)
- [Filters](#)
- [Data Lineage Tracing](#)
- [Transformations and Query Builder](#)
- [Discrepancies and Flags](#)
- [Validation Checks](#)
- [InForm](#)
- [File Watcher](#)

## Clinical Data Models and Query Builder

Users assigned the Oracle DMW\_STUDY\_DEVELOPER role have access to the following operations for clinical data models and the query builder.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Application Area: Create Work Area  
Application Area: View  
Domain: Create Data Model  
Domain: Create Load Set  
Domain: Create Variable  
Domain: View

Load Set: View  
Load Set: Modify  
Load Set: Modify Val Status to QC  
Load Set: Modify Val Status to PROD  
Table: View  
Table: Modify  
Table Instance: Modify  
Table Instance: Remove  
Table Instance: Modify Val Status to QC  
Table Instance: Modify Val Status to PROD  
Variable: Modify  
Variable: Modify Val Status to QC  
Variable: Modify Val Status to PROD  
Work Area: Create Table Instance  
Work Area: Create Load Set Instance  
Work Area: Modify  
Work Area: Modify Val Status to QC  
Work Area: Modify Val Status to PROD  
Work Area: Delete  
Work Area: Deploy (Install)  
Work Area: View

## Oracle DMW Object Operations

Data Model: Modify  
Data Model: Delete  
Data Model: Publish Dev (used to install the Development Work Area)  
Data Model: Modify Supporting Info  
Data Model: Modify Val Status to QC  
Data Model: Modify Val Status to PROD  
Data Model: Create Private Listing  
Data Model: Create Public Listing

## Blinding

Users assigned the Oracle DMW\_STUDY\_DEVELOPER role have access to the following operations for blinded data.

- [Oracle LSH Object Operations](#)

## Oracle LSH Object Operations

Table Instance: ReadData  
Table Instance: BlindBreak  
Table Instance: Unblind  
Table Instance: ReadUnblind

## Filters

Users assigned the Oracle DMW\_STUDY\_DEVELOPER role have access to the following operation for filters.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Filter: Mark as Public in Dev

## Data Lineage Tracing

Users assigned the Oracle DMW\_STUDY\_DEVELOPER role have access to the following operations for data lineage tracing.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Table Instance: View CTX Data Lineage

## Transformations and Query Builder

Users assigned the Oracle DMW\_STUDY\_DEVELOPER role have access to the following operations for transformations and the query builder.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Application Area: Create Work Area  
Domain: Create Program  
Domain: Create Variable  
Execution Setup: Modify Val Status to PROD  
Execution Setup: Modify Val Status to QC  
Execution Setup: Submit  
Program: Modify Val Status to PROD  
Program: Modify Val Status to QC  
Program: Modify  
Program: Remove  
Program Instance: Modify Val Status to PROD  
Program Instance: Modify Val Status to QC  
Program Instance: Create Execution Setup  
Program Instance: Modify  
Program Instance: Remove  
Table: Modify Val Status to PROD  
Table: Modify Val Status to QC  
Table Instance: Modify Val Status to PROD

Table Instance: Modify Val Status to QC  
Table Instance: BlindBreak  
Table Instance: ReadData  
Table Instance: ReadUnblind  
Table Instance: Remove  
Table Instance: Unblind  
Table Instance: Modfiy  
Table: Modify  
Table: Remove  
Table: View  
Work Area: Create Program Instance  
Work Area: Create Table Instance  
Work Area: Deploy (Install)  
Work Area: Modify  
Work Area: Delete  
Work Area: Modify Val Status to PROD  
Work Area: Modify Val Status to QC

## Oracle DMW Object Operations

Data Model: Load Data in Development  
Domain: Create Transformation Map  
Transformation Map: Modify  
Transformation Map: Delete  
Transformation Map: View  
Transformation Map: Modify Validation Status QC  
Transformation Map: Modify Validation Status Production  
Transformation Map: Modify Supporting Info  
Transformation Map: Deploy (Install) in Development  
Transformation Map: Modify Security  
Transformation Map: Classify

## Discrepancies and Flags

Users assigned the Oracle DMW\_STUDY\_DEVELOPER role have access to the following operations for discrepancies and flags.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Table Instance: Create Manual Discrepancy  
Table Instance: Close Discrepancy  
Table Instance: Send Discrepancy to InForm  
Table Instance: Send Discrepancy to Spreadsheet  
Table Instance: Reopen Discrepancy  
Table Instance: Answer Discrepancy  
Table Instance: Cancel Discrepancy  
Table Instance: Add Comment to Discrepancy

Table Instance: Edit Discrepancy  
Table Instance: Show Discrepancies  
Table Instance: Assign Flags

## Validation Checks

Users assigned the Oracle DMW\_STUDY\_DEVELOPER role have access to the following operations for validation checks.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Domain: Create Program  
Execution Setup: Modify Val Status to PROD  
Execution Setup: Modify Val Status to QC  
Execution Setup: Submit  
Program: Modify Val Status to PROD  
Program: Modify Val Status to QC  
Program: Modify  
Program: Remove  
Program Instance: Modify Val Status to PROD  
Program Instance: Modify Val Status to QC  
Program Instance: Create Execution Setup  
Program Instance: Modify  
Program Instance: Remove  
Table: Modify Val Status to PROD  
Table: Modify Val Status to QC  
Table: Modify  
Table: Remove  
Work Area: Create Program Instance

## Oracle DMW Object Operations

Data Model: Create VC Batch  
VC Batch: Modify  
VC Batch: Delete  
VC Batch: View  
VC Batch: Modify Validation Status QC  
VC Batch: Modify Validation Status Production  
VC Batch: Modify Supporting Info  
VC Batch: Deploy (Install) in Development  
VC Batch: Submit in Development  
VC Batch: Submit Individual VC in Development  
VC Batch: View Listings in Development

## InForm

Users assigned the Oracle DMW\_STUDY\_DEVELOPER role have access to the following operations for InForm clinical data models.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

### Oracle LSH Object Operations

Application Area: Create Program  
Load Set Instance: Create Execution Setup  
Program Instance: Create Execution Setup  
Program: Modify  
Program Instance: Modify

### Oracle DMW Object Operations

Data Model: Load Data in Development  
Data Model: Load InForm Metadata  
Web Service Location: Modify Web Service Location  
Web Service Location: Create Connection

## File Watcher

Users assigned the Oracle DMW\_STUDY\_DEVELOPER role have access to the following operations for the File Watcher.

- [Oracle DMW Object Operations](#)

### Oracle DMW Object Operations

Data Model: File Watcher Config  
Data Model: Data Load DEV

## Oracle DMW\_STUDY\_QC

The Oracle DMW\_STUDY\_QC object security role is intended for users who conduct formal testing of study objects including data models, transformations, and validation checks. They also need the ability to load data into the Quality Control lifecycle area from InForm and files, create custom listings, create and act on discrepancies, and assign flags to records. Blinding-related privileges are also included in this role.

Users with this role should have the Oracle DMW\_STUDY\_MANAGER or Oracle DMW\_STUDY\_CONFIG application role.

Oracle DMW\_STUDY\_QC allows users to perform the following operations on the specified objects.

- [Clinical Data Models and Query Builder](#)
- [Blinding](#)

- [Discrepancies](#)
- [Filters](#)
- [Flags](#)
- [Data Lineage Tracing](#)
- [Validation Checks](#)
- [InForm](#)
- [File Watcher](#)
- [Transformations and Query Builder](#)

## Clinical Data Models and Query Builder

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operations for clinical data models and the query builder.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

### Oracle LSH Object Operations

Load Set Instance: Modify  
Load Set Instance: Modify Val Status to QC  
Load Set Instance: Modify Val Status to PROD  
Table Instance: Modify  
Table Instance: Remove  
Table Instance: Modify Val Status to QC  
Table Instance: Modify Val Status to PROD  
Work Area: Create Table Instance  
Work Area: Create Load Set Instance  
Work Area: Modify  
Work Area: Modify Val Status to QC  
Work Area: Modify Val Status to PROD  
Work Area: Deploy (Install)

### Oracle DMW Object Operations

Data Model: View  
Data Model: Publish QC (used to install the QC Work Area)  
Data Model: Modify Supporting Info  
Data Model: Modify Val Status to QC  
Data Model: Modify Val Status to PROD  
Data Model: Create Private Listing  
Filter: Mark Filter Public QC

## Blinding

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operations for blinded data.

- [Oracle LSH Object Operations](#)

## Oracle LSH Object Operations

Table Instance: ReadData  
Table Instance: BlindBreak  
Table Instance: Unblind  
Table Instance: ReadUnblind

## Discrepancies

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operations for discrepancies.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Table Instance: Create Manual Discrepancy  
Table Instance: Close Discrepancy  
Table Instance: Send Discrepancy to InForm  
Table Instance: Send Discrepancy to Spreadsheet  
Table Instance: Reopen Discrepancy  
Table Instance: Answer Discrepancy  
Table Instance: Cancel Discrepancy  
Table Instance: Add Comment to Discrepancy  
Table Instance: Edit Discrepancy  
Table Instance: Show Discrepancies

## Filters

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operation for filters.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Filter: Mark as Public in QC

## Flags

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operations for flags.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Table Instance: Assign Flags



## Data Lineage Tracing

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operations for data lineage tracing.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Table Instance: View CTX Data Lineage

## Validation Checks

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operations for validation checks.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Execution Setup: Modify Val Status to PROD  
Execution Setup: Modify Val Status to QC  
Execution Setup: Submit  
Program: Modify Val Status to PROD  
Program: Modify Val Status to QC  
Program Instance: Modify Val Status to PROD  
Program Instance: Modify Val Status to QC  
Program Instance: Create Execution Setup  
Table: Modify Val Status to PROD  
Table: Modify Val Status to QC  
Work Area: Create Program Instance

## Oracle DMW Object Operations

VC Batch: View  
VC Batch: Modify Validation Status QC  
VC Batch: Modify Validation Status Production  
VC Batch: Modify Supporting Info  
VC Batch: Deploy (Install) in Quality Control  
VC Batch: Submit in Quality Control  
VC Batch: Submit Individual VC in Quality Control  
VC Batch: View Listings in Quality Control

## InForm

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operations for InForm clinical data models.

- [Oracle LSH Object Operations](#)

- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Application Area: Create Program  
Load Set Instance: Create Execution Setup  
Program Instance: Create Execution Setup  
Program: Modify  
Program: View  
Program: Modify Validation QC  
Program Instance: Modify  
Program Instance: View  
Program Instance: Modify Validation QC  
Work Area: Clone

## Oracle DMW Object Operations

Data Model: Load Data in QC

## File Watcher

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operations for the File Watcher.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Data Model: FWR Configuration  
Data Model: Data Load QC

## Transformations and Query Builder

Users assigned the Oracle DMW\_STUDY\_QC role have access to the following operations for transformations and the query builder.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Execution Setup: Modify Val Status to PROD  
Execution Setup: Modify Val Status to QC  
Execution Setup: Submit  
Program: Modify Val Status to PROD  
Program: Modify Val Status to QC  
Program Instance: Modify Val Status to PROD  
Program Instance: Modify Val Status to QC  
Program Instance: Create Execution Setup  
Table: Modify Val Status to PROD

Table: Modify Val Status to QC  
Table Instance: Modify Val Status to PROD  
Table Instance: Modify Val Status to QC  
Table Instance: BlindBreak  
Table Instance: ReadData  
Table Instance: ReadUnblind  
Work Area: Create Program Instance  
Work Area: Create Table Instance  
Work Area: Deploy (Install)  
Work Area: Modify  
Work Area: Modify Val Status to PROD  
Work Area: Modify Val Status to QC

## Oracle DMW Object Operations

Data Model: Load Data in Quality Control  
Transformation Map: View  
Transformation Map: Modify Validation Status QC  
Transformation Map: Modify Validation Status Production  
Transformation Map: Modify Supporting Info  
Transformation Map: Deploy (Install) in Quality Control  
Transformation Map: Modify Pvt Listing  
Transformation Map: Delete Pvt Listing  
Transformation Map: View Public Listing

## Oracle DMW\_STUDY\_PROD

The Oracle DMW\_STUDY\_PROD role is intended for users who work in the Production environment, including: promoting and installing clinical data models, transformations, and validation checks, loading production data from InForm and files, running transformations and validation checks on production data, reviewing data and creating custom listings, and creating and acting on discrepancies. Blinding-related privileges are also included in this role.

Users with this role should have the Oracle DMW\_STUDY\_MANAGER application role.

Oracle DMW\_STUDY\_PROD allows users to perform the following operations on the specified objects.

- [Clinical Data Models and Query Builder](#)
- [Blinding](#)
- [Discrepancies](#)
- [Filters](#)
- [Flags](#)
- [Data Lineage Tracing](#)
- [Validation Checks](#)
- [InForm](#)

- [File Watcher](#)
- [Transformations and Query Builder](#)

## Clinical Data Models and Query Builder

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operations for clinical data models and the query builder.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

### Oracle LSH Object Operations

Load Set Instance: Modify  
Load Set Instance: Modify Val Status to QC  
Load Set Instance: Modify Val Status to PROD  
Work Area: Create Table Instance  
Table Instance: Modify  
Table Instance: Remove  
Table Instance: Modify Val Status to QC  
Table Instance: Modify Val Status to PROD  
Work Area: Create Loadset Instance  
Work Area: Modify  
Work Area: Modify Val Status to QC  
Work Area: Modify Val Status to PROD  
Work Area: Deploy (Install)

### Oracle DMW Object Operations

Data Model: View  
Data Model: Publish Prod (used to install the Production Work Area)  
Data Model: Modify Supp Info  
Data Model: Modify Val Status to QC  
Data Model: Modify Val Status to PROD  
Data Model: Create Private Listing  
Filter: Mark Filter Public PROD

## Blinding

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operations for blinded data.

- [Oracle LSH Object Operations](#)

### Oracle LSH Object Operations

Table Instance: BlindBreak  
Table Instance: Unblind  
Table Instance: ReadUnblind

Table Instance: ReadData

## Discrepancies

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operations for discrepancies.

- [Oracle DMW Object Operations](#)

### Oracle DMW Object Operations

Table Instance: Create Manual Discrepancy  
Table Instance: Close Discrepancy  
Table Instance: Send Discrepancy to InForm  
Table Instance: Send Discrepancy to Spreadsheet  
Table Instance: Reopen Discrepancy  
Table Instance: Answer Discrepancy  
Table Instance: Cancel Discrepancy  
Table Instance: Add Comment to Discrepancy  
Table Instance: Edit Discrepancy  
Table Instance: Show Discrepancies  
Table Instance: Create Data Amendment  
Table Instance: Modify Data Amendment  
Table Instance: Cancel Data Amendment

## Filters

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operation for filters.

- [Oracle DMW Object Operations](#)

### Oracle DMW Object Operations

Filter: Mark as Public in Prod

## Flags

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operations for flags.

- [Oracle DMW Object Operations](#)

### Oracle DMW Object Operations

Table Instance: Assign Flags

## Data Lineage Tracing

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operations for data lineage tracing.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Table Instance: View CTX Data Lineage

## Validation Checks

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operations for validation checks.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Execution Setup: Modify Val Status to PROD  
Execution Setup: Modify Val Status to QC  
Execution Setup: Submit  
Program: Modify Val Status to PROD  
Program: Modify Val Status to QC  
Program Instance: Modify Val Status to PROD  
Program Instance: Modify Val Status to QC  
Program Instance: Create Execution Setup  
Table: Modify Val Status to PROD  
Table: Modify Val Status to QC  
Work Area: Create Program Instance

## Oracle DMW Object Operations

VC Batch: View  
VC Batch: Modify Validation Status QC  
VC Batch: Modify Validation Status Production  
VC Batch: Modify Supporting Info  
VC Batch: Deploy (Install) in Production  
VC Batch: Submit in Production  
VC Batch: Submit Individual VC in Production  
VC Batch: View Listings in Production

## InForm

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operations for InForm data.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Application Area: Create Program  
Load Set Instance: Create Execution Setup  
Program: Modify  
Program: Modify Validation PROD  
Program Instance: Create Execution Setup  
Program Instance: Modify  
Program Instance: Modify Validation PROD  
Work Area: Clone

## Oracle DMW Object Operations

Data Model: Load Data in Production

## File Watcher

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operations for the File Watcher.

- [Oracle DWM Object Operations](#)

## Oracle DWM Object Operations

Data Model: FWR Configuration  
Data Model: Data Load PROD

## Transformations and Query Builder

Users assigned the Oracle DMW\_STUDY\_PROD role have access to the following operations for transformations and the query builder.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Execution Setup: Modify Val Status to PROD  
Execution Setup: Modify Val Status to QC  
Execution Setup: Submit  
Program: Modify Val Status to PROD  
Program: Modify Val Status to QC  
Program Instance: Modify Val Status to PROD  
Program Instance: Modify Val Status to QC  
Program Instance: Create Execution Setup  
Table: Modify Val Status to PROD  
Table: Modify Val Status to QC  
Table Instance: Modify Val Status to PROD  
Table Instance: Modify Val Status to QC  
Table Instance: BlindBreak  
Table Instance: ReadData  
Table Instance: ReadUnblind

Work Area: Create Program Instance  
Work Area: Create Table Instance  
Work Area: Deploy (Install)  
Work Area: Modify  
Work Area: Modify Val Status to PROD  
Work Area: Modify Val Status to QC

## Oracle DMW Object Operations

Data Model: Load Data in Production  
Transformation Map: View  
Transformation Map: Modify Validation Status QC  
Transformation Map: Modify Validation Status Production  
Transformation Map: Modify Supporting Info  
Transformation Map: Deploy (Install) in Production  
Transformation Map: Modify Pvt Listing  
Transformation Map: Delete Pvt Listing  
Transformation Map: View Public Listing

## Oracle DMW\_STUDY\_ADMIN

The Oracle DMW\_STUDY\_ADMIN object security role is intended for superusers. It includes the object-related roles that Oracle DMW\_STUDY\_DEVELOPER and Oracle DMW\_STUDY\_QC have, plus administrator privileges including creating studies and study categories, setting up connections to InForm and File Watcher locations, and assigning user groups to objects such as data models, transformations, and validation checks. Blinding-related privileges are also included in this role.

Users with this role should have the Oracle DMW\_STUDY\_MANAGER or Oracle DMW\_SYS\_ADMIN application role.

Oracle DMW\_STUDY\_ADMIN allows users to perform the following operations on the specified objects.

- [Clinical Data Models and Query Builder](#)
- [Discrepancies](#)
- [Flags](#)
- [Filters](#)
- [Data Lineage Tracing](#)
- [Validation Checks](#)
- [InForm](#)
- [File Watcher](#)
- [Transformations and Query Builder](#)

## Clinical Data Models and Query Builder

Users assigned the Oracle DMW\_STUDY\_ADMIN role have access to the following operations for clinical data models and the query builder.



- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Application Area: Manage Security  
Application Area: Create Work Area  
Application Area: Create Program  
Domain: Create SubDomain  
Domain: Modify  
Domain: Delete  
Domain: Manage Security  
Domain: Create Load Set  
Domain: Create Variable  
Domain: Create Program  
Domain: Create Data Model  
Domain: Create Transformation Map  
Table Instance: Manage Security  
Work Area: Manage Security  
Work Area: Create Table Instance  
Work Area: Create Load Set Instance  
Work Area: Modify  
Work Area: Modify Val Status to QC  
Work Area: Modify Val Status to PROD  
Work Area: Delete  
Work Area: Deploy (Install)  
Work Area: Create Program Instance  
Variable: Modify  
Variable: Modify Val Status to QC  
Variable: Modify Val Status to PROD

## Oracle DMW Object Operations

Data Model: Create Private Listing  
Data Model: Create Public Listing  
Data Model: Modify  
Data Model: Delete  
Data Model: Deploy (Install) Model in Dev/QC/Prod  
Data Model: Modify Supporting Info  
Data Model: Modify Val Status to QC  
Data Model: Modify Val Status to PROD  
Data Model: Create VC Batch  
Data Model: Load Data in Dev/QC/Prod  
Data Model: Manage Security  
Data Model: Configure InForm  
Data Model: Load InForm Metadata  
Filter: Mark Filter Public Dev  
Filter: Mark Filter Public QC

Filter: Mark Filter Public Prod

## Discrepancies

Users assigned the Oracle DMW\_STUDY\_ADMIN role have access to the following operations for discrepancies.

- [Oracle DMW Object Operations](#)

### Oracle DMW Object Operations

Table Instance: Create Manual Discrepancy  
Table Instance: Close Discrepancy  
Table Instance: Send Discrepancy to InForm  
Table Instance: Send Discrepancy to Spreadsheet  
Table Instance: Reopen Discrepancy  
Table Instance: Answer Discrepancy  
Table Instance: Cancel Discrepancy  
Table Instance: Add Comment to Discrepancy  
Table Instance: Edit Discrepancy  
Table Instance: Show Discrepancies  
VC Batch: Modify  
VC Batch: Delete  
VC Batch: View  
VC Batch: Modify Validation Status Production  
VC Batch: Modify Supporting Info  
VC Batch: Deploy (Install) in Development/QC/Prod  
VC Batch: Submit in Development/QC/Prod  
VC Batch: Submit in Individual VC in Development/QC/Prod  
VC Batch: View Listings in Development/QC/Prod

## Flags

Users assigned the Oracle DMW\_STUDY\_ADMIN role have access to the following operations for flags.

- [Oracle DMW Object Operations](#)

### Oracle DMW Object Operations

Table Instance: Assign Flags

## Filters

Users assigned the Oracle DMW\_STUDY\_ADMIN role have access to the following operations for filters.

- [Oracle DMW Object Operations](#)

### Oracle DMW Object Operations

Filter: Mark as Public in Dev  
Filter: Mark as Public in QC  
Filter: Mark as Public in Prod

## Data Lineage Tracing

Users assigned the Oracle DMW\_STUDY\_ADMIN role have access to the following operations for data lineage tracing.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Table Instance: View CTX Data Lineage

## Validation Checks

Users assigned the Oracle DMW\_STUDY\_ADMIN role have access to the following operations for validation checks.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Execution Setup: Manage Security  
Program: Manage Security  
Program Instance: Manage Security  
Program: Modify Val Status to PROD  
Program: Modify Val Status to QC  
Program: Modify  
Program: Remove  
Program Instance: Modify Val Status to PROD  
Program Instance: Modify Val Status to QC  
Program Instance: Create Execution Setup  
Program Instance: Modify  
Program Instance: Remove  
Table: Manage Security  
Table: View  
Table: Modify  
Table: Modify Val Status to PROD  
Table: Modify Val Status to QC  
Table: Remove

## Oracle DMW Object Operations

VC Batch: Manage Security  
VC Batch: Modify  
VC Batch: Delete  
VC Batch: View

VC Batch: Modify Validation Status Production  
VC Batch: Modify Supporting Info  
VC Batch: Deploy (Install) in Development/QC/Prod  
VC Batch: Submit in Developmene/QC/Prod  
VC Batch: Submit in Individual VC in Development/QC/Prod  
VC Batch: View Listings in Development/QC/Prod

## InForm

Users assigned the Oracle DMW\_STUDY\_ADMIN role have access to the following operations for InForm.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Adapter Area: Create Remote Location  
Adapter Area: Create Web Service Location  
Connection: Modify  
Connection: Delete  
Remote Location: Modify  
Remote Location: View  
Remote Location: Create Connection  
Remote Location: Delete

## Oracle DMW Object Operations

Data Model: Configure InForm  
Data Model: Load InForm Metadata  
Web Service Location: Modify Web Service Location  
Web Service Location: Create Connection  
Web Service Location: Delete Web Service Location  
Web Service Location: View

## File Watcher

Users assigned the Oracle DMW\_STUDY\_ADMIN role have access to the following operations for the File Watcher.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Data Model: FWR Configuration

## Transformations and Query Builder

Users assigned the Oracle DMW\_STUDY\_ADMIN role have access to the following operations for transformations and the query builder.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Application Area: Manage Security  
Domain: Manage Security  
DataModel: Manage Security  
Execution Setup: Modify Val Status to PROD  
Execution Setup: Modify Val Status to QC  
Execution Setup: Submit  
Execution Setup: Manage Security  
Program: Manage Security  
Program: Manage Security  
Program: Modify Val Status to PROD  
Program: Modify Val Status to QC  
Program: Modify  
Program: Remove  
Program Instance: Modify Val Status to PROD  
Program Instance: Modify Val Status to QC  
Program Instance: Create Execution Setup  
Program Instance: Modify  
Program Instance: Remove  
Table: Manage Security  
Table Instance: Manage Security  
Table Instance: Modify  
Table Instance: Remove  
Table Instance: Modify Val Status to QC  
Table Instance: Modify Val Status to PROD  
Table Instance: ReadData  
Table Instance: BlindBreak  
Table Instance: Unblind  
Table Instance: ReadUnblind  
VC Batch: Manage Security  
Work Area: Manage Security

## Oracle DMW Object Operations

Transformation Map: Modify Private Listing  
Transformation Map: Delete Private Listing  
Transformation Map: Modify Public Listing  
Transformation Map: View Public Listing  
Transformation Map: Delete Public Listing  
Transformation Map: Manage Security for Public Listing  
Transformation Map: Modify Val Stat QC for Public Listing  
Transformation Map: Modify Val Stat PROD for Public Listing  
Transformation Map: Modify Supporting Info  
Transformation Map: Modify  
Transformation Map: Delete

Transformation Map: View  
Transformation Map: Modify Validation Status QC  
Transformation Map: Modify Validation Status PROD  
Transformation Map: Modify Supporting Info  
Transformation Map: Deploy (Install) in Development/QC/PROD  
Transformation Map: Modify Security  
Transformation Map: Classify

## Oracle DMW\_STUDY\_INST\_ACCESS

The Oracle DMW\_STUDY\_INST\_ACCESS role is intended for users who require only View access to data and discrepancy listings. Blinding-related privileges are also included in this role.

Users with this role should have the Oracle DMW\_STUDY\_CONSUMER application role.

The Oracle DMW\_STUDY\_INST\_ACCESS role allows users to perform the following operations on the specified objects.

- [Clinical Data Models and Query Builder](#)
- [Blinding](#)
- [Discrepancies](#)
- [Data Lineage Tracing](#)
- [Validation Checks](#)
- [Transformations](#)

## Clinical Data Models and Query Builder

Users assigned the Oracle DMW\_STUDY\_INST\_ACCESS role have access to the following operations for clinical data models and the query builder.

- [Oracle LSH Object Operations](#)

## Oracle LSH Object Operations

Domain: View  
Data Model: View  
Table Instance: View  
Work Area: View

## Blinding

Users assigned the Oracle DMW\_STUDY\_INST\_ACCESS role have access to the following operations for blinded data.

- [Oracle LSH Object Operations](#)

## Oracle LSH Object Operations

Table Instance: ReadData

Table Instance: BlindBreak  
Table Instance: Unblind  
Table Instance: ReadUnblind

## Discrepancies

Users assigned the Oracle DMW\_STUDY\_INST\_ACCESS role have access to the following operations for discrepancies.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Table Instance: Show Discrepancies

## Data Lineage Tracing

Users assigned the Oracle DMW\_STUDY\_INST\_ACCESS role have access to the following operations for data lineage tracing.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

Table Instance: View Data Lineage Tracing

## Validation Checks

Users assigned the Oracle DMW\_STUDY\_INST\_ACCESS role have access to the following operations for validation checks.

- [Oracle DMW Object Operations](#)

## Oracle DMW Object Operations

VC Batch: View  
VC Batch: View Listings in Development

## Transformations

Users assigned the Oracle DMW\_STUDY\_INST\_ACCESS role have access to the following operations for transformations.

- [Oracle LSH Object Operations](#)

## Oracle LSH Object Operations

Table Instance: BlindBreak  
Table Instance: ReadData  
Table Instance: ReadUnblind

## Oracle DMW\_STUDY\_INFORM\_CONFIG

This role has the privileges required to configure the link to InForm for an input clinical data model.

- [InForm](#)

## InForm

Users assigned the Oracle DMW\_STUDY\_INFORM\_CONFIG role have access to the following operations for InForm clinical data models.

- [Oracle LSH Object Operations](#)
- [Oracle DMW Object Operations](#)

## Oracle LSH Object Operations

Adapter Area: Create Remote Location  
Adapter Area: Create Web Service Location  
Connection: Modify  
Remote Location: Create Connection  
Remote Location: Modify

## Oracle DMW Object Operations

Domain: Create Data Model  
Data Model: InForm Config  
Data Model: Modify Data Model  
Data Model: Delete Data Model

## Operations

Most operations are self-explanatory. A few that may not be:

- Manage Security is required to assign user groups to an object (functional area).
- Modify Validation Status Production/QC is required to promote an object to a higher validation status, either Production or Quality Control.  
Supporting information is documentation uploaded to justify promotion to a higher validation status.
- *Deploy* (found in the Transformation Maps functional area) is required for users who create and test transformations and validation checks.
- Users who create and test clinical data models, transformations, validation checks, custom programs, and custom listings need the *install* operation on Work Areas.
- The data amendment operations on table instances are not used in DMW .
- [Operations required to view data and manage discrepancies](#)



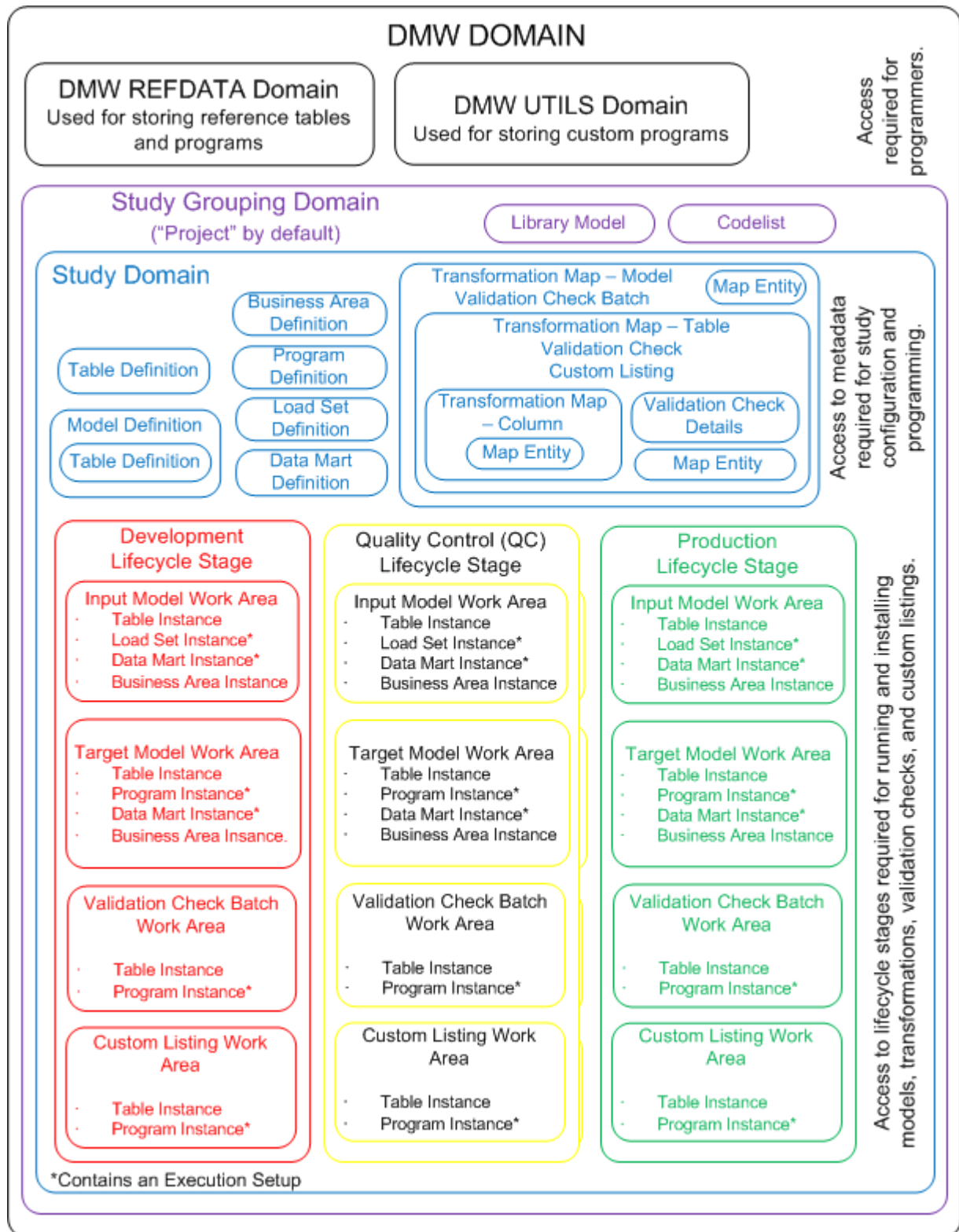
## Operations required to view data and manage discrepancies

- On the Table Instance functional area:
  - View, View Data, View Data Lineage on Custom Listing, and the appropriate discrepancy-related operations.
  - As appropriate: View Unblinded Data, Unblind Data, and/or Blind Break to view currently blinded data.
- If the user should be able to create custom listings, he or she also needs:
  - On Application Areas: Create Program, Parameter, Variable, and Table
  - On Work Areas: Create Program Instance and Table Instance, Install, Modify, and View
  - On Execution Setups: Submit

## Object ownership

[Figure 7-1](#) represents the relationships among objects in DMW. Object-owning relationships affect which user groups can access which objects. If a user group is assigned to an object, the user group gains access to all objects contained in that object by *inheritance*. You can explicitly revoke this inherited access, which also revokes access to any objects contained in that object.

Figure 7-1 Object ownership



# Index

## A

---

### actions

on discrepancies, [1-9](#), [1-11](#)

Answered discrepancy state, [1-10](#)

## C

---

Cancelled discrepancy state, [1-9](#)

Candidate discrepancy state, [1-9](#)

### categories

compare to tags and flags, [1-11](#)

clearing Oracle Applications cache, [5-8](#)

Closed discrepancy state, [1-10](#)

connect string, [3-4](#)

creating database accounts, [5-3](#)

## D

---

### data blinding

InForm hidden items, [2-8](#)

data review flags, [1-5](#)

### data sources

adding to list, [1-1](#)

data visualization tool, integrating with DMW,  
[1-15](#), [4-5](#)

### database accounts

creating, [5-3](#)

### discrepancies

actions, [1-9](#), [1-11](#)

Answered state, [1-10](#)

Cancelled state, [1-9](#)

Candidate state, [1-9](#)

Closed state, [1-10](#)

Open state, [1-9](#)

raised in DMW on InForm data, [1-8](#)

routing operation, [1-9](#), [1-10](#)

states and transitions, [1-8](#)

tags, [1-10](#)

## F

---

### File Watcher

creating for study, [3-1](#)

### File Watcher (*continued*)

study folders, [3-1](#)

suspending and resuming data loading in  
Admin page, [4-1](#)

### flags

compare to tags and categories, [1-11](#)

for subject visit tracking and data review, [1-5](#)

## G

---

Generic Visualization Business Area, [1-15](#), [4-5](#)

## I

---

### InForm

adding a web service location, [3-6](#)

connect string, [3-4](#)

selecting internal tables and views in  
administration, [1-1](#)

InForm internal tables and views available, [1-2](#)

## L

---

### loading data

File Watcher, suspending and resuming, [4-1](#)

lookup values, [2-3](#)

## O

---

### object subtypes

creating roles, [5-4](#)

Open discrepancy state, [1-9](#)

## R

---

### reports

discrepancies sent to InForm by validation  
checks, [4-2](#)

scheduled jobs, [4-2](#)

review flags, [1-5](#)

### routing operations

about, [1-9](#), [1-10](#)

---

## S

---

study File Watcher, creating, [3-1](#)  
subject visit completeness flags, [1-5](#)  
subtype operations  
    assigning roles, [5-5](#)

---

## T

---

tags  
    compare to flags and categories, [1-11](#)  
tags, discrepancies, [1-10](#)  
TMS  
    overview of integration, [1-12](#)  
    set up coding, [1-12](#)  
    statuses, [6-3](#)  
TMS Sets  
    defining, [1-12](#)

TMS Sets (*continued*)  
    defining columns, [1-13](#)

---

## U

---

user accounts  
    assigning roles, [5-2](#)  
    creating, [5-1](#)  
user groups, [5-6](#)  
    adding supported roles, [5-6](#)  
    assigning an administrator, [5-7](#)  
    creating, [5-6](#)  
    duplicating, [5-9](#)

---

## W

---

web service location, InForm, [3-6](#)