Oracle® Health Sciences Data Management Workbench Data Review Guide





Oracle Health Sciences Data Management Workbench Data Review Guide, Release 2.4.8

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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 book tells you how to use Oracle Health Sciences Data Management Workbench to review and clean data.

- Additional copyright information
- · Documentation Accessibility

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1

Basics

- Select a study
- Go to the data management pages
- Select a lifecycle stage
- Change the user interface display
- · Query by example
- Use online help
- · Change your password
- Session timeout

Select a study

- 1. Go to the Home page.
- 2. If the study you want is listed, select it.

If not, find the study:

- a. Select the study's category from the drop-down list (optional).
- **b.** In **Filter Studies** field, type all or part of the name of the study.
- c. Press Enter or click the Search icon.
 The system displays all studies that contain the string you typed.



To clear the filter, click the Remove Filter icon.

d. Select a study.



The next time you log in, the system displays the last study you were working in. You must select it to work in it.

Go to the data management pages

- 1. Click the Data Management icon at the top of any page.
- 2. Do one:
 - To view data and create discrepancies, stay on the Listings tab. To see validation check or custom listings, scroll down in the left pane.
 - To review and act on discrepancies, click the Discrepancies tab.

Select a lifecycle stage

DMW opens in the lifecycle stage you used in your last session. To change, select a different stage from the **Lifecycle** drop-down list at the top of any page under Data Management, Study Configuration, or Home:

- Development is for studies and objects being created or modified. When an
 object is checked out, the new version is in Development.
- Quality Control is for studies and objects being tested. It corresponds to UAT in InForm.
- Production is for production data in live studies.

You may have access to only one or two lifecycle stages.

Change the user interface display

Many pages in the user interface that are laid out like tables with columns and rows allow you to change the data display during your current session. See one of the following sections for details.

- Sort rows by column values
- Show, hide, and reorder selected columns
- · Change column order
- Refresh

Sort rows by column values

The system sorts only the records that are currently displayed. For example, if there are a total of 400 rows but the page shows only 50 at a time, when you sort by column value, only the 50 currently displayed rows are sorted.

- To sort on one column, click the up and down arrows on the column heading. You
 may need to widen the column to see the arrows.
- To sort on up to three column values:
 - 1. Select View, then select Sort, then Advanced.
 - 2. In the **Sort By** field, select the primary column to sort on and then select either **Ascending** or **Descending** order.



- 3. In the first **Then By** field, select the secondary column to sort on and either **Ascending** or **Descending**. Within the sort order you specified in Step 1, the system sorts records in the order you specify here.
- 4. In the second **Then By** field, select the tertiary column to sort on and either **Ascending** or **Descending**. Within the sort order you specified in Steps 1 and 2, the system sorts records in the order you specify here.
- 5. Click OK.

Show, hide, and reorder selected columns

- Select View, then select Columns, then Manage Columns. The system displays all available columns, with a check next to those that are currently displayed. To add or hide a single column, click the column name in the list.
- 2. Use the arrows to move columns from the **Hidden Columns** area to the **Visible Columns** area or the reverse. You can also reorder columns here.
- 3. Click OK.

Change column order

Drag and drop columns on the page or:

- 1. Select View, and then select Reorder Columns.
- 2. Use the arrows to move columns up or down. Columns at the top of the list are displayed leftmost on the page.
- 3. Click OK.

Refresh

Click the Refresh icon to see any changes that have occurred since you opened the window. Other users may be working on data or discrepancies you are viewing, and data may have been loaded.

Query by example

In many windows, you can filter data using empty fields displayed above columns.

- 1. If blank fields above the columns are not displayed, click the **Query By** Example icon.
- 2. Enter text in one or more fields above a column heading. Use the wildcard % before the text to return all values containing the text.
- 3. Press Enter.

To clear guery values, click the **Clear Filter** icon.

Use online help

Hover over fields with a dotted underline to get information about the field.



Click the Pelp icon to see information about the window you are on.



Tip:

If you expand the Help window and lose context, click the same help icon again with the window expanded.

• Click the **Help** link (no icon) at the top of any page to go to the Oracle Help Center page for DMW. Then link to videos, user guides, and common topics.

Change your password

To change the password you use to log in to Oracle DMW:

- 1. Log in to Oracle Life Sciences Data Hub using the URL provided by your administrator and your Oracle DMW password.
- 2. Click the **Preferences** link in the upper right corner of the My Home page.
- 3. Click the Change Password link.
- 4. Enter:
 - Known As: Enter your name as you would like it to appear in the welcome banner on screen.
 - · Old Password: Enter your current password.
 - Password: Enter your new password.
 - Repeat Password: Enter your new password again.
- 5. Click Apply.

Session timeout

DMW user sessions time out after 180 minutes maximum.

If the system is idle it times out after 20 minutes.



View data listings and create discrepancies

- · Choose a listing type and view data
- Search for data
- Review data
- Create discrepancies
- Export data to Excel or CSV
- Create a custom listing
- Copy a custom listing
- · Use the Expression Builder
- FAQs

Choose a listing type and view data

You can choose different methods to view data and show records. For example, you can view any of the following:

- Default listings to show the current data in a table
- Validation check listings to show records that include a discrepancy identified by a validation check
- Custom listings to show records that satisfy criteria that you or others set

See the following procedures for details.

- Default listings
 Default listings shows the ours
 - Default listings shows the current data in a table.
- Validation check listings
 Validation check listings show reco

Validation check listings show records that include a discrepancy identified by a validation check.

Custom listings
 Custom listings show records that satisfy criteria that you or others set.

Default listings

Default listings shows the current data in a table.

- Click the Data Management icon at the top of any page.
- 2. Select Data Review.
- Make sure the Listings tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- 5. Under **Default Listings**, select a listing.



To narrow the choice you can enter part of a listing (table) name in the **Search Default Listings** field and press Enter.

Validation check listings

Validation check listings show records that include a discrepancy identified by a validation check.

- **1.** Click the Data Management icon \blacksquare at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- 5. Select Validation Check Listings from the bottom of the left pane.



Tip:

You can choose to show disabled listings. Listings are disabled if a table they read from is not used in the study.

- 6. Expand the node of a validation check batch.
- Select one validation check in the batch to see:
 - All records with discrepancies identified by the validation check.
 - Any other discrepancies on the records.

If a data item has been fixed and the discrepancy closed, the record is not displayed.



Tip:

You may need to **scroll down** to see Validation Check Listings in the left pane.

Validation checks run in batches as configured in the Home page.

Custom listings

Custom listings show records that satisfy criteria that you or others set.

- 1. Click the Data Management icon at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- 5. Select **Custom Listings** at the bottom of the left pane.



- 6. Do one of the following:
 - **To view a saved listing**, select it in the Custom Listings pane. The current data appears on the right.
 - To copy a saved custom listing, click the More Actions icon in the Custom pane, then click Copy Custom Listings. You can modify the copy.
 - To create your own listing, click the Add icon. See "Create a custom listing".



Tip:

- You can choose to show disabled listings. Listings are disabled if a table they read from is not used in the study.
- You may need to scroll down to see Custom Listings in the left pane.
- To view deleted InForm data create a custom listing but do not install it. The system displays all records that meet the criteria, including deleted records. After you install it the deleted rows are not displayed.

Search for data

You can choose different methods to search for data. For example, you can use the following:

- Find feature to search for column values
- Filters to find data and discrepancies, save filters and filter groups, and use public filters

See the following procedure for details.

Use the Find feature

Use the Find feature

Use the Find feature to search on column values in the current records.

- 1. Click the Data Management icon at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- In the left panel, select **Default**, **Validation Check**, or **Custom** and then select a listing.
- **6.** From the Filters drop-down list, select **Find**.
- 7. To find records that satisfy at least one Find criterion, select **Any**.



To find records that satisfy all Find criteria, select All.

- 8. Enter or select column values to search for.
- To use number, character, or date operators on each column, click Advanced.
 To add criteria to a field already used, click Add Fields.
- 10. Click Search.

Review data

- View discrepancies in the Listings page
- Show all discrepancies on one data item
- View discrepancy details
- Assign and remove flags
- Show flags assigned to a record
- View data lineage
- · View data in InForm or another system
- Reprocess discrepancies that failed to be sent to InForm

View discrepancies in the Listings page

Discrepancy Indicators: Records with one or more discrepancies have a yellow rectangle on the left and the word **Yes** in the DISCREPANCY_EXISTS column.

Data items with discrepancies are highlighted in yellow. You may need to scroll to the right to see them.

State Icons: Hover over the icon to see the discrepancy's state. If a data item has multiple discrepancies, the system displays the state icon for the discrepancy that requires the most work to resolve. In order: Open, Candidate, Answered, Cancelled, Closed.

Discrepancy Filter Indicator: If you have applied a discrepancy-type filter, data items with discrepancies that meet the filter criteria have a **Star** icon.

Show all discrepancies on one data item

- 1. Click the Data Management icon at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- In the left panel, select Default, Validation Check, or Custom and then select a listing.
- 6. Select the data item.
- 7. Right-click and select **Show All Discrepancies**.





Tip:

To view details or act on one of the discrepancies, right-click the data item, and click **Go to Discrepancies**.

View discrepancy details

- 1. Click the Data Management icon at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- In the left panel, select **Default**, **Validation Check**, or **Custom** and then select a listing.
- 6. Select one or more data items with a discrepancy.
- 7. Right-click and select Go to Discrepancies.
- 8. Select one discrepancy and see its details in the lower panes.

Assign and remove flags

Use flags to help track and move the data review process. You can filter by flag in the Listings and Discrepancies pages. See Flag FAQs for more details.

- · Assign a flag to a record
- Remove a flag

Assign a flag to a record

- 1. Click the Data Management icon at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- In the left panel, select **Default**, **Validation Check**, or **Custom** and then select a listing.
- 6. Select a record by clicking one of the small rectangles on the left side of the row.



Tip:

To assign the same flag to multiple records, select the records by pressing the Shift or Ctrl key while clicking the rectangles.

7. Right-click and select Mark Flags.

- 8. Select the flag to assign.
- 9. Click the flag state to assign.



Tip:

If a data load has completed while you were viewing the page, a message appears telling you to refresh the page, and the flag is not assigned. Click the **Refresh** icon and check the data. If the flag still applies, assign it again.

Remove a flag

- Click the Data Management icon at the top of any page.
- Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- In the left panel, select Default, Validation Check, or Custom and then select a listing.
- Select one or more records by clicking one of the small rectangles on the left side of each row.
- Right-click and select Mark Flags, then the assigned flag, then Clear Flag.
 You cannot remove flags assigned in InForm. InForm flags have the prefix Inf_.

Show flags assigned to a record

Flagged records have an icon on the left for the highest priority flag currently applied:

- High priority flag
- Medium priority flag
- Low priority flag

To see which flags are applied to a record:

- 1. Click the Data Management icon \blacksquare at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a flagged record by clicking one of the small rectangles on the left side of the row.
- 5. Right-click and select **Show Flags**.



View data lineage

- 1. Click the Data Management icon \blacksquare at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- In the left panel, select Default Listings, Validation Check Listings, or Custom Listings and then select a listing.
- 6. Click on a data item.
- Right-click and select View Data Lineage.
- 8. Select one:
 - View Source Data to see upstream data that contributed to the selected data item.
 - View Target Data to see downstream data that the selected data item contributes to. Target data is not available in the Validation Check Listings page.
 - **View Preferred Path** If there are multiple source data items, one must be designated as *preferred* when the discrepancy is created, by either a validation check or a person. The system applies the discrepancy to the data items in the preferred path.
- Data lineage display

Data lineage display

The selected data item is in the top row.

- 1. Expand the node in the Name column.
 - If you selected View Source Data, the system displays the data item(s) that contributed to the current item in the immediate upstream clinical data models.
 - If you selected View Target Data, the system displays the data item(s) that this item contributes to in the immediate downstream clinical data model(s).
 - If you selected View preferred path, the system displays the one source data item designated as the preferred one.
- Expand the node of the immediate source or target, if any, to see the next source or target data item, and so on.

For each data item, the window displays:

- Name: Displayed as data_model_name.table_name.column_name.

 An asterisk (*) means the system cannot display a data item and the rest of its path. This may be because:
 - The data item has been deleted or unmapped.
 - You do not have privileges to view the data item.



- **Is Masked**: A \$ means the table contains masked data. This particular data item may not be masked.
- **Is Staging**: A # means the data item is in a staging table used in an intermediate transformation, not in a clinical data model table.
- Value: The data value.
- If the data originated in InForm, click the View Data in InForm icon to open InForm and see the data in context there.
- Preferred Path:
 - Yes if the data item is on the preferred path or the only path.
 - No if there are multiple paths and the data item is not on the preferred one.
- **Primary Key**: The primary key values of the record, in column order as *column1_name:column1_value,column2_name:column2_value* and so on.

See Data lineage FAQs.

View data in InForm or another system

- 1. Click the Data Management icon at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- 5. In the left panel, select **Default Listings**, **Validation Check Listings**, or **Custom Listing** and then select a table, validation check, or custom listing.
- 6. Select a data item that originated in InForm.
- 7. Right-click and select View Data in External Source.
- 8. Log in to InForm or whatever EDC system the data came from.

If the selected DMW data item has more than one source data item, the system displays the one on the preferred path.



Tip:

If you see a discrepancy in DMW that should have been sent to InForm or another source but wasn't, it may be that the process of sending the discrepancy to InForm failed. You can check this and fix it on the Home page. See Reprocess discrepancies that failed to be sent to InForm.

Reprocess discrepancies that failed to be sent to InForm

- 1. Go to the Home page, Validation Checks tab.
- Click the Failed to send Discrepancies icon in the upper right corner.
 For each source data system, DMW displays counts for the selected study and lifecycle stage:



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

Create discrepancies

- 1. Click the Data Management icon at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- 5. In the left panel, select **Default**, **Validation Check**, or **Custom** listings and then select a table, validation check, or custom listing.
- **6.** Select the data item(s) to create a discrepancy on. You can select multiple data items if they all have the same problem.
- 7. Right-click and select Create Discrepancy.
- 8. Fill in the fields.

Tips:

Hover over field names with dotted lines for information about the field.

Discrepancy Count displays the number of discrepancies currently open on the same data item.

9. Click OK.

Export data to Excel or CSV

Select an option from the **Export** drop-down list:

- Export All to Excel generates an .xls file that includes all data that satisfies the current filters (if any).
- **Export Current Page to Excel** generates an .xls file that includes the currently visible data.
- **Export All to CSV** generates a comma-delimited text file that includes all data that satisfies the current filters (if any).
- **Export Current Page to CSV** generates a comma-delimited text file that includes the currently visible data.



Create a custom listing



- Define query details
- Select columns to display
- Define table aliases
- Specify and test criteria
- Save and install a custom listing

Define query details

- 1. Click the Data Management icon at the top of any page.
- Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select a clinical data model from the **Model Name** drop-down list.
- 5. Select **Custom Listings** at the bottom of the left pane.
- 6. Click the + Add icon.
- 7. Enter a name and description for the new custom listing.



Tip:

Make the name 25 characters or less to avoid scrolling to read the name.

- 8. Select Mark as Public to enable all data reviewers to use this custom listing.
- Select Authorize access to this listing for users without Blind Break rights if you know that only nonblinded data will be displayed in the listing, even though at least one source table contains blinded data. Take care to select columns that do not contain blinded data.

If any source table is blinded in any way and this setting is not selected, the system blinds the entire target table, so that only users with Blind Break privileges can view any data.

10. Click OK.

Next: Select columns to display

Select columns to display

Identify the columns to display in the listing and write an expression to change data display (if needed, for example, to mask blinded data, or to append a string to all values in the column, or to concatenate two column values in a single column).



 Drag the tables or columns you want to display from the Source pane into the Selected Columns tab.



Tip:

To select multiple columns, use Ctrl+click or Shift+click.

Tables and columns that are marked Not Used in the transformation that writes to this model are not displayed here.

- 2. If you need an **Expression** to operate on a column(s) to affect the way data is displayed, you must create a 3-character **Table Alias** for its source table in the Define table aliases tab, then select it from this drop-down list.
- 3. Enter the Column Header for Display in the Custom Listings page.
- Enter a Sort Order number to determine the column's display order relative to other columns.
- 5. Select Ascending (ASC) or Descending (DESC) Sort Type for the data display.
- **6.** If you need an **Expression** to operate on the column in the SELECT clause, do one:
 - Enter the expression in the Expression field.
 - If you need to use a function and you write the expression in free text, open the **Select Packages** tab and select the packages you will use. This enables the system to generate the query code.
 - Click the Modify Expression icon to Use the Expression Builder . You can edit code generated by the Expression Builder in this field afterward.

To write an expression that operates on multiple columns, add all columns in the expression to the same row in the Selected Columns tab:

- a. Add one column to Selected Columns and highlight it there.
- b. Select the additional column(s) in the Source pane and click the **Suse in Expression** icon in the Source pane.



If you select a column that contains masked data, write an expression for the column to mask values.

Next: Define table aliases.

Define table aliases

Table aliases are required only if you are using a self-join or writing a SELECT expression on a table column.

- 1. In the **Define Table Alias** tab, select the table from the drop-down list.
- Enter an alias. The alias cannot be longer than three characters.



The system displays the alias in the Selected Columns tab.

- 3. If you need another alias, click the Add Table Alias icon.
- 4. Click OK.

Next: Specify and test criteria.

Specify and test criteria

Specify the data condition the listing will look for.

- 1. Select the Criteria tab.
- 2. Build the WHERE clause to determine which records appear in the listing. Click the Add or Modify Criteria icon and Use the Expression Builder.
- 3. In the custom listing Query Details pane, view and test the generated code:
 - Click View Source. The system generates and displays the PL/SQL code.
 - Click Test: The system generates PL/SQL code, validates it, and displays either an error message or the records retrieved.
- 4. Click OK.

Next: Save and install a custom listing.

Save and install a custom listing

- 1. In the Custom Listings pane, select the listing.
- 2. Click the More Actions icon, then:
 - Click the Save as Query icon to save the listing for use in another session. For new queries, the Save operation includes installation.
 - Click the Install Custom Listing icon to install the listing. This is required only for copied queries.

Copy a custom listing

- 1. Click the Data Management icon at the top of any page.
- 2. Select Data Review.
- 3. Make sure the **Listings** tab is open.
- 4. Select **Custom** at the bottom of the left pane.
- 5. Click the More Actions icon, then click Copy Custom Listings.
- 6. Select a project (or other study grouping).
- 7. Select a model.
- 8. Select one or more custom listings within the model.



- 9. Click **OK**. The system searches the current model for the tables and columns that the selected custom listings read from.
 - If the tables or columns do not exist, the Copy operation fails with an error message.
 - If they exist but are marked Not Used in the transformation that writes to the model, the system copies the listings as disabled.

Use the Expression Builder

There are two ways to add an expression, with different advantages:

- Use the Expression Builder user interface. This more cumbersome process
 makes the transformations, validation checks, and custom listings that use it
 easier to copy and map in the new study.
- Enter code as free text directly in the Expression Text field. This is a simpler
 process for a programmer but results in a less easily reusable transformation,
 validation check, or custom listing.

/ Important:

- If you reference a static package or function in free text, you must select it in the Selected Packages tab.
- In free text, use just the column name, not the table.column format, unless you need to use an alias, as in a self-join. In that case the alias.column format is required.

To use the Expression Builder:

- 1. In the Expression Criteria pane, select the following as needed to build the expression from left to right.
 - Add Group to add the parentheses () that surround a phrase in an expression or group smaller units of logic.
 - Add Item to add a unit of logic smaller than a group.
- 2. To add a phrase within a group, click the parentheses ().

To add a phrase outside a group, click **Expression**.

 To add an item, in the Expression Item pane select either Column, Function (for functions written by your company), or Standard Function (for Oracle SQL functions).

To create an expression using column values:

- a. For Item Type, select Column.
- b. Click the Select Column icon.

In the Select Column window, you can filter above any of the attribute columns to find the table column you want. Select a column and click \mathbf{OK} .

c. If needed, select an operator from the list.



- **d.** If needed, enter a data value. The system encloses the value you enter in single quotes.
- e. If needed, select a conjunction from the list.



Tip:

If you select a conjunction within a group, it appears within the group, at the end. If you need a conjunction outside the group, click **Expression** above, then select the conjunction.

f. Click Add. The system generates the SQL expression and displays it in the Expression Text pane.



Note:

You can edit the generated code in the Expression Text pane, but if you do, you cannot continue to build the expression in the user interface.

Click **Validate** to check the generated code.

To use a function in your library:

- **a.** For Item Type, select **Function**. The Select Function window appears, displaying a list of Oracle functions.
- b. Select a function and click **OK**.

To use a standard SQL function:

- a. For Item Type, select **Standard Function**.
- **b.** Click the **Select Standard Function** icon. A search window appears. To filter, enter all or part of the name in the field above. You can use the wildcard %.
- c. Select a function and click OK.
- 4. Define additional groups and items to complete the expression as necessary.
- 5. Click Save.
- Click Validate. The system validates the code and displays any errors or warnings.

To make a correction in the Expression Builder:

- a. Select the faulty item in the Expression Criteria pane. An Update button appears in the Expression Item pane.
- b. Make your changes in the Expression Item pane and click **Update**.
 - For more information, see Pass data as input parameter values and Pass constant values.
- Pass data as input parameter values
- Pass constant values



Pass data as input parameter values

Use curly brackets ("{" and "}") as delimiters and the fully qualified format (model.table.column) to indicate input parameter values to SQL functions or custom functions in the expression. The default input is the column value if no metadata is specified after the column name.

For example, to calculate a subject's age from his date of birth:

```
round((sysdate - {Review.LAB_SRC.dob})/365)
```

where Review is the data model name, LAB_SRC is the table name, and dob is the column name. No metadata follows the column name, so by default the system passes the Date of Birth (dob) data value to the expression.

Pass constant values

You can hard-code a value for a target column using an expression that contains only a constant value or by calling a SQL function based on constants, for example:

```
round(3.14 * power(10, 2))
```

FAQs

- Listings FAQs
- Flag FAQs
- Data lineage FAQs

Listings FAQs

- What is a clinical data model?
- One of the rows says "Yes" under the Discrepancy_Exists Column, but no cells are highlighted yellow. Where is the discrepancy?
- How can I see only open validation check discrepancies when I am viewing a Validation Check listing?
- What is a disabled listing?
- · Where can I copy a custom listing from?
- What happens if I modify a Table Alias?
- How can I view blinded data?
- How can I resend data that needs coding to TMS?

What is a clinical data model?

A clinical data model is a logical set of tables of study data. They were either loaded together into DMW from a single source or they contain data transformed by your study configurator for a purpose such as data review or analysis.



One of the rows says "Yes" under the Discrepancy_Exists Column, but no cells are highlighted yellow. Where is the discrepancy?

An active discrepancy filter has probably identified a discrepancy in a column that is not displayed.

How can I see only open validation check discrepancies when I am viewing a Validation Check listing?

You can apply a Discrepancy States and Tags filter showing only open discrepancies. However, you will see all records with any open discrepancies, even if the discrepancy raised by the validation check on the record has been manually closed, and even if the column with the open discrepancy is not displayed in the listing.

What is a disabled listing?

Listings are disabled if a table they read from is not used in the study.

Where can I copy a custom listing from?

You can copy custom listings from another study or from a different clinical data model in the same study. The system checks if the required source tables are available in the current model.

What happens if I modify a Table Alias?

If you are creating the listing and modify the alias after defining an expression or criterion that refers to the original alias, you must update the expression or criterion manually before saving.

If you are modifying a saved listing and modify an alias, the system will update the expression or criterion when you save, as long as the expression or criterion was originally created using the Expression Builder.

How can I view blinded data?

When you choose a listing that contains blinded data and you have privileges to view it, DMW will ask you to confirm that you want to access the blinded data.

After clicking Yes, you can use the padlock icon in the top right of the table to toggle between viewing real, blinded data and viewing the masking values (or, in the case where a whole table or row is blinded, seeing no data).

How can I resend data that needs coding to TMS?

If you make structural changes like updating a dictionary or adding columns to hold derived data from TMS, you can send all data that has been designated as needing coding by running the Force Rederivation job.

- Go to the Home page.
- Select a study.



- 3. Click the **Modify** icon in the Studies pane.
- 4. Click the TMS tab.
- 5. Click Force Rederivation to run Rederivation once, immediately.
- **6.** A confirmation message appears because the job may take a long time. You can still work while it runs. Click **OK**.

Flag FAQs

- Why can't I assign a flag?
- Can the flags I assign be seen in InForm?
- I wish a different flag were available.
- Why can't I change some flags?

Why can't I assign a flag?

The Assign Flags function is available only if flags have been defined for the current data model type and if you have the privileges required to assign flags.

Can the flags I assign be seen in InForm?

No. DMW flags stay in DMW.

I wish a different flag were available.

Your administrator creates the flags you can assign in DMW.

Why can't I change some flags?

Flags that start with Inf_are CRF form and section states imported from InForm as flags. After the Inf_are the name is the same as in InForm. You cannot change these flag assignments in DMW. Each of these flags has two states: Yes an No (Y and N).

Data lineage FAQs

- What is data lineage?
- When I create a discrepancy against a data item, how does that affect the data lineage?
- Why does the wrong source data item have the discrepancy?
- What is data lineage?
- When I create a discrepancy against a data item, how does that affect the data lineage?
- Why does the wrong source data item have the discrepancy?



What is data lineage?

A single data item, such as a subject's weight, appears in DMW first as loaded from InForm or another system and then in subsequent *downstream* clinical data models. DMW maintains tracks each data item as it appears in each model.

The column name may change from one model to the next, for example from WT to WEIGHT, and the value may be converted to different units and used to derive other values, such as Body Mass Index (BMI).

When I create a discrepancy against a data item, how does that affect the data lineage?

The system immediately displays the discrepancy against the corresponding data items upstream and downstream.

Why does the wrong source data item have the discrepancy?

When a data item like a derived BMI has more than one source data item, the validation check must designate a single column as the one against which to create the discrepancy, even if it is impossible to know in advance which one is faulty. A BMI that is out of range might be due to a bad value for height, weight, or unit, but one of them must be preselected. However, all relevant values can be displayed.

See also "Why is a query on a different item in InForm than in DMW?".



Review and act on discrepancies

- How do I create a discrepancy?
- · Find discrepancies
- Act on a discrepancy
- See more information about a discrepancy
- FAQs
- Review and act on discrepancies in the old UI

How do I create a discrepancy?

Go to **Home**, then **Data Management**, then **Data Review**, then **Listings**. See "Create discrepancies" for details.





Tip:

In Release 2.4.8 there are two Discrepancies pages, one old and one new.

Reach the new one by navigating to **Data Management**, then **Discrepancies**. This page has an enhanced user interface.

Reach the old one by navigating to Data Management, then Data Review, then Discrepancies. This page has more powerful filter and sorting capabilities.

Find discrepancies

There are two ways to find discrepancies that can be used together or separately: the filters in the left pane and the fields at the top.

- Use the quick filters on the left pane
- Use the search fields at the top

Use the quick filters on the left pane

These look for the exact values you enter.

1. Click the Data Management icon at the top of any page.

- Select Discrepancies.
- 3. In the left panel, search for any combination of the following: Clinical Data Model, Listing, Site, Subject, Visit, Discrepancy State.

Start at the top and work down. Your choices in the lower fields are limited by the values in the upper fields. You can select more than one value by clicking in the field again.

- 4. Click Apply.
- (Optional) To save these criteria for future use, click Save, name the filter, and click Save and Apply.



Tip:

Saving a filter allows you to modify it one criterion at a time, saving after each change.

6. Use the search fields at the top to add filter criteria.



Tip:

If you need more granular filters, go to the old Discrepancies page. See Use filters to find data and discrepancies.

- a. Click the **Home** icon at the top of the page.
- **b.** Click the Data Management icon at the top of the page.
- c. Click Data Review.
- d. Click the Discrepancies tab.
- e. Click the Filter icon.

To clear the filters, click Clear.

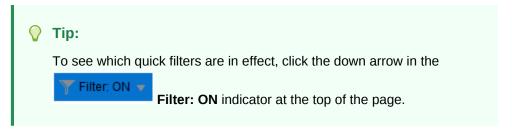
To view data after clearing, click Apply, without filters or with different ones.

Use the search fields at the top

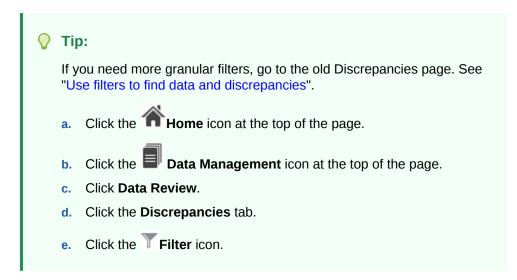
You can enter a partial value here to find all records that contain that value. For example, if you search for Subject ID=CA, you find all subject IDs that contain CA, unlike the quick filters that find only the exact value entered.

- If there are quick filters in effect when you search in these fields, the system applies the filters and searches on these values within the filter results.
- If there are no quick filters in effect, the system searches across all discrepancies.





- 1. Click the Data Management icon at the top of any page.
- 2. Select Discrepancies.
- 3. In the drop-down list above the discrepancies table, select what to search on, for example: Category, Datasource, Days since last state change, Discrepancy text. The choices depend on the columns your organization uses.
- 4. Enter a value in the text box.
- 5. Click the Search icon.



To clear, remove the value and click **Refresh** in the upper-right corner.

Act on a discrepancy

- Change the state or send to InForm or another system
- Add a comment
- · Change discrepancy text or category
- Export discrepancies on lab data

Change the state or send to InForm or another system

- 1. Click the Data Management icon at the top of any page.
- 2. Select Discrepancies.
- 3. Find discrepancies using the filters on the left and top of the page.



- 4. Select one or more discrepancies.
- From the Manage Discrepancies drop-down, select the action to take. Actions are listed only if they are valid for all selected discrepancies.

In the right panel, either select or enter a reason for your change.



Tip:

If you do both, only the selected reason is saved.

6. Click Submit.

Add a comment

- 1. Click the Data Management icon at the top of any page.
- Select Discrepancies.
- 3. Find discrepancies using the filters on the left and top of the page.
- 4. Select one discrepancy.
- 5. In the right panel, click Add Comment.
- 6. Enter the comment and click Submit.

Change discrepancy text or category

- 1. Click the Data Management icon at the top of any page.
- 2. Select Discrepancies.
- 3. Find discrepancies using the filters on the left and top of the page.
- 4. Select one discrepancy.
- 5. In the right panel, click Edit.
- 6. Edit the discrepancy text and/or select a new category.
- 7. Click Submit.

Export discrepancies on lab data

To send discrepancies to a lab, create a file and email it manually.

- 1. Click the Data Management icon at the top of any page.
- 2. Select Discrepancies.
- 3. Filter for the lab's data model and your other criteria in the filters on the left and top of the page. See Find discrepancies.
- 4. If you want to export only selected discrepancies, select the discrepancies.
- 5. From the **Export** drop-down, select an option to export:



- All to Excel
- All to CSV
- Selected to Excel
- Selected to CSV

The system exports the data to a file and asks you where to save it.

See more information about a discrepancy

- View the full record containing a discrepancy
- View the record in its source system
- · View the discrepancy in its source system

View the full record containing a discrepancy

- 1. Click the Data Management icon at the top of any page.
- 2. Select Discrepancies.
- 3. Find discrepancies using the filters on the left and top of the page.
- 4. Select one discrepancy.
- 5. From the View drop-down on the right, select Full Record.

To see a particular column:

- Enter part of its name in the Search field.
- b. Click the Search icon.
- (Optional) Select Show Only Changes to see only items with different current and original data values.

View the record in its source system

- 1. Click the Data Management icon at the top of any page.
- Select Discrepancies.
- 3. Find discrepancies using the filters on the left and top of the page.
- Select one discrepancy.
- 5. From the **View** drop-down on the right, select **Data in System**.
- 6. When the source system opens, log in.

View the discrepancy in its source system

- 1. Click the Data Management icon at the top of any page.
- 2. Select Discrepancies.
- 3. Find discrepancies using the filters on the left and top of the page.



- 4. Select one discrepancy.
- 5. From the **View** drop-down on the right, select **Discrepancy in** System.
- 6. When the source system opens, log in.

FAQs

- · Acting on a discrepancy FAQs
- InForm query and discrepancy FAQs
- Lab data discrepancy FAQs
- TMS discrepancy FAQs

Acting on a discrepancy FAQs

- Can I take an action on multiple discrepancies at once?
- Why don't I see the action I want to apply?
- Can I send discrepant data items to multiple sources?
- Why can't I send a particular data item to another source?

Can I take an action on multiple discrepancies at once?

Yes, but you should select discrepancies that are all in the same state. The discrepancies may also need the same tag depending on how your company uses the system, and may need to be from the same data source. The system only displays actions that are valid for all the selected discrepancies.

Why don't I see the action I want to apply?

If you selected multiple discrepancies, the system displays only actions that apply a valid next state for all the selected discrepancies. If you select discrepancies that do not share a valid action, the system lists no actions. You must change your selection to a set of discrepancies that are in the same state. They may also need to have the same tag applied.

If you selected a single discrepancy and the discrepant data point is derived from multiple data values from different sources, the system uses the data source identified as on the preferred path in the transformation to determine which routing action to enable. If no action is available to send the discrepancy to the source you need, you may need to enter the discrepancy against the data point in the source data model.

Can I send discrepant data items to multiple sources?

If a single discrepant data item is derived from data in more than one source, you can only send the discrepancy to InForm if an InForm data item is designated as being on the preferred path. You can always filter and use Export to Excel for sending a discrepancy to a lab.



Why can't I send a particular data item to another source?

The system uses the preferred path source specified in the transformation or validation check to determine where you can send the discrepancy. If no action is available to send the discrepancy to the right source, you can go to the Listings page, change to the source data model, and create a discrepancy against the data item there.

Add a comment to the current discrepancy detailing what you did.

InForm query and discrepancy FAQs

- Can I change the state of a discrepancy that was loaded from InForm?
- Can I create a discrepancy in DMW on a data item that originated in InForm?
- Can I send a discrepancy to InForm?
- Why can't I open InForm and see a discrepancy there?
- What happens to the discrepancy after I send it to InForm?
- If I don't send the discrepancy to InForm, can InForm users act on the discrepancy?
- Before I send the discrepancy to InForm, can I act on it?

Can I change the state of a discrepancy that was loaded from InForm?

You can only move discrepancies/queries to the Answered state in InForm. You can close them in either system.

This is true no matter which system the discrepancy/query was created in.

Can I create a discrepancy in DMW on a data item that originated in InForm?

Yes. Validation checks can also create discrepancies on a data item originating in InForm.

Can I send a discrepancy to InForm?

Yes. When you send a discrepancy on an InForm data item back to InForm, you create a new query in InForm.

InForm does not accept discrepancies on data that is *hidden* in InForm. Any resolution must occur within DMW.

Why can't I open InForm and see a discrepancy there?

You have to wait until data has been reloaded from InForm after sending the discrepancy.

What happens to the discrepancy after I send it to InForm?

InForm users can act on the discrepancy using the same rules that apply to queries. InForm users can also correct the underlying data item.



Changes made in InForm are loaded into DMW during the next scheduled data load. The discrepancy is then "in" DMW and cannot be sent to InForm again, though updates made in DMW are sent to InForm.

If I don't send the discrepancy to InForm, can InForm users act on the discrepancy?

No. InForm users can change the underlying data item, and that change is loaded into DMW during the next scheduled data load, but they can't act on the discrepancy.

Before I send the discrepancy to InForm, can I act on it?

Yes. In DMW you can apply an action that changes the state of the discrepancy and must supply a reason for the change. The state change and reason for change are sent to InForm almost immediately.

Lab data discrepancy FAQs

- Can I create a discrepancy on a data item that originated in a lab?
- How do I send these discrepancies to the lab?

Can I create a discrepancy on a data item that originated in a lab?

Yes. Validation checks can also create a discrepancy on a data item that originated in a lab.

How do I send these discrepancies to the lab?

You can use **Export All to Excel** to export discrepancies to a spreadsheet and manually send them to the source lab. Lab personnel can then respond or change the underlying data item and load the changes into DMW, and you can act on the discrepancy in DMW.

When you use the **Export All to Excel** option to send discrepancies to a spreadsheet, all discrepancies that meet the current filter criteria are included, even if they are not visible on the screen.

TMS discrepancy FAQs

- What does it mean when a discrepancy's category includes "TMS"?
- What do the different TMS Discrepancy Categories mean?
- What should I do with a TMS discrepancy?
- Why is a guery on a different item in InForm than in DMW?

What does it mean when a discrepancy's category includes "TMS"?

If your study is set up to use Oracle Thesaurus Management System (TMS) for coding source data to standard terminologies, or dictionaries, TMS processes designated data items with new or changed data during DMW transformation. If TMS is able to automatically code a designated source term to a dictionary term, it does so and derives specified data back to DMW.



TMS creates a discrepancy when it cannot automatically code a data item to a dictionary term.

What do the different TMS Discrepancy Categories mean?

- TMS in Progress prevents updates in DMW while the data item (term) awaits manual classification in TMS.
- TMS Evaluation means that the item or discrepancy has been updated either in the source system or in DMW, and triggers autoclassification on the term in TMS during the next transformation. No updates can be made in DMW while the category is TMS Evaluation.
- TMS DM Review means that the data manager should review the discrepancy in DMW.
- TMS Inv Review means that the discrepancy has been sent to InForm as a query for review by the investigator. The system also sends any subsequent updates to the discrepancy to InForm.

You can use a Discrepancy Categories filter to help process these discrepancies.

What should I do with a TMS discrepancy?

You can only review the discrepancy in DMW. TMS discrepancies must be resolved in either TMS or the source data system.

A TMS user can either:

- Classify the data item manually. TMS then closes the discrepancy and derives data to DMW.
- Send text to DMW as discrepancy text describing a problem with the data or an action required. For example, if the data item is "headache and nausea," the message could be "Split the term."

A source data system user can correct the term so that it can be classified in TMS.



Tip:

A discrepancy can be updated in the source system and in TMS at the same time. This may cause conflicts. For example, an InForm user might close a discrepancy thinking the term is a valid one while TMS does not recognize it. In this case, even though the Closed status is loaded into DMW, closing the discrepancy, TMS opens a new discrepancy when autoclassification fails.

Why is a query on a different item in InForm than in DMW?

This can happen if your study designer set up Coding Maps in Central Designer to purposefully attach a query to a different form item than the one it was raised on. This feature is intended for use with Central Coding.

If the same form item is set up for coding in TMS through DMW, when the discrepancy is sent to InForm the Coding Map routes the query to its mapped item.



Review and act on discrepancies in the old UI

- How do I create a discrepancy?
- · Act on a discrepancy
- See more information about a discrepancy
- Show blinded data

How do I create a discrepancy?

Go to Data Management, then Data Review, then Listings. See Create discrepancies for details.



Act on a discrepancy

You apply *actions* to discrepancies to move them from one state or tag value to another and/or to send them to InForm or to a spreadsheet to be sent to a lab. See the following for details.

- Apply an action to change the state or send to InForm
- Add a comment to a discrepancy
- Edit discrepancy text
- Export discrepancies for a lab

Apply an action to change the state or send to InForm

- 1. Click the Data Management icon at the top of any page except the new Discrepancies page.
- Select Data Review.
- Select the Discrepancies tab.
- 4. Select one or more discrepancies.



Tip:

See Create a new filter or Use or modify existing filters for help finding specific discrepancies.

- 5. Click the **Actions** drop-down and select the action you want to apply. The list includes all actions that are valid for *all* the selected discrepancies; for example:
 - Open Discrepancy
 - Cancel Discrepancy



- Close Discrepancy
- Send to InForm



Tip:

To send a discrepancy to a lab, use Export to Excel and manually send the spreadsheet to the lab. See Export discrepancies for a lab.

- **6.** In the pop-up window, provide a reason for the change. Do either:
 - Select a reason from the list.
 - Enter a reason.



Tip:

If you select a reason *and* enter your own reason, only the selected reason is sent to the source system. To send your own text, do not select a reason.

Click OK.

See InForm query and discrepancy FAQs, Lab data discrepancy FAQs, and TMS discrepancy FAQs.

Add a comment to a discrepancy

- 1. Click the Data Management icon at the top of any page except the new Discrepancies page.
- 2. Select Data Review.
- 3. Select the **Discrepancies** tab.
- 4. Select a discrepancy, or select multiple discrepancies to apply the same comment to all of them.



Tip:

See Use filters to find data and discrepancies.

- 5. Click the Add Comment icon.
- 6. Enter a comment.
- 7. **Internal Comment?** Leave this field blank unless the discrepancy originated in Oracle Thesaurus Management System (TMS).

If the discrepancy is from TMS:

If selected, the comment has no effect in TMS.



- If not selected, the system changes the discrepancy's status to TMS
 EVALUATION and TMS autoclassification runs on the source term during the
 next transformation job.
- Click OK.

Edit discrepancy text

- 1. Click the Data Management icon at the top of any page except the new Discrepancies page.
- Select Data Review.
- 3. Select the **Discrepancies** tab.



Tip:

See Use filters to find data and discrepancies.

- 4. Select a discrepancy.
- 5. Click the **Edit** icon.
- 6. Do one or more of the following:
 - Discrepancy: Edit the text describing the problem with the data or action required.



Tip:

If the discrepancy has been sent to InForm, you cannot edit the text.

- Category: Select a category to apply to the discrepancy. You can filter discrepancies by category.
- Action: See Apply an action to change the state or send to InForm.
- Allow Auto Close: (Appears only for discrepancies created by validation checks.) If data is updated so it no longer meets validation check criteria:
 - If selected, the validation check closes the discrepancy.
 - If unselected, the discrepancy must be closed manually.
- Select a Reason for Action from the drop-down list or enter your own reason in the text box.
- 7. Click OK.

Export discrepancies for a lab

Click the **Export to Excel** icon to generate an .xls file that includes all discrepancies that meet the current filter criteria, even if they are not visible on the screen.



You can then manually send the spreadsheet to a source lab. Lab personnel can respond or modify the underlying data item and load the changes into DMW.

See more information about a discrepancy

- View discrepancy details
- View discrepancy history
- · View the full record containing a discrepancy
- · View a discrepancy in its source system
- · View data in its source system

View discrepancy details

- Click the Data Management icon at the top of any page except the new Discrepancies page.
- Select Data Review.
- 3. Select the **Discrepancies** tab.
- 4. Select one discrepancy.
- 5. The **Details** pane for the selected discrepancy is on the bottom left. It includes:
- Subject
- Visit
- **Discrepancy**: Discrepancy text. You can edit this by clicking the **Edit** icon. You cannot edit text for discrepancies that have been sent to InForm.
- Table: The database table that contains the discrepant value.
- **Model**: The clinical data model that contains the data value against which the discrepancy was originally created.



If the model is *InForm*, the discrepancy originated as a query in InForm.

- **Item**: The table column that contains the discrepant value.
- Original Value: The original discrepant data value.
- State: The current discrepancy state: Candidate, Open, Cancelled, Answered, or Closed. To change it, select Actions from the right-click or drop-down list.



Tip:

By default, Closed and Cancelled discrepancies are not displayed. To display them, use a States and Tags filter. See Discrepancy States and Tags filter.



- Days in State
- Category: The category assigned to the discrepancy, if any. You can filter by category. To change it, click the Edit icon.
- Created
- Modified
- Tag: The tag assigned to the discrepancy, if any. Some actions apply tags.
- New Data: If Yes, the data value has been changed in the source system and the
 discrepancy has not been reviewed in DMW since then. When you or someone
 else clicks Display Full Record, the system considers it reviewed and sets this
 value to No. You can also set it to No.
- View Query in InForm: When you click this icon, the InForm Login page opens.
 After you log in, the system displays the selected query in context.
- **View Data in InForm**: When you click this icon, the InForm Login page opens. After you log in, the system displays the underlying data in context.

View discrepancy history

- 1. Click the Data Management icon at the top of any page except the new Discrepancies page.
- 2. Select Data Review.
- 3. Select the Discrepancies tab.
- 4. Select one discrepancy.
- 5. The **History** pane for the selected discrepancy is on the bottom right.
- 6. Click the Refresh icon to view any changes that have occurred since you selected the discrepancy or last refreshed.

The history of the discrepancy is displayed with the most recent change at the top.

View the full record containing a discrepancy

- Click the Data Management icon at the top of any page except the new Discrepancies page.
- 2. Select Data Review.
- 3. Select the **Discrepancies** tab.
- 4. Select one discrepancy.
- 5. On the bottom right, select the **Display Full Record** tab.
- 6. Click the Refresh icon to view any changes that have occurred since you selected the discrepancy or last refreshed.

The internal column CDR\$SKEY displayed at the bottom contains the primary key values of the record separated by tildes (~). DMW uses this value to trace data lineage.



View a discrepancy in its source system

If a discrepancy was created on data from InForm or another EDC clinical data system, then sent to the system, and then data reloaded from that system, you can open the external system and view the discrepancy/query in context there.

- 1. Click the Data Management icon at the top of any page except the new Discrepancies page.
- 2. Select Data Review.
- 3. Select the **Discrepancies** tab.
- 4. Select one discrepancy.
- In the Details pane, click the View Query in External Source icon near the bottom.

View data in its source system

To view data in context in InForm or another EDC clinical data system:

- 1. Click the Data Management icon at the top of any page except the new Discrepancies page.
- Select Data Review.
- 3. Select the **Discrepancies** tab.
- 4. Select one discrepancy.
- 5. In the **Details** pane, click the **View Data in External Source** icon at the bottom.

Show blinded data

If you have special privileges, you can choose to see sensitive, blinded data instead of masking values. The system tracks the times you view blinded data.

- Show Sensitive Data is displayed by default. Click this icon to show blinded data.
- Hide Sensitive Data is displayed when you have chosen to display blinded data. Click this icon to hide blinded data.



Use filters to find data and discrepancies

This section has information on the complex filters available in the Listings pages and in the old Discrepancies page under Data Review. Simple filters are available in the new Discrepancies page that you reach by going directly to Discrepancies from the



Data Management icon.



Tip:

By default, no cancelled or closed discrepancies are displayed when you apply any discrepancy filter. To see cancelled or closed discrepancies, use a Discrepancy States and Tags filter.



- Create a new filter
- Use or modify existing filters
- Delete a filter
- Create a public filter
- Use filter groups
- Filter Types
- **FAQs**

Create a new filter

- Click the Data Management icon at the top of any page.
- Click Data Review.
- Do one:
 - Stay in the **Listings** page to view data and create discrepancies.
 - Click the **Discrepancies** tab to view and act on discrepancies.
- Select the **Filter** option:
 - On the Discrepancies page, click the **Filter** icon.
 - On the Listings page, select **Filter** from the **Filter** drop-down list.
- Look for the type of filter you want to use. Use the scroll bar.

- 6. Click the **Add** icon for the filter type.
- 7. Fill in the fields. Use online help for information about the different filter types or see Filter Types.
- 8. To save the filter for future use, enter a name.
- 9 Click OK
- **10.** Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **11.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 12. Click OK.



Tip:

You can use multiple filters at the same time by creating or selecting them here. You can also save them as a Filter Group.

Use or modify existing filters

- 1. Click the Data Management icon at the top of any page.
- 2. Click Data Review.
- 3. Do one:
 - Stay in the Listings page to view data and create discrepancies.
 - Click the **Discrepancies** tab to view and act on discrepancies.
- 4. Select the **Filter** option:
 - On the Discrepancies page, click the **Filter** icon.
 - On the Listings page, select Filter from the Filter drop-down list.
- 5. Look for the type of filter you want to use. Use the scroll bar.
- 6. Select an existing filter from the drop-down list for the filter type.



Tip:

To see more filters, select **Show Filters Shared by Others** at the top of the window.

- 7. To modify or view the filter values, click the **Modify** icon.
 - Edit the values as needed. Use online help for information about the different filter types or see "Filter Types".
- 8. To save your edits for future use, enter a different name.



Filter names must be unique across all private, shared, and public filters that you can see in a particular study or, for Discrepancies filters, across all studies.

- 9. Click OK.
- **10.** Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **11.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 12. Click **OK**. The system applies the filter.



Tip

You can use multiple filters at the same time by creating or selecting them here. You can also save them as a Filter Group.

Delete a filter

To delete a filter, select it from the drop-down list and click the **Delete** icon.

You can delete filters you created. You cannot delete a filter if it is part of a filter group. Delete it from the group first.

Create a public filter

If you have special privileges, you can make a filter public. Data reviewers can:

- Use any public filter.
- Change public filter values temporarily.
- Change public filter values and save them using a different name.
- 1. Create a new filter. Give the filter a name and save by clicking **OK**.
- In the main Filter window, select Public from the drop-down to the right of the filter name.

Use filter groups

Filter groups apply multiple filters at the same time.

- Create or modify a filter group
- Apply an existing filter group
- Filter group example

Create or modify a filter group

- 1. Click the Data Management icon at the top of any page.
- 2. Click Data Review.



- 3. Do one:
 - Stay in the **Listings** page to view data and create discrepancies.
 - Click the **Discrepancies** tab to view and act on discrepancies.
- 4. Select the **Filter** option:
 - On the Discrepancies page, click the Filter icon.
 - On the Listings page, select Filter from the Filter drop-down list.
- 5. In the Filter Group area:
 - To create a new filter group, click the Filter Group *Add icon.
 - To create a new group based on an existing group, select the group from the list and click the Filter Group **Modify** icon.
 - To modify an existing group, select the group from the list and click the Filter Group Modify icon.



Tip:

To find a filter group, select **Search** at the bottom of the Filter Group list. Enter part or all of the name with the wild card % and/or enter the class (Public, Private, or Shared). Click **Search**.

The select the filter group from the list and click **OK**.

- **6.** Select filters from the drop-down list of their filter type.
- Select Keep Active for the filters that you want to remain active if you leave the page or change clinical data models.
- **8.** Enter a **Name** and **Description** to create a new group. Leave as is to modify a group.
- 9. If you are creating a new group based on an existing group, select **Save As Copy**.



Tip:

Leave **Save As Copy** unselected if you are modifying an existing group.

- 10. Click OK.
- **11.** To allow other people to use the filter group, select **Shared** from the drop-down to the right of the filter group name.
- 12. Click **OK** to apply the filters.

Apply an existing filter group

- 1. Click the Data Management icon at the top of any page.
- 2. Click Data Review.



- 3. Do one:
 - Stay in the Listings page to view data and create discrepancies.
 - Click the **Discrepancies** tab to view and act on discrepancies.
- 4. Select the **Filter** option:
 - On the Discrepancies page, click the Filter icon.
 - On the Listings page, select Filter from the Filter drop-down list.
- 5. Select the group from the **Filter Group** list at the bottom of the Filter window.
- 6. Click OK.

Filter group example

A filter group could contain the following four filters:

- A shared Subjects filter named BOSTON HOSPITAL that filters for subjects at the Boston Hospital site.
- A private Visits filter named CYCLE A that filters for records collected in visits that are part of Cycle A.
- A public Discrepancy Categories filter called INFORM that filters for discrepancies on data that originated in InForm.
- A private Discrepancy State Dates filter called LATEST that filters for records
 whose discrepancy state changed between specific dates. You need to update the
 dates each time you use the filter.

These filters are applied to the data at the same time, so that the system displays only data that satisfies the criteria for all filters.

If all filters are set to Keep Active, as long as you stay in the current study and lifecycle stage, the filters apply, if possible. If you view data in a table that does not have a column required for the filter—such as a Visit column or Site column in this example—the system ignores that filter.

Filter Types

- Subject filter
- Visit filter
- Subject Visit Flags filter
- Visit Day filter
- Visit Date filter
- Record Flags filter
- Data Change Date filter
- Discrepancy Category filter
- Discrepancy Change Dates filter
- Discrepancy State Dates filter



- Discrepancy States and Tags filter
- Discrepancy User filter
- **Discrepancy Origin filter**
- Models and Tables filter
- **Data Source filter**
- Copy a custom listing

Subject filter

Filter records based on characteristics of subjects, including their country, site, investigator, or ID.

- 1. Select the **Filter** option on the Listings or Discrepancies page under Data Management.
- 2. In the **Subjects** row, click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. Filter Driver Data Model: Select a model from the list.



Tip:

Use the same model as the filter driver in all filters for the same study. Filters using different driver models cannot work at the same time.

- Filter Type: Select one:
 - Countries
 - Sites
 - Site IDs
 - **Investigator Names**
 - Investigator IDs
 - Subject IDs
 - Unique Subject IDs (ID unique across studies)



Tip:

Enter a value above any column to filter the rows displayed.



Note:

If the Subject Visit table in the filter driver data model does not have a column mapped to the SDTM identifier for Country, Site, Site ID, Investigator Name, Investigator ID, Subject ID, or Unique Subject ID, the column is not displayed.

- Select one or more rows to be the filter criteria.
- 6. Check **Exclude Based On Criteria** to filter **out** records that satisfy the criteria. Leave unchecked to display the records that satisfy the criteria.
- 7. Filter Availability:
 - Study Level makes the filter available in all data models in the current study and lifecycle.
 - Data Model Level makes the filter available only in the current data model and lifecycle.
- **8. Filter Name**: To save the filter for use in another session, that is, after you log out or change to a different study, enter a name.



Tip:

Filter names must be unique across all the private, shared, and public filters that you can see in the current study and lifecycle.

- Description: Enter additional text to help you and other users know what this filter does.
- **10. Save As Copy**. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 11. Click OK.
- **12.** Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **13.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 14. Click **OK** in the main Filters window.

Visit filter

To filter for a single visit:

- Select the Filter option on the Listings or Discrepancies page under Management.
- 2. In the **Visits** row, click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. Filter Driver Data Model: Select a model from the list.





Tip:

Use the same model as the filter driver in all filters for the same study. Filters using different driver models cannot work at the same time.

- **4. Filter Type**: Select one of the following:
 - Visit Cycle
 - Visit Number
 - Visit Name
- Select a row to be the filter value.



Tip:

Enter part of a value above any of the columns to filter the choices displayed. For example, type the name of a visit cycle to see only visits in that cycle.

- **6.** Select **Exclude Based On Criteria** to filter **out** records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
- 7. Filter Availability:
 - Study Level makes the filter available in all data models in the current study and lifecycle.
 - Data Model Level makes the filter available only in the current data model and lifecycle.
- 8. **Filter Name**: To save the filter for use in another session, that is, after you log out or change to a different study, enter a name.



Tip:

- Description: Enter additional text to help you and other users know if this filter meets their needs.
- **10. Save As Copy**. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 11. Click OK.
- 12. Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **13.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 14. Click **OK** in the main Filters window.



Subject Visit Flags filter

On the Listings page, use this filter to find records with particular Subject Visit flag values assigned. As you browse data in different models and tables, if the current table does not have a Visit column, the system ignores this filter.

On the Discrepancies page, use this filter to find discrepancies whose underlying data have particular Subject Visit flag values assigned.



If the data is in a table that is not a Subject Visit table, use the Record Flags filter under Data.

- Select the Filter option on the Listings or Discrepancies page under Data Management.
- 2. In the **Flags** row, click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. Filter Driver Data Model: Select a model from the list.



Tip:

Use the same model as the filter driver in all filters for the same study. Filters using different driver models cannot work at the same time.

- 4. Select whether you want to retrieve data that meet **Any** or **All** conditions.
- 5. The system lists all flags and flag states. You can enter part or all of a flag or flag state name above the column to filter. For each flag state:
 - Select Include to find records with the flag state applied.
 - Select **Exclude** to find records that do not have the flag state applied.
 - If you select neither Include nor Exclude, the flag state is not included in the filter criteria at all.
- **6. Filter Availability** is **Study**. Saved filters of this type are available for use only in the current study and lifecycle.
- Filter Name: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

- **8. Description**: Enter additional text to help you and other users know if this filter meets their needs.
- **9. Save As Copy**. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 10. Click OK.
- **11.** Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **12.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 13. Click **OK** in the main Filters window.

Visit Day filter

To create a filter based on the visit day number in the study design:

- Select the Filter option on the Listings or Discrepancies page under Data Management.
- 2. In the **Visit Day** row, click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. In the **Condition** drop-down, select an operator: <, <=, <>, =, >, >=, Between, Is Not Null (has any value), and Is Null (has no value).
 - The system displays 0, 1, or 2 fields depending on which operator you select. Enter visit day numbers as required.
- 4. **Filter Driver Data Model**: Select the clinical data model that contains the Subject Visit table that you want the filtering logic to use. This does not restrict you to using the filter only in that model.
 - As you browse data in different models and tables, if the current table does not have a Visit column, the system ignores this filter.
- 5. Select **Exclude Based On Criteria** to filter **out** records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
- **6. Filter Availability** is **Study Level**; filters of this type are available in all data models in the current study and lifecycle.
- 7. **Filter Name**: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

- 8. **Description**: Enter additional text to help you and other users know if this filter meets their needs.
- **9. Save As Copy**. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.



- 10. Click OK.
- 11. Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **12.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 13. Click **OK** in the main Filters window.

Visit Date filter

To create a filter based on the actual visit date:

- Select the Filter option on the Listings or Discrepancies page under Management.
- 2. In the **Visit Date** row, click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. In the **Condition** drop-down, select an operator : <, <=, <>, =, >, >=, Between, Is Not Null (has any value), and Is Null (has no value).
 - The system displays 0, 1, or 2 date fields depending on which operator you select. Enter values as required.
- 4. **Filter Driver Data Model**: Select the clinical data model that contains the Subject Visit table that you want the filtering logic to use. This does not restrict you to using the filter only in that model.
 - As you browse data in different models and tables, if the current table does not have a Visit column, the system ignores this filter.
- 5. Select Exclude Based On Criteria to filter out records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
- Filter Availability is Study Level; filters of this type are available in all data models in the current study and lifecycle.
- 7. Filter Name: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

- Description: Enter additional text to help you and other users know if this filter meets their needs.
- 9. Save As Copy. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 10. Click OK.
- **11.** Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.



- **12**. To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 13. Click **OK** in the main Filters window.

Record Flags filter

On the Listings page, use this filter to find records with particular Record flag states, or values, assigned.

On the Discrepancies page, use this filter to find discrepancies whose underlying data have particular Record flag states assigned.



If the data is in a Subject Visit table, use the Subject Visit Flags filter filter under Visits.

- Select the Filter option on the Listings or Discrepancies page under Management.
- 2. In the **Record Flags** row, click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. Select whether you want to retrieve data that meet **Any** or **All** conditions.
- 4. The system lists all flags and flag states, or values. You can enter part or all of a flag or flag state name above the column to filter. For each flag state:
 - Select Include to find records with the flag state applied.
 - Select Exclude to find records that do not have the flag state applied.
 - If you select neither Include nor Exclude, the flag state is not included in the filter criteria at all.
- 5. Filter Availability is All Studies. Saved filters of this type are available for use in all studies in the current lifecycle.
- Filter Name: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

- Description: Enter additional text to help you and other users know if this filter meets their needs.
- 8. **Save As Copy**. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 9. Click OK.



- **10.** Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **11.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 12. Click **OK** in the main Filters window.

Data Change Date filter

The Data Change Date filter displays records whose most recent update occurred during the time period specified.

- Select the Filter option on the Listings or Discrepancies page under Management.
- 2. Scroll to the **Data/Change Dates** row and click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. In the **Condition** drop-down, select an operator to be used to select the dates. The options are: <, <=, <>, =, >, >=, Between, Is Not Null (has any value), and Is Null (has no value).

Note:

Selecting Is Not Null retrieves all records; there is always a value for last-changed-date. If the record has not been updated, it is the same as the creation date.

The system displays 0, 1, or 2 date fields depending on which operator you select. Enter values as required.

- Select Exclude Based On Criteria to filter out records that satisfy the criteria.
 Leave unchecked to display records that do satisfy the criteria.
- 5. **Filter Availability** is **Study Level**; filters of this type are available in all data models in the current study and lifecycle.
- **6. Filter Name**: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

- Description: Enter additional text to help you and other users know if this filter meets their needs.
- 8. Save As Copy. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 9. Click OK.



- 10. Select Keep Active to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- 11. To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 12. Click **OK** in the main Filters window.

Discrepancy Category filter

The Discrepancy Category filter displays only records that have one or more discrepancies of the categories specified.

- Select the **Filter** option on the Listings or Discrepancies page under Management.
- 2. Scroll to the Category row and click the * Add icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. In the **Discrepancy Categories** drop-down, select one or more categories to be used to filter, or click All and then deselect categories.
- 4. Check Include *(No Category)* include or exclude discrepancies with no assigned category.
- 5. Select Exclude Based On Criteria to filter out records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
- 6. Filter Availability is All Studies. Saved filters of this type are available for use in all studies in the current lifecycle.
- 7. Filter Name: Enter a descriptive name for the filter to save it to use in another session: that is, after you log out or work in a different study.



Tip:

- 8. **Description**: Enter additional text to help you and other users know if this filter meets their needs.
- 9. Save As Copy. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 10. Click OK.
- 11. Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- 12. To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 13. Click **OK** in the main Filters window.



Discrepancy Change Dates filter

The Discrepancy Change Dates filter displays records that have one or more discrepancies whose most recent update occurred during the time period specified. To create a Discrepancy Change Dates filter:

- Select the Filter option on the Listings or Discrepancies page under Data Management.
- 2. Scroll to the **Discrepancies/Change Dates** row and click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. In the **Condition** drop-down, select an operator: <, <=, <>, =, >, >=, Between, Is Not Null (has any value), and Is Null (has no value).



Selecting Is Not Null retrieves all records; there is always a value for last-changed-date. If the record has not been updated, it is the same as the creation date.

The system displays 0, 1, or 2 date fields depending on which operator you select. Enter values as required.

- Select Exclude Based On Criteria to filter out records that satisfy the criteria.
 Leave unchecked to display records that do satisfy the criteria.
- 5. Filter Availability is All Studies. Saved filters of this type are available for use in all studies in the current lifecycle.
- Filter Name: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

- Description: Enter additional text to help you and other users know if this filter meets their needs.
- **8. Save As Copy**. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 9. Click OK.
- **10.** Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **11.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 12. Click **OK** in the main Filters window.



Discrepancy State Dates filter

The Discrepancy State Date filter displays only records that have one or more discrepancies whose most recent state change occurred during the time period specified.

- Select the Filter option on the Listings or Discrepancies page under Management.
- 2. Scroll to the **Discrepancies/State Dates** row and click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. In the **Condition** drop-down, select an operator : <, <=, <>, =, >, >=, Between, Is Not Null (has any value), and Is Null (has no value).



Selecting Is Not Null retrieves all records; there is always a value for last-changed-date. If the record has not been updated, it is the same as the creation date.

The system displays 0, 1, or 2 date fields depending on which operator you select. Enter values as required.

- 4. Select **Exclude Based On Criteria** to filter **out** records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
- **5. Filter Availability** is **All Studies**. Saved filters of this type are available for use in all studies in the current lifecycle.
- **6. Filter Name**: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

- Description: Enter additional text to help you and other users know if this filter meets their needs.
- 8. **Save As Copy**. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- Click OK.
- **10.** Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **11.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 12. Click **OK** in the main Filters window.



Discrepancy States and Tags filter

Use this filter to find discrepancies in a particular state, with or without a substate (tag).

- In the Listings page, the filter finds records with discrepancies that meet the criteria.
- In the Discrepancies page, the filter finds discrepancies that meet the criteria.
- Select the Filter option on the Listings or Discrepancies page under Management.
- 2. Scroll to the **Discrepancies/States and Tags** row and click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. Discrepancy State and Tag. The list includes all discrepancy states followed by all possible substates, or tags, for each state. Each state—for example, Open or Candidate—is also displayed without any tags. Selecting that option finds discrepancies with that state and no tags. To filter for all discrepancies in a state, regardless of tag, select all state/tag combinations for the state.



Tip:

By default, no cancelled or closed discrepancies are displayed when you apply any discrepancy filter. To see cancelled or closed discrepancies, select the state explicitly.

- 4. Reopened. Select Yes to view reopened discrepancies only; No to view discrepancies that are not currently reopened; or All to see discrepancies without regard to whether they are reopened or not.
- 5. Data Changed. Select Yes to view discrepancies whose underlying data has been updated since the discrepancy was created; No to view discrepancies whose data has not changed since the discrepancy were created; or All to see discrepancies without regard to whether their data has changed.
- Select Exclude Based On Criteria to filter out records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
- 7. **Filter Availability** is **All Studies**. Saved filters of this type are available for use in all studies in the current lifecycle.
- **8. Filter Name**: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

Filter names must be unique across all the private, shared, and public filters that you can see in the current study and lifecycle.

Description: Enter additional text to help you and other users know if this filter meets their needs.



- 10. Save As Copy. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 11. Click OK.
- 12. Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- 13. To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 14. Click **OK** in the main Filters window.

Discrepancy User filter

Use this filter to retrieve discrepancies by the person who created or most recently modified a discrepancy.

- 1. Select the Filter option on the Listings or Discrepancies page under Data Management.
- 2. Scroll to the **Discrepancies/User** row and click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- **3. Filter Type**. Select the way you want to search:
 - Created By
 - Modified By
- 4. The system displays all DMW users, with their user name, full name as entered in the system, and any external systems such as InForm or TMS that they also use. You can enter part or all of any of these values above the column to filter.
- 5. Select Exclude Based On Criteria to filter out records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
- 6. Filter Availability is All Studies. Saved filters of this type are available for use in all studies in the current lifecycle.
- 7. Filter Name: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

- 8. Description: Enter additional text to help you and other users know if this filter meets their needs.
- 9. Save As Copy. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 10. Click OK.
- 11. Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.



- **12.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 13. Click **OK** in the main Filters window.

Discrepancy Origin filter

Use this filter to retrieve discrepancies by the way they were created.

- Select the Filter option on the Listings or Discrepancies page under Management.
- 2. Scroll to the **Discrepancies/Origin** row and click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- 3. Discrepancy Origins. Select one or more to search for:
 - All returns all discrepancies, regardless of origin.
 - **InForm** returns discrepancies created as queries in InForm.
 - Manual returns discrepancies created manually in DMW.
 - **TMS** returns discrepancies created as omissions in coding system Oracle Thesaurus Management System (TMS).
 - Validation Check returns discrepancies created by validation checks in DMW.
- 4. Select **Exclude Based On Criteria** to filter **out** records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
- 5. Filter Availability is All Studies. Saved filters of this type are available for use in all studies in the current lifecycle.
- Filter Name: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

- Description: Enter additional text to help you and other users know if this filter meets their needs.
- 8. Save As Copy. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 9. Click OK.
- 10. Select Keep Active to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **11.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 12. Click **OK** in the main Filters window.



Models and Tables filter

Use this filter to retrieve discrepancies by the table or data model against which they were originally raised.

- Select the Filter option on the Listings or Discrepancies page under Management.
- 2. Scroll to the **Models and Tables** row and click the **Add** icon or select a filter from the drop-down list and click the **Modify** icon.
- **3. Filter Type**. Select the structure you want to search:
 - Model The system lists the models in the current study.
 - Table The system lists the models and tables in the current study.
- 4. Select one or more models or tables. You can enter part or all of a model or table name above the column to filter.
- 5. Select **Exclude Based On Criteria** to filter **out** records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
 - **Filter Availability** is **Study**. Saved filters of this type are available for use only in the current study.
 - **Filter Name**: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Filter names must be unique across all the private, shared, and public filters that you can see in the current study and lifecycle.

- Description: Enter additional text to help you and other users know if this filter meets their needs.
- **Save As Copy**. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 6. Click OK.
- 7. Select **Keep Active** to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- 3. To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 9. Click **OK** in the main Filters window.

Data Source filter

Use this filter to retrieve discrepancies by their original data source or data source type —for example, a lab or InForm.



- Select the Filter option on the Listings or Discrepancies page under Management.
- Scroll to the Data Sources row and click the Add icon or select a filter from the drop-down list and click the Modify icon.
- **3. Filter Type**. Select the way you want to search:
 - **Datasource** The system lists InForm and all labs used in the current study.
 - **Datasource Type** The system lists Labs (for all labs used in the current study), InForm, and Unknown.
- Select the data source or type to search. You can enter part or all of a model or table name above the column to filter.
- Select Exclude Based On Criteria to filter out records that satisfy the criteria. Leave unchecked to display records that do satisfy the criteria.
- Filter Availability is All Studies. Saved filters of this type are available for use in all studies in the current lifecycle.
- Filter Name: Enter a descriptive name for the filter to save it to use in another session; that is, after you log out or work in a different study.



Tip:

Filter names must be unique across all the private, shared, and public filters that you can see in the current study and lifecycle.

- **8. Description**: Enter additional text to help you and other users know if this filter meets their needs.
- **9. Save As Copy**. If you are modifying an existing filter, select this box to save your filter with a different name, leaving the original unchanged.
- 10. Click OK.
- 11. Select Keep Active to keep the filter in effect if you navigate between the Listings and Discrepancies pages or change clinical data models.
- **12.** To allow other people to use a saved filter, select **Shared** from the drop-down to the right of the filter name.
- 13. Click **OK** in the main Filters window.

Copy a custom listing

- 1. Click the Data Management icon at the top of any page.
- 2. Make sure the **Discrepancies** tab is open.
- 3. Select **Custom Listings** at the bottom of the left pane.
- 4. Click the More Actions icon, then click Copy Custom Listings.
- 5. Select a project (or other study grouping).



- 6. Select a model.
- 7. Select one or more custom listings within the model.
- **8.** Click **OK**. The system searches the current model for the tables and columns that the selected custom listings read from.
 - If the tables or columns do not exist, the Copy operation fails with an error message.
 - If they exist but are marked Not Used in the transformation that writes to the model, the system copies the listings as disabled.

FAQs

- How do I find...?
- How do data filters work on the Discrepancies page?
- What does the star mean?
- How do I know if any filters are applied?
- How can I tell which filters are applied?
- How do I turn filters off?
- Why can't I make my filters public?
- How do I find...?
- How do data filters work on the Discrepancies page?
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- Why can't I make my filters public?

How do I find...?

- Discrepancies created or modified before or after a particular date? Create a Discrepancy State Dates filter.
- All Open or Candidate discrepancies? Create a Discrepancy States and Tags filter.
- Discrepancies on the same subject, site, investigator, or country? Create a Subject filter.
- Discrepancies on data from the same lab? Create a Data Source filter.
- Discrepancies assigned to my role for review? Create a Discrepancy States and Tags filter.
- Discrepancies created by the same validation check? Create a Discrepancy Origin filter or go to Validation Check Listings in the Listings page.
- Discrepancies from the same visit? Create a Visit filter.



- Closed and cancelled discrepancies? Create a Discrepancy States and Tags filter.
- Discrepancies I created? Create a Discrepancy User filter.

Other types of filters: Subject Visit Flags filter, Visit Day filter, Visit Date filter, Record Flags filter, Data Change Date filter, Discrepancy Change Dates filter, Models and Tables filter, Discrepancy Category filter.

When a filter is applied, the message "Filters On" appears. To see which filters are currently applied, click the **Current Filters** icon. To remove all current filters, click the **Filter Off** icon. To selectively turn off, turn on, or modify filters, click the **Filter** icon. See Use filters to find data and discrepancies

How do data filters work on the Discrepancies page?

When you go to the Discrepancies page from the Listings page with Keep Active selected for your filters, the system continues to apply the same filters, except:

- Data Change Dates filters are ignored.
- If any of the current Subject or Visit filters applies only to a specific data model, the system displays only discrepancies in that model.
- If different Subject and Visit filters have different driver data models and they are applied at the same time, the system ignores all Subject and Visit filters.

A message appears when any of these situations occur.

What does the star mean?

If you apply a discrepancy filter in a Listings page, records with discrepancies that meet the filter criteria have a star icon.

How do I know if any filters are applied?

• In the **Listings** page, the Filter drop-down is displayed as blue and says "Filter Filter: ON The Filter on The

In the Discrepancies page, "Filters On" is displayed in blue: Filters On

How can I tell which filters are applied?

- In the **Listings** page, select **Current Filters** from the Filter: ON drop-down.
- In the **Discrepancies** page, click the **Current Filters** icon.

The Current Filters window lists the filters currently applied, with the following information:

- Filter The name or, if it has no name, TEMPORARY FILTER.
- Filter Type
- Class



- Private: You created the filter.
- Shared: Someone created the filter and shared it.
- Public: Official filter that is always available.

How do I turn filters off?

- In the Listings page:
 - To turn all filters off, select Clear Filters from the Filter: ON drop-down.
 - To clear selected filters, select the Filters icon from the Filter: ON drop-down.
- In the **Discrepancies** page:
 - To turn all filters off, click the Clear Filters icon.
 - To clear selected filters, click the $\overline{}$ **Filters** icon

Why can't I make my filters public?

Special privileges are required.



5

Run jobs and check history

- · View and edit your subscriptions to job status notifications
- · Run transformations and view run history
- · Run validation check batches and view run history
- · Reprocess discrepancies that failed to be sent to InForm
- · Check if data files loaded
- FAQs

View and edit your subscriptions to job status notifications

You can subscribe to receive email notifications about the completion status of jobs.

- Go to the Home page and select the study.
- 2. In the Studies title bar, click the A Notify icon.
- Select the checkbox for each type of job and completion status that you want to be notified about:
 - Job types: File loads, InForm loads, Transformations, Validation Checks
 - Completion statuses: Success, Warning, Failure



Your subscriptions for the current study appear as selected. An administrator can also subscribe or unsubscribe you from notifications.

To stop receiving a particular type of notification, deselect its checkbox.

4. Click OK.

To subscribe or unsubscribe to notifications for other studies, select a different study and repeat the process.

Run transformations and view run history

- 1. Go to the **Mome** page, **Transformations** tab.
- 2. To view all jobs, click the View Full Job History icon.

To view only recent jobs again, click the View Recent Jobs Only icon.

- 3. See:
- View transformation job history
- Run a transformation
- Cancel a transformation job

View transformation job history

Transformations are displayed by the name of their target clinical data model.

- To view table transformations, click a transformation's node.
- To view run history and pending jobs, select a transformation in the upper pane.
- **To view log files**, click the icon in the column for the type of job:
 - Log: The most recent manually submitted job.
 - Triggered Job Log: The most recent triggered job.
 - Install Job Log: The most recent installation of the transformation.

Run a transformation

To run or schedule a transformation:

- 1. Go to the Home page, Transformations tab.
- 2. Select a transformation and click the **Submit Job** icon.



Tip:

The **Submit Job** icon is not active if the selected transformation has not been installed. Check the Install Status column.

If the installation status of the transformation is Warning, you may still be able to run the batch. Check the installation log file.

- 3. Enter values:
 - Submission Mode: Select one:
 - Full mode includes data deletion. Use Full mode only if you are confident that you are reloading all current data.
 - Incremental is faster and does not include data deletion.

If you are submitting a transformation for a single table and the table is defined with Unit of Work processing, select:

- Full UOW includes data deletion. Use Full UOW only if you are confident that you are reloading all current data for each subject or subject visit that has any data included.
- Incremental UOW is faster and does not include data deletion.





Tip:

Set up regular Incremental loads at frequent intervals and do Full loads at longer intervals.

 Force Execution: Select if you want to run the job even though the source data currency, parameter values, and the version number of the program(s) have not changed since the last run. The system uses Full mode regardless of the Submission Mode setting. Full mode includes data deletion.

If not selected and all the conditions are the same as the last run, the system does not execute the job and returns a status of Success.

- Submission Type:
 - Immediate Run the job once, as soon as possible.
 - Scheduled Set up a regular schedule.
 - Deferred Run the job once, at a future time.
- Trigger Downstream Transformations and Validation Checks: Select to make this job trigger validation checks on the target model and transformations from the target model to all others that come after it, in sequence. This can happen only if the source models are set up to trigger downstream processes.

Click the Refresh icon for an update to the **Job Status**.

Cancel a transformation job

Select a transformation in the Run History pane and click:

- Cancel Job to cancel the currently running or next pending job.
- Cancel All Jobs to cancel the currently running or next pending job and all future jobs in the schedule for the selected transformation. Available only for scheduled jobs.



If there is an immediate or deferred job for the same transformation, or another schedule for the same transformation, those jobs are not affected.

• Cancel Triggered Job to cancel the currently running or pending job. Available only for jobs that are set up to be triggered by another job.

Run validation check batches and view run history

1. Go to the Home page, Validation Checks tab.



- 2. From the **Model** drop-down list, select the clinical data model.
- 3. Select a validation check batch in the upper pane.

The system displays information about its validation checks in the middle pane and information about its run history in the lower pane.

4. To view all jobs, click the View Full Job History icon.

To view only recent jobs again, click the View Recent Jobs Only icon.

To view log files, click the icon in the column for the type of job:

- Log (Run History pane) The most recent manually submitted job.
- Triggered Job Log (Run History pane) The most recent triggered job.
- Install Job Log (Validation Check Batch pane) The most recent installation of the validation check batch.



A validation check can be *disabled* so that it is not included in the batch execution. To find out if a check was included in the run, check the log file

See:

- Run a validation check batch
- · Cancel a validation check batch job

Run a validation check batch

You must run validation checks as a batch.

- 1. Go to the Home page, Validation Checks tab.
- 2. Select a validation check batch and click the \checkmark Submit Job icon.



Tip:

The **Submit Job** icon does not appear if the validation check batch is not installed. Check the Installed Status.

If the installation status of a validation check batch is Warning, you may still be able to run the batch. Check the installation log file. If the status is Warning because one of the source tables is not used in the current study, the batch runs without input from that table.

- 3. Enter values:
 - Submission Mode: Select one:
 - Full mode processes all records.



- Incremental mode processes only new and changed records.
- Force Execution: Select to run the job even though the source data currency, parameter values, and the version number of the program(s) have not changed since the last run. The system uses Full mode regardless of the Submission Mode setting. Full mode includes data deletion.

If not selected and all the conditions are the same as the last run, the system does not execute the job and returns a status of Success.

- Submission Type: Select:
 - Immediate to run the job once, as soon as possible.
 - Scheduled to set up a regular schedule.
 - Deferred to run the job once, at a future time.
- Trigger Downstream Transformations and Validation Checks: Select this
 checkbox if you want the system to detect all transformations and validation
 checks set up for this data model and all others that come after it, and submit
 them sequentially.



This option appears only if the validation check batch is set up to allow it.

- Click the Refresh icon at any time for an update.
- To check the log file, click the icon in the Log column.

Cancel a validation check batch job

Select a validation check batch in the Run History pane and click:

- Cancel Job to cancel the currently running or next pending job.
- Cancel All Jobs to cancel the currently running or next pending job and all future jobs in the schedule for the selected validation check batch. Available only for scheduled jobs.

Note:

If there is an immediate or deferred job for the same batch, or another schedule for the same batch, those jobs are not affected.

• Cancel Triggered Job to cancel the currently running or pending job.

Available only for jobs that are set up to be triggered by another job.



Reprocess discrepancies that failed to be sent to InForm

Validation checks with an Initial Action of Send to InForm immediately send discrepancies they create to InForm as queries. To check the status of this operation:

- Go to the Home page, Validation Checks tab.
- Click the Failed to Send Discrepancies icon in the upper right corner.

The system displays counts for the selected study and lifecycle stage:

- Processing for System shows the number of discrepancies currently being processed.
- Failed Processing for System shows the number of discrepancies that should have been sent to InForm but weren't.
- 3. If any discrepancies failed to be sent, click the Reprocess Discrepancies icon to send them again. Click the Refresh icon to see progress.

Check if data files loaded

- View data files not processed
- View data load history
- Review data load errors (optional)

View data files not processed

- 1. Go to the Home page and select a study.
- 2. Select the Files Not Processed tab.

The system displays files that were uploaded but could not be loaded into the selected study. A file may not be loadable because:

- It is misnamed or in nonmatching case, compared to the file specification defined for the clinical data model.
- There is a mistake in the File Specification regular expression defined for the model.
- There is a matching File Specification, but its end date has passed.
- There is a matching File Specification, but its data loading is suspended.
- There is a matching File Specification, but the model is not installed.
- View unprocessed files.

Columns include:

- Status: The possible statuses are:
 - DETECTED: The file has been detected in the watched folder but has not yet been submitted.



- MISSING: The file was detected but deleted before the scheduled deletion or archive date.
- DELETED: The file was deleted by File Watcher as scheduled.
- ARCHIVED: The file was archived by File Watcher as scheduled.
- File Modified: The modification date of the file on the file system.
- Detection Date: The date and time the file was detected, using the date and time in the DMW database.
- Archive Date displays the scheduled archive date before the file is archived and the actual archive date afterward.



Archiving is not supported in this release.

- **Deletion Date** displays the scheduled deletion date before the file is deleted and the actual deletion date afterward.
- **Date Missing**: If the file is overwritten or removed from the file system before it is archived or deleted, then the Date Missing is store here.
- File Error: Information about the problem.

View data load history

- 1. Go to the Home page, Data Loads tab.
- 2. To view all jobs, click the View Full Job History icon.

To view only recent jobs again, click the View Recent Jobs Only icon.

3. You can filter by entering a value in the blank field above any column. If blank fields are not displayed, click the Query By Example icon.

Columns include:

- Data Model: The clinical data model into which data was or will be loaded.
- Type:
 - FILEWATCHER for data loaded from a file.
 - INFORM for data loaded from InForm.



All pending jobs for InForm data loads are for the Production lifecycle stage. It isn't possible to schedule InForm data loads for the Development or Quality Control lifecycle stage.

File Name/InForm Load Process:



- For files, the full path of the file loaded.
- For InForm, the type of data load: INFORM_DEFINITION, INFORM_METADATA, INFORM_MANUAL_DATA or INFORM_SCHEDULED_DATA.
- Last Load Results shows the job status: Success, Warnings, or Failure for completed jobs.
- **Columns with icons**: Click the icon to open the error, log, or output file.
- 4. See the following (if necessary):
- Statuses for uncompleted jobs

Statuses for uncompleted jobs

For incomplete jobs, the system displays the job's current status. Click the **Refresh** icon to update.

- Pending: The job has not yet started running.
- Started: The job has begun pre-processing.
- Executing: The Program has connected to the database and is running.
- Finalizing: The job has begun post-processing.
- Aborted: The job has been manually stopped while underway.
- On Hold: The job is waiting for the quiesce process to complete for the clinical data model work area.
- **Expired**: The system removed the job from the queue after the timeout interval passed.
- Duplicate: The job is a duplicate of another job; the currency of the source data, parameter values, and executable instance version are the same. The system does not rerun the job unless the person submitting the job chooses to force reexecution.

Review data load errors (optional)

To review data load errors:

- Go to the Home page and select the study.
- 2. Make sure the **Data Loads** tab is selected.
- 3. Open a file in one of the following columns:
 - Last Load Results column: Contains the results of the most recent data load. This file is produced whether the data load is successful or failed.
 - View Output column: Produced during a data load (the SQL*Loader log).
 This file is produced whether the data load is successful or failed.
 - View Error File column: Created when a text file for a data load contains more fields than there are columns in the table you're loading the data into. This file is produced for failed data loads only.





Tip:

This column is typically empty.

 View Comprehensive Error Report column: The error log includes a list of the specific data record and field from the file that caused the error. This file is produced for failed data loads only.

FAQs

- Why can't I see a job that ran a while ago?
- · Why am I seeing a Diagnostics Icon?

Why can't I see a job that ran a while ago?

By default you can see only recent jobs. To see a job that happened longer ago, click the View Full Job History icon.

To change back, click the View Recent Jobs Only icon.

This applies to the Home page Data Loads tab and the Run History pane of the Transformations and Validation Checks tab.

Why am I seeing a Diagnostics Icon?

The icon indicates that your administrator is running diagnostics for troubleshooting purposes. Performance may be slower than usual.



6

Document Revision History

Date	Revised Part Number	Changes
October 2019	E96069-03	Updated the template.
November 2018	E96069-02	Describe how to use the columns on the Data Loads tab to view data load errors. For more information, see Review data load errors (optional).
May 2018	E96069-01	Original version.



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