Oracle® Life Sciences Data Hub

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Preface

This preface contains the following topics:

- Audience on page vii
- Documentation Accessibility on page vii
- Finding Information and Patches on My Oracle Support on page viii
- Finding Documentation on the Oracle Technology Network on page ix
- Related Documents on page x
- Conventions on page x

This book contains step-by-step instructions for the most common tasks in the Oracle Life Sciences Data Hub (Oracle LSH).

Audience

This manual is intended for all users who need to view Oracle LSH data through reports and visualizations.

Documentation Accessibility

Our goal is to make Oracle products, services, and supporting documentation accessible to all users, including users that are disabled. To that end, our documentation includes features that make information available to users of assistive technology. This documentation is available in HTML format, and contains markup to facilitate access by the disabled community. Accessibility standards will continue to evolve over time, and Oracle is actively engaged with other market-leading technology vendors to address technical obstacles so that our documentation can be accessible to all of our customers. For more information, visit the Oracle Accessibility Program Web site at http://www.oracle.com/accessibility/.

Accessibility of Code Examples in Documentation

Screen readers may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, some screen readers may not always read a line of text that consists solely of a bracket or brace.

Accessibility of Links to External Web Sites in Documentation

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/support/contact.html or visit http://www.oracle.com/accessibility/support.html if you are hearing impaired.

Finding Information and Patches on My Oracle Support

Your source for the latest information about Oracle Life Sciences Data Hub is Oracle Support's self-service Web site My Oracle Support (formerly MetaLink).

Before you install and use an Oracle software release, always visit the My Oracle Support Web site for the latest information, including alerts, release notes, White Papers, and patches.

Creating a My Oracle Support Account

You must register at My Oracle Support to obtain a user name and password account before you can enter the Web site.

To register for My Oracle Support:

- 1. Open a Web browser to http://support.oracle.com.
- **2.** Click the **Register here** link to create a My Oracle Support account. The registration page opens.
- **3.** Follow the instructions on the registration page.

Signing In to My Oracle Support

To sign in to My Oracle Support:

- Open a Web browser to http://support.oracle.com.
- 2. Click Sign In.
- **3.** Enter your user name and password.
- **4.** Click **Go** to open the My Oracle Support home page.

Searching for Knowledge Articles by ID Number or Text String

The fastest way to search for product documentation, release notes, and white papers is by the article ID number.

To search by the article ID number:

- 1. Sign in to My Oracle Support at http://support.oracle.com.
- **2.** Locate the Search box in the upper right corner of the My Oracle Support page.
- **3.** Click the sources icon to the left of the search box, and then select **Article ID** from the list.
- **4.** Enter the article ID number in the text box.

5. Click the magnifying glass icon to the right of the search box (or press the Enter key) to execute your search.

The Knowledge page displays the results of your search. If the article is found, click the link to view the abstract, text, attachments, and related products.

In addition to searching by article ID, you can use the following My Oracle Support tools to browse and search the knowledge base:

- Product Focus On the Knowledge page, you can drill into a product area through the Browse Knowledge menu on the left side of the page. In the Browse any Product, By Name field, type in part of the product name, and then select the product from the list. Alternatively, you can click the arrow icon to view the complete list of Oracle products and then select your product. This option lets you focus your browsing and searching on a specific product or set of products.
- Refine Search Once you have results from a search, use the Refine Search
 options on the right side of the Knowledge page to narrow your search and make
 the results more relevant.
- Advanced Search You can specify one or more search criteria, such as source, exact phrase, and related product, to find knowledge articles and documentation.

Finding Patches on My Oracle Support

Be sure to check My Oracle Support for the latest patches, if any, for your product. You can search for patches by patch ID or number, or by product or family.

To locate and download a patch:

- 1. Sign in to My Oracle Support at http://support.oracle.com.
- **2.** Click the **Patches & Updates** tab. The Patches & Updates page opens and displays the Patch Search region. You have the following options:
 - In the Patch ID or Number is field, enter the number of the patch you want. (This number is the same as the primary bug number fixed by the patch.) This option is useful if you already know the patch number.
 - To find a patch by product name, release, and platform, click the Product or Family link to enter one or more search criteria.
- **3.** Click **Search** to execute your query. The Patch Search Results page opens.
- **4.** Click the patch ID number. The system displays details about the patch. In addition, you can view the Read Me file before downloading the patch.
- **5.** Click **Download.** Follow the instructions on the screen to download, save, and install the patch files.

Finding Documentation on the Oracle Technology Network

The Oracle Technology Network Web site contains links to all Oracle user and reference documentation. This Web site interface is subject to change without notice.

To find Oracle Health Sciences documentation:

- Go to the Oracle Technology Network at http://www.oracle.com/technetwork/index.html and log on.
- 2. Go to the Oracle Documentation page at http://www.oracle.com/technology/documentation/index.html.

Or mouse over the Support tab, then click Documentation Archive.

- **3.** Scroll down to the Applications section and click Oracle Health Sciences Applications.
- **4.** Click the product and version you need. A page opens with links to the user documentation for that release.

To find user documentation for other Oracle products:

- 1. Go to the Oracle Technology Network at http://www.oracle.com/technetwork/index.html and log on.
- 2. Go to the Oracle Documentation page at http://www.oracle.com/technology/documentation/index.html or
- Mouse over the Support tab, then click **See All...** under Documentation.
- **3.** Navigate to the product you need and click the link.
- **4.** Click the link for the documentation you need.

Related Documents

This section lists the documents in the Oracle Life Sciences Data Hub documentation set, followed by their part number. The most recent version of each guide is posted on Oracle Technology Network; see "Finding Documentation on the Oracle Technology Network" on page ix.

- Oracle Life Sciences Data Hub Installation Guide (Part E18152-01)
- Oracle Life Sciences Data Hub Implementation Guide (Part E18308-01)
- Oracle Life Sciences Data Hub System Administrator's Guide (Part E18305-01)
- Oracle Life Sciences Data Hub Application Developer's Guide (Part E18306-01)
- Oracle Life Sciences Data Hub User's Guide (Part E18307-01)

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
monospace	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

Getting Started

This section contains information on the following topics:

- What Can I Do with the Oracle Life Sciences Data Hub? on page 1-1
- Logging In on page 1-2
- Navigating the Life Sciences Data Hub User Interface on page 1-7
- Setting Preferences on page 1-2
- Using Online Help on page 1-7
- Standard Buttons and Icons on page 1-8
- Using the Keyboard and the Mouse on page 1-11

What Can I Do with the Oracle Life Sciences Data Hub?

The Oracle Life Sciences Data Hub (Oracle LSH) allows your company to gather data from many other systems such as clinical data management systems, clinical trial management systems, adverse event reporting systems, even financial or other nonclinical systems, together in one data repository where you can analyze data from all these sources together as necessary.

For example, your company can create programs to compare data from different trials in the same therapeutic area, compare adverse events reported for different drugs, or compare data from a current trial with data from a closed trial.

Oracle LSH allows your company to develop large sets of reports executed together and produced as a single- or multi-volume PDF output with a table of contents, page numbering, and hyperlinks. You can develop custom templates for use in these Report Sets.

Oracle LSH helps you remain in compliance with regulatory requirements by supporting the validation of all programs and other defined objects that handle data in Oracle LSH, and auditing changes to data over time. You can create and label snapshots of data at a particular point in time and later run the version of a program that was current at that time on that data to recreate your original results.

Each time you generate a report on data, you can generate a coversheet that traces the history of the reported data in Oracle LSH: when and from where the data was loaded into Oracle LSH, what programs and other objects manipulated the data in Oracle LSH, and whether those objects have been validated.

Your security privileges determine what reports you can see and what you can do in Oracle LSH. Depending on your privileges, you may be able to do the following:

- View reports that have already been generated on Oracle LSH data. See Chapter 4, "Viewing Reports and Other Outputs" and Chapter 3, "Searching" for more information.
- Create onscreen visualizations of Oracle LSH data. See Chapter 6, "Creating Data Visualizations" for more information.
- Generate reports on the latest data, or on a data snapshot. See Chapter 5, "Generating Reports and Running Other Jobs" for more information.
- Load data into Oracle LSH. See Chapter 5, "Generating Reports and Running Other Jobs" for more information.
- Create Data Marts for export out of Oracle LSH. See Chapter 5, "Generating Reports and Running Other Jobs" for more information.
- Run and view reports on sensitive, blinded data during the course of a trial. See Chapter 5, "Generating Reports and Running Other Jobs" for more information.

For information on creating the programs and other defined objects required to load data and to produce reports, data visualizations, and data marts, see the Oracle Life Sciences Data Hub Application Developer's Guide.

For information on developing a custom Oracle LSH implementation design for your company, see the Oracle Life Sciences Data Hub Implementation Guide.

For information on administrative tasks, see the Oracle Life Sciences Data Hub System Administrator's Guide.

For instruction on installing Oracle LSH, see the Oracle Life Sciences Data Hub Installation Guide.

Logging In

To log in to Oracle LSH, you must have a browser on your computer and a URL, username and password provided by your company:

- Open your internet browser.
- Enter the URL provided by your company.
- Enter your Oracle LSH username and password, as provided by your company.

Note: After you have logged in for the first time you should change your password. See "Change Password" on page 1-4.

- **4.** Press **Enter** or click the **Login** button. The Oracle Applications Navigator screen opens.
- 5. Click the Life Sciences Data Hub hyperlink. The system displays all the screens to which you have security access as hyperlinks.
- **6.** Click on one of the hyperlinks; for example, **My Home** or **Outputs**. The system opens the corresponding Oracle LSH screen.

Setting Preferences

You can specify your preferences for some aspects of Oracle LSH's display and behavior.

There are general preferences that are the same for many Oracle applications, including:

- Display Preferences on page 1-3
- Access Requests on page 1-4

There are other preferences developed especially for Oracle LSH, including:

- User Preferences on page 1-5
- User Connections on page 1-6

Note: You must click Preferences from an Oracle LSH screen such as My Home to see the Oracle LSH-specific preferences. If you still cannot see some of these preferences, your company's policy may be to set them for you.

To set your preferences:

- Click the **Preferences** link in the upper right corner of the My Home screen.
- Click the link in the panel on the left side of the screen to display the preferences you want to set.
- Enter your preferences.
- Click **Apply**.

Details for each type of preference are displayed in the following sections.

Display Preferences

Display preferences affect the way information is displayed for you in Oracle LSH.

Languages

American English is the only option in Oracle LSH Release 2.1.4. for both language preferences:

Current Session Language American English.

Default Application Language American English.

Accessibility

There is one Accessibility preference:

Accessibility Features Choose one of these settings:

- Standard Accessibility. Renders Oracle LSH screens accessible to users using assistive technologies.
- Screen Reader Optimized. Optimizes screens for screen readers. This option may degrade the output for sighted readers.
- None. If you choose this option, some Oracle LSH screens may include features that are not accessible to some users.

Regional

There are several regional preferences:

Territory This setting has no effect in Oracle LSH Release 2.1.4.

Date Format From the drop-down list, select the way you want Oracle LSH to display dates.

Timezone From the drop-down list, select your time zone.

Number Format From the drop-down list, select the way you want Oracle LSH to display numbers.

Currency This setting has no effect in Oracle LSH Release 2.1.4.

Client Character Encoding This setting is used when uploading and downloading files to and from your computer through your browser. If you use non-English characters in source code, object names, or data, Oracle recommends that you change this setting to **Unicode** (UTF8) to ensure that these characters are displayed correctly in Oracle LSH.

Change Password

Use this section to change the password you use to log on to Oracle LSH.

Known As Enter your name as you would like it to appear in the welcome banner onscreen.

Old Password Enter your current password.

Password Enter your new password.

Repeat Password Enter your new password again.

Start Page

These settings determine the screen that opens when you log in to Oracle LSH.

Responsibility Select Oracle LSH Responsibility to access the Oracle LSH user interface.

Page Select the tab you want to see when Oracle LSH opens; for example, My Home.

Notifications

You may receive emails notifying you of an event in Oracle LSH (such as the release of an updated report) or requesting an approval from you. These messages also appear in the Notifications section of your Home page.

Email Style From the drop-down list, choose the style you prefer.

Access Requests

If you are unable to access part of the Oracle LSH user interface or perform a function that you feel you need to do, you can request increased privileges.

To request additional access:

1. Click the **Preferences** button.

- 2. Click Access Requests in the Preferences tab. The system displays your current
- **3.** Click the **Help** button and follow instructions there.

User Preferences

The following user preferences are specific to Oracle LSH. You can change the following settings:

Preferred Domain

When you log in to Oracle LSH, Oracle LSH will automatically open the Domain whose name you enter here. You can click the Search icon to see a list of Domains and select one. If you type all or the beginning of the Domain name and then click the Search icon, you see only the Domains that match what you entered.

You can change Domains in the Application Development screen as necessary.

Preferred Validation Status for Simple Search and Browse

Check the box if you prefer to see only objects and outputs whose validation status is Production when you conduct a Simple Search or browse the Reports or Applications tab. (You can request to see objects or outputs of any validation status when you use Advanced Search regardless of this setting.)

This setting is recommended for people who only need to view production data and reports in Oracle LSH. It is not recommended for people who are developing Oracle LSH applications.

Database Password Management

Use this preference to change the password for your database user account.

Database Account Name The system displays your database user account name, if you have a database account.

Old Password Enter your current password.

New Password Enter your new password.

Confirm Password Enter your new password again.

SAS Connection Type

This preference applies only to application developers who will work in SAS to create or upload programs to run on Oracle LSH data.

Oracle LSH handles data access from SAS as an integrated development environment (IDE) differently, depending on the connection mode you specify here:

Connected Mode. When you launch SAS from an Oracle LSH Program instance, Oracle LSH downloads views based on the Table Descriptors defined in the Program. You can see the current data in Oracle LSH while you work in SAS. If your program writes data to data sets, when you execute the program in the SAS IDE you pull data from Oracle LSH over the network and write to local data sets.

Your PC must have SAS Access to Oracle as well as the SAS client installed and must be connected to the Oracle LSH database through a network.

- **Disconnected Mode**. When you launch SAS from an Oracle LSH Program instance, Oracle LSH downloads data sets with the same structure as the Program's Table Descriptors to your PC. In addition, Oracle LSH downloads the actual data contained in the Table instances to which the Table Descriptors are mapped. You can write your program working on the downloaded data.
 - Your PC must have the SAS client installed and must be connected to the Oracle LSH database through a network. SAS Access to Oracle is not required.
- SAS Connected Mode with Work Area Data. This mode is the same as Connected mode except that it connects to the Work Area schema in the database. From SAS, you can browse views of current data in all Table instances in the Work Area, not just the Table instances linked to Table Descriptors of the Program.

You must use the SAS Access to Oracle tool to connect to Oracle LSH.

SAS IDE Client

This preference applies only to application developers who will work in SAS to create or upload programs to run on Oracle LSH data. This setting determines the SAS client that is used when you launch a SAS integrated development environment (IDE) session. Your company may have removed this preference or added options.

User Connections

To create or run Load Sets to load data into Oracle LSH from an external Oracle system, you must have an account on the external system that allows you to access the data you are loading. Enter information about your external Oracle system accounts so that when you create or run a Load Set, Oracle LSH can log on to the external system using your account to perform the data load. No other Oracle LSH user can use your connections.

To add a user connection for yourself, do the following:

1. From the **Adapter Name** drop-down list, select the adapter name that corresponds to the type of data you want to load: one of the Oracle Clinical adapters or Oracle Tables and Views for any Oracle-based system. Adapters correspond to Load Set types. For further information, see "Defining Load Sets" in the Oracle Life Sciences Data Hub Application Developer's Guide.

Note: You must create a different User Connection for each Oracle Clinical adapter you use, even for the same Oracle Clinical instance. You can use the same Oracle Clinical username and password for each.

- 2. From the **Remote Location** drop-down list, select the external database from which you need to load data.
- **3.** Click **Add User Connection**. The Create Connection screen opens.
- **4.** Enter values for the following fields:
 - Name. Enter a meaningful name for the connection. For example, OC Randomization from *location_x*.
 - Description. Enter a meaningful description of the connection to help you determine later on that this is the connection you need to use.
 - **User Name**. Enter your username in the external system. Oracle LSH will use this information to log on to the external system.

- **Password**. Enter your password in the external system. Oracle LSH will use this information to log on to the external system.
- **5.** Classify the Connection to help you find it. Choose an appropriate hierarchy and level; for example, the project and study for which you need the connection.
- Click **Apply**. Oracle LSH returns you to the User Connections screen.

Navigating the Life Sciences Data Hub User Interface

The tabs you see in the Oracle LSH user interface depend on your security access. You should be able to see the My Home tab and the Reports tab.

If you are an administrator or a programmer you may see additional tabs. Information about the Classifications, Security, and Administration tabs is included in the Oracle Life Sciences Data Hub System Administrator's Guide and for the Applications tab in *Oracle Life Sciences Data Hub Application Developer's Guide.*

My Home

The My Home screen has two sections, one above the other: Notifications and Job Executions.

Notifications If you click on the My Home tab you see a section on Notifications. These are messages sent to you within Oracle LSH. They may require action on your part or simply provide information. For further information on Notifications, see Chapter 2, "Using Notifications".

Job Executions If you scroll down the page you see a section on Job Executions. Every time you run a job—for example, run a report on fresh data, or load data from an external system—the system displays information on the progress of the job on this screen. For further information, see Chapter 7, "Tracking Job Execution".

Reports

If you click on the Reports tab, you see two subtabs: Outputs and Visualizations.

Outputs The Outputs subtab has two purposes: to display existing reports, Report Sets, and Data Marts; and to display the submission screen for reports, Report Sets, and Data Marts as well as Workflows and Load Sets so that you can run the same job on fresh data as necessary. For further information, see Chapter 4, "Viewing Reports and Other Outputs" and Chapter 5, "Generating Reports and Running Other Jobs".

Visualizations In the Visualizations subtab you can see Business Areas that you can use to create visualizations—graphical or tabular displays of Oracle LSH data—in Oracle Business Intelligence Enterprise Edition or Oracle Discoverer Plus. Business Areas consist of a set of views of Oracle LSH tables and their data, with joins and hierarchies defined to allow you to best compare and analyze the data. For further information, see Chapter 6, "Creating Data Visualizations".

Using Online Help

You can get context-sensitive online help for any screen in Oracle LSH (except pop-up windows) by clicking the Help link in the upper right corner of every screen.

The information you see in online help is taken from one of the following Oracle LSH user manuals, depending on the topic:

- Oracle Life Sciences Data Hub User's Guide (this book)
- Oracle Life Sciences Data Hub Application Developer's Guide
- Oracle Life Sciences Data Hub System Administrator's Guide

In addition, you can see these books and the Oracle Life Sciences Data Hub Implementation Guide under Health Sciences in the navigation tree on the left side of the help screen.

Standard Buttons and Icons

Many Oracle LSH screens display the icons and buttons described in the following sections:

- Buttons on page 1-8
- Icons on page 1-9

Buttons

The following button functions are the same throughout Oracle LSH application development.

Apply Oracle LSH applies changes you have made on the current screen to the database and opens a new screen. Always paired with **Cancel**.

Cancel Oracle LSH discards any work you have done in the current screen and returns you to the previous screen. Always paired with **Apply**.

Check In Oracle LSH saves the new version of the object definition in the database and allows other Definers to check out the object, according to normal security limitations. Only the person who checked the object out can check it in (except for Report Set definitions, which have shared editing; see "Concurrent Editing" in the Oracle Life Sciences Data Hub Application Developer's Guide).

Check Out To modify an existing object definition, you must check it out first. See "Understanding Object Versions and Checkin/Checkout" in the Oracle Life Sciences Data Hub Application Developer's Guide for further information.

Continue Used for processes that require a series of screens. Oracle LSH saves your work temporarily and displays the next screen in the process. If you cancel before the Save or Apply operation at the end of the process, which saves your work in the database, the system discards the temporarily saved work.

Copy Creates a copy of each selected object definition or instance that you can paste into a new location. The original object remains unchanged. To copy, you must first select the item(s) you want to copy and click the Copy button. Then go to the location into which you want to paste the copy, and click Paste. The system prevents you from doing anything else until you either cancel or paste. You can copy multiple objects from the same container at the same time. When you click Paste, the system pastes all the objects into the new location. See "Copying Objects" in the Oracle Life Sciences Data Hub Application Developer's Guide.

Move Moves each selected objects to a different location without breaking any links; use Paste to complete the operation. See "Moving Objects" in the Oracle Life Sciences Data Hub Application Developer's Guide.

Paste Places one or more object(s) into a single Oracle LSH location to complete the Copy or Move operation.

Uncheck Oracle LSH discards the new version of the object you checked out. Only the person who checked the object out can uncheck it. The previous version continues to function as before.

Icons

Oracle LSH uses icons for actions and to represent object types. See:

- Action Icons on page 1-9
- Object Icons on page 1-10

Action Icons

The following icons appear on the main Application Development screen. Some appear on many other screens as well.

Check Out 1943



You must check out object definitions to modify them.

Check In



You must check in object definitions to install and use them.

Clone



Cloning is an option only for Work Areas. See "Cloning Work Areas for Testing and Production" in the Oracle Life Sciences Data Hub Application Developer's Guide

Collapse



When Oracle LSH displays the Collapse icon, the child objects are displayed, but you can click the icon to hide them.

Create Child



Click Create Child to create a new object that is a child of the row object. The type of object you can create as a child varies depending on the parent.

- For an Application Area, Work Area is the only child you can create in this way. To create definitions of primary objects, either click Manage Definitions or create an instance and a definition in a Work Area within the Application Area. Oracle LSH automatically creates the new definition in the Application Area that contains the Work Area.
- For a Work Area, you can create any primary object type: Business Area, Data Mart, Load Set, Program, Report Set, Table, or Workflow. Oracle LSH automatically creates the new definition in the Application Area that contains the Work Area, and an instance of it in the Work Area.

Expand P



Oracle LSH displays either the Expand or the Collapse icon to the left of every object that owns one or more objects. When Oracle LSH displays the Expand icon, the child objects are hidden, but you can click the icon to show them.

Focus



Use the Focus icon to move your selected container to the top of the tree and expand all its branches.

Manage Definitions



Click this icon to create or modify the definitions contained in the Domain or Application Area.

Mapping



Click this icon to open the Mapping screen and map Table instances to Table Descriptors inside Program instances or other Oracle LSH executable objects.

Move



Use the Move operation to remove an object from its current location and paste it into a new location.

Reorder



Click Reorder to rearrange the display of objects on this screen.

Select



- There are two kinds of icons to select objects in Oracle LSH.
- **Square**. The square checkbox allows you to select multiple objects. **Circle**. The circular radio button allows you to select only one object.

Select the required objects. Then click a button in the toolbar immediately above, such as **Copy** to copy all selected objects or **Remove** to remove all selected objects.

Version History



Click this icon to see the version history of the object.

Object Icons

Each Oracle LSH object type has its own icon, shown below.

Domain



Application Area



Work Area 😨



Business Area



Variable



Data Mart



Load Set



Notification =



Notification With Approval Request





Using the Keyboard and the Mouse

There are two ways to navigate around Oracle LSH screens and invoke actions:

- Using the Mouse
- Using the Keyboard

Using the Mouse

Point to the field or button you want to use. Left-click to select a field or invoke the action of the button.

To enter text in a field, select it and then type the text.

Using the Keyboard

Use the Tab and arrow keys (up, down, left and right) to navigate around the screen. The active onscreen item is outlined with a dotted line. If an enterable field is active, anything you type appears in the field.

To move from one frame of the screen to another, press Ctrl+Tab.

Press Enter to invoke the action of a button when the button is active.

Press the spacebar to select a radio button or checkbox.

Using Notifications

This section contains information on the following topics:

- About Notifications on page 2-1
- Viewing Notifications on page 2-2
- Reassigning Notifications on page 2-3
- Requesting Additional Information on page 2-3

The Oracle Life Sciences Data Hub (Oracle LSH) Home Page displays all your notifications. You can use the View drop-down list to filter the displayed notifications. You must refresh the screen periodically to see the latest notifications.

About Notifications

Notifications are messages sent to you within Oracle LSH either to give you information or to request your approval. Notifications that do not require a response are called FYI (For Your Information) Notifications. Notifications that request a response are called Approval Notifications.

You can view a Notification by clicking its hyperlink.

View Use the View drop-down list to select which Notifications to display. The choices are:

- **Open Notifications** displays all FYI and Approval Notifications that you have not yet viewed or responded to.
- **FYI Notifications** displays all Notifications of type FYI that you have not yet viewed.
- Notifications From Me displays all the Notifications you send; for example, if you use the Request Further Information option to request information from someone else, you get a copy of the Notification that goes to the other person.
- To Do Notifications displays all Approval Notifications to which you have not yet responded.
- **All Notifications** displays all of the above types of Notifications.

The following information is displayed for each Notification. You can sort your Notifications by clicking on any heading: From, Type, Subject, Sent, or Due. By default they are displayed by date, with the most recent at the top.

From Name of the user who sent the Notification.

Type There are the following types of Notifications:

- FYI (For Your Information). No response necessary.
- Approval Request. A response—Accept or Reject—is requested. Oracle LSH keeps a record of the response.

Subject The subject of the Notification; should contain information about the contents of the Notification. Click on the hyperlink in the Subject column to view the entire Notification.

Sent The date on which the Notification was sent.

Due The due date of the Notification. This is applicable only for Notifications of type Approval. If you do not respond by the due date, the Approval will either time out with a status of failure or go to a different person for approval.

Viewing Notifications

When you have Notifications and select a View that displays them, the following information is displayed for each Notification.

The process that sent the Notification.

Type This information appears across the top of the screen, under the My Home and other tabs. It also states whether a response is required.

Subject The Notification displays a summary of its contents.

Sent The date and time of when the notification was sent.

Due A unique ID that Oracle LSH generates.

Status The status of the notification: Open, Closed, Cancelled (for Notifications that have timed out).

If a notification requiring approval has been approved or rejected, that information is contained in the body of the notification: "This notification was closed with status Approved/Rejected." The Status is set to Closed.

Message The system displays the message of the notification below these fields.

URL In the message, there may be a link to a report or other output. Click the link to display the output.

Acting on Notifications

For informational Notifications, click **OK** to indicate that you have read the Notification. Its status changes to Closed and it no longer appears as an Open Notification.

Select **Display next notification after my response** if you have multiple notifications to view and you prefer not to go back to the Home page and click on the next one. Whether you click OK, reassign the notification, or request information, when you have finished your work on the current notification, the system displays the next one in the order you have displayed

Click **Reassign** to reassign the notification to an alternate user. See "Reassigning Notifications" on page 2-3

Click **Request Information** if you need additional information regarding the notification. See "Requesting Additional Information" on page 2-3.

Click **Return to Worklist** to return to the Oracle LSH Home Page.

Acting on an Approval Request

For Approval Requests, your choices are to:

- Approve
- Reject
- Reassign; see "Reassigning Notifications" on page 2-3
- Request additional information; see "Requesting Additional Information" on page 2-3

Reassigning Notifications

If you are not able to action an assigned notification for any reason, you can reassign it to another Oracle LSH user.

To Reassign a Notification:

- In the Notification screen, click **Reassign**. The Reassign Notification screen appears.
- Select the user to whom you want to reassign the Notification. Click the search icon to search and select the required user. See Chapter 3, "Searching" on page 3-1.
- Select one of the following:
 - **Delegate your response.** Select this option if you want to give the new user authority to respond to the notification on your behalf, but you want to retain ownership of the notification yourself. For example, a manager might delegate all vacation scheduling approvals to an assistant.
 - **Transfer notification ownership.** Select this option if you want to give the new user complete ownership of and responsibility for the notification. For example, use this option if you should not have received the notification and you want to send it to the correct recipient or to another recipient for resolution. A transfer will have the effect of changing the approval hierarchy for the notification. For example, a manager might transfer a notification about a certain project to another manager who now owns that project.
- Include any additional comments for the new assignee.
- Click **Submit**. The system sends the request to the specified user and returns to your Home Page.

Requesting Additional Information

As part of the notification process, you can request additional information from either members of the workflow or any other Oracle LSH user.

To Request for Additional Information:

1. In the Notification screen, click **Request Information**. The Request Information screen appears.

- **2.** Use the Request More Information From option to specify the user or role from whom you want to request information.
 - Workflow Participant. To specify another user or role previously involved in this workflow process, select this option and select the user or role you want from the pull-down menu.
 - Any User. Select this option to specify any Oracle LSH user. Click the search icon to search and select the required user. See Chapter 3, "Searching" on
- **3.** In the Information Requested box, type the information you need from the user.
- **4.** Click **Submit**. The system sends the request to the specified user and returns to your Home Page.

Searching

This section contains information on the following topics:

- Simple Search on page 3-1
- Advanced Search on page 3-2
- Using Special Characters on page 3-5
- Search Results on page 3-6

In most Oracle Life Sciences Data Hub (Oracle LSH) screens you can perform a Simple Search for outputs (such as reports and log files) or object definitions (for application developers), or link to another screen to perform an Advanced Search.

Use Simple Search if you know the exact name or title of the output or object definition you are looking for, or if you know how to use special characters to find a name or title you are not sure of. You can also use Simple Search to find all outputs or object definitions that are classified to a particular value (such as Study 12345).

Advanced Search allows you to search by many criteria, including classification, creation date, creator, and validation status, and allows you to refine your search in other ways. Advanced Search also allows the use of special characters to help you find an output or object when you do not know its exact name; see "Using Special Characters" on page 3-5.

Oracle LSH returns all the results that satisfy the search criteria and to which you have at least View access.

Simple Search

The simple search feature is available at the top of many Oracle LSH screens. To perform a simple search:

- 1. In the **Search** drop-down list, select the category of object for which you want to search: Outputs (includes reports, log files, and Execution Setups), Definitions (object definitions and instances; for application developers), or both plus object instances (All Types).
- **2.** In the empty field next to the drop-down list, enter one of the following:
 - If you know the exact name of the object you are looking for, enter it. In the case of Report Sets and Report Set Entries, you can also enter the exact title.
 - If you know how the output or definition is classified, you can enter a classification value (one of the folder names in the Outputs screen). The system then returns all outputs or definitions classified the same way.

If you are not sure of the name, title, or classification, you can use special characters or Advanced Search. In simple searches you can use the following special characters:

% \$+

See "Using Special Characters" on page 3-5 and "Advanced Search" on page 3-2 for further information.

Note: If the system finds more than 2000 search results, it ends the search with an error. If this happens, use Advanced Search to specify additional criteria and narrow the search.

3. Click **Go**. The system displays the search results at the bottom of the screen, with a hyperlink to each one. See "Search Results" on page 3-6 for information on how the system displays the search results.

Advanced Search

Advanced search allows you to filter a search for Oracle LSH objects in many different ways, separately or in combination with one another.

This section includes the following topics:

- Advanced Search Settings on page 3-2
- Advanced Search Criteria on page 3-3

For information on how the system displays search results, see "Search Results" on page 3-6.

Advanced Search Settings

The upper part of the Advanced Search screen allows you to set conditions to apply to the search. The settings are:

Show Objects With Validation Status Of Check as many validation statuses as apply as follows:

- **Production**. Select Production to find reports on clinical trials or other real-world data; select Production also to find fully validated object definitions.
- Quality Control. Select Quality Control to find object definitions currently being formally tested.
- **Development**. Select Development to find object definitions currently under development.
- **Retired**. Select Retired to find object definitions no longer in use.

Include Report Set Subchapters If set to **Yes**, the system searches on the name and title of Report Set chapters and subchapters as well as the name and title of Report Sets as a whole (and other outputs). Your search results may include chapters and subchapters contained in Report Sets.

Show All Versions If set to **Yes**, the search results include all versions: for outputs, the result of every submission of the same report; for definitions, all versions of the same definition over time.

If set to **No**, the search results include only the most recent version of each object definition or output.

Note: for Execution Setups the system always displays only the version of an Execution Setup whose status is Runnable Active, regardless of the Show All Versions setting.

Show Identical Outputs If set to **Yes**, the search results include all outputs from all successful and failed submissions, even if they display the same data.

If set to No, the search results include only the last successful submission output.

Advanced Search Criteria

All or Any Conditions You must select one of the following:

- All. The system returns only objects that meet all the search criteria that you enter below.
- **Any**. The system returns objects that meet any of the search criteria that you enter below.

Hierarchy (Optional) Use this option to search by classification value.

- 1. From the Hierarchy drop-down list, select the classification hierarchy you want to use in the search. The system displays additional fields populated with information from the hierarchy you selected.
 - For example, you might have a hierarchy called Project-Study.
- 2. From the Level drop-down list, select the level you want to use in the search.
 - For example, in the Project-Study hierarchy you might select the Study level.
- **3.** From the next drop-down list, select one of the following, depending on what you know about the exact wording of the level value you want to search on:
 - is
 - with all of the words
 - with at least one of the words
 - without the words

See examples under **Name and Title** below.

4. In the next field, enter a word or phrase to complete the search for the correct level value.

For example, if you chose the Study level and know you are looking for reports on Study01, enter Study01 in the field on the right and choose Is from the drop-down list.

Note: If you want to search on multiple classification values, select Hierarchy from the Add Another drop down list at the bottom of this section, click Add, and repeat.

5. Include Children in Results. If set to **Yes**, the search returns not only objects classified to the level you specify but also, if the level you specify has a child level,

all objects classified to values in the child level that are related to the value you specified. For example, if you chose the Project level and specified Project12345, the search would return objects classified to Project12345 and also objects classified to all studies that are part of Project12345.

If set to No, the search returns only objects classified to the level and value you specify.

Name or Title Use this option to search on the name of an object definition or the name or title of an output (report, Report Set, Report Set Entry, or Data Mart).

- If you are looking for a particular object and know its name, enter the name in the field on the right and select with the exact phrase from the drop-down list.
- If you are searching for one or more objects and know all the words contained in their names but are unsure of the order, enter the words in the field on the right and select with all of the words from the drop-down list.
- If you are searching for one or more objects and think their names might include a particular word or phrase, enter the word or phrase and select with at least one of the words from the drop-down list. You can use special search characters; see Using Special Characters on page 3-5.
- If you know names of objects that satisfy the other search criteria but which you do not want to see, enter a word or phrase in the following field and select without the words from the drop-down list. You can use special search characters; see Using Special Characters on page 3-5.

Creation Date Use this option to search for objects or outputs by their creation date:

- Choose **is between** from the drop-down list and dates in the two other fields. Enter a date manually or use the pop-up calendar to populate the date fields with the Start and End date of the period within which you want to search.
- Choose is from the drop-down menu if you know the exact date the object was created, and enter the date in the first date field, either manually or using the pop-up calendar.

Created By Use this option to search for objects or outputs by the username of the person who created them.

- If you know it, enter the user ID of the person who created the object and choose with the exact phrase from the drop-down list.
- Enter several possible user IDs and choose with any of the words from the drop-down list. If you are not sure of the spelling, you can use special search characters; see Using Special Characters on page 3-5.
- See other examples under **Name and Title** above.

Add Another the Add Another button allows you to search on criteria and additional criteria values.

You can search on the following criteria that are not included in the main Advanced Search screen:

- Description
- Last Updated By
- Object Type
- Version Label

You can search for additional values for the following criteria that are included in the main Advanced Search screen:

- Created By
- Hierarchy
- Name or Title

Select another type of search criterion from the drop-down list and click Add. The system displays additional fields appropriate for that criterion immediately above the Add Another button. Enter values in these fields.

Buttons The buttons in the Advanced Search screen do the following:

- **Go** begins the search, using the criteria specified on the screen.
- Clear deletes all the values you have entered on the Search screen and any existing search results.
- **Add** displays additional fields for the type of criterion you selected from the **Add Another** drop-down list.

Using Special Characters

Oracle LSH supports the use of special characters in searching. To use special characters, type them into the Search field with the word or phrase for which you are searching, as shown in the "Usage Example" column in Table 3–1.

If the word or phrase you are searching for contains one of the special characters (for example, Study_01), enter a backslash (\) immediately before the special character contained in the word or phrase; for example, *Study*_01. Alternatively, enclose the word or phrase in curly brackets {} and the system treats the special characters as normal characters.

You cannot search on reserved words such as syn or table. See "Special Characters and Reserved Words" in the Oracle Life Sciences Data Hub Application Developer's Guide.

Oracle LSH uses Oracle Text in searching. For complete and current information on searching using special characters, see the Oracle Text Reference Guide at http://download-west.oracle.com/docs/cd/B10501_ 01/text.920/a96518.pdf; see instructions "Finding Documentation on the Oracle Technology Network" on page -ix.

Special characters for use in Oracle LSH searching

Char- acter	Description	Usage Example	Sample Outcome	Available in Search Type
%	multicharacter wildcard	head%	headache, head pain	Simple, Advanced
_	single-character wildcard	organi_ation	organization, organisation	Simple, Advanced
\$	language stem; finds words with same linguistic stem (root)	\$swollen	swollen, swelling	Simple, Advanced
?	fuzzy search; finds words spelled similarly	?center	centre	Simple, Advanced
&	AND; can be used in combination with other special characters	Bos% & ?centre	Boston Medical Center (intersection of the two result sets)	Advanced

Table 3-1 (Cont.) Special characters for use in Oracle LSH searching

Char- acter	Description	Usage Example	Sample Outcome	Available in Search Type
I	OR; can be used in combination with other special characters	Bos% ?centre	union of the two result sets: Boston Medical Center, Boston Hospital, Pagham Centre Hospital	Advanced
~	NOT; can be used in combination with other special characters	Study% ~ Study1	all results for Study except those for Study1	Advanced
-	Minus	headache - aspirin	finds all headache and aspirin results, but gives lower score to those that contain "aspirin"	Advanced

Search Results

Oracle LSH retrieves a list of objects that satisfy the search criteria within the limits of the screen from which you launched the search. For each item retrieved it gives the following information:

- **Name** of the object retrieved, with a hyperlink to the object. Click on the name to view the object.
- **Description** of the object retrieved.
- **Type**. Object Type of the object retrieved.
- Location of the object with a hyperlink to the location (Application Area or Library for object definitions, Work Area for object instances).
- Version.
- Validation Status: Development, Quality Control, Production, or Retired.
- **Date and Time** of the object's creation.

Viewing Reports and Other Outputs

This section contains information on the following topics:

- What Is an Output? on page 4-1
- Browsing in the Outputs Screen on page 4-1
- Sorting to Change the Display Order on page 4-4
- Focussing, Expanding, and Collapsing the Display on page 4-5
- Viewing Outputs and Related Information on page 4-5
- Printing Outputs on page 4-7

See also:

- Chapter 5, "Generating Reports and Running Other Jobs"
- Chapter 3, "Searching"
- Chapter 6, "Creating Data Visualizations"

What Is an Output?

An output is a file generated by the system when a user submits a Program, Report Set, Load Set, Data Mart, or Workflow for execution. Most of the outputs you see are either Report Sets or individual reports generated by Programs.

Depending on your security privileges and the way your company has set up classifications, you may see other types of outputs including log files, error files, Data Marts that contain Oracle LSH data ready for export to a different system (for submission or for sharing with a partner institution, for example), and copies of data loaded into Oracle LSH in file format (SAS or text).

The Outputs subtab of the Oracle LSH Reports tab displays all types of outputs as well as Execution Setups for generating new outputs on fresh data; see Chapter 5, "Generating Reports and Running Other Jobs".

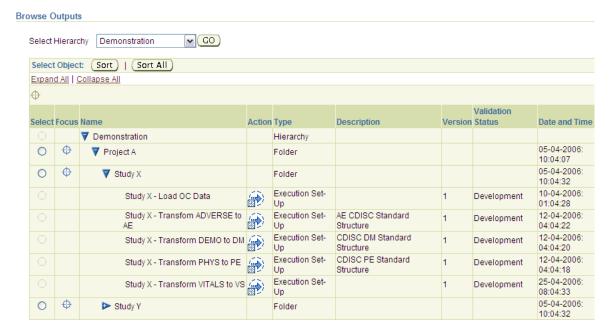
You can see only those outputs and Execution Setups to which you have security access.

Browsing in the Outputs Screen

Oracle LSH displays outputs according to the way they are classified in your company. Classifications are based on hierarchies. You can select the hierarchy, or classification system, through which you want to browse for outputs. To find an output, do the following:

- 1. Click the **Reports** tab. The **Outputs** subtab is displayed by default.
- From the **Select Hierarchy** drop-down list, select the classification system you want to use and click **Go**. The system displays the most general classifications as folders.

You can tell they are folders because they have a + icon next to their name and in the Type column it says Folder.



- Click the + icon for the folder that is most likely to contain the output you are looking for. The system displays folders for the more specific classifications that are related to the general classification you clicked, as well as any outputs that are classified directly to the general classification.
- Continue to click + icons until you reach the specific classification you need.
- When you find the output you want, click the Report-with-Glasses icon in the **Action** column The system displays information about the output.
- Click the **View File** button to see the output.

The same output may be classified in several ways; if so, it appears in several folders, possibly in different hierarchies.

If you have many folders or many outputs in a folder, you may want to sort the folders or outputs to change the display order and make it easier to find the one you are looking for. See "Sorting to Change the Display Order" on page 4-4 for further information.

Example You are looking for a demography report on patients participating in Study 12345 at Boston Hospital. Study 12345 is part of Project ABC.

Your company uses a Project/Study hierarchy to classify all reports by the name of their study or project. When you select Project/Study from the Select Hierarchy drop-down list, you see a folder for each Project, including Project ABC. When you click the + icon next to the folder for Project ABC, you see a folder for each of the studies included in that project, including Study 12345, plus any reports that are classified to Project ABC as a whole. If you click the + icon next to the folder for Study 12345, you see all the reports that are classified to Study 12345, including the Boston Hospital demography report.

Your company also classifies reports by the geographical location of the site that collected the report data. Therefore you can find the same report using the hierarchy Continent/Country/Site. The system displays a folder for each continent that has at least one study site, including North America. You click the + icon for the North America folder. The system displays two folders labeled U.S. and Canada. You click the + icon for the U.S. folder. The system displays a folder for every site in the U.S. that is participating in any study for your company. You click the + icon for the Boston Hospital folder. The system displays all reports classified to Boston Hospital, including Study 12345 Demography.

Note: Oracle LSH displays the most recent report that was submitted with its Parameters set the same way. If the same Execution Setup was submitted multiple times, each with different Parameter settings, Oracle LSH displays all the outputs. But if it ran multiple times with the same Parameter and other settings, Oracle LSH displays the outputs of only the most recent job.

To see older outputs, use Advanced Search with Show Identical Outputs set to Yes.

Information Displayed For each output and Execution Setup, the Outputs subtab displays the following information:

- Name. For outputs, this is the title. For Execution Setups, this is the name of the Execution Setup.
- **Action**. Click the icon in the Action column to submit an Execution Setup or to view an output's properties and the output itself.
 - Submit Execution Setup icon:



This graphic shows the Submit Execution setup icon.

View output icon:



- **Type**. The type of object displayed: Hierarchy, Folder, Execution Setup, or Output.
- **Description**. The description defined for the hierarchy, folder, Execution Setup, or output.
- Version.
- Validation Status. The validation status of the Execution Setup or output; it can be either Development, Quality Control, Production, or Retired.
- **Date and Time.** For outputs, this is the date and time the output was executed. For Execution Setups, this is the date and time of the most recent execution.

Sorting to Change the Display Order

To change the display order and make folders and outputs easier to find, use the Sort function. You can sort on any combination of Name, Date, Type, and Validation Status, in any combination of ascending or descending order.

To sort, do the following:

- 1. In the **Select** column, click the radio button for the folder whose contents you want to sort.
- **2.** Click **Sort**. The system displays the Sort screen.
- 3. In the First Row, from the Column drop-down list, select the name of the column you want to use as the primary sort criteria. The choices are:
 - **Name**. The name of the folder, output, or execution setup. Folders are always listed above outputs and execution setups, but you can sort them relative to each other.
 - **Type**. The type of object displayed: Hierarchy, Folder, Execution Setup, or
 - **Validation Status.** There are four validation statuses: Development, Quality Control, Production, and Retired. Unless you are a programmer you probably have access only to Production items.
 - **Date and Time.** The date and time the folder or execution setup was created, or that the output was generated.
- 4. In the First Sort row, from the Order drop-down list, select the type of order you want the system to use: Ascending or Descending.
 - For the Name, Type, and Validation Status columns, ascending means in alphabetical order from A to Z, while descending means reverse alphabetical order (from Z to A). For the Date column, ascending means chronological order, while descending means reverse chronological order (most recent on top).
- 5. (Optional) In the Second Sort row, from the Column drop-down list, select the secondary sort criteria you want to use. From the **Order** drop-down list, select the type of order you want the system to use: Ascending or Descending. The system uses this column to sort items that have the same value for the primary criteria.
 - For example, if you use Type for the First Sort criteria in descending order, you see all the outputs just below the folders. If you use Date and Time as the Second Sort criteria, the system displays the outputs in the order in which they were generated.
- **6.** (Optional) In the **Third Sort** row, from the **Column** drop-down list, select the tertiary sort criteria you want to use. From the Order drop-down list, select the type of order you want the system to use: Ascending or Descending. The system uses this column to sort items that have the same value for the secondary criteria.
 - For example, if you use Type for the First Sort criteria and Date and Time for the Second Sort, if you use Name for the Third Sort criteria, the system displays outputs that were created at the same time in alphabetical order.
- **7.** (Optional) Do the same in the **Fourth Sort** row.
- 8. Click Apply. The system returns you to the Outputs screen with the items displayed in the order you specified.

Focussing, Expanding, and Collapsing the Display

You can use the Focus, Expand All and Collapse All functions to control the way items are displayed on screen.

Focus You can click the icon in the **Focus** column for any high-level folder to see only that folder, so that you can see more of the contents of that folder on screen at a

When you click Focus for a folder, the system adds a Focus icon with the name of the hierarchy as a hyperlink just below the Expand All and Collapse All links. To go back to the full display of all folders in the hierarchy, click this link.

Expand All Clicking Expand All is equivalent to clicking the + icon for all folders and all levels of subfolders, so that you can see all folders and all outputs and execution setups, except that no more than 10 items are displayed in any particular node. (You can click another link to see the next 10 items, and so on.) After clicking Expand All you can click the - icon for any folders whose contents you do not want to view.

Collapse All Clicking **Collapse All** is equivalent to clicking the - icon for all folders and all levels of subfolders, so that you can see only the top-level folders. After clicking Collapse All you can click the + icon for any folders whose contents you want to view.

Viewing Outputs and Related Information

To view an output in the Reports tab/Outputs subtab, do the following:

- Find the output in the appropriate hierarchy; see "Browsing in the Outputs Screen" on page 4-1 or Chapter 3, "Searching".
- Click its icon in the Actions column:



The main screen for the output opens, displaying submission information (see "Viewing Output Submission Information" on page 4-6.

- **3.** Click **View File**. The system opens a dialog box.
- Click **Open**. The system opens the output file.

Or click **Save** to save the file to your PC.

Note: If you submitted the job that generated the output you want to see, you can also view it from the Job Executions section of your My Home screen. See Chapter 7, "Tracking Job Execution".

Printing Outputs

You can print the file if your company has set up global printing:

- Find the output in the appropriate hierarchy; see "Browsing in the Outputs Screen" on page 4-1 or Chapter 3, "Searching".
- Click its icon in the Actions column:



The main screen for the output opens, displaying submission information (see "Viewing Output Submission Information" on page 4-6.

- **3.** Click **Print**. The system opens a dialog box.
- **4.** From the **Printer** drop-down list, select the printer you want to use.
- 5. From the Coversheet drop-down list, select Summary Coversheet, Detailed Coversheet, or blank (no coversheet). See "Generating a Coversheet with Validation and Data Currency Information" on page 4-7.
- 6. Click Print. The system sends the job to the printer you specified and displays a confirmation message with a print job ID.

Viewing Output Submission Information

When you click on an output's View icon in the Action column, the system opens the Output Properties screen, which displays information about how the output was generated, as follows:

- **Title**. The title of the actual report or other output.
- **File Name**. The name of the actual file; it may or may not be the same as the title, plus an appropriate file type extension such as .pdf.
- **Job ID**. The Job ID is a system-generated unique ID for the job—a single execution of the Program, Report Set, or other object—that produced the output.
 - You can click on the Job ID hyperlink to see additional information about the job; see "Viewing a Job's Details and Monitoring Its Progress" on page 7-1.
- **Execution Status**. The execution status displayed represents the stage of execution the job reached before it ended. See "Execution Statuses" on page 7-9 for details.
- **Description**. The description of the Program, Report Set, or other object that generated the output.
- Validation Status. The validation status of the Program, Report Set, or other object that generated the output; the statuses are: Development, Quality Control, Production, and Retired. You may have access only to Production-status outputs.
- **Execution Setup**. The name of the Execution Setup that a user submitted to generate the output.
- **Execution User.** The username of the person who submitted the Program, Report Set, or other object to generate the output.
- **Job Start Time**. The date and time at which the execution began.
- **Blinding Status**. The blinding status of the output. If set to No, the output does not contain blinded data. If Yes, the output does contain blinded data and only users with special privileges can view the output.
- **Primary Output**. If set to Yes, the output is the primary reason for executing a Program, Report Set, Data Mart, or Load Set input file. If set to No, the file is a log or error file.
- Submission Parameters. Click the Submission Parameters subtab to see the values of all the user-defined Parameters that were used in the execution of the output.
- **System Parameters**. Click the **System Parameters** subtab to see the values of all the system Parameters that were used in the execution of the output.

Generating a Coversheet with Validation and Data Currency Information

You can generate a summary or detailed coversheet for any job. The Summary Coversheet gives information on when the job ran, its parameter values and data currency, and the validation status of its outputs and source and target tables. The Detailed Coversheet provides the same information for every job that processed the data fed into the current job, beginning with the job or jobs that loaded data into Oracle LSH.

To help ensure that the data manipulation performed in Oracle LSH does not corrupt data, Oracle LSH provides tools to help your company test and validate the defined objects—such as Programs, Load Sets, and Tables—that affect data in Oracle LSH. As your developers create and test these objects, they change their validation status from Development to Quality Control to Production according to your company's standards.

To create a coversheet, do the following:

- From the Job Details screen, select Generate Summary Coversheet or Generate **Detailed Coversheet** from the Actions drop-down list.
- Click **Go**.
- Click **Refresh**. The system displays a link to the coversheet in a new row in the Outputs subtab of the Job Details screen.
- To view the coversheet, click its View icon.

Note: When you print an output, you have the option to print either the summary or detailed coversheet; see "Printing Outputs" on page 4-5.

Note: If the name of an executable has a tilde (~) preceding it, it has been removed. You cannot submit it for re-execution.

Printing Outputs

To print an output, do the following:

- In the Output properties screen (which you reach by clicking the Job ID from the Outputs or My Home screen) click **Print**.
- From the Printer drop-down list, select the printer you want to use.
- 3. From the Coversheet drop-down list, select the coversheet you want to print, if
- Click **Print**. The system sends the output to the printer.

Generating Reports and Running Other Jobs

This section contains information on the following topics:

- What Types of Jobs Are There? on page 5-1
- Running a Job from Reports, My Home, or Applications on page 5-2
- Setting Submission Details on page 5-3
- Setting Source Data Currency on page 5-6
- Setting Load Set, Data Mart, or Program Parameters on page 5-10
- Running Report Sets and Workflows on page 5-19
- Resubmitting a Job with the Same or Similar Settings on page 5-25

The last chapter described how to find reports and other outputs that have already been generated. If you have the necessary security privileges, you can run new jobs to generate reports on current data and view the resulting reports.

You may also be able to run jobs to load data into Oracle Life Sciences Data Hub (Oracle LSH) from another system; for example, SAS or Oracle Clinical; or to generate data files for export out of Oracle LSH to a regulatory agency or partner institution. See "What Types of Jobs Are There?" on page 5-1 for more information.

In addition to running jobs in the Reports tab, you can run jobs from the My Home page and, if you have the necessary privileges, from the Applications tab; see "Running a Job from Reports, My Home, or Applications" on page 5-2.

To track the jobs progress, go the Job Execution section of your My Home page; see Chapter 7, "Tracking Job Execution". You can also see the output from there, if any; see Chapter 4, "Viewing Reports and Other Outputs".

What Types of Jobs Are There?

Oracle LSH has different types of executables that perform different functions. Depending on your security privileges, you may be able to submit any of these for execution:

- **Programs** generate reports and/or transform data and write data to Oracle LSH database tables.
- **Report Sets** generate a whole set of reports with a unified table of contents.
- Load Sets load data into Oracle LSH from another system. Load Sets can load SAS files, text files, or data from an external Oracle system. There are specialized Load Sets for loading data and meta-data from Oracle Clinical. For detailed information

- on the different types of Load Sets, see "Load Set Types" in the Oracle Life Sciences Data Hub Application Developer's Guide.
- **Data Marts** produce files containing data intended for export out of Oracle LSH; for example, for submission to a regulatory agency or to send to a partner. For detailed information on the different types of Data Marts, see "Data Mart Types" in the Oracle Life Sciences Data Hub Application Developer's Guide.
- Workflows can include any number of the other types of executables united in a single execution process. For example, a Workflow execution could run one or more Load Sets to load the most current data from SAS into Oracle LSH, then run several Programs to transform the data, and finally generate a Report Set with the most current data available in the source system.

Executing any of these executable objects is called a job.

Running a Job from Reports, My Home, or Applications

This section contains the following topics:

- Running a Job in the Reports Tab on page 5-2
- Running a Job from the My Home Tab on page 5-3
- Running a Job from the Applications Tab on page 5-3

Running a Job in the Reports Tab

In the Reports tab you can submit any Execution Setup to which you have security access; in other words, any Execution Setup you can see.

To run any type of executable in the Reports tab, do the following:

- Find the Execution Setup you need. You find Execution Setups the same way you do outputs; see "Browsing in the Outputs Screen" on page 4-1 and Chapter 3, "Searching".
- **2.** Click the Execution Setup icon in the Action column for the Execution Setup:



The system then displays the Execution Setup.

- 3. Look at the default Submission Details and change any you need to change. See "Setting Submission Details" on page 5-3.
- In the Submission Parameters subtab, look at the default values and change any you need to change. See "Setting Load Set, Data Mart, or Program Parameters" on page 5-10.
- In the Source Data Currency subtab, specify whether you want to operate on the most recent data or on a snapshot based on either a snapshot label or on a refresh timestamp. See "Setting Source Data Currency" on page 5-6 for further information.

You can also click on the Output icon in the Outputs tab, then click the Job ID hyperlink and then click **Re-Submit**.

Running a Job from the My Home Tab

In the My Home tab you can submit any Execution Setup that you have previously submitted. By default, the system uses the Parameter values and data currency used by the previous execution. You can change these if necessary.

Note: The submission uses the latest version of the executable instance, even if the previous submission used an earlier version.

- Find the record of the job in the Job Executions section. You can sort on any column heading by clicking it.
- 2. Click the Job ID hyperlink. The Job Execution Details screen for that job opens.
- Click **Re-Submit**. The Submission screen for the Execution Setup you previously used opens.
- 4. Change submission details and Parameter settings if necessary; see "Setting Submission Details" on page 5-3.
- Click **Submit**. The system submits the job and displays a message with the Job ID. Go back to the My Home page (by clicking the My Home breadcrumb or tab) to view the job's progress.

Running a Job from the Applications Tab

If you have access to the Applications tab, you can go to any executable object instance to which you have security access and click Submit to run the default Execution Setup.

To run a different Execution Setup, select **Execution Setup** from the **Actions** drop-down list, and click **Submit** for the Execution Setup you choose.

Setting Submission Details

The submission detail settings control various aspects of job execution. Depending on the type of object being executed and the way the Execution Setup is defined, you may or may not see all possible submission details. The complete list includes the following details:

Execution Priority From the drop-down list, select the priority—Low, Normal, or High—that this job should have relative to other jobs.

Submission Type From the drop-down list, select the timing of the submission:

- **Immediate**. The system executes the job as quickly as possible after you click Submit.
- Deferred. The system displays additional screens to allow you to schedule a single execution at a later time. Enter the date and time you want to execute the job in the fields that appear at the bottom of the section.
- **Scheduled**. The system displays additional screens to allow you to schedule multiple executions at regular intervals.

Submission Mode From the drop-down list, select **Full** or **Incremental**. This field applies only to jobs that load data to tables that use Reload processing.

- **Incremental** mode compares the records being loaded or written in the current job to those loaded or written to the same tables in the previous job makes appropriate updates and insertions but does not delete any data.
- Full mode also compares and performs updates and insertions, but in addition full mode processing soft-deletes any records that are not included in the current job.

If you are incrementally adding records to a table, or loading updated versions of different subsets of data, select Incremental. If you are reloading a complete set of the most up-to-date records that may be missing some records due to deletions, select Full. See "Reload Processing" in the Execution chapter of the Oracle Life Sciences Data Hub Application Developer's Guide.

Data Currency From the drop-down list, select one of the following:

- **Current Immediate Source**. The system processes the current data in the tables or data sets that are read by the job.
- **Most Current Available.** This option triggers a **backchain** operation in which the system checks for more current data and executes jobs along the data flow to bring the most current data possible to the current job. See "Backchaining" in the Execution chapter of the Oracle Life Sciences Data Hub Application Developer's Guide.
- **Specify Snapshot.** You can run the job on noncurrent data by specifying a data snapshot—the state of data at a previous point in time. If you select this option, you must specify the snapshot you want to use in the Data Currency subtab; see "Setting Source Data Currency" on page 5-6 for further information.

Note: The Execution Setup may be defined with a fixed data snapshot that you cannot change.

Blind Break This Parameter is relevant only when one or more source Table instances either currently or formerly contained blinded data. Special privileges are required to run a job on real data that is either currently blinded or was formerly blinded. Different special privileges are required to see the resulting output(s). The choices available depend both on the state of the data and on your security privileges. They are:

- **Not Applicable.** If none of the data has ever been blinded, the only option available is **Not Applicable**. No special privileges are required.
- **Dummy**. If any of the data has ever been blinded, this option appears. If you do not have the privileges required to run the job on real data, this is the only option available. If you do have the privileges required, you see **Dummy** plus one of the following options, depending on the state of the data and your privileges. Select **Dummy** to run the job on dummy (not real) data.
- **Real (Blind Break)**. If any of the data is currently blinded, and you have the required privileges, you can select this option to run the job on the real data, according to your company's policies. The table(s) containing the blinded data remain blinded after you run the job.
- **Real (Unblinded)**. If any of the data was formerly blinded but is currently unblinded and none of the data is currently blinded, and you have the required privileges, you can select this option to run the job on the real data, according to your company's policies.

Notify on Completion From the drop-down list, select the conditions in which you want to receive a notification of the job's ending status:

- **Success.** If you select Success, you receive a notification if the job ends with a status of Success, Warning, or Failure. This is the default value.
- **Warning**. If you select Warning, you receive a notification if the job ends with a status of Warning or Failure.
- **Failure**. If you select Failure, you receive a notification if the job ends with a status of Failure.
- **Never**. If you select Never, you do not receive a notification no matter what status the job ends with.

Force Duplicate Execution When you submit a job, Oracle LSH checks the Parameter settings, Blind Break setting, data currency, and executable object instance version and compares them with previous executions of the same executable object.

- No. If the settings and data currency are the same, so that the job would duplicate a previous job, the system does not run the job.
- **Yes**. The system runs the job even if it does duplicate a previous job.

Note: In the case of Report Sets, setting **Force Duplicate Execution** to Yes affects only the Report Set Entries that are selected for inclusion in the job.

Timeout Value Enter the number of minutes or hours, for example, past the scheduled execution time, after which the system should no longer start the job. For example, if a report is scheduled to run once a day, you might enter a timeout period of 24 hours, so that, if the system is down for that period, the system does not attempt to generate a report for that day.

Timeout Unit From the drop-down list, select the unit of time you want the system to use, together with the Timeout Value, to determine how long to try to run the job before timing out.

Apply Snapshot Label From the drop-down list, select the tables to which you want to apply a snapshot label to identify the state of data immediately after this job is executed:

- **Both**. The system applies the label to both source and target tables.
- **Targets**. The system applies the label only to target tables.
- **None**. The system does not apply a label to any table.

Note: It does not make sense to apply a snapshot label on a job with a repeating execution schedule, because the same label is applied each time.

Also note that when you run a Load Set you can apply a snapshot label only to its target Table instances because its source tables or files are not located in Oracle LSH. You can select either Both or Target to apply a label to the target Table instances.

Label Enter the text of the snapshot label that you want to apply to the Table instances you specified. If the label already exists for another currency of any of the same Table instances, the system automatically moves the label, and the log file contains a record of the change.

Schedule Submission Details If you select **Scheduled** in the Submission Type field, the system displays the following fields at the bottom of the section:

- **Frequency Type**. From the drop-down list, select Daily, Hourly, Monthly, or Weekly.
- **Start Date**. Click on the calendar icon to select the date.
- **Start Time.** Enter the time you want the first job of the series to start. Use 24-hour time; for example, enter 23:00 to start the job at 11:00 p.m.
- **Ongoing.** Select this radio button if you do not want to set an end date for the schedule.
- **End Date.** Click on the calendar icon to select the end date, if you want to set one.
- **End Time**. Enter the time after which you want the scheduled job executions to stop. Use 24-hour time.
- Frequency Details. The system displays different fields depending on the Frequency Type you selected. Enter values as directed to complete the schedule.

Setting Output Suffixes To distinguish the output of this job from the output of a different execution of the same Program or other executable object, you can enter text that the system will append to the title and description of the output during this execution. The system applies the text you enter to all Planned Outputs of this job, including the log file. The system does not apply the suffix to the coversheet.

- **Output Title Suffix.** The system appends a space and then this text after the output's title. If the suffix length plus the title length together are more than 200 characters, the system truncates the suffix.
- **Output Description Suffix.** The system appends a space and then this text to the output's description. If the suffix length plus the title length together are more than 2000 characters, the system truncates the suffix.

Note: If the system truncates these values, you can resubmit with shorter values for the suffixes or edit the title and description by going to Job Executions in the My Home page, clicking the **Job ID**, clicking **Re-Submit**, and modifying as necessary.

Setting Source Data Currency

When you run a report or other job, you may want to use the most current data, data snapshots from a previous point in time, or data snapshots that have been labeled because they represent data at a signficant stage; for example, Interim or Final. You may need to use source data with different labels; for example, because you are reporting on data from different studies. You may also want to use a label for some studies or tables and the most current data for other studies or tables.

The Submission screen's Data Currency tab displays all the source Table instances to be used for that submission, arranged by Work Area. The default setting for each table is Current for current data. You can specify the source data currency you want using lists of values at three levels:

for all source Table instances, across Work Areas

- for all source Table instances in a particular Work Area
- for individual source Table instances

The list of values at each level provides these options:

- **Snapshot Labels.** The list of values includes every label that is applied to every source Table instance to be used for the submission within the scope of the list of values: across Work Areas, within a single Work Area, or for a single Table instance. When you select a label, the system displays it for all Table instances in scope that have that label and that do not already have a label displayed.
- **Most Current Label.** When you select this option, for each Table instance in the scope of the list of values, the system displays the label with the most recent timestamp, whatever it may be. The system does not change the data currency setting for Table instances that have no labels or for Table instances that already have a label displayed.
- **Most Current Data**. The system overwrites all labels you have applied and resets all source Table instances in the Work Area to use the most current data.
- **Clear Currency**. The system removes all currency settings.
- No Change (represented by a blank line). This option allows you to explore the options in the drop-down list and return to the previous setting even if you do not remember what it was. This option is not required at the across-Work Area level.

The current setting for each Table instance is displayed in the columns **Source Currency** (for labels) and **Refresh TS** (for timestamps).

The settings you select apply only to the current submission. After you submit the job, the settings return to the default value, which is to use the current data. If you want to reuse the settings you specified or make a few changes, go to the My Home page, click the **Job ID**, and click **Re-Submit**. You can modify all settings as necessary.

When you use the Most Current Label or specify a specific snapshot, you can work iteratively; the system preserves your first selections as you continue to work on additional Table instances.

Example 1

Table instance DEMOG has the following currencies:

- 01JAN = INTERIM1
- 01FEB = INTERIM2
- 01MAR
- 01APR = FINAL
- 01MAY

Table instance VIT has the following currencies:

- 01JAN = INTERIM1
- 15FEB
- 20MAR

You can select:

A Snapshot Label. If you select FINAL, the system displays FINAL for DEMOG and does not change the default setting of Current for VIT because VIT does not have the label FINAL. If you then select INTERIM1, the system displays

INTERIM1 for VIT and does not change the setting for DEMOG because it already has a label displayed.

- Most Current Label. Given the same Table instances at their default Current setting, if you selected Most Current Label, the system would display FINAL for DEMOG and INTERIM1 for VIT at the same time because those are the most recent timestamps with a label for each Table instance.
- Most Current Data. In either case, if you selected Most Current Data after setting labels for the two Table instances, the system would reset the data currency for both Table instances to Current. If the submission ran with these settings, the system would process the 01MAY timestamped data in DEMOG and the 20MAR timestamped data in VIT.

Example 2

If you are running a report on data from five studies, each of which uses a different Work Area, and three of the studies are closed and all their Table instances labeled FINAL, one of the studies is near completion, and the other has completed the first interim analysis, you could select the label FINAL at the across-Work Area level to pick up all the Tables instances in the closed studies and some of the Table instances in the nearly completed study. You could then select Most Current Label at the across-Work Area level to get the most recent data with a snapshot label in the noncompleted studies. All other data would still be set to Current.

Limit Snapshot by Cut-Off Date Use this option to limit the snapshots available for selection to those up to and including a particular point in time. For example, you may not want to use any labels that have been applied to data in the last month. You can select a cut-off date from a calendar.

The cut-off date affects the snapshot labels displayed in all the Data Currency lists of values. By default, the cut-off date is the current date (sysdate).

Setting Data Currency Across All Work Areas

If you want to use a label that is assigned to data in different Work Areas, use the Use **Snapshot** drop-down at the top of the Data Currency tab:

- (Optional) Select a cut-off date; see "Limit Snapshot by Cut-Off Date" on page 5-8.
- 2. The Use Snapshot drop-down displays all snapshot labels assigned to any of the data for the submission, arranged by timestamp with the most recent first, with the standard options at the bottom. Do one of the following:
 - Select a snapshot label and click **Apply**. The system displays that label for each Table instance that has the label, regardless of which Work Area the Table instance is in. Table instances that do not have the selected label are not affected.
 - Select **Most Current Label** and click **Apply**. The system displays the most recent label associated with every source Table instance that has a label, regardless of the text of the label or what Work Area the Table instance is in.
 - Select **Most Current Data** and click **Apply**. The system overwrites all labels you have applied and resets all source Table instances to use the most current data.
 - Select **Clear Currency** and click **Apply**. The system removes all currency settings.

Setting Data Currency for Table Instances in a Single Work Area

To set source data currency for multiple Table instances in the same Work Area, use the **Snapshot Label** drop-down in the Work Area's row:

- (Optional) Select a cut-off date; see "Limit Snapshot by Cut-Off Date" on page 5-8.
- The Use Snapshot drop-down in each Work Area's row displays all snapshot labels assigned to any of the data in the Work Area for the submission, arranged by timestamp with the most recent first, with the standard options at the bottom. Do one of the following:
 - Select a snapshot label. The system displays that label for each Table instance in the Work Area that has the label. Table instances that do not have the selected label are not affected.
 - Select **Most Current Label**. The system displays the most recent label associated with every source Table instance in the Work Area that has a label, regardless of the text of the label.
 - Select **Most Current Data**. The system overwrites all labels you have applied and resets all source Table instances in the Work Area to use the most current data.
 - Select **Clear Currency**. The system removes all currency settings from all source Table instances in the Work Area.
 - Select the blank line to leave any previous settings unchanged.

Setting Data Currency for a Single Source Table Instance

To set source data currency for one Table instance at a time, use the **Snapshot Label** drop-down in the Table instance's row:

- (Optional) Select a cut-off date; see "Limit Snapshot by Cut-Off Date" on page 5-8.
- The Use Snapshot drop-down in each Table instance's row displays all snapshot labels assigned to any of the data in the Table instance, arranged by timestamp with the most recent first, with the standard options at the bottom. Do one of the following:
 - Select a snapshot label. The system displays that label for the Table instance.
 - Select **Most Current Label**. The system displays the most recent label associated with the Table instance.
 - Select Most Current Data. The system overwrites any label you have applied and resets the Table instances to use the most current data.
 - Select Clear Currency. The system removes the currency settings from the Table instance.
 - Select the blank line to leave the previous setting unchanged.

Note on Load Sets and Data Currency: You cannot specify a snapshot in a source system to load into Oracle LSH. Oracle LSH loads the most current data available in the location you specify. Oracle LSH records the data currency of the loaded data as follows:

For Oracle Clinical Data Extract Oracle and SAS Views, the system gives the timestamp of the most recent batch validation job in Oracle Clinical (unless you specify a Current view, in which case the system uses the sysdate).

If you run a Load Set for which the system uses the batch validation timestamp more than once before batch validation runs in Oracle Clinical (and the Load Set version and Parameter settings remain the same), the system considers the run a duplicate job and does not execute the load unless you specify Force Duplicate Execution.

- For all other loads from Oracle systems, the system uses the sysdate at the time of the Load Set execution.
- For loads of data in files (SAS and text) there is no data currency given. However, you can apply a label to the target Table instances.

Setting Load Set, Data Mart, or Program Parameters

This section contains the following topics:

- Setting Parameters on page 5-10
- Load Set Submission Parameters on page 5-11
- Data Mart Submission Parameters on page 5-17
- Program Submission Parameters on page 5-19

In many Execution Setups you can set Parameter values to determine how or on what data a job is executed. Some Parameters are required; if you do not supply a value, the execution fails. Some Parameters may have a fixed value that you cannot change.

Each type of Load Set and Data Mart, and some types of Programs have different predefined Parameters that are explained in the sections below.

Setting Parameters

In the Parameters subtab of a Load Set, Data Mart, or Program check the current settings of the Parameters and change them if necessary.

- 1. In the Submission Parameters subtab, the system displays the following information:
 - **Parameter Required?** If set to **Yes**, the Parameter must have a value or the job cannot run. If set to No, a value is not required.
 - **Parameter Value**. If the Parameter currently has a value, the system displays the value.
- 2. Set the Parameters that are required and any others you choose to set. Settable Parameters have an enterable field in the Parameter Value column. Depending on how each Parameter is defined, you can set its value in one of the following ways:
 - Enter a value. Some Parameters are defined so that the system checks the value you enter when you submit the Execution Setup.

Note: Some Parameters may accept multiple values. In this case, enter a comma (,) between one value and the next. Never enter a comma as part of a single value; the system interprets it as the delimiter between two values.

- Select a value from the drop-down list.
- Click the Search icon:



The system then displays the values the Parameter is allowed to have. Click the Quick Select icon to select a value:



(or click the checkbox in the **Select** column and then the **Select** button) for the value you want. Or, if multiple values are allowed, click multiple checkboxes or Select All.

Load Set Submission Parameters

Different types of Load Sets have different predefined Parameters, described below:

- SAS on page 5-11
- Text on page 5-12
- Oracle Tables and Views on page 5-15
- Oracle Clinical Global Meta-Data on page 5-15
- Oracle Clinical Data Extract Views on page 5-16
- Oracle Clinical Data Extract SAS Views on page 5-16
- Oracle Clinical Study Data on page 5-16
- Oracle Clinical Design and Definition on page 5-16
- Oracle Clinical Labs on page 5-17
- Oracle Clinical 4.5 Stable Interface on page 5-17
- Oracle Clinical Randomization on page 5-17

SAS Using a SAS Load Set you can load a single data set or multiple data sets contained in a SAS transport file. The predefined Parameters for SAS Load Sets are:

- BLOB ID (Temporary). Do not enter a value for this parameter. It is for internal use only.
- **Dataset File Name.** Browse to the file you want to upload. If you want to use a remote file, leave this field blank and enter appropriate values for the following parameters.
- **Load from Server OS.** You have the option to load a data set from your local computer or from a remote system. Set this parameter to Yes (default is No) if your data set is either on the Oracle LSH DP server or on another computer that has its drives NFS-mounted on the DP server computer. If you set this parameter to No, you must upload a data set file from your local computer.

Note: The system can load remote SAS data set files only from an Oracle LSH DP Server that is running the SAS and the SQL*Loader services. See the chapter on Setting Up Services in the Oracle Life Sciences Data Hub System Administrator's Guide for more information.

- **Server OS Filename**. If you set Load From Server OS to Yes, enter the absolute path of the remote data set file else leave this parameter blank.
- **Maximum Allowed Errors**. Tolerance factor; the maximum number of invalid records you are willing to accept before SQL*Loader stops the loading process and marks the Load Set job as failed. The default value of this parameter is 99999.

Note: If you are uploading a SAS CPORT or XPORT file, note that the value you enter here applies to each data set contained within the CPORT or XPORT file.

Direct. If set to Yes (default is No), the system uses the direct path INSERT to load data from the SAS dataset file into the Oracle LSH target Table instance.

Note: When writing to multiple Table instances, if all the Table instances are not of the Transactional High Throughput processing type, the system uses the direct path INSERT for the Transactional High Throughput processing type Tables and the conventional INSERT for Tables of other data processing types. The Load Set job completes with warnings and writes warning messages to the job log.

Drop and Recreate Indexes. If set to Yes (default), and if the value of the parameter Direct is Yes, the system drops all non-unique indexes before running a data-loading job and recreates the non-unique indexes after loading data into the target Tables. The system does not drop indexes if Direct is set to No.

Text Using a Text Load Set, you can load a single text file in either fixed or delimited format. The predefined Parameters for Text Load Sets are:

- **Text Data File Name**. Browse for the text data file you want to load.
- **Data Format.** Choose either Fixed or Delimited:
 - Fixed. The system uses the Load Set's target Table Descriptor Column definitions to interpret the data type and length of the values in the text file. The file must contain the correct number of characters for each value in each column of each record.
 - **Delimited**. With delimited records, you specify the character used in the source file between each record as the separator character. Different records in the same column can be of different lengths, up to the maximum allowed. The system loads the contents between the separator character into each consecutive Column of the target Table instance.

For example, if you have a Table instance with Columns Patient ID, Patient Initials, and Date of Birth, and the separator character was a comma, and the date format was DDMMYYYY, the first two records might look like this:

54602, EKP, 04081969

```
66781, BAH, 22011975
```

Delimiter Character. (Required for Delimited-format Load Sets only.) Specify the character used as the value delimiter in the source text file. In the example above, the comma (,) is the separator character. The default character is the comma (,). You can use any two unicode characters as a delimiter. For example, to use tab as the delimiter character, enter \t.

Note: Even if you specify that this is a fixed format Load Set, this Parameter is displayed. The system does not use this value.

Enclosing Character. (For Delimited-format Load Sets only; recommended but not required.) If any record value may contain the delimiter character, you need an enclosing character. Specify the character used to enclose each value. The default character is double quotation marks (").

For example, if a double quotation mark (") were the enclosing character, the same two records would look like this in the source text file:

```
"54602", "EKP", "04081969"
"66781", "BAH", "22011975"
```

You can use any single unicode character as an enclosing character.

Both delimiter and enclosing characters should be characters that never appear in the data content of the file.

The delimiter character and the enclosing character must be different. If they are the same, the Load Set execution will fail.

Note: Even if you specify that this is a fixed format Load Set, this Parameter is displayed and is required. The system does not use this value.

- Skip Records. If you prefer not to load records at the beginning of the file, enter the number of records you want the system to skip. The default value is zero (0).
- **TMP BLOB ID**. This Parameter is for internal use only. Do not modify it.
- **Max Errors**. Tolerance factor; the maximum number of invalid rows you are willing to tolerate before the SQL*Loader stops the load process. If you do not enter a value here, the job fails on the first error and generates an error file. The default value is 99999.
- Date Format. Enter the date format used in the source text file, if any. If you do not enter a value, the system uses the format DD-MON-YYYY. If you enter a value, you must enter a valid Oracle to_date format string. Valid formats include:

```
DD-MM-YYYY, DD-MON-YYYY, DD.MM.YYYY, DD.MON.YYYY,
DD/MM/YYYY, DD/MON/YYYY, MM-DD-YYYY, MM.DD.YYYY,
MM/DD/YYYY, YYYY-MM-DD, YYYY-MON-DD, YYYY.MM.DD,
YYYY.MON.DD, YYYY/MM/DD, YYYY/MON/DD
```

Load From Server OS. You have the option to load a file from your local computer or from a remote system. Set this parameter to Yes (default is No) if your file is either on the Oracle LSH DP server or on another computer that has its drives NFS-mounted on the DP server computer. If you set this parameter to No, you

must upload a text file from your local computer when running the Text Load Set job by providing its name in the Data File Name parameter.

Note: The system can load remote text files only from an Oracle LSH DP Server that is running the SQL*Loader service. Contact your Oracle LSH administrator for more information.

- **Server OS Filename**. If you set Load From Server OS to Yes, enter the absolute path of the remote file with the filename and extension, else leave this parameter blank.
- **Direct.** Set to Yes if you want to use the direct path INSERT to load data from the text file into the Oracle LSH target Table. If the Table Descriptor mapped to the Text Load Set is not of the Transactional High Throughput processing type, the system loads data using the conventional INSERT and writes warning messages to the job log.

Note: See the Oracle Database Utilities Guide (part number B14215-01) for more information on this SQL*Loader Command-Line Parameter.

(Optional) Rows. For direct path loads (when you set Direct to Yes), this parameter indicates the number of rows that SQL*Loader reads together at one time from the datafile before writing them to the target Table and committing to the database. If you leave this parameter blank, by default the system reads all the rows from the datafile and then writes the data to the target Table.

For conventional path loads, (if you set Direct to No), this parameter indicates the number of rows that SQL*Loader assigns to the bind array. If you leave this parameter blank, Oracle LSH calculates the number of rows.

Note: A very high or a very low value for Rows can adversely affect the system's performance. Enter a value only if you are absolutely sure that you need to change this.

See the Oracle Database Utilities Guide (part number B14215-01) for more information on this SQL*Loader Command-Line Parameter.

- **Drop and Recreate Indexes.** If set to Yes (default), and if the value of the parameter Direct is set to Yes, the system drops all non-unique indexes before running a data-loading job and recreates the non-unique indexes after loading data into the target Tables. The system does not drop indexes if Direct is set to No.
- Recoverable. Set to Yes (default) if you want the system to recover data in the event of a failure. If set to No, the data becomes unrecoverable because SQL*Loader does not maintain a redo log file for the data.

Note: See the Oracle Database Utilities Guide (part number B14215-01) for more information on the SQL*Loader UNRECOVERABLE clause. To download a PDF copy of the guide, go to the Oracle Technology Network and paste the following URL in the address bar:

http://download.oracle.com/docs/cd/B19306_ 01/server.102/b14215/part ldr.htm#i436326

Oracle Tables and Views Using an Oracle Tables and Views Load Set, you can load one or more tables or views from an Oracle system. The predefined Parameters for Oracle Tables and Views are:

- **Remote Location**. From the drop-down list, select the Remote Location from which you want to load tables or views.
 - If the correct location does not appear on the list, you may need to set up your own connection to it. Click the **Preferences** link at the top of the screen and follow instructions in "User Connections" on page 1-6. You must have a valid username and password on the remote location to run the Load Set.
- **Direct.** Set this parameter to Yes if you want to use the direct path INSERT to load data into target Table instance(s) of Transactional High Throughput data processing type.

Note: When writing to multiple Table instances, if all the Table instances are not of the Transactional High Throughput processing type, the system first inserts data into the Transactional High Throughput processing type Tables using the direct INSERT and subsequently inserts data using the conventional INSERT into Tables of other data processing types. The Load Set job completes with warnings and writes warning messages to the job log.

Drop and Recreate Indexes. This parameter applies only when you set Direct to Yes.

If set to Yes (default), the system drops all non-unique indexes before running a data-loading job and recreates the non-unique indexes after loading data into the target Table instances. The system does not drop indexes if Direct is set to No.

This parameter applies only to Load Sets loading data into Table(s) of Transactional High Throughput data processing type.

Logging. This parameter applies only when you set Direct to Yes.

If set to Yes (default), in the event of a failure the system can recover data committed to the database. If set to No, the system does not maintain a redo log file and cannot recover any data when a database failure occurs.

Oracle Clinical Global Meta-Data Oracle Clinical Global Meta-Data Load Sets load the OC Questions (with DVGs, if any) and Question Groups you have defined in a particular Oracle Clinical Domain and converts them to Oracle LSH defined objects. The predefined Parameters for Oracle Clinical Global Library Meta-Data Load Sets are:

Remote Location. Click the Search icon, search, and select the Remote Location from which you want to load Oracle Clinical Global Library meta-data. If the correct location does not appear on the list, you may need to set up your own

connection to it. Click the Preferences link at the top of the screen and follow instructions in "User Connections" on page 1-6. You must have a valid username and password on the remote location to run the Load Set.

Library Domain Name. From the list of values, select the name of the Oracle Clinical Global Library Domain that you want to load.

Oracle Clinical Data Extract Views Oracle Clinical Data Extract Oracle Views Load Sets load the OC DX Oracle views and data. They have the following predefined Parameters:

- Remote Location. Click the Search icon, search, and select the Remote Location from which you want to load data and meta-data. If the correct location does not appear on the list, you may need to set up your own connection to it. Click the Preferences link at the top of the screen and follow instructions in "User Connections" on page 1-6. You must have a valid username and password on the remote location to run the Load Set.
- **View Type.** From the list of values, select the Oracle Clinical Study or Study Set Access Account that maintains the views you want.

Oracle Clinical Data Extract SAS Views Oracle Clinical Data Extract SAS Views Load Sets load OC DX SAS views and data and meta-data. They have the following predefined Parameters:

- Remote Location. Click the Search icon, search, and select the Remote Location from which you want to load data. If the correct location does not appear on the list, you may need to set up your own connection to it. Click the Preferences link at the top of the screen and follow instructions in "User Connections" on page 1-6. You must have a valid username and password on the remote location to run the Load Set.
- View Type. From the list of values, select the Oracle Clinical Study or Study Set Access Account that maintains the views you want.

Oracle Clinical Study Data Oracle Clinical Study Data Load Sets load Study-specific nonpatient data, including discrepancies, DCFs, page tracking, patient statuses, and more. They have the following predefined Parameters:

- Remote Location. Click the Search icon, search, and select the Remote Location from which you want to load data. If the correct location does not appear on the list, you may need to set up your own connection to it. Click the Preferences link at the top of the screen and follow instructions in "User Connections" on page 1-6. You must have a valid username and password on the remote location to run the Load Set.
- **Study**. Specify the study from which to load data.

Oracle Clinical Design and Definition Oracle Clinical Design and Definition Load Sets load the meta-data on which CRFs are based, including DCMs, DCIs, Procedures, Copy Groups, and DX Queries and Templates. They have the following predefined Parameters:

Remote Location. Click the Search icon, search, and select the Remote Location from which you want to load meta-data. If the correct location does not appear on the list, you may need to set up your own connection to it. Click the Preferences link at the top of the screen and follow instructions in "User Connections" on page 1-6. You must have a valid username and password on the remote location to run the Load Set.

Study. Specify the study from which to load data.

Oracle Clinical Labs Oracle Clinical Labs Load Sets load lab reference ranges and associated meta-data from Oracle Clinical Labs-related tables. They have the following predefined Parameters:

- Remote Location. Click the Search icon, search, and select the Remote Location from which you want to load labs meta-data. If the correct location does not appear on the list, you may need to set up your own connection to it. Click the Preferences link at the top of the screen and follow instructions in "User Connections" on page 1-6. You must have a valid username and password on the remote location to run the Load Set.
- **Lab**. Specify the lab for which to load data.

Oracle Clinical 4.5 Stable Interface Oracle Clinical 4.5 Stable Interface Load Sets load any Oracle Clinical table that is documented in the Oracle Clinical 4.5 Stable Interface Guide.

They have one predefined Parameter: **Remote Location**. Click the Search icon, search, and select the Remote Location from which you want to load data or meta-data. If the correct location does not appear on the list, you may need to set up your own connection to it. Click the Preferences link at the top of the screen and follow instructions in "User Connections" on page 1-6. You must have a valid username and password on the remote location to run the Load Set.

Oracle Clinical Randomization Oracle Clinical Labs Load Sets load real or dummy treatment pattern information for Oracle Clinical studies. They have the following predefined Parameters:

- Remote Location. Click the Search icon, search, and select the Remote Location from which you want to load real or dummy data. If the correct location does not appear on the list, you may need to set up your own connection to it. Click the Preferences link at the top of the screen and follow instructions in "User Connections" on page 1-6. You must have a valid username and password on the remote location to run the Load Set.
- **Study**. Specify the study for which to load real or dummy treatment codes.

Data Mart Submission Parameters

Different types of Data Marts have different predefined Parameters, as follows:

- Text on page 5-17
- Oracle Export on page 5-18
- SAS on page 5-18

Text Text Data Marts put the Oracle LSH data into one or more text files. They have the following predefined Parameters:

- Zip Result Flag.
 - No. If set to No, the system does not generate a zipped file. The Data Mart output consists of one text file for each Table Descriptor and the log file. The system disregards the defined Export Filename.
 - **Zip**. If set to Zip, the system generates a zipped file that includes the text files generated for each Table Descriptor and the log file.

- **Both**. If set to Both, the system generates a text file for each Table Descriptor, creates a zipped file that contains all the text files and the log file, and also leaves a copy of each text file outside the zipped file.
- First Row Desc. If you are loading a fixed-format Text Data Mart, this Parameter must have a value. It determines the way the Data Mart handles the first row for each Table Descriptor:
 - **Yes**. If set to Yes, the system inserts the Column names as the first row in the text file for each Table Descriptor. If the Column name is too long for its length, the system truncates it. If it is a different format, the system inserts a warning in the Data Mart log file.
 - No. If set to No, the system starts the file with the data of the first record, not the column names.
- Operating System. Select your operating system: UNIX or MS Windows. The system inserts the appropriate carriage return for the operating system at the end of every record.
- **Separator Character** (Delimited-format Text Data Marts only). Oracle LSH appends the separator character (delimiter) to every column value of every row (except the last value, where there is a carriage return instead) in order to clarify where one value ends and the next one begins.
 - The separator character should not appear as part of any column value of any record. The default value is a comma (,). You can enter any other single character.
- **Enclosing Character** (Delimited-format Text Data Marts only). If you select Yes for the Use Enclosing Character Parameter, the system prepends and appends the enclosing character to every character and date column value of every record. The character should be one that does not appear as part of any column value of any record. The default value is a double quotation mark (").
- **Use Enclosing Character** (Delimited-format Text Data Marts only). Select Yes or No to determine whether or not Oracle LSH uses the enclosing character or not.

Oracle Export The Oracle Export Utility requires the following parameters. More information is available in the Oracle Export Utility documentation.

- **Compress**. Should Oracle Export export data into a single extent? The default value is Y.
- **Statistics**. Specifies the type of database optimizer statistics to generate when the exported data is imported. Options are ESTIMATE, COMPUTE, and NONE. The default value is ESTIMATE.

SAS SAS Data Marts have the following Parameters:

- **Mode**. Select the mode that corresponds to the type of output you need: CPORT, XPORT, or Dataset. The default value is CPORT.
- Zip Result Flag. The Zip Results Parameter setting has an effect only for SAS Data Marts of the Dataset mode. CPort and XPort Data Marts cannot be zipped.

For SAS Dataset Data Marts, if set to No, the system does not generate a zipped file. The Data Mart output consists of one sas7bdat file for each Table Descriptor, plus the log file. If set to Zip, the system generates a zipped file that includes the sas7bdat file generated for each Table Descriptor and the log file. The system also generates and uploads the individual SAS data sets for each Table Descriptor as separate outputs.

Program Submission Parameters

Oracle BI Publisher Programs

Oracle LSH BI Publisher Programs have the following predefined submission Parameters:

- BIP Report Output Format. Contains a list of output formats supported by BI Publisher. Select the desired report output format. An Oracle LSH Definer may have set a value for this Parameter from an Oracle LSH BI Publisher Program. You can change this value to generate a report in another format.
- **BIP Template**. This refers to the layout template that you need to attach to a BI Publisher report. You must type out the name of the layout template (the value in the **Name** field from the BI Publisher Layout screen) in the text box manually. A template name may already be present that an Oracle LSH Definer set at the time of creating the Program. Do not change this name unless you really want to use another template and are sure its template file exists in your local system.

Note: Refer to the BI Publisher Report Designer's Guide for complete details. You can browse through the documentation online and download what you need from the Oracle Technology Network. Use this hyperlink to go to the list of available documentation for the Oracle Business Intelligence Suite Enterprise Edition (version 10.1.3.4) http://download.oracle.com/docs/cd/E10415 01/doc/nav/portal booklist.htm

Informatica

The Informatica adapter has the following predefined Parameters:

- Bulk Load. Set this Parameter to Yes if you use bulk loading in the Informatica workflow. Oracle LSH supports bulk loading of data only for the staging data processing type. The system drops all indexes on the staging Tables and recreates them after job execution, when you set this Parameter to Yes.
- **Drop and Recreate Index**. If set to Yes, the system drops all indexes on all target Table instances before the Oracle LSH Informatica Program is executed, and recreates them after execution. If you do not want to recreate indexes for all the target Table Descriptors, you can call an Oracle LSH API that allows selective index management. See "Using APIs" in the Oracle Life Sciences Data Hub Application Developer's Guide.
- **Recover Workflow**. If set to Yes, Oracle LSH recovers a suspended Informatica workflow using the Informatica recover mechanism. If set to No, Oracle LSH aborts a suspended Informatica workflow and restarts it.
- **WF Name**. This is the name of the Informatica workflow that you want Oracle LSH to execute. You must provide this name at the time of submitting the Oracle LSH Informatica Program's Execution Setup.

Running Report Sets and Workflows

See the following topics on generating Report Sets and Workflows:

- Setting Submission Details on page 5-3
- Setting Source Data Currency on page 5-6

- Instances Subtab on page 5-20
- Ready and Refresh on page 5-21
- Setting Parameters for Report Set and Workflow Submission on page 5-21

Instances Subtab

The submission screen displays different information for Report Sets and Workflows in the Instances subtab:

Report Sets For Report Sets, you see the Report Set structure. Expand the Report Set node (+) to see all chapters, expand chapters to see sections, and so on. You can **Expand All**, expand a particular node, or select a **Focus** icon to hide the other nodes. (To see all nodes again, click the Report Set title just below Expand All and Collapse All.)

Click any chapter or section's hyperlink to set its Report Set Entry Parameters or the Parameters of its assigned Program instance; see Setting Parameters for Report Set and Workflow Submission on page 5-21.

Check the box in the **Include** column to include a chapter or section (Report Set Entry) in the execution. Uncheck the box to exclude that Report Set Entry.

Workflows For Workflows, you can expand the Workflow node (+) to see all executable objects contained in the Workflow. Click any object's hyperlink to view or set its submission Parameters. See "Setting Load Set, Data Mart, or Program Parameters" on page 5-10 for information on setting Parameters for each object type.

Report Sets and Workflows The Instances subtab displays the following information:

- Full Title. For Report Sets, this column displays each Report Set Entry's concatenated full title that includes its Entry Number Prefix, Parent Number, Delimiter, Entry Number, Entry Number Suffix, and Title.
 - For Workflows, this column displays the name of each executable object contained in the Workflow.
- **Ready**. If a checkmark in a green circle is displayed, all required Parameters associated with the object on that line have a value. For Parameters with a static list of values, the system checks if the value is valid.
 - If an X in a red circle is displayed, at least one Parameter does not have a value, or has an invalid value. See "Ready and Refresh" on page 5-21
- **Validation Status** of the object on that line.
- Volume Name. (Applies only to Report Sets) If the Report Set Entry begins a new volume of the Report Set, the system displays the volume name.
- **Program Name**. (Applies only to Report Sets) If a Program instance is assigned to the Report Set Entry, the system displays its name.
- Program Checked Out By. (Applies only to Report Sets) If the assigned Program instance is checked out, the system displays the username of the person who checked it out.
- **Planned Output Name**. (Applies only to Report Sets) If a Planned Output of the assigned Program instance is assigned to the Report Set Entry, the system displays its name.

Filename Reference. (Applies only to Report Sets) If there is a Planned Output assigned, the system displays its filename.

Ready and Refresh

Use the **Ready** column and the **Refresh** button to ensure that all required Parameters have values and to validate the values before you submit the job. You cannot submit the job until the Parameter values are ready.

The system displays the **Ready** icon (below) if all required Parameters associated with the object on that line have a value and if all Parameters with a static list of values have a valid value. The system checks all Report Set Entries that are children of the Report Set instance or Report Set Entry for which the icon is displayed; if any child Report Set Entry is not ready, the **Not Ready** icon is displayed for the parent as well.

The system displays the **Not Ready** icon (below) if any required Parameter does not have a value, or if any Parameter with a static list of values has an invalid value.

Ready



Not Ready



Use these icons to find missing and invalid values, fix them, and then click the **Refresh** button at the top of the screen. The system then validates all values for all included Report Set Entries or the whole Workflow at once, including Parameters whose values are passed from another Parameter and those that are validated programmatically, and resets the icons in the Ready column.

Note: If you have included or excluded Report Set Entries since the last time you refreshed, you may need to click **Refresh** before you can submit the job.

Setting Parameters for Report Set and Workflow Submission

This section contains the following topics:

- Program Parameters on page 5-21
- Report Set and Workflow Parameters on page 5-22
- Post-Processing Parameters on page 5-22
- Setting All Parameters for a Report Set or Workflow Submission on page 5-24

Program Parameters

A Report Set contains Programs that may have Parameters, and a Workflow may contain Programs, Load Sets or Data Marts that may have Parameters. You may need to set values for these Parameters to determine which data the system processes.

Report Sets To see Program Parameters in a Report Set, do the following:

- 1. Click the hyperlink for a Report Set Entry (chapter or section). The Report Set Entry Execution Setup screen opens.
- Click the Program subtab. The system displays the Parameters of the Program assigned to the Report Set Entry. This Program generates the report associated with the Report Set Entry's chapter or section.

3. Follow instructions in "Setting All Parameters for a Report Set or Workflow Submission" on page 5-24.

Workflows To see Parameters of Load Sets, Programs, or Data Marts contained in a Workflow, do the following:

- 1. Click the hyperlink for the Load Set, Program, or Data Mart. The Execution Setup screen for that object opens.
- Click the Program subtab. The system displays the Parameters.
- **3.** Follow instructions in "Setting All Parameters for a Report Set or Workflow Submission" on page 5-24.

Report Set and Workflow Parameters

In the Parameters subtab there may be Parameters set up specifically to share their value to other Parameters in the Report Set, Report Set Entry, or Workflow.

See "Setting All Parameters for a Report Set or Workflow Submission" on page 5-24 for instructions on setting these Parameters.

Post-Processing Parameters

The following Parameters are used to determine whether PDF post-processing occurs, and if so, how to format the Report Set.

Depending on how the Report Set is defined, you may not be able to change these values or even see all these Parameters. See "Report Set and Workflow Parameters" on page 5-22 for instructions.

Post-Process (Report Set-level only) If set to **Yes**, the Report Set uses post-processing to generate one or more volumes of concatenated reports in PDF format. If set to No, the system disregards all the other Post-Processing and Overlay Templates Parameters. The Programs run and produce individual outputs.

Post-processing may take a long time, so you may prefer to run a Report Set without it while you are developing the Report Set and are primarily concerned with testing its Programs.

Paper Size Select either A4 (European and Japanese standard) or US Letter (North American standard).

Note: The system uses this setting to determine which OTD Files to use from the specified OTD. Setting this Parameter does not guarantee that your reports will print correctly for the size of paper. That depends on the OTD file itself and on the output of the Program.

Language In Oracle LSH Release 2.1.4 there is only one option: English, United States.

Start Page Number (Report Set-level only) Enter a number. The actual starting page number displayed on the first page of the Report Set is always one (1). The value of the Starting Page Parameter does not change this. However, if your Report Set is really a continuation of another Report Set that you have defined separately, you may want to enter the number of pages in the first Report Set as the value for the Starting Page Parameter. XML Publisher displays page numbers as "1 of x," "2 of x," and so on. If you

enter a Starting Page value of 400, XML Publisher displays page one as "1 of (x+400)" where *x* is the number of pages in the current Report Set.

Watermark Text Enter the text, if any, that you want in the watermark. (A watermark is text printed across the page so that it appears to be beneath the content of the report.) If the Overlay Template Definition file you specify does not have a watermark defined, the system ignores this value.

If you want the watermark to display the current validation status (Development, Quality Control, or Production) of the Report Set or Report Set Entry, enter: <VS>

To substitute your own terminology for any of the three validation statuses, enter three pipes (1) after the VS, each followed by the value you want to display when the validation status is Development, Quality Control, or Production, respectively. For example:

- To display "Dev," "QC," or "Final," enter: <VS | Dev | QC | Final>
- To display no watermark if the validation status is Production, but "Dev" or "QC" if the validation status is Development or Quality Control, enter: <VS | Dev | QC | >

You can also have a string of fixed text on either side of the validation status or its equivalent, or only fixed text.

- To display y text before the validation status and x text after it, enter: y <VS|Dev|QC|Final> x
- To display the string xyz by itself, enter: 'xyz'

Examples of Validation Status-Based Watermark Values

Parameter Value	Development	Quality Control	Production
<vs></vs>	Development	Quality Control	Production
<vs dev="" final="" qc="" =""></vs>	Dev	QC	Final
<vs dev qc ></vs dev qc >	Dev	QC	<none></none>
$y < VS \mid Dev \mid QC \mid Final > x$	y Dev x	y QC x	y Final x

Coversheet (Report Set-level only) If set to Yes, XML Publisher incorporates the coversheet in the PDF output. The default setting is No.

Coversheet Orientation (Report Set-level only) Select either **Portrait** (vertical) or Landscape (horizontal) for the paper orientation default value for the cover sheet. The default value is Portrait.

TOC (Report Set-level only) If set to **Yes**, XML Publisher generates a table of contents (TOC) for the Report Set. If set to No, XML Publisher does not generate a table of contents.

TOC Orientation (Report Set-level only) Select either **Portrait** (vertical) or **Landscape** (horizontal) for the paper orientation default value for the table of contents. The default value is Portrait.

Pre-Narrative Orientation Select either **Portrait** (vertical) or **Landscape** (horizontal) for the paper orientation default value for narratives that appear before or instead of reports. The default value is Portrait.

Post-Narrative Orientation Select either **Portrait** (vertical) or **Landscape** (horizontal) for the paper orientation default value for narratives that appear after reports. The default value is Portrait.

Note: There is no Parameter for content orientation because the system determines this automatically based on the actual dimensions of each Program output.

The following Parameters appear only for Report Set Entries:

Calc Title Do not enter a value here. This Parameter may be used to receive a value generated by the Program instance during Report Set execution.

Hlink1...5 Target You can define hyperlinks to other Report Set Entries in the Overlay Template. If you want to create a hyperlink to another Report Set Entry in this Report Set Entry in the Report Set output, enter the target Report Set Entry's name here. Use the other Hlink...Target Parameters to create links to additional Report Set Entries.

Hlink1...5 Text For each Hlink...Target Report Set Entry you defined, enter the hyperlink text you want displayed. If you leave this blank the system uses target Report Set Entry's Full Title.

Setting All Parameters for a Report Set or Workflow Submission

Depending on how each Parameter is defined, you may or may not be able to change its value. If you can set its value, you will be able to do one of the following in the Default Value column:

Enter a value. Some Parameters are defined so that the system checks the value you enter when you submit the Execution Setup.

Note: Some Parameters may accept multiple values. In this case, enter a comma (,) between one value and the next. Never enter a comma as part of a single value; the system interprets it as the delimiter between two values.

Click the Search icon:



The system then displays the values the Parameter is allowed to have. Click the Quick Select icon to select a value:



(or click the checkbox in the Select column and then the Select button) for the value you want. Or, if multiple values are allowed, click multiple checkboxes or Select All.

The system displays the following information for each Parameter:

- **Prompt**. The Prompt identifies the Parameter.
- **Allowed Values**. The system displays the method that determines the Parameter's allowed values, if any:

- **None**. The system does not limit the values you can enter. However, during execution the system may validate the value you enter.
- Static List of Values. You must pick from a list of values that do not change.
- **Program Generated List of Values.** You must pick from a list of values that are generated dynamically.
- Classification List of Values. You must pick from a list of values that are derived from a classification hierarchy level.
- Valid indicates whether or not the value is valid. See icons under "Valid" below.
- **Propagation** indicates whether the Parameter is a source or target of value propagation, or neither. See icons under "Propagation" below.

Valid

The system displays the Ready icon if the value is valid or if there is no value and none is required. The system displays the Not Ready icon if the value is not valid or it there is no value and the Parameter is required.





Not Ready



Propagation

The icon in the Propagation column indicates whether the Parameter is a source or target of value propagation, or neither.

Parameter shares its value with one or more Parameters



Parameter gets its value from another Parameter



No value propagation



Resubmitting a Job with the Same or Similar Settings

You can resubmit a job with the same settings or modify existing settings as necessary.

- Go to the **My Home** page.
- Click the **Job ID** hyperlink. The Job Execution Details screen opens.
- Click **Re-Submit**. The Submission Details screen opens.
- Make any changes required to system parameters, submission parameters, or data currency.
- Click **Submit**. The system submits the job.

Creating Data Visualizations

This section contains the following topics:

- About Visualizations on page 6-1
- Creating a Visualization on page 6-2
- Setting Data Currency and Blinding Values on page 6-2

About Visualizations

Visualizations are onscreen displays of data immediately upon request. In the Oracle Life Sciences Data Hub (Oracle LSH) you can open supported visualization tools directly from the Visualizations subtab of the Reports tab to create data visualizations.

Before you can create a Visualization, a Definer must set up a Business Area instance containing pointers to the data you require. The Definer classifies the Business Area instance so that Oracle LSH displays it appropriately, according to your company's classification system, in the Visualizations subtab of the Reports tab. You open the visualization tool within the context of a particular Business Area and have access to the data in that Business Area from that visualization tool. See "Defining Business Areas for Visualizations" in the Oracle Life Sciences Data Hub Application Developer's Guide for more information.

Oracle LSH security controls access to the data.

You can find documentation for Oracle Discoverer Plus and Oracle Business Intelligence Enterprise Edition on the Oracle Technology Network, go to the Oracle Technology Network at: http://www.oracle.com/technology/index.html

For information on using Oracle Discoverer Plus 10.1.2.3 to create visualizations, see the Oracle Discoverer Desktop User's Guide. To see a PDF copy of this book, enter the following URL:

```
http://download-west.oracle.com/docs/cd/B25016_
04/doc/dl/bi/B13917_03/B13917_03.pdf
```

For information on using Oracle Business Intelligence Enterprise Edition 10.1.3.3 to create visualizations—Answers and Dashboards—see the Oracle Business Intelligence Answers, Delivers, and Interactive Dashboards User's Guide. To see a PDF copy of this book, enter the following URL:

```
http://download.oracle.com/docs/cd/E10415_
01/doc/bi.1013/b31767.pdf
```

For information on other visualization tools that your company has created or supports, follow your company's instructions.

Creating a Visualization

To find a Business Area instance and create a Visualization:

- Go to the Visualizations subtab of the Reports tab.
- From the Select Hierarchy drop-down list, select the classification hierarchy that applies to the data you need, according to your company's classification system.
 - Oracle LSH populates the lower part of the screen with nodes representing the high-level values of the classification hierarchy you selected.
- Expand the + nodes to see more specific classifications until you find the Business Area you are looking for.

Note: If you cannot find the Business Area you are looking for, it is possible that the Oracle LSH Definer did not classify it. You must contact the Oracle LSH Definer responsible for creating and maintaining Business Areas, or if you have sufficient privileges, classify the Business Area yourself.

See "Classifying Objects and Outputs" in the chapter on common development tasks in the Oracle Life Sciences Data Hub Application *Developer's Guide* for instructions.

4. Click the Business Area's icon:



Oracle LSH opens the Launch Visualization screen.

5. If you have the necessary security privileges and want to view noncurrent or blinded data, click Launch Settings. See "Setting Data Currency and Blinding Values" on page 6-2. All blind breaks are audited.

If you want to see current, nonblinded data, click Launch Visualization. Oracle LSH launches the appropriate visualization tool and allows you access to the correct data.

In Discoverer, you must select a Workbook. If you choose to create a new Workbook you see the Business Area and its Tables displayed.

> **Note:** The first time you launch an Oracle Discoverer visualization, a java applet is downloaded to your PC.

When you launch an Oracle Discoverer visualization, you may see a Discoverer login window. You do not need to do anything. Oracle LSH takes care of the login.

When you launch an OBIEE visualization, log in with your Oracle LSH username and password in OBIEE.

Setting Data Currency and Blinding Values

This section contains the following topics:

- Setting the Blind Break Value on page 6-3
- Setting the Shared Snapshot Label Value on page 6-3

You can determine the blinding status and currency of the data you see by clicking the Launch Settings button and selecting a value for Blind Break and Shared Snapshot Label.

Setting the Blind Break Value

This setting is relevant only when one or more source Table instances either currently or formerly contained blinded data. Special privileges are required to view real data that is either currently blinded or was formerly blinded.

Note: You must have Read Data privileges in order to see any data at all.

If you launch the Oracle Business Intelligence Presentation Services from outside Oracle LSH (using the Presentation Services public URL), you cannot see blinded data regardless of your privileges.

The following choices are available depending both on the state of the data and on your security privileges:

- **Not Applicable**. If none of the data has ever been blinded, the only option available is **Not Applicable**. No special privileges are required.
- **Dummy**. If any of the data has ever been blinded, this option appears. If you do not have the privileges, this is the only option available. If you do have the privileges required, you see **Dummy** plus one of the following options, depending on the state of the data and your privileges. Select **Dummy** to view dummy (not real) data.
- **Real (Blind Break)**. If any of the data is currently blinded, and you have the required privileges, you can select this option to view real data in Oracle Business Intelligence Enterprise Edition or Oracle Discoverer, according to your company's policies. The table(s) containing the blinded data remain blinded after you run the visualization.
- **Real (Unblinded)**. If any of the data was formerly blinded but is currently unblinded and none of the data is currently blinded, and you have the required privileges, you can select this option to view real data, according to your company's policies.

Setting the Shared Snapshot Label Value

If all the relevant Table instances share one or more snapshot labels, those snapshot labels appear in this drop-down list and you can select one. See "Setting Source Data" Currency" on page 5-6 for more information on snapshot labels.

In addition, you normally have the option to view the current data.

Tracking Job Execution

This section contains information on the following topics:

- Viewing a Job's Details and Monitoring Its Progress on page 7-1
- Job Statuses on page 7-9
- Execution Statuses on page 7-9

Every time you submit a job of any kind—Program, Report Set, Data Mart, Load Set, or Workflow—the system displays a record of the job in the Job Executions section of your My Home page.

To sort jobs by columns, click the heading of a column. Click the heading again to reverse the order.

Note: Only elevated column headings can be sorted; for example, Job ID or Execution Status.

For information on the Notifications section of the My Home page, see Chapter 2, "Using Notifications". For information on submitting jobs for execution, see Chapter 5, "Generating Reports and Running Other Jobs".

Viewing a Job's Details and Monitoring Its Progress

After you submit a job, note its job ID. To monitor its progress, go to the My Home page and click the hyperlink of the job ID. Click **Refresh** periodically to see the latest job status.

The system provides the following types of information for each job:

- Job Execution Information on page 7-1
- Job Execution Details on page 7-2

See also:

- Job Statuses on page 7-9
- Execution Statuses on page 7-9

Job Execution Information

The system displays the following information about jobs in your Home page:

Job ID The system-generated ID of the job. You can click on the Job ID hyperlink to view execution details for the job. You can sort on the Job ID by clicking the column heading.

Submission Type The way the job was submitted for execution:

- **Immediate**. The job was run as soon as it was submitted.
- **Deferred.** The job was set up to run once at a later point in time from when it was submitted.
- **Scheduled**. The job was one of series of regularly scheduled executions of the same executable object.
- **Backchain**. The job was run as part of a backchain process ensuring that another job ran on the most current data available. For further information see "Backchaining" in the chapter on execution in the Oracle Life Sciences Data Hub Application Developer's Guide.

Job Status The highest job status the job has achieved. If the job is in progress, the status displayed is the current status. If the job has ended in failure or been aborted, the system displays the execution status the job had at the time it ended. See "Job Statuses" on page 7-9. You can sort on the job status by clicking the column heading.

Note: To update the job status as the system processes the job, click Refresh.

Executable Name The name of the object instance executed by this job.

Note: If the name of the executable has a tilde (~) preceding it, it has been removed.

Execution Setup Name The name of the Execution Setup that was executed by this job.

Submit TS The timestamp of the job was submission. You can sort on the submission date by clicking the column heading.

Start TS The timestamp of the beginning of the job. You can sort on the start timestamp by clicking the column heading. Scheduled jobs display the scheduled timestamp as the Start TS if they have not yet begun to execute.

End TS The timestamp of the end of the job. You can sort on the end timestamp by clicking the column heading.

Job Execution Details

If you click on the Job ID hyperlink, the system opens the Job Execution Details screen, displaying the following information for the job:

- Submission Properties on page 7-4
- Outputs Subtab on page 7-5
- Output Properties on page 7-5
- Subjobs on page 7-6

- Submission Parameters on page 7-7
- System Parameters on page 7-7
- Data Currency on page 7-7

You can perform the following actions by clicking the buttons at the top of the screen:

- Click **Return** to return to your My Home page.
- For jobs currently being executed, click Refresh periodically to display the most current information.
- Click **Re-Submit** to submit a new job of the same executable and Execution Setup. By default, the system uses the Parameter values and data currency used by the previous execution. You can change these if necessary. However, the submission uses the latest version of the executable instance, even if the previous submission used an earlier version.

Note: If the Re-Submit button is inactive, something has changed since the job was run—for example, the executable instance has been removed—and the Execution Setup can no longer be submitted.

Click Cancel Job to stop a job that the system is currently processing, or a deferred or scheduled submission that the system has not yet begun to process. If you cancel a scheduled submission, you get a message asking if you want to cancel only the next scheduled job or all scheduled jobs.

Note on Backchain Jobs: When a Definer sets up a backchain execution process, he or she must submit a job for each Program or Load Set that may be executed as part of the backchain (if the system detects more recent data upstream in the data flow). The job is displayed with a Submission Type of Backchain but is inactive until the backchain logic triggers its execution. If you cancel this job, you effectively deactivate the submission. The backchain process that was set up to invoke this job can no longer invoke it or any job that is dependent on it (upstream, or earlier, in the data flow).

Click **View Log** to see the log file for a completed job.

Note: Subjobs have their own log files. Executions of Report Sets and Workflows have subjobs, which are displayed in the Subjobs subtab. Click the link on the Job ID in the Subjobs subtab to see the details of the subjob. You can click the **View Log** button there to see the subjob's log file.

From the **Actions** drop-down list you can select either of the following and click **Go** to perform the action. See "Generating a Coversheet with Validation and Data Currency Information" on page 4-7 for further information.

- **Generate Detailed Coversheet**
- **Generate Summary Coversheet**

Submission Properties

The Job Execution Details screen includes values for the following properties in the upper portion of the screen:

Job ID The system-generated unique ID for the job.

Submission Type The way the job was submitted for execution:

- **Immediate**. The job was run as soon as it was submitted.
- **Deferred.** The job was set up to run once at a later point in time from when it was submitted.
- **Scheduled**. The job was one of series of regularly scheduled executions of the same executable object.
- **Backchain**. The job was run as part of a backchain process ensuring that another job ran on the most current data available. See "Backchaining" in the chapter on execution in the Oracle Life Sciences Data Hub Application Developer's Guide.

Job Status The highest job status the job has achieved. If the job is in progress, the status displayed is the current status. If the job has ended in failure or been aborted, the system displays the execution status the job had at the time it ended. See "Job Statuses" on page 7-9. You can sort on the job status by clicking the column heading.

Note: To update the job status as the system processes the job, click Refresh.

Execution Status The highest execution status the job has achieved, up to and including Complete. If the job is in progress, the status displayed is the current status. If the job has ended in failure or been aborted, the system displays the execution status the job had at the time it ended. See "Execution Statuses" on page 7-9 for a complete list and description of each execution status.

Error Message If the job failed because it generated an error message, this field has a value—either an Oracle error number or a short message. See the log file for further information about the error.

Submitted By The username of the person who submitted the job for execution.

Submit TS The date and time the job was submitted for execution.

Start TS The date and time the job execution started.

End TS The date and time the job execution ended.

Execution Setup The name of the Execution Setup used to run the job.

Execution Setup Validation Status The validation status of the Execution Setup used to run the job.

Executable Name The name of the Program, Report Set, Workflow, Load Set, or Data Mart that was executed.

Executable Type The type of object that was executed: Program, Report Set, Workflow, Load Set, or Data Mart.

Work Area The Work Area that contains the executed object instance.

Application Area The Application Area that contains the Work Area that contains the executed object instance.

Domain The Domain that contains the Application Area that contains the Work Area that contains the executed object instance.

Outputs Subtab

In the Outputs subtab, Oracle LSH displays a row for each output generated by the job, if any.

To view the actual output, click the icon in the View column.

To view output properties, click the hyperlink in the Name column.

Oracle LSH displays the following information about each output:

Name The name of the output.

View Click the icon in this column to view the actual output.

Title The title of the output; may or may not be the same as the name.

Description If the output has a description, the system displays it here.

Primary Flag If Primary Flag is set to **Yes**, the output constitutes a primary reason for the job execution; it is a report on Oracle LSH data.

If set to **No**, the output is a log or error file produced as a result of running the job but not the primary reason for running the job.

Error Flag If Error Flag is set to **Yes**, the output is an error file generated by the job execution.

Output Properties

Click **Print** to print a copy of the output file.

The Output Properties screen displays the following information. Click **Update** to change the fields indicated (if you have the required privileges):

Title The title is relevant only for primary outputs, which display the title. By default the title is the same as the output's name. Click **Update** to change the title.

File Name The file name, with extension, of the actual output. Click **View** to save or display the actual output.

Job ID The unique identifier of the job that produced the output. Click the hyperlink to see job details.

Execution Status The highest execution status reached by the job that produced the output; see "Execution Statuses" on page 7-9.

Description The Definer can enter a description of the output. Click **Update** to change the description.

Validation Status The validation status of the output. If you have the necessary privileges, you can change the validation status; select Support Validation Info from the Actions drop-down list. For information about validation statuses, see "Validating Objects and Outputs" in the Oracle Life Sciences Data Hub Application Developer's Guide.

Execution Setup The name of the Execution Setup from which the output was generated.

Execution User The username of the person who submitted the job that produced the output.

Job Start Time The date and time the job execution started.

Blinding Status Outputs can have the following values for Blinding Status:

- **Not Applicable**. If none of the data in the output was ever blinded, the output's blinding status is Not Applicable.
- **Dummy.** If any of the data in the output is from a blinded Table instance, but the output includes only dummy data, the output's blinding status is Dummy.
- **Blinded**. If any of the data in the output is from a blinded Table instance and the output includes the real, sensitive data, the output's blinding status is Blinded. Special privileges are required to view the output.
- **Unblinded**. If any of the data in the output is from a Table instance that has been unblinded, and none of the data is from a Table instance that is still blinded, the output's blinding status is Unblinded. Special privileges are required to view the output.

Primary Output If Primary Output is set to **Yes**, the output constitutes a primary reason for the job execution; it is a report on Oracle LSH data.

If set to No, the output is a log or error file produced as a result of running the job but not the primary reason for running the job.

Subjobs

If the job is the execution of a Report Set or Workflow, it has subjobs, and the system lists them in this section. Report Set subjobs are the executions of each Program in each Report Set Entry. Workflow subjobs are each Load Set, Program, Report Set, or Data Mart contained in the Workflow.

Program, Load Set, and Data Mart executions do not have subjobs.

Jobs submitted as part of a backchain process are not considered subjobs even though they are not submitted directly by a user. They are listed separately and have a submission type of Backchain.

Name The Job ID of the subjob. You can click on the hyperlink to see the job detail information for the subjob; see "Job Execution Details" on page 7-2.

Type The type of object executed as a subjob by the master job. The system displays not only the object type (Load Set, Program, Report Set, or Data Mart) but also the technology type of the object type; for example, SAS Program or Text Load Set.

Job Status The current job status of the subjob; see "Job Statuses" on page 7-9 for further information.

Execution Status The highest execution status reached by the subjob, up to and including Complete. If the job is in progress, the status displayed is the current status. If the job has ended in failure or been aborted, the system displays the execution status the job had at the time it ended. See "Execution Statuses" on page 7-9.

Submission Parameters

Submission Parameters are the Parameters displayed in the Execution Setup for the object—Program, Load Set, Report Set, Data Mart, or Workflow—executed by the job. The system displays them here with the value this job used for each Parameter. The display is the same as in the Execution Setup; if the job had subjobs, those Parameters are also displayed.

Name The system displays the name of the Program, Load Set, Report Set, Data Mart or Workflow instance that was executed as the master job. If the master job was a Program, Load Set, or Data Mart, you can view its Parameters by expanding its node (+). If the master job was a Report Set or Workflow, when you expand its node (+) the system displays the subjobs. You can expand the node of each subjob to see its Parameters.

Type The type of the object shown on the same line.

Value The Parameter value in effect at submission.

System Parameters

System parameters are predefined. Their values can be set in the Execution Setup definition or, if allowed during Execution Setup definition, at runtime.

Name The system displays the name of the Program, Load Set, Report Set, Data Mart or Workflow instance that was executed as the master job. Expand its node (+) to view the system parameters.

The system displays the external and internal names of the system parameter.

Type The object type of the object listed in the **Name** column.

Value The value in effect at submission. If a parameter is not required, it may have no value.

Data Currency

In the Data Currency subtab you can:

- view data currency information for source Table instances
- apply snapshot labels to source and target Table instances; see "To Apply a Snapshot Label" on page 7-8
- remove snapshot labels from source and target Table instances; see "To Remove a Snapshot Label" on page 7-8

Note: You must have modify privileges on the Table instance to be able to apply or remove its snapshot label.

Table The name of a Table instance that the job either read data from or wrote data to.

Is Target If **Yes**, the job wrote data to the Table instance. If **No**, the job read data from the table instance.

Work Area The name of the Work Area that contains the Table instance.

Application Area The name of the Application Area that contains the Work Area that contains the Table instance.

Domain The name of the Domain that contains the Application Area that contains the Work Area that contains the Table instance.

Snapshot Label The label applied to Table instance records to identify the currency used by the job. For source tables the currency reflects either the refresh timestamp that was current at the time the job started or that was explicitly selected using a snapshot. For target tables, the currency reflects the refresh timestamp that is determined when the job begins to execute. There may one, multiple, or no snapshot labels.

Source Currency Information Reflects data currency in the external system from which the data was loaded into Oracle LSH. This information is supplied by the particular Adapter used by the Load Set to retrieve and load the data and may include a timestamp, a label, and/or a sequence number, depending on the external system and its adapter. This information is carried forward to appear for jobs whose sources are all tables that are populated by the same Load Set.

Refresh TS The refresh timestamp of the Table instance records that corresponds to the end timestamp of the job.

To Apply a Snapshot Label You can apply the same snapshot label to any or all of the source and target Table instances of a job at the same time as follows:

Note: You must have modify privileges on the Table instance to be able to apply or remove its snapshot label.

- 1. Click the **Select** checkbox for each Table instance to which you want to apply a snapshot label.
- 2. Click **Apply Snapshot Label**. The system opens the Apply Snapshot Label screen.
- **3.** In the **Snapshot Label** field, enter the snapshot label you want to apply.
- **4.** Click **Apply**. The system applies the label and returns to the Job Details screen.

Note: You can repeat this procedure to apply additional snapshot labels to the same or different Table instances.

To Remove a Snapshot Label You can remove a particular snapshot label from any or all of the source and target Table instances of a job at the same time as follows:

Note: You must have modify privileges on the Table instance to be able to apply or remove its snapshot label.

- 1. Click the **Select** checkbox for each Table instance from which you want to remove the snapshot label.
- **2.** Click **Remove Snapshot Label**. The system opens the Apply Snapshot Label screen.
- In the **Snapshot Label** drop-down list, the system displays all the labels currently applied to the Table instances you selected. Select one that you want to remove. You can only remove one label at a time.
- Click **Apply**. The system removes the label and returns to the Job Details screen.

Job Statuses

Oracle LSH uses the following statuses to track the progress of a job. You must refresh the screen to see updates.

Pending The job has not yet started running.

The job has begun pre-processing. Started

Executing The Program has connected to database and is running.

Finalizing The job has begun post-processing.

Success The job has completed successfully without warnings.

The job has completed successfully with warnings.

Failure The job has completed with a fatal error.

Aborted The job has been manually aborted.

The job is waiting for the Work Area quiesce process to complete.

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. Therefore the system does not rerun the job unless the person submitting the job chooses to force reexecution. To view the job that this one would duplicate, paste the Duplicate Job ID in the search window and locate the job.

Execution Statuses

Execution statuses provide more detailed information than job statuses. For diagnostic purposes, the system displays the highest execution status a job reached, even if the job ended in failure.

Submitted Submitted is the initial execution status of the job on the job queue. This phase is required.

Initializing The job is waiting for OWB operator processing to begin. This phase is required.

Serializing The job is waiting for another instance of same program to complete. This phase is necessary only if the Program writes to target tables that require serialization. For further information, see "Data Processing Types" in the chapter on execution in the *Oracle Life Sciences Data Hub Application Developer's Guide.*

Backchain The system is performing backchain processing; examining the executable instances upstream to check if they have backchain Execution Setups defined and if so, if their source data is more current than their target data, and rerunning qualifying jobs as necessary to maximize data currency. This phase is required only for jobs specifying a data currency of Most Current Available. For a more complete description of backchaining, see "Backchaining" in the chapter on execution in the Oracle Life *Sciences Data Hub Application Developer's Guide.*

Recovering The system is rolling back data written to tables in the previous execution of same program that did not complete successfully. This phase is required only if the Program writes to targets and last job failed without recovering.

Pre-Execution Function The system is executing a technology-specific pre-execution function. This phase is required only by some technology types.

Obtain Service The system is obtaining a service instance appropriate for the Program's technology type and specified priority, given the service instances currently available for the technology type. This phase is required.

Pending Logon The system is waiting for the Program to start and connect to the database. This phase is required for all jobs except Workflow master jobs.

Executing The Program has connected to the database and is executing. This phase is required.

Completing The system is performing post-execution table completion processing. This phase is required only if the Program writes to target tables.

Complete The job has successfully completed processing.

Fail Backchain The job failed during backchain processing.

Fail Logon The job failed to connect to the database.

Failed The job failed at a phase not specified by one of the other failure statuses.

Rolling Back The system is rolling back target tables to their pre-job state due to the job's execution failure.

Rolled Back The system completed rolling back target tables to their pre-job state due to the job's execution failure.

Managing User Groups

This section contains information on the following topics:

- Adding Users and Assigning Roles on page 8-1
- Removing Users and Unassigning Roles on page 8-2

A user's ability to see reports and definitional objects depends on belonging to a user group with access to the object. In addition, a user must have the proper role within the user group to be able to take any action on the object, such as to view a report or modify a Program definition. As the group administrator, it is your responsibility to add users to appropriate roles in the groups you administer.

A user group can include multiple users and a user can belong to multiple groups.

The LSH system administrator is responsible for creating user groups, assigning roles to the group, and assigning a group administrator to each group. For information on exactly what privileges each role conveys to the user, ask your administrator.

You must have group administrator privileges for a particular user group to add users to the group.

Adding Users and Assigning Roles

To add a user to a group, you must assign the user to a role within the group. You can associate a user with multiple roles within the group as necessary and depending on your company's policies. You cannot assign yourself to a group.

To add a user to a role of a user group, go to the User Group subtab of the Security tab and do the following:

- In the user group box, type the name of the user group to which you want to assign users.
 - If you are not sure of the name, you can use special characters (see "Using Special Characters" on page 3-5).
- 2. Click Search. The system displays all the groups you administer that match the search criteria.
- **3.** Click the required user group. The Group screen appears.
- Click the plus (+) icon to see the roles assigned to the user group.
- Find the role you want to assign to the user you are adding, and click its Add User 5.
- Type the user name, first name, and/or last name of the user.

If you are not sure of the name, you can use special characters (see "Using Special Characters" on page 3-5).

- **7.** Click **Search**. All the users matching the search criteria appear.
- Select one or more users you want to assign to the role.
- **9.** Click **Select**. The system assigns the selected user(s) to this role within this user group and returns to the User Group screen.
- **10.** Repeat until you have added all the users and given each user all the roles he or she needs within the group.

Note: Some roles may include privileges on blinded data. To perform any operation on blinded data and some operations on unblinded data, a user must have one of these roles and, in addition, the appropriate blinding-related application role. Application roles must be assigned to users by an administrator with special privileges: the Data Blind Administrator. Communicate with your Data Blind Administrator to be sure that the users in your group have the blinding-related application roles they need.

Note: Request your system administrator to clear the Oracle Applications cache after you assign user groups or modify user group assignments. See "Clearing Oracle Applications Cache" in the Oracle *Life Sciences Data Hub System Administrator's Guide.*

Removing Users and Unassigning Roles

To remove a user from a role in a user group, go to the User Group subtab of the Security tab and do the following:

- 1. In the User Group box, type the name of the user group to which the user belongs. If you are not sure of the name, you can use special characters (see "Using Special Characters" on page 3-5).
- 2. Click **Search**. The system displays all the groups you administer that match the search criteria.
- **3.** Click the required user group. The Group screen appears.
- Click the plus (+) icon to see the roles assigned to the user group.
- Find the role you want to unassign the user from, and click its plus (+) icon to see the users assigned to the role.
- Find the user you want to unassign from the role, and click its Remove icon.

Note: Unassigning a user from all the roles associated with a user group removes that user from the user group.

Glossary

activity

An element of a Workflow; either an executable object such as a Program, a structural object such as a Fork, or a Notification.

adapter

An interface between Oracle LSH and another system. Oracle LSH includes adapters that allow you to load data into Oracle LSH from other systems, to transform data by creating Programs in integrated development environments, and to create visualizations of Oracle LSH data for display in other systems.

application

The set of all the defined objects required to perform a particular business function such as loading and analyzing data for a study or producing a particular set of reports.

Application Area

A container that is used to develop and manage the Oracle LSH objects required for a single business application (such as a study, project, or set of reports); contains one or more Work Areas where the set of object instances (such as Table and Program instances) necessary for the business application are installed.

Application Area library

A set of object definitions contained directly in an Application Area.

audit

A record of each change made to each record in a Table instance defined with a processing type that includes auditing, with the timestamp of the change and the user ID of the person who made the change. You can recreate the state of data in an audited table as it was at any point in time.

blind break

A single execution of a job on data defined as blinded in Oracle LSH, so that the sensitive blinded data is displayed in the job output, but is not permanently unblinded. Blind breaks may be required for patient medical emergencies or for reporting purposes during the course of a clinical trial.

blinded data

Data that must be hidden in Oracle LSH because its display would reveal patient treatment patterns in a double-blind clinical trial. If you specify that a table supports blinding, Oracle LSH creates a partition, allowing you to load the blinded data in the "real data" partition of the table and, optionally, to load dummy data in the "dummy

data" partition. Oracle LSH requires standard object security privileges to run a Program on dummy data but requires additional security privileges to run the same Program on real (blinded) data.

browse

Navigate through the user interface looking for an output or definitional object.

Business Area

Oracle LSH definitional object used by a visualization tool such as Oracle Business Intelligence Enterprise Edition or Oracle Discoverer Plus to create ad hoc, onscreen visualizations of Oracle LSH data.

check constraint

A check constraint applies to a particular Table column and specifies allowed data values for that column.

child object

An object contained in, or owned by, another object.

classification

(1) The act of associating an Oracle LSH object definition or object instance with one or more values in one or more classification hierarchies, for the purpose of categorizing the object so that it can be found during searching and browsing. (2) The actual classification hierarchy value or set of values associated with an Oracle LSH object definition or object instance. (3) The Oracle LSH subsystem of single- and multi-level hierarchies and their values used in searching and browsing.

classification hierarchy

Hierarchical or flat structure consisting of one or more levels, with one or more values in each level. If a hierarchy contains multiple levels, they must be logically related and the values in each level must be logically related to values in adjacent levels (each value must be related to one and only one value in the next higher hierarchy level, but can be related to many values in the next lower level). Used in searching and browsing.

cloning

A special copy operation for Work Areas that results in an identical Work Area, including all its contained object instances and mappings. All object instances in the clone have the same version number and validation status as their counterparts in the original Work Area, and the two Work Areas share a user-specified label.

constraint

A constraint on an Oracle LSH Table or Column similar to an Oracle column or table constraint. See also **check constraint**, **primary key constraint**, and **unique key constraint**.

Consumer

An Oracle LSH user who retrieves (consumes) information from the Oracle LSH database by running and viewing reports and creating onscreen data visualizations.

container object

An object that contains, or owns, another object; also called a parent object or organizational object.

Data Mart

(1) A large quantity of data extracted from one or more user-defined Oracle LSH Table instances in one of several formats. (2) The definitional object that generates the Data Mart output.

data source

An Oracle LSH Table instance or **source data system** table, view, or data set from which an Oracle LSH Program reads data.

data transformation

See Program.

date data type

The Oracle date data type is defined as the number of days since the beginning of the Julian Calendar in a floating point numeric. Oracle LSH stores all date values in this format but displays dates and accepts entry of dates in one of several European, US or Standard formats (such as DD-MON-YYYY) based on user preference.

Definer

An Oracle LSH user who develops applications by defining objects in Oracle LSH, typically a programmer.

definition

See object definition.

definitional object

Objects defined by the user in Oracle LSH, including Oracle LSH Tables, executables, and their components; includes both object definitions and object instances. See also object definition and object instance.

development environment

An installed Work Area whose usage intent is set to Development and whose database schemas are used for the purpose of developing Oracle LSH object definitions and instances. Oracle LSH supports maintaining separate Work Areas and schemas as development, quality control, and production environments so that data from a development or quality control environment is never mixed with production data.

Domain

A container that is used to group Application Areas and/or other Domains and/or to store and control a library of object definitions.

Domain library

A set of object definitions contained directly in a Domain; intended as a collection of valid, production-quality object definitions suitable for reuse.

dummy data

Alternative data with blinded information obfuscated, processed instead of the real (sensitive, blinded) data for the purpose of testing Programs and producing reports prior to unblinding the real data.

Entry

See Report Set Entry.

execution

(1) The running of a particular Oracle LSH job; for example, running a Program to generate an output. (2) The Oracle LSH runtime subsystem that manages the execution of jobs.

Execution Setup

A defined object that is a component of each Oracle LSH executable object instance (Programs, Report Sets, Data Marts, Load Sets, Workflows) whose purpose is to control the execution of the executable object. It includes input Parameters whose values are either bound or settable at submission. The Execution Setup serves as the basis for the submission form of an executable object.

Execution Template

An Execution Setup that has been explicitly made available for use as a template to other instances of the same executable object definition version. Definers can use Execution Templates as the basis for an Execution Setup in another instance of the same executable object definition.

foreign key constraint

In Oracle LSH, a foreign key constraint defines a relationship between two Table instances in the same Work Area. One installed Table contains a column or set of columns (the foreign key) that corresponds to the column or set of columns comprising the Primary Key of another installed Table in the same schema. The foreign key columns are populated by reference to the values of the other Table's primary key columns. You can define a foreign key only for a Table instance; not a Table definition.

full reload processing

Processing mode for executables writing to Reload Tables in which all rows in a data source are reinserted in their current state by a Program or other executable object, and rows that are not reloaded are soft-deleted. Oracle LSH automatically detects which rows are new inserts, which are updates, which are unchanged and implicitly deletes any rows that are not reloaded.

IDE

See Integrated Development Environment (IDE).

incremental reload processing

Processing mode for executables writing to Reload Tables in which only those rows that have been added or modified since the last time the same Program or other executable object was run are processed. Unchanged rows can also be reloaded and are ignored by the processing. Incremental reload processing does not delete records and therefore can be used to selectively load different subsets of data without impacting other data in the target table.

index

A non-unique index provides a way to optimize access to data in a table via columns included in the index. See also unique indexes unique key constraint and primary key constraint.

instance

See object instance.

installation

The process of converting selected Oracle LSH object instances in a single Work Area into installable components such as PL/SQL packages and DDL scripts and instantiating those components in an Oracle LSH schema.

Integrated Development Environment (IDE)

In Oracle LSH, an external source code development software application that can be launched directly from the Oracle LSH user interface for the purpose of writing or editing Program source code, integrated with Oracle LSH by a system that includes: a syntax-directed editor, graphical tools for program entry, integrated support for compiling and running the program, and a mechanism for relating compilation errors back to the source. Oracle LSH Release 2.1.4 supports IDEs for Oracle PL/SQL, SAS, and Oracle Reports.

library

See Domain library and Application Area library.

Load Set

an Oracle LSH executable whose purpose is to move data and meta-data into Oracle LSH from an external source data system that is connected to Oracle LSH by an adapter customized for the source data system. The adapter handles constraints on the structure of the target Table Descriptors, provides the Parameters, and supplies the source code for the installed Load Set.

mapping

(1) (noun) A mapping defines the relationship between a Table Descriptor in a Program or other executable object and a Table instance in a Work Area that the executable object reads from or writes to. Each column of the Table Descriptor and the Table instance must be mapped to a column of a compatible data type and length in the other, or to a constant. (2) (verb) Creating a mapping.

master job

A job launched by the submission of an Execution Setup. When a user submits a Load Set, Program, Data Mart, Report Set, or Workflow, the resulting job is a master job. Some master jobs have subjobs: Report Set executions include Program executions as subjobs. Workflow executions may include Program, Load Set, Data Mart, and/or Report Set executions as subjobs.

narrative

A block of text that annotates a generated report or report set. May precede the body of the report (pre-narrative) or follow it (post-narrative).

Notification

Message routed within Oracle LSH or (optionally) by email; contains a subject name, text, and one or more hyperlinks to Oracle LSH outputs or other objects; can be used for collecting informal approvals or comments or for broadcasting text.

object definition

The definitional meta-data details of an Oracle LSH object, stored in an Application Area or Domain library and created (normally) through an instance of the definition that is contained in a Work Area. The meta-data varies depending on the definition's object type, but includes a name, subtype, validation status and classification(s). For example, Table definitions also contain Columns and Constraints; Program definitions contain Source Code, Parameters, Planned Outputs, and Table Descriptors.

object instance

An instance of Oracle LSH object definition; contains a pointer to an object definition, which contains most of the definitional details, and a few attributes including a name, subtype, validation status, classification(s), and (for executable instances only) mappings. Object instances are located in a Work Area and installed in the database.

object subtype

Subcategory of a predefined object type that serves to differentiate classification and security requirements among objects of the same object type; for example, Financial Report Set and Clinical Report Set. Object subtypes have the same operations allowed as their object type. One subtype for each object type is shipped with Oracle LSH; an Administrator may define additional object subtypes.

object type

A predefined category of Oracle LSH definitional objects shipped with Oracle LSH; for example, Report Sets or Tables. Object instances constitute a separate object type; that is, a Report Set instance is a different object type from a Report Set definition and can have different classification and security requirements defined at the subtype level.

operation

An action that can be performed by a user on an object; for example, view or modify. Operations are predefined for object types. The Oracle LSH Administrator defines roles and associates them with operations on object subtypes as part of the Oracle LSH security system.

Oracle LSH schema

A set of Oracle database schemas (one primary schema and one or more auxiliary schemas) that owns all permanent objects that are populated by the installation of a single Oracle LSH Work Area, including tables, views, packages, or schema stores such as Discoverer Plus EULs. an Oracle LSH schema also contains all data loaded into its tables.

organizational object type

Category of Oracle LSH object types used solely as containers of other objects; includes Domains and Application Areas.

output

In Oracle LSH, a file generated by the execution of a Program, Workflow, Report Set, or Data Mart; either the primary output reporting on or containing data, or a secondary output such as a log file or an error file. Also called an actual output to distinguish it from a Planned Output definition.

Overlay Template Definition (OTD)

A layout template for PDF outputs of Oracle LSH Report Sets; can include boilerplate text, graphical elements such as logos and lines, and placeholders for Parameter values for data (such as Study) and publishing specifications (such as font style and size).

Parameter

A defined object that acts as a simple scalar variable and is based on an Oracle LSH Variable definition. In a Program or other Oracle LSH executable object, an input Parameter supplies a runtime value to the executable object and an output Parameter holds a value generated during execution. In addition to a pointer to an Oracle LSH Variable, a Parameter contains a list of allowable values, rules for validating the

supplied value, a mandatory/not mandatory setting, and classification(s). Parameter values can be propagated within the context of a Report Set or a Workflow.

Parameter Set

A definitional object created automatically by Oracle LSH to contain the Parameters contained in a single primary definitional object.

parent object

An object that contains, or owns, another object; also called a container object.

Planned Output

An object definition contained in an Oracle LSH executable object definition that serves as a placeholder for an actual output to be generated during execution and specifies the classification(s) of the actual output. Primary Planned Outputs report on or contain data; secondary Planned Outputs include log files and error files.

primary key constraint

A column or set of columns whose value(s) identify a row in a Table as unique; often a unique ID. The system enforces the following constraints on the data contained in primary key columns: values cannot be null, and the value or combination of values in primary key column(s) must be unique for each row.

privilege

In Oracle LSH, a privilege is an operation on an object subtype assigned to a user through a role in a user group. A user has the privilege necessary to perform an operation on an object when he or she is assigned to a user group that has access to the object, and within that user group is assigned to a role that allows the operation on the object's subtype.

production environment

An installed Work Area whose usage intent is set to Production and whose database schemas contain only valid Oracle LSH objects interacting with real clinical or other data in an audited and regulatory-compliant manner.

Program

An Oracle LSH defined executable object that functions as a computer program to transform data and/or generate one or more reports. Contains Source Code and one or more Table Descriptor(s); may also contain one or more Planned Outputs and Parameters.

quality control (QC) environment

An installed Work Area whose usage intent is set to Quality Control and whose database schemas are used for the purpose of testing Oracle LSH object definitions, adapters, and loads of data and meta-data before using them in a production environment. Oracle LSH supports maintaining separate Work Areas and schemas as development, quality control, and production environments so that data from a development or quality control environment is never mixed with production data.

report

(1) The primary output generated by a Program; contains a set of clinical or other data for in-house review or submission to regulatory agencies. Reports may be displayed as listings, figures, tables, or text and may be generated in one of several file formats. (2) A predefined output generated by the system on demand; for example, a coversheet for a report.

Report Set

(1) A collection of reports generated by a single execution process and integrated with a table of contents. May be generated in PDF format using custom templates with graphics and including bookmarks and hyperlinks. (2) The primary Oracle LSH definitional object that produces the Report Set output.

Report Set Entry

One of the items in the table of contents of a Report Set; may contain other Report Set Entries, narratives, and/or one or more reports generated by a single Program; a Report Set chapter or subchapter.

role

(1) User-defined component of the Oracle LSH security system corresponding to a professional title or function; assigned to operations on object subtypes, to user groups, and to individual users within those groups. To perform a particular operation on an Oracle LSH object, a user must have a role assigned to that operation for the object's subtype in a user group with access to the object. (2) Predefined application roles shipped with Oracle LSH that control access to portions of the Oracle LSH user interface.

runtime

The point in time when a user submits an executable object for execution.

runtime subsystem

The Oracle LSH subsystem that manages the execution of installed executable object instances as well as the tracking of, and access to, the progress and results of the executions.

search

Facility for finding existing defined objects and outputs in Oracle LSH, using criteria including object type, name, and classifications (including keywords). Oracle LSH includes simple and advanced search options.

snapshot

A set of data, or data and objects, at a particular point in time.

Source Code

(uppercase) A secondary definitional object owned by an Oracle LSH Program containing a file of user-written computer instructions (**source code**) whose purpose is to perform a task.

source code

(lowercase) The computer instructions used by a Program to perform a task. Source code may be written in an Integrated Development Environment (IDE) in the context of an Oracle LSH Program or written outside Oracle LSH and then uploaded and stored in Oracle LSH; in Oracle LSH, source code is stored in the definitional object called **Source Code**.

source data system

An application external to, but integrated with, Oracle LSH that collects data loaded into or accessed by Oracle LSH through an adapter.

Source Table Descriptors

A **Table Descriptor** used to link a Program to a Table instance containing data used as input to the Program.

staging table processing

Data processing type used for Programs that write to Tables defined as Staging. If the Table is defined as Not Audited, each time the Program that writes to it is executed, the system hard-deletes the data resulting from the previous execution. If the Table is defined as Audited, the system saves a copy of the complete set of data resulting from the previous execution, but operates only on current data.

structure

See Workflow Structure and Table structure.

subjob

A subjob is a job that is executed as part of a master job. For example, Report Set executions are master jobs that include Program executions as subjobs, and Workflow executions are master jobs that can include Load Set, Program, Report Set, and/or Data Mart executions as subjobs.

subtype

See object subtype.

Table

an Oracle LSH meta-data representation of a table-like object (Oracle view or SAS dataset); includes a description of the object as a whole, its columns, and constraints that apply to one or more of its columns. Appears as an Oracle view to all installed Programs except those based on SAS technology, where it appears as a SAS dataset or SAS view.

Table constraint

See constraint.

Table Descriptor

An instance of an Oracle LSH Table defined within an Oracle LSH executable object—Load Set, Program, Workflow, Report Set, or Data Mart—or in a Business Area, for the purpose of linking the executable object or Business Area to an installed Table and its data by mapping.

Table structure

The number of Columns a Table definition contains and the data type and length of each one.

Target Table Descriptors

A **Table Descriptor** used to link a Program to a Table instance to which the Program writes data.

test environment

See quality control (QC) environment.

transform, transforming Program

See **Program**.

transactional processing

Data processing type used to write to Table instances defined as transactional. Programs writing to transactional Tables must use explicit Insert, Update, and Delete commands in their source code.

transition

An element of a Workflow that defines one workflow activity as sequential to another and specifies the condition, if any, for the execution of the second.

unblind

Change a Table instance's blinding status from Blinded to Unblinded.

unique key constraint

A column or combination of columns that identifies a row in a Table as unique; similar to a primary key except that null values are allowed in columns that are part of the unique key. You can explicitly disallow null values at the column level.

usage intent

An attribute of Work Areas indicating the Work Area's purpose; either Development, Quality Control, or Production. Oracle LSH enforces rules based on the interaction of a Work Area's usage intent attribute and the validation status of the Work Area and the object instances contained in it.

user group

Unit defined by an Oracle LSH Administrator for use in security that includes one or more users and one or more roles, and is assigned to one or more Oracle LSH objects. To perform an operation on an Oracle LSH object or output, a user must belong to a user group assigned to that object and be assigned a role within that user group that permits the operation on the object's subtype.

validation

(1)Process through which object definitions and instances reach the stage where they can be declared stable and valid according to an Oracle LSH customer's policies. (2) Process required by regulatory agencies to certify that a computer system used in clinical trials is stable and functions properly.

validation status

An object attribute that indicates the life cycle stage of the object: Development, Quality Control, Production, or Retired. Oracle LSH enforces rules based on the interaction of a Work Area's usage intent attribute and the validation status of the Work Area and the object instances contained in it.

Variable

An Oracle LSH defined object equivalent to a SAS variable or Oracle table column that serves as a source definition for Oracle LSH Parameters and Table Columns. Oracle LSH creates Variables from Oracle table columns and SAS dataset variables the first time a particular Oracle table or SAS dataset is loaded into Oracle LSH. The user can define Variables during Parameter or Table Column definition.

version

Restorable, saved state of an object definition.

visualization

An ad hoc graphical and/or text presentation of data created in an interactive onscreen environment.

Work Area

A container in an Application Area where Definers create the object instances required to support the business purpose of the Application Area. Work Areas have two special operations: <code>installation</code>, during which some or all of the object instances contained in the Work Area are instantiated or upgraded in an Oracle LSH schema and the Oracle LSH schema is created if necessary; and <code>cloning</code>, which creates a duplicate Work Area that shares a label with the original Work Area.

Workflow

An executable Oracle LSH defined object that includes other Oracle LSH executable defined objects such as Load Sets, Programs, Data Marts, and Report Sets, as well as Notifications; executed as a whole in a defined sequence that can include conditional branching.

Workflow Structure

Predefined object that controls the execution of the Workflow; a Workflow Structure can detect the completion status of the previous activity and fire the next one or more activities as specified for their type: Start, End, And, Or, Fork.

XML Publisher

Oracle product integrated with Oracle LSH for use in generating PDF-format Report Sets and enabling the use of custom overlay templates. Also used to produce internal PDF-format reports.