Oracle® Health Sciences Data Management Workbench Data Review Guide





Oracle Health Sciences Data Management Workbench Data Review Guide, Release 3.3

F74430-01

Copyright © 2017, 2023, Oracle and/or its affiliates.

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

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

If this is software, software documentation, data (as defined in the Federal Acquisition Regulation), or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs) and Oracle computer documentation or other Oracle data delivered to or accessed by U.S. Government end users are "commercial computer software," "commercial computer software documentation," or "limited rights data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, reproduction, duplication, release, display, disclosure, modification, preparation of derivative works, and/or adaptation of i) Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs), ii) Oracle computer documentation and/or iii) other Oracle data, is subject to the rights and limitations specified in the license contained in the applicable contract. The terms governing the U.S. Government's use of Oracle cloud services are defined by the applicable contract for such services. No other rights are granted to the U.S. Government.

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

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

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

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

Contents

Preface

	Documentation accessibility	Vii
	Related resources	vii
	Access to Oracle Support	Vii
1	Basics	
	Oracle DMW Home	1-1
	Select a study from the Home page	1-2
	Designate Favorite Studies	1-2
	Use the Discrepancy Dashboard	1-3
	Discrepancies by State	1-6
	Discrepancies by Origin graph	1-6
	Discrepancies by Site graph	1-6
	Discrepancies by Age graph	1-7
	Select a study from Study Manager	1-8
	Access Data Management options	1-9
	Select a lifecycle stage	1-9
	Customize the user interface display	1-10
	Sort rows by column values	1-10
	Refresh	1-10
	Use online help	1-13
	Change your password	1-11
	Session timeout	1-11
	Check the network connection status	1-13
2	Monitor study health	
	Study Health Monitor	2-2
	Study Health Monitor details panel	2-3



4 View data listings, display data flow, and create discrepancies

Choose a listing type	4-1
Default listings	4-1
Custom listings	4-2
Validation check listings	4-2
Search for data	4-3
Use the Find feature	4-3
Review data	4-4
View a single record from data listings	4-5
Compare records in data listings	4-6
View Subject Summary	4-6
View discrepancies in the Listings page	4-7
View discrepancy details	4-8
Show all discrepancies on one data item	4-8
Assign and remove flags	4-9
Assign a flag to a record	4-9
Remove a flag	4-10
Show flags assigned to a record	4-10
View data lineage	4-11
View data in InForm or another system	4-12
View InForm Comments	4-13
View InForm Answer History	4-13
Use keyboard shortcuts on listings	4-13
Customize the listings or discrepancy views	4-14
Create discrepancies	4-15
Reprocess discrepancies that failed to be sent	4-16
Export data to Excel or CSV	4-17
View data flow	4-17
Create a custom listing	4-19
Define query details	4-20
Select columns to display	4-21
Select packages	4-22
Define table aliases	4-23
Specify and test criteria	4-23
Save and install a custom listing	4-24
Copy a custom listing	4-24
Use the Expression Builder	4-25
Pass data as input parameter values	4-27



Pass constant values		4-2
FAQs		4-2
Listings FAQs		4-2
What is a clinical data model?		4-2
One of the rows says "Yes" under the highlighted yellow. Where is the disc	ne Discrepancy_Exists Column, but no cells are crepancy?	4-
What is a disabled listing?		4-
Where can I copy a custom listing fr	rom?	4-
What happens if I modify a Table Ali	ias?	4-
How can I view blinded data?		4-
How can I resend data that needs c	oding to TMS?	4-
Flag FAQs		4-
Why can't I assign a flag?		4-
Can the flags I assign be seen in InI	Form?	4-
I wish a different flag were available		4-
Why can't I change some flags?		4-
Data lineage FAQs		4-
What is data lineage?		4-
	st a data item, how does that affect the data	4-
iineage?		4-
lineage? Why does the wrong source data ite Review and act on discrepancie		4-
Why does the wrong source data ite		4-
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy?	es	4-
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie	es	4-
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies	es	4- !
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel	es	4- !
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top	es	4- ; ;
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data	es	4- ; ;
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy	es	4- ; ; ;
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy Change the state or send to InForm or a	es	4-
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy Change the state or send to InForm or a Add a comment	es	4- ; ; ; ;
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy Change the state or send to InForm or a Add a comment Edit a Discrepancy	es	4-
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy Change the state or send to InForm or a Add a comment Edit a Discrepancy Edit the text of multiple discrepancies	es	4- ! ! ! ! !
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy Change the state or send to InForm or a Add a comment Edit a Discrepancy Edit the text of multiple discrepancies Export discrepancies on lab data	es	4.
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy Change the state or send to InForm or a Add a comment Edit a Discrepancy Edit the text of multiple discrepancies Export discrepancies on lab data See more information about a discrepancy	es another system	4.
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy Change the state or send to InForm or a Add a comment Edit a Discrepancy Edit the text of multiple discrepancies Export discrepancies on lab data See more information about a discrepancy View the full record containing a discrep	es another system	4
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy Change the state or send to InForm or a Add a comment Edit a Discrepancy Edit the text of multiple discrepancies Export discrepancies on lab data See more information about a discrepancy View the full record containing a discrep	es another system	4-
Why does the wrong source data ite Review and act on discrepancie How do I create a discrepancy? Use keyboard shortcuts on discrepancie Find discrepancies Use filters in the left panel Use the search fields at the top Show blinded data Act on a discrepancy Change the state or send to InForm or a Add a comment Edit a Discrepancy Edit the text of multiple discrepancies Export discrepancies on lab data See more information about a discrepancy View the full record containing a discrep	es another system	4- ; ; ; ;



Acting on a discrepancy FAQs	5-10
Can I take an action on multiple discrepancies at once?	5-10
Why don't I see the action I want to apply?	5-11
Can I send discrepant data items to multiple sources?	5-11
Why can't I send a particular data item to another source?	5-11
InForm and Clinical One query and discrepancy FAQs	5-11
Can I change the state of a discrepancy that was loaded from InForm or Clinical One?	5-12
Can I create a discrepancy in DMW on a data item that originated in InForm or Clinical One?	5-12
Can I send a discrepancy to InForm or Clinical One?	5-12
Why can't I open InForm and see a discrepancy there?	5-12
What happens to the discrepancy after I send it to InForm or Clinical One?	5-12
If I don't send the discrepancy to InForm or Clinical One, can users act on the discrepancy in InForm or Clinical One?	5-12
Before I send the discrepancy to InForm or Clinical One, can I act on it?	5-12
Lab data discrepancy FAQs	5-13
Can I create a discrepancy on a data item that originated in a lab?	5-13
How do I send these discrepancies to the lab?	5-13
TMS discrepancy FAQs	5-13
What does it mean when a discrepancy's category includes "TMS"?	5-13
What do the different TMS Discrepancy Categories mean?	5-13
What should I do with a TMS discrepancy?	5-14
Why is a query on a different item in InForm than in DMW?	5-14
Use filters to find data and discrepancies	
Create a new filter	6-1
Advanced Filters	6-3
Use or modify existing filters	6-5
Delete a filter	6-6
Create a public filter	6-6
FAQs	6-7
How do data filters work on the Discrepancies page?	6-7
How do I know if any filters are applied?	6-7
How can I tell which filters are applied?	6-8
How do I turn filters off?	6-8
Why can't I make my filters public?	6-8
Advanced: Run jobs and check history	
View and edit your subscriptions to job status notifications	7-1



Run transformations and view run history	7-2
Run validation check batches and view run history	7-2
Generate the Discrepancy Differences Report	7-2
Reprocess discrepancies that failed to be sent to InForm	7-2
Check if data files loaded	7-3
View data files not processed	7-3
View data load history	7-4
Statuses for uncompleted jobs	7-5
Review data load errors (optional)	7-5
FAQs	7-6
Why can't I see a job that ran a while ago?	7-6
Why am I seeing a Diagnostics Icon?	7-6



Preface

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

- Documentation accessibility
- Related resources
- Access to Oracle Support

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Related resources

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

Access to Oracle Support

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



1

Basics

This section contains the following topics:

Oracle DMW Home

After logging into Oracle DMW, you'll land on the Home page. From here, you can designate "Favorite Studies", view discrepancy summaries on the Discrepancy Dashboard, select a study to work on, or use the navigation options along the top panel to move to a different Oracle DMW work area.

- Select a study from the Home page
- Designate Favorite Studies

You can mark certain studies as "Favorites" on the Home page. Favorite studies are always shown on the Home page Studies panel directly below the study you last selected. Designating favorite studies gives you immediate access to your most current work without having to filter through all studies in DMW.

Use the Discrepancy Dashboard

The discrepancy dashboard is an interactive, graphic overview of the study's discrepancies, beneficial to data managers who need a quick, at-a-glance summary of a study's progress. Selecting a study from the left navigational panel displays the study's discrepancy dashboard in the center section of the page.

- Select a study from Study Manager
- Access Data Management options
- Select a lifecycle stage
- Customize the user interface display
- Use online help
- · Change your password
- Session timeout
- Check the network connection status

Oracle DMW Home

After logging into Oracle DMW, you'll land on the Home page. From here, you can designate "Favorite Studies", view discrepancy summaries on the Discrepancy Dashboard, select a study to work on, or use the navigation options along the top panel to move to a different Oracle DMW work area.

The three main sections of the page are:

- Studies panel (left side of the screen): The last-accessed study is listed at the top of the Studies panel, followed by Favorites. For more information on actions you can do here, see Select a study from the Home page and Designate Favorite Studies.
- 2. **Discrepancy Dashboard** (center part of the screen): After selecting a study, a graphic summary of the Discrepancies is shown in this section. For more information, see Use the Discrepancy Dashboard.

3. Navigation & toolbar (top of the screen): Other areas of Oracle DMW such as Study Manager and Administration can be accessed from here. The availability of options depend on your user permissions and whether or not you have selected a study in the Studies panel.

Select a study from the Home page

- 1. Do one of the following:
 - If you see the study you want listed in the Studies panel, select it. The Studies panel should show the last-accessed study followed by any designated favorites
 - If you do not see the study you want, find it through the fields in the Studies panel:
 - Select the category for the study from the Filter By drop down list (top of the Studies panel).
 - b. Type all or part of the name of the study in the Search Study field. After entering the 4th character of the name, the list of studies should automatically refresh to display results.
 - c. Press Enter.

The system displays all studies that contain the string you typed.



Tip:

To load all available studies in the Studies panel, you must first complete a search and then remove all search criteria. The Studies panel will then refresh to display the full list of studies you can scroll through.

d. Select a study. The study's Discrepancy Dashboard loads in the main Workbench section of the page.



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

Designate Favorite Studies

You can mark certain studies as "Favorites" on the Home page. Favorite studies are always shown on the Home page Studies panel directly below the study you last selected. Designating favorite studies gives you immediate access to your most current work without having to filter through all studies in DMW.

To designate a favorite study, first make sure you are on the Home page by clicking



along the top of the screen.

1. Search for the study you want by using the Search Study and Filter By fields at the top of the Studies panel.



next to the study you want to mark as a favorite.

The star becomes yellow favorite study.

, indicating that it has been successfully saved as a

When you access the Home page again, you'll see the study you marked as a favorite in the list below your last-accessed study.

To remove a study from Favorites, click the yellow star next to the study you'd like to un-Favorite.

Use the Discrepancy Dashboard

The discrepancy dashboard is an interactive, graphic overview of the study's discrepancies, beneficial to data managers who need a quick, at-a-glance summary of a study's progress. Selecting a study from the left navigational panel displays the study's discrepancy dashboard in the center section of the page.



For details on selecting a study, see Select a study from the Home page.

The dashboard initially displays discrepancies across all countries and sites in a selected study. The total number of discrepancies within the study is shown in the right corner of the section, under **Refresh**. The discrepancies in the study are displayed as four different graphs: State, Origin, Site, and Age.

Selecting a country and/or site from the filter menus along the top of the page refines the discrepancies for all four of the graphs as well as the total discrepancy count on the dashboard within the selected parameters.

Hovering over a data set in a graph (the **Open** bar of the State graph, for example) displays additional information such as the number of discrepancies.



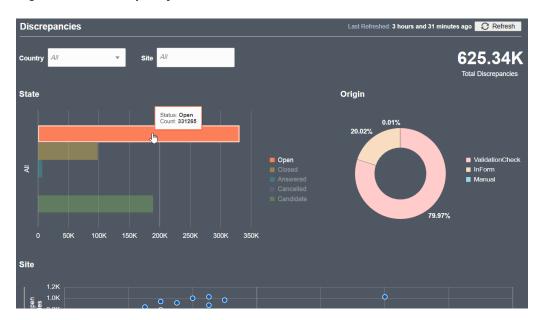


Figure 1-1 Discrepancy Dashboard Initial View

Clicking a data set within any of the graphs on the discrepancy dashboard takes you to the Discrepancies interface, where the filters from the graph section have already been applied. For example, clicking the **Manual** section of the Origin graph takes the user to the Discrepancies page where the Advanced Filter has been set to "Discrepancy Origin = Manual". This pre-filtered data allows data managers to navigate to the discrepancies within the data set with a single click.



Origin Origin: Manual 3.49% Data Management Workbench Study: UPMGFILTERSTUDY | Filter: on 🔻 | 64 Discrepancies Go to Listings Manage Discrepancies Download Report DISC_ID TAG SUBJECT VISIT LISTING Select a saved filter □ ? 193436 SentToInForm АЗ Wk 2 **FRMVS** Advanced Filters 193435 SentToInForm **FRMVS** Discrepancy Origin = 'Manual' 8 193434 SentToInForm A3 Wk8 **FRMVS** Model 173477 CA1000 **ASUBJVIS** Enter or select Model Name 173480 CA1000 ASUBJVIS SentToSpreadsheet Visit 1 Listing ? 173482 GailTag CA1000 Visit 2 **ASUBJVIS** Enter or select Listing Name **3** 173484 CA1000 Visit 3 ASUBJVIS Country 4456402 MA0001 ΑE Enter or select Country 4456287 MA0001

Figure 1-2 Dashboard to Discrepancies Interface with One Click

The time stamp in the upper right corner of the section shows when the data was last refreshed. If multiple users are actively working on a study or if your session has been idle, you may want to manually refresh the page by clicking Refresh.

Note:

Clicking **Refresh** triggers a job to update the data in the background. There may be a delay in displaying the refreshed data on the dashboard while the job processes.

For additional details about each graph, please see the topics below:

Discrepancies by State

This bar graph on the dashboard shows the discrepancies within the selected study and splits them up into the five available statuses: Answered, Candidate, Closed, Open, Cancelled. The number of discrepancies in this graph may be refined by Country or Site if any of those filters have been applied to the dashboard.



Discrepancies by Origin graph

The Origin donut graph is divided into sections that represent where the discrepancies were created. Discrepancy origins can include those created by queries in InForm or another external source, by a Validation Check, and/or by Manual production in Oracle DMW.

Discrepancies by Site graph

Each plot in the scatter chart on the dashboard is a different site within the study. The y-axis always represents the number of open discrepancies but the x-axis can display any of the different states, depending on which status you choose from the drop down menu below the chart.

Discrepancies by Age graph

In the Age graph, each bar represents a site and the colors within the bar represent the age range of the discrepancies.

Discrepancies by State

This bar graph on the dashboard shows the discrepancies within the selected study and splits them up into the five available statuses: Answered, Candidate, Closed, Open, Cancelled. The number of discrepancies in this graph may be refined by Country or Site if any of those filters have been applied to the dashboard.

Placing your cursor over any of the bars in the graph displays a small box containing the status name and the exact count of discrepancies with that status.

Clicking on any of the bars in the graph brings you to the Discrepancies page where the results have been filtered by whichever State you clicked on the dashboard. For example, clicking the "Open" bar in the graph takes you to the Discrepancies interface where all discrepancies in the study with the status of "Open" are shown.

Discrepancies by Origin graph

The Origin donut graph is divided into sections that represent where the discrepancies were created. Discrepancy origins can include those created by queries in InForm or another external source, by a Validation Check, and/or by Manual production in Oracle DMW.

Hovering your cursor over a section of the graph pops up a box showing the Origin name along with the exact count of discrepancies within the study that came from the corresponding origin.

Clicking a section of the donut takes you to the Discrepancies page where the results have been filtered to reflect the origin section clicked on the dashboard.

Discrepancies by Site graph

Each plot in the scatter chart on the dashboard is a different site within the study. The y-axis always represents the number of open discrepancies but the x-axis can display any of the different states, depending on which status you choose from the drop down menu below the chart.

The default filter of the Site graph is "Answered" but you can use the "State" drop down menu located below the graph to display discrepancies by Cancelled, Candidate, and Closed.



Hovering over any plot within the scatter chart pops up a small box containing additional information about the site: Site name, country, number of open discrepancies, and the number of discrepancies for the state selected in the drop down menu below the chart.

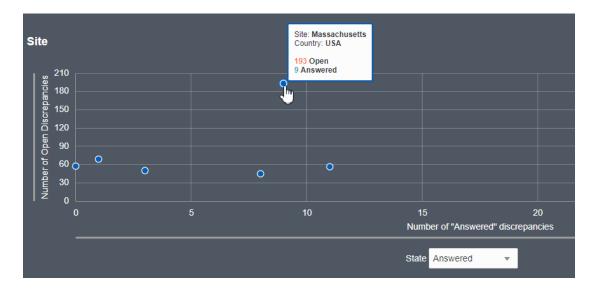


Figure 1-3 Discrepancies by Site

The Site scatter chart is zoomable - you can place your cursor over the graph and use your mouse wheel to zoom in and out on the data plots. If you are using a tablet or mobile device, you can use the "pinch" and "expand" gestures to change the scope of the graph.

Clicking on any of the plots within the chart takes you to the Discrepancies interface where the corresponding filters have already been applied. For example, the filters applied after clicking a plot may include Site = "Boston" and Discrepancy State = Open, Answered.

Discrepancies by Age graph

In the Age graph, each bar represents a site and the colors within the bar represent the age range of the discrepancies.

The Age graph is filtered by "Since Last Opened" by default, but can be changed to display discrepancies filtered by "Since Last Answered" using the drop down menu above the graph.

If you position your cursor anywhere over the Age graph, you can use your mouse wheel to zoom in and out on the data. The zoom function also supports "pinch" and "expand" gestures on tablets and mobile devices. The Age graph features a zoom and scroll component at the bottom that lets you scroll across the data on the x-axis when there are too many sites to show on the initial screen.

nce Discrepancy Change



If space allows, the number of discrepancies within each age block is displayed directly on the bar in the graph. Hovering the cursor over each section of the bar pops up a window with additional information including site name, discrepancy age group, and number of discrepancies within that age block.

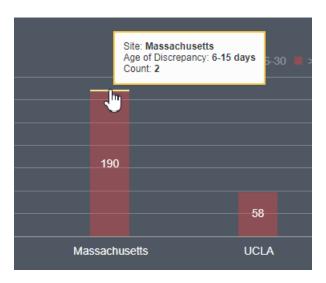


Figure 1-4 Discrepancies by Age detail

Clicking on any of the bars within the Age graph takes you to the Discrepancies interface where the Discrepancy State Change Date, Site, and Discrepancy State = Open filters have been set according to which bar and age group you clicked.

Select a study from Study Manager

- 1. If not open already, click Study Manager in the navigation bar to open the Study Manager interface. If you have already selected a study from the Home page, the selection carries over to Study Manager.
- 2. To select a new or different study, do one of the following:
 - If you see the study you want listed in the Studies panel, select it.
 - If you do not see the study you want, find it through the fields in the Studies panel:
 - a. Select the category for the study from the drop-down list of the first field (top of the Studies panel).
 - **b.** Type all or part of the name of the study in the search field.
 - c. Press Enter or click the Search icon.
 The system displays all studies that contain the string you typed.





Tip:

To clear the search filter, click the Remove filter

d. Select a study.



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

Access Data Management options

1. If not open already, click home in the navigation bar to open the Home page and select a study from the Studies panel on the left.



For details on selecting a study, see Select a study from the Home page.

- 2. Click Data Management in the navigation bar.
- 3. Do one of the following:
 - To view data and create discrepancies, click Listings. To see custom listings or validation check (VC) listings, scroll down the left panel and expand a data model.
 - To review and act on discrepancies, click Discrepancies.
 - To view how the data flows between the input model and the target model, click **Data** Flow. For example, a flow diagram shows the mapping between the models and indicates the success or failure of the data flow. It also indicates any warnings within the flow.
 - To create or manage custom listings, click Custom Listing Manager.

Select a lifecycle stage

Oracle DMW opens in the lifecycle stage you used in your last session. To change it, select a different stage from the **Lifecycle** drop-down menu at the top of the data shown within the Home, Study Configuration, or Data Management page. The stages you can choose are:

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



The lifecycles displayed to you depend on your account privileges so it's possible that you may only have access to one or two stages.

Customize the user interface display

Many pages that use tables in Oracle DMW allow you to customize the columns and rows during your session.



Oracle DMW displays up to 500 records at a time. If your study includes more than 500 records, use the filter options as described in Create a new filter or the search fields to located them.

See one of the following sections for details:

- Sort rows by column values
- Refresh

Sort rows by column values

You can sort data in a single column or up to three columns. For example:

- To sort on one column, click the up and down arrows in the column heading to sort the data in ascending or descending order. You may need to widen the column to see the arrows.
- To sort on up to three columns (for all tables except the ones in the Listings or Discrepancies pages):
 - Select View from the toolbar at the top of the table. Then select Sort > Advanced.
 - 2. In the **Sort By** field, select the primary column to sort on and then select **Ascending** or **Descending** for the order.
 - 3. In the first **Then By** field, select the secondary column to sort on and then select **Ascending** or **Descending**. Within the sort order you specified in step 2, the system sorts records in the order you specify
 - 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 2 and 3, the system sorts records in the order you specify here.
 - 5. Click OK.

Refresh

Click **Refresh** from the navigation bar for Listings or Discrepancies pages or the **Refresh** icon from the upper-right corner of a table for other pages to see any changes



that occurred since you opened the page. Other users can work on data or discrepancies you view and you may need to refresh the page to see the latest content.

Use online help

- Hover over fields to display tooltip information (not available for all fields).
- Click the question mark icon to see information about the tab, view, or dialog box you opened.
- Click the Help link in the navigation bar (under your account name) to open the Oracle Help Center page for Oracle DMW. You can access links to videos, user guides, and common topics from this page.

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

Oracle DMW user sessions time out after 180 minutes maximum.

If the system remains idle for more than 20 minutes, it times out and you must log in again.

Check the network connection status

If you experience slow response times when you download files or perform actions on data, you can check the status of your network connection. If you see the download speed across the network is slow or the latency is high (time it takes the application to respond to an action), you may need to close unnecessary applications or work from a wired connection.

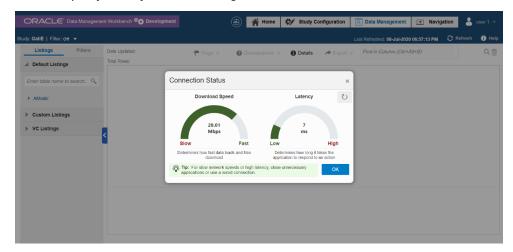
To check the status of the network connection:

- 1. If you are on the **Home** page, you can skip to step 3. If not, click Data Management in the navigation bar.
- From the drop-down menu, select Listings to open the listings page or Discrepancies from the drop-down menu to open the discrepancies for the study you selected.



3. Click *User Name* > **Connection Status** from the navigation bar to open the Connection Status dialog box.

For example, you may see something similar to this:



- 4. To rerun the test on the speed and latency of your network, click the **Refresh** icon next to the Latency chart.
- 5. Click **OK** to close.



Monitor study health

You can access the Study Health Monitor page at any time by clicking **Study Health** from the

Dashboards drop-down menu in the toolbar at the top of the page.



The Study Health Monitor shows the status of the following items for all the studies in the Production lifecycle:

- InForm loads
- Clinical One loads
- Other data loads
- Transformation jobs
- Validation checks
- Discrepancy queue

It automatically refreshes this data for all the studies every 15 minutes. You can manually refresh the data of an individual study by clicking the Refresh icon under the study name.



If you need to change the refresh default value of 15 minutes, you can modify the dmeStudyHealthSchChg.sql script that came with Oracle DMW. For more information, see Change the Study Health Monitor data refresh frequency in the Administration Guide.

To monitor study health:

from the toolbar. The left panel lists studies with the most failures at the top so you can locate them quickly. The right panel appears empty.

Note:

To search for a particular study, enter in a few letters of the study name in the **Search Study** field. To sort the list, select one of the options from the **Sort by** drop-down list: Study Name, Oracle Data Capture Load Failures, Other File Load Failures, Transformation Jobs Failures, Validation Check Failures, or Discrepancy Queue Failures.

- 2. Click the row with the study you want to view. The right panel populates with details on the study you chose.
- Review the details for each item in the study. For example, you can hover over the bars in the bar graph or areas of the donut charts to see more information (job ID, job status,

date and time of run, duration of run). If necessary, use the scroll bars to scroll through the list of studies or to the Discrepancy Queue details.

• Study Health Monitor

You can sign in to Oracle DMW and view the Study Health Monitor by clicking

Study Health from the **Dashboards** menu in the top toolbar. This page lists all studies in the Production life cycle and includes details on data loads, transformations, validation checks, and discrepancies in queue for each study.

• Study Health Monitor details panel
After you open the Study Health Monitor, you can click a study row to open a panel
on the right. The panel shows details on the status for each item in the study.

Study Health Monitor

You can sign in to Oracle DMW and view the Study Health Monitor by clicking Study

Health from the **Dashboards** menu in the top toolbar. This page lists all studies in the Production life cycle and includes details on data loads, transformations, validation checks, and discrepancies in gueue for each study.

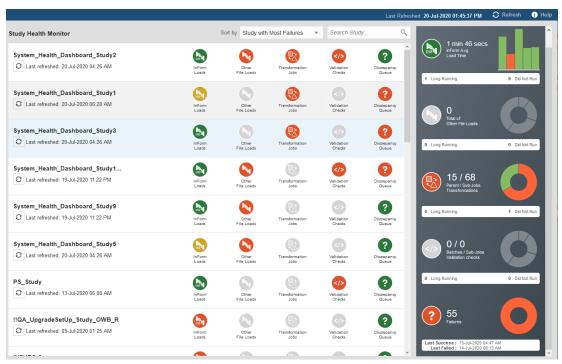
The Study Health Monitor lists the studies with the most failures at the top so you can identify them quickly and take action. You also see the date and time that Oracle DMW last refreshed the data. (Oracle DMW automatically refreshes the data every 15 minutes.) You can also sort the studies by a particular status or search for a particular study by name.

When you click a study row, you open a panel on the right that shows details on the status of each item in the study. The color of the icon next to each chart reflects the status of the last job that ran (for Oracle Data Capture loads) or the status for the majority of data loads, transformation jobs, validation checks, or discrepancies. Depending on how the job ran, you see one or all of the following colors in the icons, bar chart, or donut charts:

- Green = Success
- Blue = Executing
- Yellow = Warning
- Red = Failure

For example, you see a page similar to this:





You can hover your cursor over the bar graph or donut charts to see more information on the status (for example, job ID, date and time of an Oracle Data Capture load, percentage of other data loads, transformations, validation checks, or discrepancies in a particular state).

Study Health Monitor details panel

After you open the Study Health Monitor, you can click a study row to open a panel on the right. The panel shows details on the status for each item in the study.

The color of the icon next to each chart reflects the status of the last job that ran (for Oracle Data Capture loads) or the status for the majority of data loads, transformation jobs, validation checks, or discrepancies. The colors show as green (success), blue (executing), yellow (warning), or red (failure). See the following chart for details on the study health details.

Study Item (with example icons)	Description
InForm Loads	Shows the last five Oracle InForm jobs loaded for the study. The bar graph shows the order in 5, 4, 3, 2, 1 and reflects the status color for each job. The height of the bar represents the amount of time it took to load the data. Next to the icon, you see the average amount of time it took to run all Success or Warning jobs among five jobs (in minutes and seconds). It also indicates the number of long running jobs and jobs that were scheduled, but did not run.
Clinical One Loads	Shows the last five Oracle Clinical One Platform jobs loaded for the study. The bar graph shows the order in 5, 4, 3, 2, 1 and reflects the status color for each job. The height of the bar represents the amount of time it took to load the data. Next to the icon, you see the average amount of time it took to run all Success or Warning jobs among five jobs (in minutes and seconds). It also indicates the number of long running jobs and jobs that were scheduled, but did not run.



Study Item (with example icons)	Description
Other Data Loads	Shows the total number of data loads within the last day (24 hours) from systems other than Oracle InForm for the study. It also shows the number of long-running jobs and jobs that were scheduled, but did not run. The donut chart shows the status for the percentage of jobs that loaded. For example, if 90% of the jobs loaded successfully and 10% failed, most of the donut chart shows as green and a small portion shows as red.
Transformation Jobs	Shows the number of main transformations (Parent) and table-level jobs (Sub-Jobs) in the transformations within the last day (24 hours) for the study. It also shows the number of long-running jobs and jobs that were scheduled, but did not run. The donut chart shows the status for the percentage of transformation jobs.
Validation Checks	Shows the number of batches and validation checks (Sub-Jobs) within the last day (24 hours) in the study. It also shows the number of long-running jobs and jobs that were scheduled, but did not run. The donut chart shows the status for the percentage of validation checks.
② Discrepancy Queue	Shows the number of discrepancies in the queue and their status of Pending, Processing, Tried once, Tried twice, or Failed to send to InForm or an external system. It also shows the date, month, year, and time (in hours and minutes) of the last successfully sent or failed discrepancy.

Note:

For Oracle InForm, transformation, and validation check jobs, if a job takes 30% longer than the last successful job and at least 60 minutes to successfully run, it counts as a long-running job. For other file loads, if a job takes 75% longer than the last successful job and at least five minutes to successfully run, it counts as a long-running job. For more details on default values you can change, see Change the Study Health Monitor profile values in the Administration Guide.



3

View data load schedule

You can view how data loads are scheduled throughout the day across all active trials in the Production lifecycle with the **Data Load Schedule**, located under the **Dashboards** menu in the toolbar.



System Administrators can rearrange the data loads directly on the **Data Load Schedule** interface. For more information on how to edit the data load schedule, please see Modify data load schedule using the dashboard in the Administration Guide.

The **Data Load Schedule** dashboard is a visual representation of the distribution of data loads in the Production lifecycle over 24 hours. The data loads are color-coded:

- Green indicates the data load start time.
- Gray represents the recurring data loads before and after the start time.
- **Blue** indicates a data load start time that has been edited by a System Administrator, but the change hasn't been applied yet.

Clicking an entry on the **Data Load Schedule** opens a panel on the right that displays additional information about the data load, such as start time, frequency, and the average duration of the data load. You can also hover over a data load on the schedule to display the same information in a hoverbox, with the average duration of the data load shown in the gold circle (in minutes).

When the **Data Load Schedule** initially loads, the page displays the **current** configuration. Selecting **draft** from the **Configuration** field above the timetable displays any in-progress edits to the data load schedule made by System Administrators.

Clicking **Statistics** opens up a pop-up window where you can see a more condensed version of the schedule organized as a bar graph. Each bar represents an hour time block and the numbers in and above the bars show how many data loads are scheduled within that hour. The same color-coding of the data loads is carried over to this view.



4

View data listings, display data flow, and create discrepancies

This section contains the following topics:

- Choose a listing type
- · Search for data
- · Review data
- Customize the listings or discrepancy views
 You can hide, pin, or reorder columns on the Listings page or Discrepancies interface by using Table Settings function at the top of the grid.
- Create discrepancies
- Reprocess discrepancies that failed to be sent
- Export data to Excel or CSV
- View data flow
- Create a custom listing
- Copy a custom listing
- · Use the Expression Builder
- FAQs

Choose a listing type

Listings are divided into three different types:

- Default listings
- Custom listings
- Validation check listings

Default listings

Default listings shows the current data in a table.

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

Select Listings from the drop-down menu.

- 3. Expand **Default Listings** in the left panel. Then, expand a clinical data model from the list.
- **4.** Select a listing to open it.

To locate a listing, enter part of a listing name in the Search field and click the \bigcirc **Search** icon.

Custom listings

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

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Listings** from the drop-down menu.
- 3. Expand **Custom Listings** in the left panel. Then, expand a clinical data model from the list.
- 4. Select a custom listing to open it.

To locate a listing, enter part of a listing name in the Search field and click the **Search** icon.



Tip:

- You can choose to show disabled listings by selecting Show disabled CLs under the Search field. Oracle DMW disables listings if they read from a table that 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. For details on creating a custom listing, see Create a custom listing.

Validation check listings

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

1. After you select a study, click Data Management in the navigation bar.





For details on selecting a study, see Select a study from the Home page.

- 2. Select **Listings** from the drop-down menu.
- 3. Expand **VC Listings** (Validation Check Listings) at the bottom of the left panel. Then, expand a data model from the list.

Note:

- To locate a listing, enter part of a listing name in the Search field and click the Search icon.
- You can choose to show disabled listings by selecting Show disabled VCs.
 Oracle DMW disables listings if they read from a table that is not used in the study.
- 4. 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 someone fixed a data item and closed the discrepancy, you cannot see the record.

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

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 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. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

2. Select **Listings** from the drop-down menu.



- 3. Expand one of the listings in the left panel (**Default Listings**, **Custom Listings**, or **VC Listings**). Then, expand a clinical data model from the list.
- 4. Select a listing to open it.
- Click inside the Find in Column field at the top of the table to open the Columns drop-down list.



Tip:

You can skip the remaining steps and use keyboard shortcuts to access the Find field by pressing **Ctrl+Alt+S**. Start typing a word and press the space bar to open the drop-down list. Then use the arrow keys to select an option. You can press the space bar again to open more options and build an equation. When done, press **Tab** to navigate to the **Apply** icon



and press Enter.

6. Press the space bar to open the **Operators** drop-down list. Build the find criteria you need. For example, you can select equals (=), **contains**, **starts with**, greater than or equal to (>=).

To enter text (string values), add single quotes around the text (for example, 'Boston').



Tip:

When searching or filtering with string values, we recommend using the **contains** operator. This is because Oracle DMW allows multiple spaces (such as leading and trailing blank spaces) in data displayed on the Listings and Discrepancies interfaces.

7. Click the **Apply** icon to apply the find. (Click the **Clear** icon to clear the Find criteria.)

Review data

The following topics describe how to view discrepancies in a listing, view details, assign and remove flags, view data lineage, and reprocess discrepancies.

View a single record from data listings

You can access a view of a single record that displays all of the columns on the Listings grid in a vertical manner. This can help you focus on one record at a time while being able to vertically scroll through the information.

Compare records in data listings

You can select up to 100 records within the Listings grid to compare in a focused, vertical view. This may be helpful if you want to review and analyze multiple records without scrolling horizontally across the entire Listings grid.

View Subject Summary

You can see the overall status of all forms and visits completed for a patient in a view called Subject Summary, similar to InForm's Time and Events Schedule. The



Subject Summary uses color-coded cells and icons that allow you to quickly view the status of any critical CRFs.

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

You can view item and form level comments entered in InForm on DMW's Default Listings UI as well as track the review progress in DMW by marking the comments as reviewed.

View InForm Answer History

You can access real-time InForm Answer History detail associated with any data point directly in the Default Listings grid during review

Use keyboard shortcuts on listings

View a single record from data listings

You can access a view of a single record that displays all of the columns on the Listings grid in a vertical manner. This can help you focus on one record at a time while being able to vertically scroll through the information.

- 1. Do one of the following:
 - Select a study from the Home page
 - · Select a study from Study Manager
- 2. After you select a study, click Data Management in the navigation bar.
- 3. Select **Listings** from the drop-down menu.
- Select the Listings type in the left panel of the screen to load the listings in the center grid.



For details on selecting and viewing listings type, see Choose a listing type

- **5.** Right-click on the record you wish to view independent of the full Listings results.
- 6. Select View Record from the context menu.

You are taken to an isolated, vertical view of the record. From here, you can view more information about your selection in the panel on the right, assign flags, create a discrepancy, or navigate to any associated discrepancies.

To return to the previous view of the Listings grid, click **Exit View**.



Compare records in data listings

You can select up to 100 records within the Listings grid to compare in a focused, vertical view. This may be helpful if you want to review and analyze multiple records without scrolling horizontally across the entire Listings grid.

- Do one of the following:
 - · Select a study from the Home page
 - Select a study from Study Manager
- 2. After you select a study, click Data Management in the navigation bar.
- **3.** Select **Listings** from the drop-down menu.
- **4.** Select the Listings type in the left panel of the screen to load the listings in the center grid.



For details on selecting and viewing listings type, see Choose a listing type

- 5. Use Ctrl+click or Shift+click to select multiple rows in the Listings grid.
- 6. Right-click the selection and choose **Compare Records** from the context menu.

You are taken to an isolated, vertical view of the selected records. From here, you can view more information about your selection in the panel on the right, assign flags, create a discrepancy, or navigate to any associated discrepancies.

To return to the previous view of the Listings interface, click **Exit Comparison**.

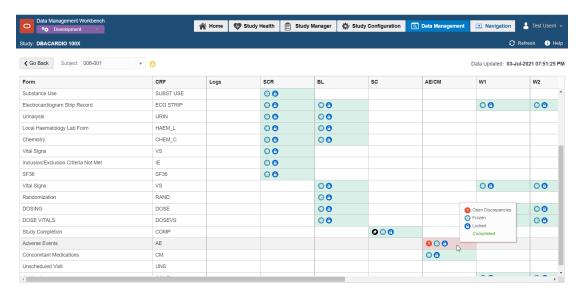
View Subject Summary

You can see the overall status of all forms and visits completed for a patient in a view called Subject Summary, similar to InForm's Time and Events Schedule. The Subject Summary uses color-coded cells and icons that allow you to quickly view the status of any critical CRFs.

Hover over any cell in the grid to see more information about what each icon and color means.



Figure 4-1 Subject Summary example



The Subject Summary can be accessed by right-clicking a record on either the Listings or Discrepancies page and selecting **View Subject Summary** from the context menu. You can also access the Subject Summary from the toolbar by clicking **Data Management** > Subject Summary and selecting the subject from the drop down list.

View discrepancies in the Listings page

If a user creates or comments on a discrepancy, the record appears with one of the following icons next to the appropriate data point:

Table 4-1 Discrepancy Icons

Discrepancy Icon	Description
?	Open discrepancy on the data item. Needs attention. Discrepancies with one or more entries show with a number next to the icon. For example, you see a "2" if the data item has two discrepancies:
?	Candidate for a discrepancy. Needs attention.
⊘	Closed or cancelled discrepancy.
0	Answered discrepancy. Review comments.
②	Cancelled discrepancy.

You can also see a duplicate version of the discrepancy icon to the left of the row if a data item includes a discrepancy. It appears in the second column of the listing.



View discrepancy details

1. After you select a study, click Data Management in the title bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Listings** from the drop-down menu.
- 3. Expand one of the listings in the left panel (**Default Listings**, **Custom Listings**, or **VC Listings**). Then, expand a clinical data model from the list.
- 4. Select a listing to open it.
- 5. Select one or more data items with a discrepancy.
- Right-click and select Go to Discrepancies from the drop-down menu. Or, click Discrepancies > Go to Discrepancies (or Show All Discrepancies to see all of them).
- 7. Select a discrepancy from the Discrepancies panel on the right to see details on it.

Show all discrepancies on one data item

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Listings** from the drop-down menu.
- 3. Expand one of the listings in the left panel (**Default Listings**, **Custom Listings**, or **VC Listings**). Then, expand a clinical data model from the list.
- 4. Select a listing to open it.
- Select a data item.
- 6. Click **Details** at the top of the table to open the Discrepancies panel on the right.
- 7. Expand Additional Information to view more details. For example, you can click View in Source to access the source of the data (if connected to InForm or another supported source). Or, click Assign Flags to assign a flag and state to the data point.





Tip:

To view details or act on one of the discrepancies, right-click the data item, and select Go to Discrepancies from the drop-down menu. Select one discrepancy to see its details in the lower panel.

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. After you select a study, click Data Management in the navigation bar.



Note:

For details on selecting a study, see Select a study from the Home page.

- Select **Listings** from the drop-down menu.
- 3. Expand **Default Listings** listings in the left panel. Then, expand a clinical data model from the list.
- 4. Select a listing to open it.
- Select the row with the record you want to flag, right-click anywhere in the row and click **Assign Flags**. Or, click **Flags** > **Assign Flags**. (To assign the same flag to multiple records, select the records by pressing the **Shift** or **Ctrl** key while you select records.) The Assign Flags dialog box opens.



Tip:

You can skip the remaining steps and use keyboard shortcuts to assign a flag to a record by pressing Ctrl+Alt+F. Use the down arrow keys to select options and press **Tab** to navigate to fields and buttons.

- 6. In the Flags field, select the previously created flag name you want to use from the dropdown list.
- 7. In the States field, select the previously created state name from the drop-down list. The names are associated with a high, medium, or low flag state.
- Click **Assign**. You can see the flag state in the first column of the listing (up and red for high state, sideways and yellow for medium, or down and green for low).





Tip:

If a data load completes while you were viewing the page, you see a prompt to refresh the page and Oracle DMW cannot assign the flag. Click the **Refresh** icon and check the data. If the flag still applies, assign it again.

Remove a flag

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Listings** from the drop-down menu.
- Expand Default Listings listings in the left panel. Then, expand a clinical data model from the list.
- 4. Select a listing to open it.
- 5. Select the row with the flag by clicking the arrow icon at the beginning of the row (first column).



Tip:

To select multiple records with flags, press the Shift or Ctrl key while you select records.

- 6. Right-click and select **Show Flags**. The Show Flags dialog box opens.
- 7. Select the flag you want to clear and click the **Clear Flag** icon on the right.



You cannot remove flags assigned in InForm. InForm flags use a prefix of ${\tt Inf}_.$

8. Click OK.

Show flags assigned to a record

For each flagged record, Oracle DMW shows a colored arrow in the first column of the listings (with a flag icon header) to represent the flag with the highest priority for the record. For example, you may see any of the following arrows if the record includes a flag:

- 🏄 = High priority flag

To see the flags applied to a record:

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Listings** from the drop-down menu.
- Expand Default Listings listings in the left panel. Then, expand a clinical data model from the list.
- Select a listing to open it.
- 5. Select the row with the flag by clicking the arrow icon at the beginning of the row (first column).



Tip:

To select multiple records with flags, press the Shift or Ctrl key while you select records.

- 6. Right-click and select **Show Flags**. The Show Flags dialog box opens. You can expand the flags to see details on the state or change it.
- Click OK.

View data lineage

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Listings** from the drop-down menu.
- 3. Expand **Default Listings**, **Custom Listings**, or **VC Listings** in the left panel. Then, expand a clinical data model from the list.
- 4. Select a listing to open it.
- 5. Click anywhere in the row of the record.
- 6. Right-click and select one of the following to open a graphical representation of the source, target, or preferred path:



- Show Preferred Path If there are multiple source data items, one must be designated as *preferred* when the discrepancy is created by a validation check or a person. The system applies the discrepancy to the data items in the preferred path.
- View Source Data to see upstream data that contributed to the selected data
- 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.



Click the tabs at the top of the graphic to display the source, target, or preferred path.

View data in InForm or another system

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- Select **Listings** from the drop-down menu.
- 3. Expand Default Listings in the left panel (Default Listings, Custom Listings, or **VC Listings**). Then, expand a clinical data model from the list.
- Select a listing to open it.
- 5. Select a data item that originated in InForm or a system connected through the generic connector.
- 6. Right-click and select View Data in External Source.
- 7. 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.

View Data in External Source is not supported for Clinical One.

View InForm Comments

You can view item and form level comments entered in InForm on DMW's Default Listings UI as well as track the review progress in DMW by marking the comments as reviewed.

An indicator column at the front of the Listings grid uses a speech bubble icon to show at the row level that there are InForm comments available to view. Hovering over the speech bubble icon in an individual cell displays a small window where you can quickly view the comment. When the speech bubble icon is green, it means that a DMW user has reviewed the comment.

You can search for Listings records with InForm Comments by using the following Advanced Filter options:

- Has Form Level Comment
- Has Item Level Comment
- Comment Change Date

When a data point is selected, the right-hand panel displays an expandable **InForm Comments** section. If an entire row is selected, all comments (both item and form level) are shown in the **InForm Comments** section. If only the cell containing the commented data point is selected, the panel shows the item level comment.

You can mark an InForm comment as **Confirmed** (reviewed) by clicking the circular checkmark icon in the **InForm Comments** section of the right-hand panel.



InForm Comments are only available in Oracle DMW when the IRV_CUR_COMMENT and IRV_CUR_USER views have been loaded for the InForm study.

View InForm Answer History

You can access real-time InForm Answer History detail associated with any data point directly in the Default Listings grid during review

Clicking a data point on the Listings grid for an InForm study opens a panel on the right side of the page that now displays an expandable InForm Answer History section, giving you and your data managers on-demand access to EDC audit data in DMW, enabling a more efficient data review process. Since InForm Answer History data is pulled from the InForm Trial in real time, it also includes any new updates made in InForm since the most recent DMW Dataload.

Use keyboard shortcuts on listings

After you select a study, a listing, and a record, you can save time and avoid using a mouse by using keyboard shortcuts to access an action or use search fields to find records.



Table 4-2 Keyboard Shortcuts for Listings

Keyboard Shortcut	Description
Ctrl+Alt+F	Assign a flag to a record: Opens the Assign Flags dialog box for the record you selected in a listing. For more details, see Assign a flag to a record.
Ctrl+Alt+S	Open the Find field: Opens the Find field at the top of the list of records in a listing. For more details, see Use the Find feature.
Ctrl+C	Copies column data in one or more rows (Copy Without Column Headers): Select the column data you want to copy and use the keyboard shortcut to copy it. To copy adjacent rows in the column, press the Shift key as you select data items. You see a "Copied Successfully" message that lists what you copied above the table. Press Ctrl+V to paste it. For example, you can paste the data into the Discrepancy text field of the Create Discrepancy dialog box. Or, paste it into any other application (for example, an Excel spreadsheet or Notepad).



Note:

To copy column data with the header and row number details, select the column data and select **Copy With Column Headers** from the right-click menu. You cannot use a keyboard shortcut.

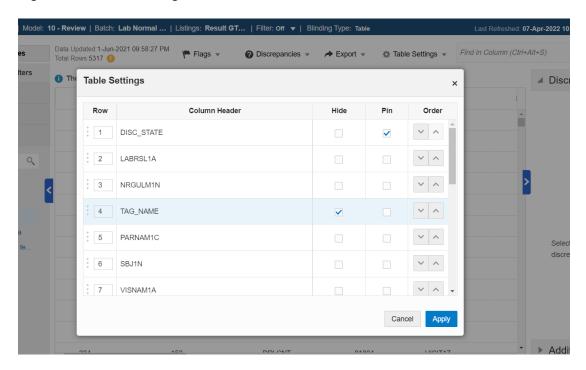
Customize the listings or discrepancy views

You can hide, pin, or reorder columns on the Listings page or Discrepancies interface by using **Table Settings** function at the top of the grid.

Click the **Table Settings** button at the top of the grid next to the filter search and select **Open**.



Figure 4-2 Table Settings



Once the Table Settings box has opened, you can customize the grid in the following ways:

- **Reorder columns**: You can reorder columns by changing the row numbers in the **Row** column, dragging the column rows to the desired location by using the drag and drop
 - function at the beginning of each row, or clicking the directional arrows at the end of each row in the **Order** column.
- Hide columns: Select the checkbox in the Hide column.
- **Pin (or freeze) columns**: Select the checkbox in the **Pin** column for columns you wish to have fastened to the left side of the grid when you horizontally scroll.

Click **Apply** to save your changes and close the Table Settings dialog box.



To remove all changes you've made to the display of the grid, click **Table Settings** again and select **Clear**.

Create discrepancies

To create a discrepancy on a data item:

1. After you select a study, click Data Management in the navigation bar.



Note:

For details on selecting a study, see Select a study from the Home page.

- 2. Select **Listings** from the drop-down menu.
- 3. Expand **Default Listings**, **Custom Listings**, or **VC Listings**. Then, expand a clinical data model from the list.
- 4. Select a listing to open it.
- 5. In the appropriate row, select one or more data items where you want to create a discrepancy. (You can select multiple data items if they all have the same issue.)



Tip:

To select multiple data items, press the Shift or Ctrl key while you select items.

- Right-click and select Create Discrepancy. The Create Discrepancy dialog box opens.
- For the State, select Open (definitely a discrepancy) or Candidate (possibly a discrepancy).
- 8. In the **Discrepancy** field, enter details about the discrepancy (required). Then, fill in the remaining optional fields if necessary (**Category** and **Action** you want taken [for example, Ready to Send, Send to Spreadsheet, Needs Review]). To include a phrase set by you (for example, your name), select **Append User Name**.
- 9. Click **Create**. Each selected data item appears with a discrepancy icon. You can also see the discrepancy icon in the second column of the listing. For details on the discrepancy icons, see View discrepancies in the Listings page.

Reprocess discrepancies that failed to be sent

- 1. Navigate to **Study Manager** and click the **Validation Checks** tab.
- 2. Click the **Failed to send Discrepancies** icon in the upper right corner. The Reprocess Discrepancies dialog box opens.

For each source data system, Oracle DMW displays the external system, discrepancy tag, and counts for the selected study and lifecycle stage. In the Discrepancy Tag column you see:

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



4. Click OK.

Export data to Excel or CSV

After you select a study and open a listing, you can export the data. To export the data in a listing, click **Export** from the top of the listing table to open the Export Listings options.

You can select one of the following export options:

• **Excel**: Generates an .xls file that includes all the data that satisfies the current filters (if any are used).



If the record set you are attempting to export contains more than one million rows, you must use the .csv format.

• **CSV**: Generates a comma-delimited text file that includes all data that satisfies the current filters (if any are used).

Clicking the **Export** button generates a background job that compiles the listing into the selected file type, allowing you to continue working in other parts of DMW while the export is processing. When the export is ready, you are prompted to download the file to your computer.

Export History

The Export History section of the window retains a record of listing exports requested in the last 24 hours, up to a maximum of 25 Exports per study and lifecycle.

View data flow

The data flow diagram shows how clinical data models map to each other. It shows an image of the input model and how the data flowed to the target model (successfully, with errors, or with warnings). This helps you locate areas you may need to troubleshoot.

For more details on viewing the data flow, see this video:



To view the Data Flow Diagram:

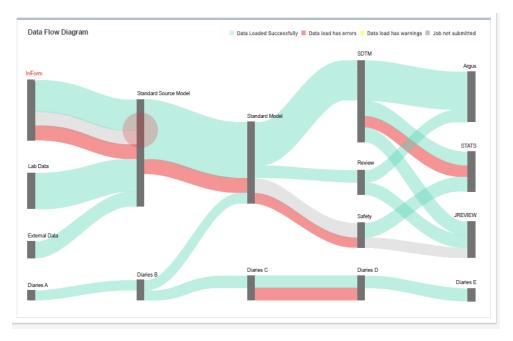
1. After you select a study, click Data Management in the navigation bar.



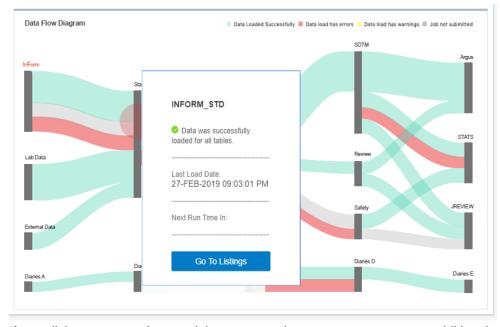
To display the data flow, select a study with 25 data models or less. (See Select a study from the Home page for details on selecting a study.)

2. Click **Data Flow** from the drop-down menu. You see a diagram showing the data flow. The width of the flow paths are proportional to the flow rate.

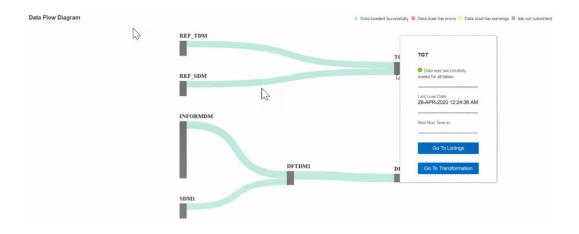
For example, you may see something similar to this:



- 3. Review the color of the flows to determine if the data loaded successfully (green path), includes errors (red path), includes warnings (yellow path), or shows light gray (job not submitted).
- 4. Click on a data model in the data (dark gray, vertical bars) to see more details on the status. For example, if you click an input data model with the area you want to inspect, a dialog box opens with details on the data load, date of the last data load, and next expected run time for the model:



If you click on a target data model you want to inspect, you may see an additional option. For example:



Note:

Depending on the amount of details shown, you may need to use the vertical and horizontal scroll bars to see all the content (if available). And, if the system finds errors (for example, failures when loading data into the data model), the dialog box includes a link to the log file.

- 5. If you opened a data model to see details, you may see some or all of the following options:
 - Users with Study Manager roles can click **Go To Listings** to open the Listings tab and review the data in the appropriate listing. (Click the left arrow icon in the browser toolbar to return to the Data Flow Diagram page.)
 - Users with Study Configurator roles, can click Go To Listings to open the Listings tab or Go To Transformation to open the Transformation tab in Study Configuration (for the current lifecycle). The tab opens with the source and target tables used in the transformation for the target data model. (Click the left arrow icon in the browser toolbar to return to the Data Flow Diagram page.)
 - Users with the DMW Exclude Internal Datamodel from Listings in Production role can click Go To Transformation to open the Transformation tab in Study Configuration if they select an InForm internal data model in the data flow. But, they cannot access the Go To Listings option.
 - If available, click Log to download the log file and see details on any errors.

Note:

Click anywhere in the Data Flow Diagram title bar to close the data model dialog box.

6. Click any main menu button in the navigation bar to exit the Data Flow Diagram page.

Create a custom listing

You can create a custom listing and define the access, columns displayed, table aliases, and data conditions. See this video for details: Video

This section contains the following topics:

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

Define query details

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Custom Listing Manager** from the drop-down menu to open the Custom Listing Manager tab.
- 3. Click the Add icon from the Custom Listings header in the left panel to open the Add Custom Listing dialog box.
- Enter the appropriate information for the new custom listing in the Name and Description fields.



Tip:

Use a name with 25 characters or less to avoid scrolling to see the full name.

 Select Authorize access to this listing for users without Blind Break rights if you know that the listing only displays non-blinded data, 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.

- 6. Select Mark as Public to enable all data reviewers to use this custom listing.
- 7. Do the following:
 - Continue on to Select columns to display to continue defining your custom listing.
 - Click Test to verify your custom listing. After reviewing the Test Results, click Close.



• Click **OK** to close the dialog box and save the custom listing with the details you entered. You can return to this procedure and search for it to continue defining it later.

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).

- 1. If not done already, open the custom listing you created in Define query details.
- Click the Selected Columns tab. Then drag the tables or columns you want to display from the Source panel 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.

- 3. If you need an **Expression** to operate on a column(s) to affect the way data is displayed, you must create a three-character **Table Alias** for its source table in the **Define table** aliases tab, then select it from this drop-down list.
- 4. Enter the Column Header for Display in the Custom Listings page.
- 5. Enter a **Sort Order** number to determine the column's display order relative to other columns.
- 6. Select Ascending (ASC) or Descending (DESC) Sort Type for the data display.
- 7. 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. (For more details, see Use the Expression Builder.)

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.



Note:

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

- 8. If necessary, use the following icons in the table toolbar to do the following:
 - The **Select Table Alias** icon opens a Select Table Alias dialog box. You can use the drop-down list to assign an alias to the selected column. Click **OK** when done.
 - The **Reorder Columns** icon opens the Reorder Columns dialog box. You can select a column and click the appropriate arrows to change the order. Click **OK** when done.
 - The **Delete Column** icon deletes the selected column.
 - The Detach icon detaches the table from the page for you to see the whole table. Click X in the upper-right corner to close it.
- Do one of the following:
 - Continue on to Select packages to continue defining your custom listing.
 - Click OK to close the dialog box and save the custom listing with the details you entered. You can return to this procedure and search for it to continue defining it later.

Select packages

Identify the packages of functions (for example, static functions that you defined in the study configuration) that you want included in the listing.

- 1. If not done already, open the custom listing you created in Define query details.
- 2. Click the **Selected Columns** tab to open the list of packages you their path that you can add to the custom listing.
- 3. In the Select column, select the packages you want. You can choose one of the following:
 - Leave the drop-down field over the Select column set to All.
 - Select the packages you want to include and click Selected. The custom listing only includes the package you selected.
 - Select the packages you do not want to include select and click Not Selected.
 The custom listing only includes the packages you did not select.
- 4. If necessary, use the following icons in the table toolbar to do the following:
 - The **Idle** icon holds the packages loading.
 - The Clear Filter icon clears a filter.



- The **Query by Example** icon opens fields at the top of each column for you to enter the name, description, or path to locate it.
- The Detach icon detaches the table from the page for you to see the whole table. Click X in the upper-right corner to close it.
- 5. Do one of the following:
 - Continue on to Define table aliases to continue defining your custom listing.
 - Click **OK** to close the dialog box and save the custom listing with the details you entered. You can return to this procedure and search for it to continue defining it later.

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. If not done already, open the custom listing you created in Define query details.
- In the Define Table Alias tab, select the table from the drop-down list.
- 3. Enter an alias. Use an alias with three characters or less.

The system displays the alias in the Selected Columns tab.

- 4. If necessary, click View to access options to see all or specific columns, detach the table, sort, or reorder columns. (For more details on customizing the view, see Customize the user interface display.) You can also use the following icons in the toolbar to do the following:
 - The Delete Column icon deletes the selected column.
 - The Add Table Alias to add another alias.
 - The **Remove Table Alias** icon deletes the alias.
 - The Detach icon detaches the table from the page for you to see the whole table. Click X in the upper-right corner to close it.
- Click OK.
- 6. Do one of the following:
 - Continue on to Specify and test criteria to continue defining your custom listing.
 - Click **OK** to close the dialog box and save the custom listing with the details you entered. You can return to this procedure and search for it to continue defining it later.

Next: Specify and test criteria.

Specify and test criteria

Specify the data condition the listing will look for.

- 1. If not done already, open the custom listing you created in Define query details.
- Select the Criteria tab.



- 3. Build the WHERE clause to determine which records appear in the listing. Click the Add or Modify Criteria icon and Use the Expression Builder.
- 4. 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.
- 5. Do one of the following:
 - Continue on to Save and install a custom listing to continue defining your custom listing.
 - Click OK to close the dialog box and save the custom listing with the details you entered. You can return to this procedure and search for it to continue defining it later.

Save and install a custom listing

1. In the Custom Listings panel, select the listing you created.



For details on creating a custom listing, see Create a custom listing.

- 2. Click the More Actions icon from the Custom Listings title bar, then do one of the following:
 - 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. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Custom Listing Manager** from the drop-down menu to open the Custom Listing Manager tab.
- 3. From the Custom Listings header in the left panel, click the More Actions icon, then click Copy Custom Listings.
- 4. Select a project (or other study grouping).



- 5. Select a model.
- 6. Select one or more custom listings within the model.
- 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**.

3. To add an item, in the Expression Item pane select **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 **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.
- Make your changes in the Expression Item pane and click **Update**.
 For more information, see the following sections.
- 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

This section includes the following topics:

- Listings FAQs
- Flag FAQs
- Data lineage FAQs

Listings FAQs

This sections includes details on these listing questions:

- 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?
- 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.

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 your account includes the privileges to view it, Oracle DMW prompts you to confirm that you want to access the blinded data.

After clicking **Yes**, you can use the **Show Blinded Data** field in the Filters tab of the Listings page or the Filter panel of the Discrepancies page to toggle between viewing or not viewing blinded data or masking values.

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.

- 1. Open the Home page.
- 2. Select a study.
- 3. Click the Modify Study icon in the Studies panel.
- Click the TMS tab.
- Click Force Rederivation to run Rederivation once, immediately. A confirmation message opens to notify you of a long processing time. But, you can still work while the rederivation runs.



6. 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?

You can only see Oracle DMW flags in Oracle 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?

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?.



5

Review and act on discrepancies

The section contains the following topics:

- How do I create a discrepancy?
- Find discrepancies
- Act on a discrepancy
 Once you find the discrepancies you need to locate, you can act on them to change the state, send to InForm or another system, modify the description, or export the details.
- See more information about a discrepancy
- FAQs

How do I create a discrepancy?

You create a discrepancy on a data item by selecting a study and clicking Data

Management in the navigation bar. Then, select Listings from the drop-down menu. You can then select a listing, locate the data item with the possible discrepancy, right-click on it, and select Create Discrepancy. For full details on creating a discrepancy, see Create discrepancies.

You can also see this video for details: Video

· Use keyboard shortcuts on discrepancies

Use keyboard shortcuts on discrepancies

After you open the Discrepancies page, and select one or more discrepancies, you can save time and avoid using a mouse by using keyboard shortcuts to perform actions or use search fields. (The number of actions you can take on a discrepancy vary depending on the state of the discrepancy.)

Table 5-1 Keyboard Shortcuts for Discrepancies

Keyboard Shortcut	Description	
Ctrl+Alt+S	Search for a column value: Use the keyboard shortcut and press Enter to open the Search field drop-down list and select the column you want to search. For more details, see Use the search fields at the top.	



Table 5-1 (Cont.) Keyboard Shortcuts for Discrepancies

Keyboard Shortcut	Description	
Ctrl+Alt+E	Edit a discrepancy: Opens the Edit Discrepancy dialog box in the right panel. For more details, see Edit a Discrepancy.	
	You can only edit one discrepancy at a time. To open the Edit Discrepancy dialog box for more than one discrepancy at a time, select multiple discrepancies and click Edit for each discrepancy you opened. Do not use the keyboard shortcut.	
Ctrl+Alt+Q	Ready to Send to InForm (if available): Opens the Ready to Send to InForm dialog box in the right panel. Ready to Send to Clinical One (if available): Opens the Ready to Send to Clinical One dialog box in the right panel.	
	For more details, see Change the state or send to InForm or another system.	
Ctrl+Alt+C	Close one or more discrepancies: Opens the Close Discrepancy dialog box in the right panel (for one or more discrepancies). For more details, see Change the state or send to InForm or another	

Find discrepancies

You can find particular discrepancies using one or both of the following methods:

system.

- Filters in the left panel (use one or more fields, build an advanced filter with a formula, or both)
- Search fields at the top of the table

See the following sections for details:

- Use filters in the left panel
- Use the search fields at the top
- Show blinded data

Use filters in the left panel

To find discrepancies, use the filter fields in the left panel. You can use one or more fields, build an advanced filter formula, and save a favorite filter for later use.

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Discrepancies** from the drop-down menu.
- 3. In the left panel, do one or more of the following:
 - Select a saved filter from the **Saved Filters** fields drop-down menu, if available. The fields used in the filter automatically populate.
 - Click Advanced Filters to open a text box. Click inside the box to open a drop-down menu, select a filter item and start building your formula using the appropriate operators. The criteria you select determines what additional items you can access.
 See Advanced Filters for more information.
 - Click in one or more of the following fields to enter or select the quick filter criteria you
 want to use (with or without an advanced filter formula). Use the scroll bars to see all
 your choices:
 - a. Model: Lists the models in the study (only shown through Discrepancies page).
 - **b. Listing**: Lists the listings for the model you selected (only shown through Discrepancies page).
 - **c. Country**: Lists the countries of the study or listing (depending if you accessed the filters from Listings or Discrepancies).
 - **d. Site**: Lists the location of where the study or listing was done.
 - e. Subject: Lists the available subject IDs.
 - Visit: Lists the available names of visits.
 - g. **Discrepancy State**: Lists the available discrepancy states. You can select **Answered**, **Cancelled**, **Candidate**, **Closed**, **Open**.



Tip:

By default, you cannot see cancelled or closed discrepancies. You must apply the **Discrepancy State** filter of **Cancelled** or **Closed** to see them.

- h. Discrepancy Tag: Lists the available discrepancy tags (for example, ClosedWithAnswer, NeedsDMReview, ClosedAsIs).
- 4. If your account includes the appropriate privileges and you need to show blinded data, select Show Blinded Data and click Yes when prompted. (The system tracks the number of times you view blinded data.)
- 5. If you want to keep displaying the filtered data, select **Keep the Filter in effect**.
- 6. Click Apply.
- 7. (Optional) To save the filter criteria for future use, click Save, name the filter, and click Save and Apply. If you want to use this filter as a template to create a new filter, click Create New and repeat these steps.





Tip:

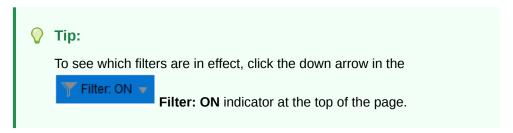
Saving a filter allows you to modify it one field at a time, saving after each change. To edit or delete filters, see Use or modify existing filters or Delete a filter. To make a filter public, see Create a public filter.

To clear the filters, click **Clear**. To view the data after clearing the filters or creating a new filter, click Apply.

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 filters that find only the exact value entered.

- If there are 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 filters in effect, the system searches across all discrepancies.



1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- Select **Discrepancies** from the drop-down menu.
- In the drop-down list above the discrepancies table, select what to search on, for example: Category, Datasource, Days since last state change, Validation **check**. The choices depend on the columns your organization uses.



Tip:

You can skip the remaining steps and use keyboard shortcuts to access the Search field by pressing Ctrl+Alt+S. Press Enter to open the Search field drop-down list of available columns you can search. Use the arrow keys to select the column name. Then press **Tab** to navigate to next field and enter a value. Press Enter to find the data under the criteria you specified.

- Enter a value in the text box.
- Click the Search icon.



6. To clear the filters, remove the value entered in the text box and click **Refresh** from right of the navigation bar.

Show blinded data

As described in Use filters in the left panel, you can select **Discrepancies** from the **Data**Management menu to drill down into the data and locate specific items. If your account includes the appropriate privileges and you need to show or hide blinded data, do one of the following:

- To show blinded data, select Show Blinded Data from the Filter panel on the left and click Yes when prompted. (The system tracks the number of times you view blinded data.)
- To hide blinded data, clear the Show Blinded Data field and click Yes when prompted.



If you selected a listing instead of discrepancies and clicked **Yes** when prompted to access blinded data (if available), the **Show Blinded Data** field appears selected already in the Filters panel (tab).

Act on a discrepancy

Once you find the discrepancies you need to locate, you can act on them to change the state, send to InForm or another system, modify the description, or export the details.

See this video for details: Video

This section describes how to complete the following tasks:

- Change the state or send to InForm or another system
- Add a comment
- Edit a Discrepancy
- Edit the text of multiple discrepancies
 You can edit the text of up to 20 discrepancies at one time, provided that they did not originate from InForm or an external source.
- · Export discrepancies on lab data

Change the state or send to InForm or another system

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

2. Select **Discrepancies** from the drop-down menu.



- **3.** Find the discrepancies you need to locate using the filters on the left panel or the top of the page. (See Find discrepancies for details on using the filters.)
- Select one or more discrepancies. To select adjacent rows, press Shift as you
 click rows (or press the down arrow key). To select nonadjacent rows, press Ctrl
 as you click rows.



Tip:

You can skip the remaining steps and use keyboard shortcuts to select **Ready to Send to InForm** by pressing **Ctrl+Alt+Q**. Or, close one or more discrepancies by pressing **Ctrl+Alt+C**. Use the down arrow keys to open the drop-down list and select an option. Press **Tab** to navigate to fields and enter a comment (if necessary). Press **Tab** to navigate to **Submit** and press **Enter**.

- 5. From the Manage Discrepancies drop-down, select the action to take (for example, Ready to Send to InForm). The drop-down list only includes valid actions for the discrepancies you selected. A new dialog box with the name of the action you selected opens in the right panel.
- 6. In the Reason field, select a reason from the drop-down list. Or, enter reason in the Comment field instead. (If you select a reason and enter a comment, Oracle DMW only saves the reason.
- 7. Click Submit.

Add a comment

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Discrepancies** from the drop-down menu.
- 3. Find the discrepancies you need to locate using the filters on the left panel or the top of the page. (See Find discrepancies for details on using the filters.)
- 4. Select one discrepancy.
- 5. In the right panel, click Add Comment.
- 6. Enter the comment and click **Submit**.

Edit a Discrepancy

- 1. Do one of the following:
 - Select a study from the Home page
 - Select a study from Study Manager
- 2. After you select a study, do one of the following:



- If you selected a study from Study Manager, click Data Management in the navigation bar and select Discrepancies from the drop-down menu.
- If you selected a study from Home, you can navigation to the discrepancies interface by clicking any of the data sets in the graphs on the Discrepancy Dashboard. For more information, see Use the Discrepancy Dashboard.
- 3. Find the discrepancies you need to locate using the filters on the left panel or the top of the page. (See Find discrepancies for details on using the filters.)
- Select a discrepancy.
- 5. In the right panel, click **Edit**.



Tip:

You can skip the remaining steps and use keyboard shortcuts to edit one discrepancy at a time by pressing **Ctrl+Alt+E**. Edit the **Discrepancy** field (if available). Press **Tab** to navigate to the **Category** field (if necessary), use the down arrow key to open the drop-down menu and select an option. Press **Tab** to navigate to **Submit** and press **Enter**.

- 6. Edit the **Discrepancy** or **Category** fields or select an **Action**. When you select an Action, you can also choose an associated **Reason** for the action and add a **Comment**. You can also select or clear the **Allow Auto Close** option.
- 7. Click Submit.

Edit the text of multiple discrepancies

You can edit the text of up to 20 discrepancies at one time, provided that they did not originate from InForm or an external source.

To edit discrepancy text, you must first select a study and navigate to the Discrepancies interface. For more information on these topics, please see Select a study from the Home page, Select a study from Study Manager, or Use the Discrepancy Dashboard. You can also navigate to the Discrepancies interface by clicking **Data Management** > **Discrepancies** from the top of the screen.

- After filtering the discrepancies to your preferences using the options in the left panel, select multiple discrepancies from the grid. To select adjacent rows, press Shift as you click rows (or press the down arrow key). To select nonadjacent rows, press Ctrl as you click rows.
- 2. From Manage Discrepancies, select the Edit Discrepancy Text option. The number of selected discrepancies is displayed in parentheses after Edit Discrepancy Text.



Note:

You can also right-click the group of selected discrepancies in the grid to display a context menu where the Edit Discrepancy Text is an available option.

A pop up window is displayed where you can enter text that is applied to all selected discrepancies.



3. Click **Save** to apply the new text to the selected discrepancies.

Export discrepancies on lab data

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

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Discrepancies** from the drop-down menu.
- 3. Find the discrepancies you need to locate using the filters on the left panel or the top of the page. (See Find discrepancies for details on using the filters.)
- 4. If you want to export only selected discrepancies, select the discrepancies. To select adjacent rows, press Shift as you click rows (or press the down arrow key). To select nonadjacent rows, press Ctrl as you click rows.
- **5.** Select one of the following from the **Export** drop-down list:
 - All to Excel
 - All to CSV
 - Selected to Excel
 - Selected to CSV

The system exports all or selected data to a Microsoft Excel or CSV file and prompts you to save it.

See more information about a discrepancy

This section contains the following topics:

- View the full record containing a discrepancy
- View related subject listings
 You can quickly navigate to the listing where the discrepancy was created from the Discrepancies interface.
- View the record in its source system
- View the discrepancy in its source system

View the full record containing a discrepancy

1. After you select a study, click Data Management in the navigation bar.



Note:

For details on selecting a study, see Select a study from the Home page.

- 2. Select **Discrepancies** from the drop-down menu.
- 3. Find the discrepancies you need to locate using the filters on the left panel or the top of the page. (See Find discrepancies for details on using the filters.)
- 4. Select one discrepancy.
- 5. From the •• View drop-down in the top section of the right panel, select Full Record to open the Full Record dialog box.
- 6. To see a particular column, enter part of the column name in the Search field and click to locate it.
- (Optional) Select Show Only Changes to see only items with different current and original data values.
- 8. Click X to close the Full Record dialog box.

View related subject listings

You can quickly navigate to the listing where the discrepancy was created from the Discrepancies interface.

- 1. After you select a study, click Data Management in the navigation bar.
- 2. Select **Discrepancies** from the drop-down menu.
- 3. Find the discrepancies you need to locate using the filters on the left panel or the top of the page. (See Find discrepancies for details on using the filters.)
- From the View drop-down in the top section of the right panel, select View All Subject Listings.

You can also access the **View All Subject Listings** option from the context menu displayed after right-clicking a discrepancy in the results grid.

You are taken to the Listings interface where the corresponding Subject filter has already been applied to Listings results.

View the record in its source system

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Discrepancies** from the drop-down menu.
- 3. Find the discrepancies you need to locate using the filters on the left panel or the top of the page. (See Find discrepancies for details on using the filters.)



- 4. Select one discrepancy.
- 5. From the View drop-down in the top section of the right panel, select Query in External Source.
- 6. When the source system opens, log in.

View the discrepancy in its source system

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Select **Discrepancies** from the drop-down menu.
- 3. Find the discrepancies you need to locate using the filters on the left panel or the top of the page. (See Find discrepancies for details on using the filters.)
- Select one discrepancy.
- From the View drop-down in the top section of the right panel, select Data in External Source.
- 6. When the source system opens, log in.

FAQs

- Acting on a discrepancy FAQs
- InForm and Clinical One guery 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.



Note:

To select adjacent rows, press **Shift** as you click rows (or press the down arrow key). To select nonadjacent rows, press **Ctrl** as you click rows.

For information on how to edit the text of multiple discrepancies at once, please see Edit the text of multiple 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 and Clinical One query and discrepancy FAQs

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



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

You can only move discrepancies/queries to the Answered state in InForm and Clinical One. 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 or Clinical One?

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

Can I send a discrepancy to InForm or Clinical One?

Yes. When you send a discrepancy on a data item back to InForm or Clinical One, you create a new query in the external system.

InForm doesn't accept discrepancies on data that is *hidden* in InForm. Any resolution must occur within DMW.

DMW does not allow for discrepancies to be sent to Clinical One for blinded data.

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 or Clinical One?

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

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

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

No. Users can change the underlying data item in the external system, 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 or Clinical One, 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 the external system 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 guery 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.



6

Use filters to find data and discrepancies

This section has information on the standard (quick) and advanced filters available in the Listings pages and in the Discrepancies page. Quick filters include a list of fields where you can enter data or select options from a drop-down list. Advanced filters include numerous categories with operators for you to build a filter formula from a list of drop-down options (depending on the criteria and operators you use). You can use the quick and advanced filters together, if necessary.



Tip:

By default, you cannot view canceled or closed discrepancies unless you use the **Discrepancy State** field in the filter. For more details, see Create a new filter.

For more details, see this video: Video

This section contains the following topics:

- Create a new filter
- · Use or modify existing filters
- Delete a filter
- · Create a public filter
- FAQs

Create a new filter

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Do one of the following:
 - Select Listings from the drop-down menu to open the listings page. Expand a
 default, custom, or VC listing, expand a data model, and select a listing. Then click
 the Filters tab from the left panel.
 - Select **Discrepancies** from the drop-down menu to open the discrepancies for the study you selected. The filter panel appears on the left.
- 3. In the left panel, do one or more of the following:

- Click Advanced Filters to open a text box. Click inside the box to open a drop-down menu, select a filter item and start building your formula using the appropriate operators. The criteria you select determines what additional items you can access. See Advanced Filters for more information.
- Click in one or more of the following fields to enter or select the guick filter criteria you want to use (with or without an advanced filter formula). Use the scroll bar to see all your choices:
 - a. **Model**: Lists the models in the study (only shown through Discrepancies
 - **b. Listing**: Lists the listings for the model you selected (only shown through Discrepancies page).
 - c. Country: Lists the countries of the study or listing (depending if you accessed the filters from Listings or Discrepancies).
 - **d. Site**: Lists the location of where the study or listing was done.
 - e. Subject: Lists the available subject IDs.
 - Visit: Lists the available names of visits.
 - g. Discrepancy State: Lists the available discrepancy states. You can select Answered, Cancelled, Candidate, Closed, Open.



Tip:

By default, you cannot see cancelled or closed discrepancies. You must apply the Discrepancy State of Cancelled or Closed to see them.

h. **Discrepancy Tag**: Lists the available discrepancy tags (for example, ClosedWithAnswer, NeedsDMReview, ClosedAsIs).



If your account includes the appropriate privileges and you need to show blinded data, select **Show Blinded Data** and click **Yes** when prompted. (The system tracks the number of times you view blinded data.) If you selected a listing, saw a prompt to access blinded data, and clicked Yes, the **Show Blinded Data** field appears selected already. To stop showing blinded data, clear this field and click Yes when prompted.

- 4. If you want to keep displaying the filtered data, select **Keep the Filter in effect**.
- 5. Click Apply.
- (Optional) To save the filter criteria for future use, click Save, name the filter, and click Save and Apply. Use a unique name across all the private, shared, and public filters that you can see in the current study and lifecycle. If you want to use this filter as a template to create a new filter, click **Create New** and repeat these steps.



To edit or delete filters, see Use or modify existing filters or Delete a filter. To make a filter public, see Create a public filter.

- 7. To clear the filters, click **Clear**. To view the data after clearing the filters or creating a new filter, click **Apply**.
- Advanced Filters

Advanced Filters

As described in Create a new filter, you can find particular records and discrepancies by creating a filter (or using a previously saved one).

The filter panel includes an Advanced Filters field that allows you to use additional filter criteria with operators to build a formula. You can use advanced filters with or without the quick filter fields.

Once you click inside the **Advanced Filters** field, the text box opens. Click in the text box to select a filter and start building your formula using these guidelines:

 Use the space bar to open the list of operators, categories, or linking options when building an advanced filter. For drop-down lists, press the space bar to select the first option in the list. If you start typing to build an equation, you see the operator drop-down list highlight options and filter the list based on what you entered. Press the space bar to select what you typed.



The operators depend on the filter you choose. For example, you may see an operator of =, != (not equal to), is empty, or is not empty with one filter category or exactly, before, after, between, is empty, or is not empty with another category. Once you select a filter, operator, and value (if required), you can use the AND or OR linking option to build on the formula.

 Use single quotes around any alpha characters you manually enter (for example, 'Boston').



Tip:

When searching or filtering using string values, we recommend using the **contains** operator. This is because Oracle DMW allows multiple spaces (such as leading and trailing blank spaces) in data displayed on the Listings and Discrepancies interfaces.

- Use a comma (outside single quote if quote used) to add multiple entries or a range of numbers. For example, to show a range of 1 to 10, enter 1, 10.
- Select dates from the pop-up calendar. Click the left (<) or right (>) arrows to move backward or forward through the months. The date appears in the DD-MMM-YYYY format.



- Click * to remove the advanced filter from the formula.
- Click X to close the Advanced Filters text box.

The following table lists the advanced filters you can use to drill down to the data you need to access:

Table 6-1 Advanced filter options

Advanced Filter	Available Operators	Description
Discrepancy Category	=, !=, is empty, is not empty	Lists the records with the discrepancy category that you specify (for example, From InForm, TMS IN PROGRESS, QC: Manual).
Discrepancy Change Date	exactly, before, after, between, is empty, is not empty	Lists the records with the most recent discrepancy change update that occurred during the time period you specify.
Discrepancy State Change Date	exactly, before, after, between, is empty, is not empty	Lists the records with the most recent discrepancy state change update that occurred during the time period you specify.
Discrepancy Created by User	=, !=, is empty, is not empty	Lists the records with the discrepancies created by the user you specify.
Discrepancy Modified by User	=, !=, is empty, is not empty	Lists the records with the discrepancies modified by the user you specify.
Discrepancy Origin	=, !=, is empty, is not empty	Lists the records with discrepancies that originate from the application you specify (for example, InForm, TMS).
Data Source Name (for Discrepancies only)	=, !=, is empty, is not empty	Lists the records from the data source you specify (for example, InForm, Undetermined).
Data Source Type (for Discrepancies only)	=, !=, is empty, is not empty	Lists the records for the data source type you specify (for example, InForm, Unknown).
Record Level Flag	=, !=	Lists the records with the flag priority level you specify.
Subject Visit Flag	=, !=	Lists the records with the subject visti flag you specify.
Site ID	=, !=, is empty, is not empty	Lists the records with the site ID values you specify.
Investigator Name	=, !=, is empty, is not empty	Lists the records with the investigator names you specify.
Investigator ID	=, !=, is empty, is not empty	Lists the records with the investigator IDs you specify.
Unique Subject ID	=, !=, is empty, is not empty	Lists the records with the unique subject IDs you specify.
Visit Date	exactly, before, after, between, is empty, is not empty	Lists the records with the visit date you specify.



Table 6-1 (Cont.) Advanced filter options

Advanced Filter	Available Operators	Description
Visit Day	=, !=, >, >=, <, <=, between, is empty, is not empty	Lists records with the visit day numeric values you specify.
Visit Number	=, !=, is empty, is not empty	Lists records with the visit number values you specify.
Visit Cycle	=, !=, is empty, is not empty	Lists records with the one or more visit cycle numeric values you specify.
Data change date (for Listings only)	exactly, before, after, between, is empty, is not empty	Lists records that data that changed during the time period you specify.
Discrepancy Reopened	=	Lists records that do or do not include discrepancies that were reopened. Can specify Y (for yes) or N (for no).
Discrepancy Data Changed	=	Lists records that do or do not include discrepancies with changed data. Can specify Y (for yes) or N (for no).
Validation Check (for Discrepancies only)	=, !=, is empty, is not empty	Lists discrepancies that have been created from Validation Checks.

Use or modify existing filters

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Do one of the following:
 - Select Listings from the drop-down menu to open the listings page. Expand a listing, expand a data model, and select a listing. Then click the Filters tab from the left panel.
 - Select **Discrepancies** from the drop-down menu to open the discrepancies for the study you selected. The filter panel appears on the left.
- 3. In the **Saved Filters** field, select the filter you want to use or edit. The fields automatically populate with the criteria saved for the filter. For example, if the filter used a formula, you see it appear in the **Advanced Filters** field.
- 4. Do one of the following:
 - Click Apply to use the saved filter without changes.
 - Make any necessary changes to the fields or formula. For more details, see Create a new filter and Advanced Filters. Then click Apply.



5. If you made changes to the filter and you want to save it, click Save. When prompted, click Save and Apply. If you want to use this filter as a template to create a new filter, click Create New, enter a new filter name, select Save as Public Filter (if you want it available to others), and click Save and Apply.



To edit a saved filter name (or use a filter as a template and give it a new name), select the filter and click Edit Filter at the top of the left panel. Enter a new filter name, select Save as Public Filter (if you want it available to others), and click Save and Apply.

Delete a filter

To delete a filter, follow these steps:

1. After you select a study, click Data Management in the navigation bar.



For details on selecting a study, see Select a study from the Home page.

- 2. Do one of the following:
 - Select Listings from the drop-down menu to open the listings page. Expand a
 listing, expand a data model, and select a listing. Then click the Filters tab
 from the left panel.
 - Select Discrepancies from the drop-down menu to open the discrepancies for the study you selected. The filter panel appears on the left.
- 3. In the **Saved Filters** field, select the filter you want to delete. The fields automatically populate with the criteria saved for the filter. For example, if the filter used a formula, you see it appear in the **Advanced Filters** field.
- 4. Click Delete filter from the top of the Filters panel.
- 5. Click **Remove** when prompted to delete the filter.

Create a public filter

If your account includes the appropriate 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. After you select a study, click Data Management in the navigation bar.



Note:

For details on selecting a study, see Select a study from the Home page.

- 2. Do one of the following:
 - Select Listings from the drop-down menu to open the listings page. Expand a listing, expand a data model, and select a listing. Then click the Filters tab from the left panel.
 - Select Discrepancies from the drop-down menu to open the discrepancies for the study you selected. The filter panel appears on the left.
- 3. In the **Saved Filters** field, select the filter you want to make public. The fields automatically populate with the criteria saved for the filter. For example, if the filter used a formula, you see it appear in the **Advanced Filters** field.
- 4. Click Edit Filter at the top of the Filter panel. Enter a new filter name, select Save as Public Filter (if you want it available to others), and click Save and Apply.

FAQs

- How do data filters work on the Discrepancies page?
- 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 data filters work on the Discrepancies page?

When you open the Discrepancies page from the Listings page (**Discrepancies** > **Go to Discrepancy**) and you leave the **Keep the Filter in effect** option selected in the Filters panel, the system continues to apply the same filters with these exceptions:

- If any of the current Subject or Visit filters only apply to a specific data model, the system only displays 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 conditions occur.

How do I know if any filters are applied?

You can determine if the Listings or Discrepancies pages use filters by looking at the Filter field at the left of the navigation bar. For example,

If the page includes filtered data, the Filter field appears as On: Filter: On If you select the drop-down for the field, you see the toggle switch show blue with a white

circle to the right when the page uses one or more filters:





You also see a list of any filters used, including advanced filters. For example, if you used the Site or Discrepancy State filter, you see it listed as an applied filter in the drop-down list.

• If the page does not include filtered data, the Filter field appears as Off:

If you select the drop-down, you see the toggle switch show gray with a white

circle to the left:

How can I tell which filters are applied?

To determine the current filters in use on the Listings or Discrepancies page, select the drop-down list from the **Filter** field on the left of the navigation bar (Filter: On). You see a list of one or more filters applied to the data (including advanced filters, if used). For example, if the data uses the Discrepancy State field, you see it listed with the state used for the filter:



Note:

If the Filter field appears as Filter: Off, the data was not filtered.

How do I turn filters off?

From the Listings or Discrepancies page, you can turn the filters off by selecting **Clear** from the Filters tab or panel on the left.

Why can't I make my filters public?

To make a filter public, your account needs the appropriate privileges. For more details, see Create a public filter.

7

Advanced: Run jobs and check history

This section contains the following topics:

- View and edit your subscriptions to job status notifications
- · Run transformations and view run history
- Run validation check batches and view run history
- Generate the Discrepancy Differences Report
 You can generate the Discrepancy Differences report from the Discrepancies interface to
 view any variances between discrepancies in Oracle DMW and the source system.
- 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.

1. Click **Home** in the navigation bar and select a study from the Studies panel.



For details on selecting a study, see Select a study from the Home page.

- 2. Select Study Manager from the toolbar.
- 3. In the Studies title bar, click the Notify icon.
- 4. Select the checkbox for each type of job and completion status that you want to be notified about:
 - Job types: File loads, Clinical One 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.

5. Click OK.

To subscribe or unsubscribe to notifications for other studies, select a different study and repeat the steps in this procedure.

Run transformations and view run history

To run transformation jobs and view the run history, please refer to the following topics in the Study Setup Guide:

- Run transformations and view run history
- View transformation job history
- Run a transformation
- Cancel a pending tranformation job

Run validation check batches and view run history

For more information about running validation check batches and viewing the run history, please see the following topics in the Study Setup Guide:

- Run a validation check batch
- Cancel a validation check batch job
- View run history

Generate the Discrepancy Differences Report

You can generate the Discrepancy Differences report from the Discrepancies interface to view any variances between discrepancies in Oracle DMW and the source system.

The Discrepancy Differences Report compares the data currently loaded into Oracle DMW with discrepancy data in InForm or Clinical One to highlight discrepancies that may need manual intervention. The results are available for download in an Excel spreadsheet, split into two sheets:

- **Discrepancy_Differences**: Contains discrepancies where the text, state, or revision do not match between Oracle DMW and the source system.
- Missing_Discrepancies: Contains discrepancies that are missing from Oracle DMW but found in the source system.

To generate the Discrepancy Differences Report, click the Discrepancy Differences

Report icon above the Discrepancies grid. In the subsequent Discrepancy Differences Report pop-up, you can click **Generate Report** button to create a new Discrepancy Differences Report or download one of the previously-generated files.

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:

 Click Study Manager in the navigation bar and select a study from the Studies panel.



- 2. Click the **Validation Checks** tab to open tables on the validation check batches for a model and run history.
- 3. Click the Failed to Send Discrepancies icon in the upper-right corner of the tab.

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.
- 4. If any discrepancies fail to send, click the Reprocess Discrepancies icon to send them again. Click the Refresh icon to see progress.

Check if data files loaded

The section contains the following topics:

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

View data files not processed

- 1. Click **Study Manager** in the navigation bar and select a study from the Studies panel.
- Click the Files Not Processed tab to open a table with uploaded files that did not load into the selected study.

A file may not load into a study for any of these reasons:

- It is misnamed or uses the different capitalization 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 the end date passed.
- There is a matching File Specification, but data loading is suspended.
- There is a matching File Specification, but the model is not installed.
- 3. View unprocessed files.

Columns include:

- File Name: Name of the file.
- Path: Path to the file location.
- 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 Type: The type of file.
- 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

- Click Study Manager in the navigation bar and select a study from the Studies panel.
- 2. Click the **Data Loads** tab to open a table with details on files that loaded into the selected study.
- 3. To view all jobs, click the View Full Job History icon.

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

4. 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 Job shows the date of the last completed job.
- Last Load shows the date of the last load time.
- Last Load Results shows the job status: Success, Warnings, or Failure for completed jobs.
- View Output opens a file with the output of the data load history.
- View Error File opens an error file on the data load.
- View Comprehensive Error Report opens a detailed error report on the data load.
- User Name shows the name of user who loaded the data.
- Next Run Date shows the date of the next data load run.
- Frequency shows how often data loads into the study.
- Units shows the size of the data load.
- **Columns with icons**: Click the icon to open the error, log, or output file.



For details on viewing errors in reports, see Review data load errors (optional).

· Statuses for uncompleted jobs

Statuses for uncompleted jobs

As described in View data load history, you can view data load history through the Data Loads tab on the Home page. For incomplete jobs, the system displays the job's current status. Click the Refresh icon to update the table.

- 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:



 Click Study Manager in the navigation bar and select a study from the Studies panel.



For details on selecting a study, see Select a study from the Home page.

- Click the Data Loads tab to open a table with details on files that loaded into the selected study.
- 3. Open a file in one of the following columns:
 - Last Load Results: Contains the results of the most recent data load. This file is produced whether the data load is successful or failed.
 - **View Output:**: Produced during a data load (the SQL*Loader log). This file is produced whether the data load is successful or failed.
 - View Error File: 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: 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.