Data Qualification Guide

Oracle[®] Health Sciences LabPas
Release 3.1

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About this guide

In this preface

Overview of this guide

The LabPas *Data Qualification Guide* provides step-by-step instructions for reviewing data that is collected in LabPas CT studies.

Audience

This guide is for everyone who uses the Oracle® Health Sciences LabPas application to review study data. This audience includes the study manager or other persons who are assigned these tasks at your facility.

Documentation

All documentation is available from the Oracle Software Delivery Cloud (https://edelivery.oracle.com) and the Oracle Technology Network (http://www.oracle.com/technetwork/documentation).

All documents may not be updated for every LabPas release. Therefore, the version numbers for the documents in a release may differ. For a complete list of the documents in this LabPas release, their release version numbers, and part numbers, see the *Release Notes*.

Item	Description	Last updated
Release Notes	The *Release Notes* document presents information about new features, enhancements, and updates for the current release.	3.1
Known Issues	The *Known Issues* document presents information about known issues for the current release.	3.1
User Guide	The *User Guide* provides online access to all tasks you can perform from the LabPas application, as well as supporting concepts and reference information. You can access the *User Guide* from the Help button in the LabPas application.	3.1
Administration Guide	This guide provides a roadmap for configuring and setting up the LabPas application, setting up the LabPas Recruiting module, and viewing and printing reports. This guide contains step-by-step instructions and field definitions you can use to perform tasks such as setting up roles and permissions; setting up various aspects of a facility, such as instruments, samples, and vessels; and configuring the LabPas user interface and messaging.	3.1
Clinical Trial Design and Resource Management Guide	This guide provides a roadmap and step-by-step instructions for a variety of tasks, such as creating clinics, creating studies, planning clinic schedules, planning staff assignments, configuring and setting up the LabPas application, designing a clinical trial and recruitment, and viewing and printing reports and labels.	3.1
Recruiting User Guide	This guide provides step-by-step instructions for setting up and managing recruitment, including adding and contacting volunteers, scheduling, managing advertising campaigns, and performing other related operations. It also includes instructions for screening volunteers in a clinical trial.	3.1
Sample Management Guide	This guide provides step-by-step instructions for processing and tracking samples in the lab.	3.1
Clinical Data Entry Guide	This guide describes how to use the LabPas application to accomplish the typical tasks you would perform while gathering data during a clinical trial. It contains step-by-step instructions and field definitions you can use to perform data entry while capturing data about doses, samples, tests, adverse events, and other observations.	3.1

Item	Description	Last updated
Data Qualification Guide	This guide provides step-by-step instructions for reviewing data that is collected in LabPas CT studies.	3.1
Installation Guide	This guide provides step-by-step instructions for installing the LabPas application.	3.1
Secure Configuration Guide	This guide provides essential secure configuration considerations for the LabPas application.	3.1
Ad Hoc Reports Database Views Guide	This document provides details of the database views used in ad hoc reports. The descriptions include the details of each view as well as corresponding fields where you can verify data.	3.1
Specification for the HL7 Lab Data Interface	This document provides the information that is needed to set up jobs and exchange files automatically between LabPas facilities and the labs that process their samples.	3.1
Specification for the Mortara E-Scribe Interface	This document provides the information needed to set up jobs and import Mortara ECG files.	3.1
Third Party Licenses and Notices	This document includes licenses and notices for third party technology that may be included in or distributed with the LabPas software.	3.1

If you need assistance

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

C H A P T E R 1

Getting started

In this chapter

The LabPas application

The LabPas application allows you to create, manage, and automate many tasks involved in early phase clinical trials. The application consists of the following modules.

- **LabPas CT module**—Use the LabPas CT module to establish the elements, settings, and properties on which a study is built. You can set up and configure:

  - Users

  - Facilities

  - Instruments

  - Storage devices

  - Sample and vessel types

  - Test panels

  - Global settings

- **LabPas Resource Management**—Use the LabPas Resource Management module to create and manage clinics, studies, and staff assignments.

- **LabPas Recruiting module**—Use the LabPas Recruiting module to manage volunteer recruitment. You can:

  - Develop study-specific call scripts.

  - Define study inclusion and exclusion criteria.

  - Search the recruiting database for potential volunteers.

  - Receive calls from potential volunteers.

  - Manage advertising campaigns.

  - Schedule outgoing phone calls.

  - Track caller responses.

  - Record volunteer information.

  - Create a schedule of events.

  - Schedule and process screening events.

  - Assign volunteers to studies.

- **LabPas DQ module**—Use the LabPas DQ module to review the data that is collected in LabPas CT studies.

Users, permissions, and roles

A system administrator sets up users' security roles and permissions in the LabPas CT module. Security roles define a specific set of permissions, which authorize users to perform certain functions or to access specific pages and data.

When a system administrator assigns you to a role, you are automatically assigned the permissions associated with that role.

For more information on users, security, and permissions, see *Setting up the LabPas CT module*.

Navigation

Most pages in the LabPas application, including the LabPas Resource Management module and the LabPas Recruiting module, have the following sections:

1   *Main menu* (on page 4)

2   *Page heading* (on page 5)

3   *Data frame* (on page 5)
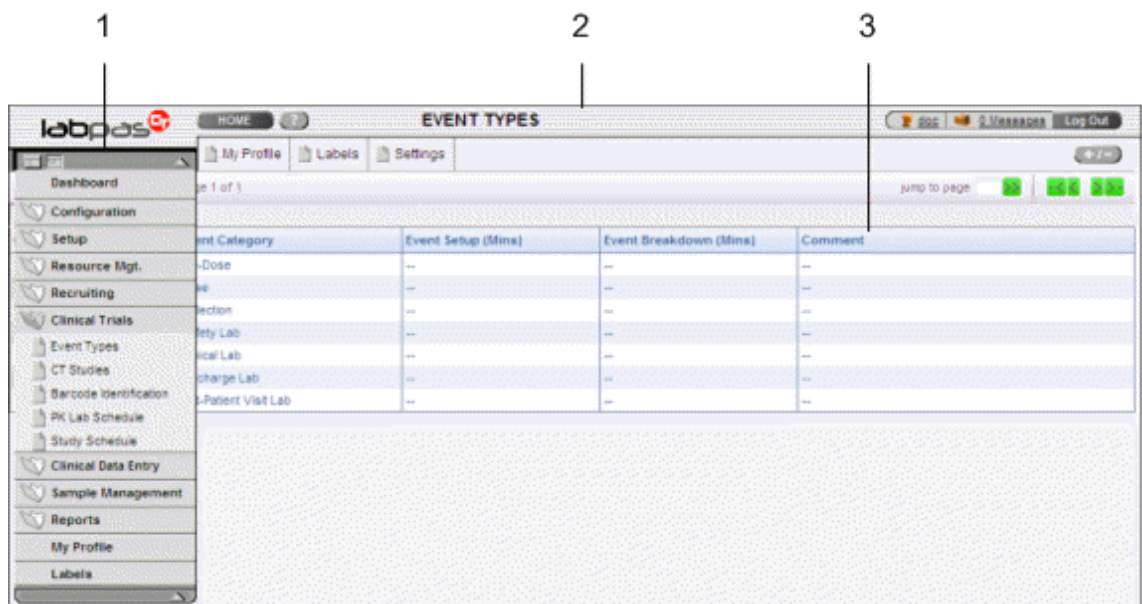
Main menu

The main menu, located in the upper left corner of the page, is a directory of the pages that you access.

- To expand the collapsed main menu, click the down arrow.

  The menu automatically collapses a few seconds after you move the cursor off the menu.

- To keep the main menu expanded, click the page icon (▦).

- To navigate through the application, expand the main menu, click a folder, and select a page in the folder.

Page heading

The page heading is similar on all LabPas pages.
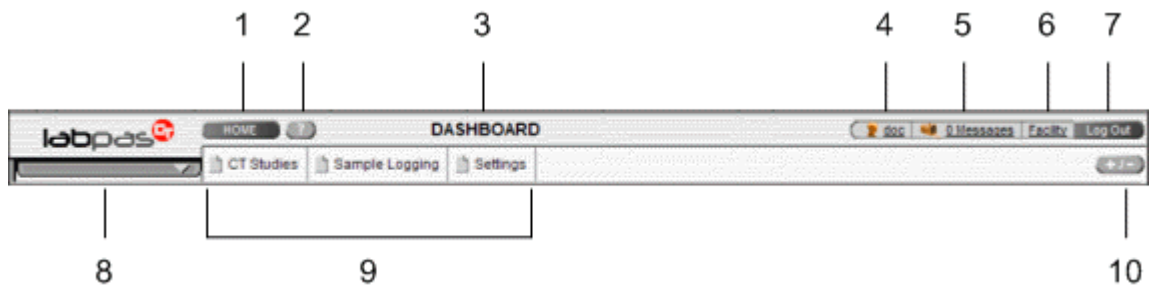
1—Home button	Open your home page, as configured on the My Profile page.
2—Help button	Open the *User Guide*, in a separate window, to the section that corresponds to the current page.
3—Page name	Name of the currently selected page.
4—User name	Your user name. Opens your My Profile page.
5—Message indicator	Open the Inbox page in a new window.
6—Facility name	Name of the facility that you are using. Opens the Change Facility dialog box. This link appears only if you have access to more than one facility.
7—Log Out button	End the current session.
8—Main menu bar	Open the main menu, a directory of the pages that you can access.
9—Bookmarks	Shortcuts to menu options. You create your own bookmarks for frequently used options.
10—Bookmarks button	Open a dialog box where you can select and set the order of up to 10 items to be displayed as bookmarks.

Data frame

The data frame contains one or more of the following.
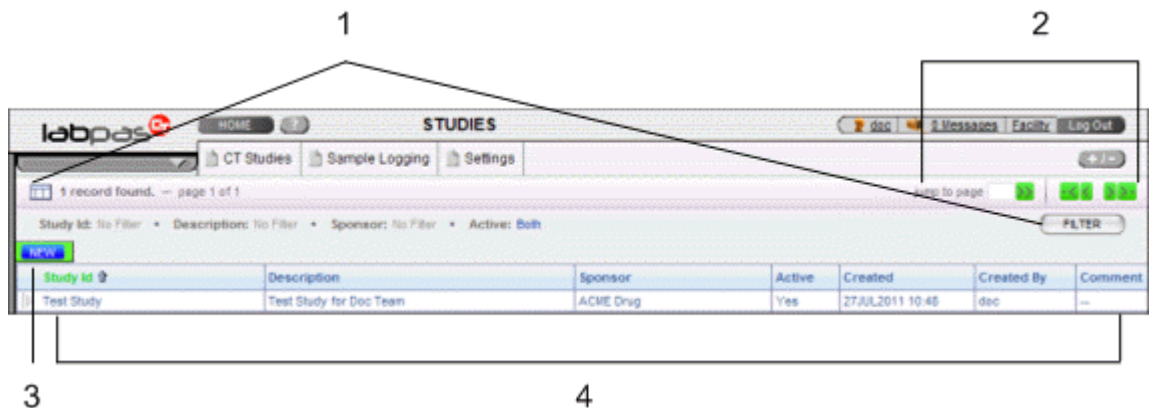
1 **Grid tools**—Use the grid setup and filter options to limit and order your selections.

2 **Navigation tools**—Navigation arrows at the top of a data frame. Use the arrows to navigate between pages. The arrows are enabled only when more than one page of data is available.

3 **Grid function buttons**—Buttons such as ADD, EDIT, and DELETE appear above data grids.

   - Buttons with white backgrounds function only when items in the grid are checked.

   - Buttons with green backgrounds do not require any items to be checked to function.

4 **Data grids**—Generally, data grids are tables of information.

Logging on

You access the LabPas application using a web browser. The LabPas Resource Management module and the LabPas Recruiting module are accessed through the LabPas CT module.

1   To log on, do one of the following:

- In the address field of your browser, type http://*<server name>*/LabPAS and press **Enter**.

- In the address field of your browser, type http://*<server IP address>*/LabPAS and press **Enter**.

- From the desktop, double-click the shortcut for the LabPas CT module.

The User Logon page appears.

2   Type your user ID and password, and click **LOGON**.

> **Note:** The password field is case-sensitive.

Your home page appears.

> **Note:** If the application is not used for a predetermined period of time, your session times out and you must log on again.

Logging off

To exit the LabPas application securely, log off rather than close the web browser. If you do not log off, you might be prevented from logging back on for a short period of time.

If your session times out, log back on and then log off to exit securely from the application.

- In the page header of any page, click **Log Out**.

Changing the contents of the data grid

For each data grid, you can specify the columns to appear in the data frame and the sort order for the data.

To change only the sort order for the currently displayed grid, click the header for any column that displays an up arrow or down arrow.

1   Click the grid setup icon (⊞).

    The Column Selection dialog box for the current data grid appears.

2   Select each column to display.

3   Optionally, select the column to sort on and the sort order for the column.

4   Click **APPLY**.

Filtering grid data

Use the FILTER button to limit the data that appears in the data grid.

1   In the top right corner of any page, click **FILTER**.

The Study Selection Criteria dialog box for the current data grid appears.

2   Enter your selections and click **APPLY**.

Setting a home page

1   In the upper-right corner of any page, click your user name.

The Configure User Profile page appears.

2   From the **Home Page** drop-down menu, select a page name.

3   Click **UPDATE**.

The selected page is now your home page.

Creating a bookmark

Bookmarks are shortcuts that you create for frequently accessed pages. Your bookmarks appear in the page heading. Bookmarks allow you to access a page with a single click.

1   On any page, click the **Bookmark** button ( ) in the page heading

The Bookmarks dialog box appears.

2   To select a page to bookmark, click the arrow to the left of any menu item.

The parent menu item opens and displays the sub-menu items. You can expand only one menu item at a time.

3   Select one or more menu items.

4   Type a sequence number in the field to the right of each item, and click **APPLY**.

You cannot repeat sequence numbers that have already been assigned. For example, you cannot specify that more than one page is sequence number 1.

Deleting a bookmark

1   On any page, click the **Bookmark** button in the page heading.

    The Bookmarks dialog box appears.

2   Click the arrow to the left of any menu item to expand it.

    The parent menu item opens and displays the sub-menu items. You can expand only one menu item at a time.

3   Deselect the menu items that do not require bookmarks.

4   If necessary, enter new sequence numbers for the remaining items.

5   Click **APPLY**.

Working with messages

The LabPas message function allows you to communicate within the application with LabPas users.

Reading a message

1   On any page, click the Messages icon in the page heading.

    The Inbox dialog box appears.

2   Select one or more messages, and click **DISPLAY**.

    Message details appear. You can do the following:

    - Reply to the message.

    - Forward the message.

    - Using the navigation arrows, view next and previous selected messages.

3   Click **DONE**.

4   To close the Inbox, click **DONE**.

Sending a message

1   On any page, click the Messages icon in the page heading.

    The Inbox dialog box appears.

2   Click **NEW**.

    The New Message dialog box appears.

3   Fill in the **To** field with one or more user or group names separated by commas, or select the recipients as follows:

    a   Click the ellipsis button **(...)** next to the **To** field.

        The Address Book dialog box appears.

    b   Select one or more users or groups.

    c   Click **SAVE**.

4   Fill in the **Subject** and **Message Details** fields.

5   Click **SEND**.

6   To close the Inbox, click **DONE**.

Deleting a message

1   On any page, click the Messages icon in the page heading.

    The Inbox dialog box appears.

2   Select one or more messages.

3   Click **DELETE**.

    A confirmation dialog box appears.

4   Click **OK**.

5   To close the Inbox, click **DONE**.

Adding a message group

You can set up groups of users as message recipients.

1   On any page, click the Messages icon in the page heading.

    The Inbox dialog box appears.

2   Click **NEW**.

    The New Message dialog box appears.

3   Click the ellipsis button (**...**) next to the **To** field.

    The Address Book dialog box appears.

4   Click **EDIT GROUPS**.

    The Groups dialog box appears.

5   Click **NEW**.

    The New Group dialog box appears.

6   Enter a name for the group and an optional comment, and select the users to include.

7   Click **SAVE**.

Editing a message group

1   On any page, click the Messages icon in the page heading.

    The Inbox dialog box appears.

2   Click **NEW**.

    The New Message dialog box appears.

3   Click the ellipsis button (**...**) next to the **To** field.

    The Address Book dialog box appears.

4   Click **EDIT GROUPS**.

    The Groups dialog box appears.

5   Select a group and click **EDIT**.

The Edit Group Details dialog box appears.

6   Edit the group information and member list.

7   Click **SAVE**.

Deleting a message group

1   On any page, click the Messages icon in the page heading.

The Inbox dialog box appears.

2   Click **NEW**.

The New Message dialog box appears.

3   Click the ellipsis button (**...**) next to the **To** field.

The Address Book dialog box appears.

4   Click **EDIT GROUPS**.

The Groups dialog box appears.

5   Select a group and click **DELETE**.

A confirmation message appears.

6   Click **OK**.

C HAPTER 2
Data qualification

In this chapter

LabPas DQ module

In the LabPas DQ module, you review data that is collected in LabPas CT studies.

To access the LabPas DQ module:

- You must be assigned a user role.
- You must have valid LabPas DQ module security permissions.

External users who are configured from a second active directory on the LDAP server and users who have been added to the External User Access list are granted access to the study in the LabPas DQ module.

External users can view only data from groups assigned to periods and groups assigned to screening visits with a Released status of Yes. Query records created by internal users are not visible to external users.

> **Note:** External users do not need to be assigned to a role or a facility.

Logging on to the LabPas DQ module

1   In a Web browser, type the following:

    `http://<Server IP address>/LabPASDQ`

> **Note:** In the address field, **LabPASDQ** is case-sensitive.

2   Press **Enter**.

    The logon page appears.

3   Type your user ID and password.

    Use the same user name and password that you used to log on to the network and the LabPas CT module.

4   Click **LOGON**.

    The LabPas DQ module opens. For more information, see DQ navigation.

    If no filter criteria are currently selected, or if criteria are selected but the study is locked, the Selection Criteria dialog box appears. For more information, see *Filter Criteria bar* (on page 21).

5   To set or reset the filter criteria:

    a   Click the **Filter** button.

    b   From the **Study Id** drop-down list, select a study.

    c   Fill in the fields.

        Field descriptions for the Selection Criteria dialog box

Field	Description	Notes
Study Id	Study for which to view data.	REQUIRED.
		Only unlocked studies to which you have access appear.
		Studies are listed alphabetically in ascending order.
Period	Period for which to view data.	
Group	Group number for which to view data.	
Screening Visit	Screening visit for which to view data.	
Adverse Events	• **Yes**—AE forms appear. • **No**—AE forms do not appear.	
Subject No.	Subject number for which to view data.	Subject numbers are separated by commas.

Field	Description	Notes
Screening No.	Screening number for which to view data.	Screening numbers are separated by commas.
Time Point	Time point for which to view data.	
Screening Event	Screening event for which to view data.	
Event Type	Event types for which to view data.	
Approval Status	• **Approved**—Approved items appear. • **Not Approved**—Not Approved items appear. • **Both**—All items, regardless of approval status, appear.	
Monitor Review Status	• **Reviewed**—Reviewed items appear. • **Not Reviewed**—Not Reviewed items appear. • **Both**—All items, regardless of monitor review status, appear.	
Query Status	• **All**—All queries appear. • **Open**—Open queries appear. • **Answered**—Answered queries appear. • **Re-Issued**—Re-issued queries appear. • **Closed**—Closed queries appear.	Default value is All.
Query User Name	The User ID of the user that originally created the query.	
Event Category	The configured event category.	

d   Click **APPLY.**

DQ navigation

The LabPas Data Qualification interface consists of the following areas:

- *Filter Criteria bar* (on page 21)
- *Event Tree* (on page 21)
- Item Details
- *Queries* (on page 25)
- *Change Log* (on page 25)

Filter Criteria bar

The Filter Criteria bar displays the filter selections that are currently applied to the page.

You can filter study data by various fields. If you do not set a filter, the selection defaults to all. By default, the LabPas DQ module displays previously made selection criteria in an unlocked study.

Event Tree

The Event Tree displays the data set for the selected study and its components, according to the settings in the Filter Criteria bar. The event tree is a hierarchy, with collapsible nodes representing each level of study data.

The Study node is the root of the tree. You use the plus sign (**+**) to the left of each node to expand it and the minus sign (**-**) to collapse it.

When you select a node, the data in the Item Details, Change Log, and Queries sections refresh with information about your selection.

A green check mark to the right of an item indicates that it has a Monitor Review Status of Reviewed. The check mark does not appear for items reviewed in the current session. To display items reviewed in the current sessions, refresh the page or log into the LabPas DQ Module again.

Field descriptions for the Event Tree

> **Note:** A red exclamation mark to the right of a node indicates that one or more queries exist in that node or in one of its branches. After you close the queries, the exclamation mark no longer appears the next time you log into the LabPas DQ module.

Level	Node	Description	Notes
1	Study	Root of the hierarchy.	
2	Subject	Each approved subject in the study.	Format: Subject *<subject number>*.

Level	Node	Description	Notes
2	Candidate	Each candidate who fulfills both of the following criteria: • Is not associated with a subject. • Has one of the following statuses: ▪ Accepted ▪ Approved ▪ Completed ▪ Consent Withdrawn ▪ Dropped ▪ Pending Candidate ▪ Screen Fail	Format: Candidate <*screening number*>.
3	AE form	Each AE form associated with the study and subject.	Format: AE <*AE description*>
3	Period and Group	Each period that a subject is scheduled in.	Each entry displays the period number (or a dash, if the period is blank) and group number.
3	Screening Visit and Group	Each screening visit with a completed or in progress event for the current study and subject.	Each entry displays the screening visit and group number.

Level	Node	Description	Notes
4	Event	Each in progress, missed, failed or completed event.	For a scheduled event that is a child of a Period/Group entry, the time point and event type appear.
		Scheduled events appear before ad hoc events.	For a scheduled event that is a child of a Screening Visit and Group entry, the event and event category appear.
		Screening events that are associated with the Check-In or Check-Out event category do not appear.	An AE observation that is associated with an AE form is a child of the AE form. All other observations are children of a Period and Group entry.
			Format for ad hoc PK events:
			• Adhoc - PK Testing
			Format for ad hoc Draw and Testing events:
			• Adhoc *<panel name>*
			Format for ad hoc Other events:
			• Adhoc Other *<category>*
			Format for Observation events:
			• Observation *<event category>*

Item Details

When you select a node other than the study in the Event Tree, related information appears in the Item Details area. The Item Details area lists data item nodes, which can be expanded to display specific item details for the selected data item. The value for each item appears in blue.

When test nodes are not expanded, the test name, test value, and reference ranges display in a string to facilitate reviewing test records in the panel.

Notes:

• A dash (-) appears for a field without a value.

• Event nodes include all data provided on the Study - Events page.

- For all events, the Entry Date/Time node displays the first date and time the data was saved.

  - If data was saved using the Sample page and Sample Logging is required, this is the date and time that the data on the Sample page was saved.

  - If the Sample page is not used, this is the date and time from the Sample Logging page.

Level	Selected Event Tree node	Nodes that appear
1	Study	- Study Information - Group
2	Subject	- Subject Information - Subject Approval - Demographics
2	Candidate	- Subject Information - Demographics
3	AE form	- AE Form Data
3	Period and Group	- Schedule Details
3	Screening Visit and Group	- Schedule Details
4	Dose event	- Dose
4	PK Testing event	- PK Collection
4	Clinical Testing event	- Clinical Draw Data
4	Testing event	- Testing - *<Name of each test>*
4	Other event	- Other *<event category>*
4	Observation event	- Observation

Queries

You use queries to question the data that is displayed in the LabPas DQ module. Each query can include multiple threads. Each thread represents a line of communication between the LabPas DQ module and the Study - Queries page.

Clicking a query expands and highlights the corresponding node in the Event Tree, if the query is associated with an item that is different than the currently selected item. A query brings up the Item Details, Queries list, and Change Logs as if that item were selected within the Event Tree.

The Queries box displays:

• Related queries, when an item associated with a query is selected.

• All threads relating to the query.

• Queries linked to an item's child nodes.

> **Note:** The CT Data Queries report lists all active and closed data queries for a study. For more information, see *LabPas CT Reports (for use with the LabPas CT module)* (on page 37).

Field descriptions for Queries

Field	Description	Notes
Status	Status of the query: • Open • Answered • Re-issued • Closed	Queries can be opened, re-issued, and closed on this page, but they can be answered only on the Study - Queries page.
Field	Name of the item detail against which the query was raised.	
Entry Date/ Time	Date and time the query thread was created.	
Data Status	Status of the data being questioned in the query. • If the query status is Open, Re-Issued or Closed, data status is blank. • If the query status is Answered, data status is Changed or Unchanged.	Data status is selected on the CT Study - Queries page.
Name	User Id of the user that created the query thread.	
Query	Text of the query thread.	REQUIRED.

Change Log

The Change Log displays an audit trail of changes made to data in the node that you select in the Event Tree.

Field descriptions for the Change Log

Field	Description
Change Date	Date the change was made.
Changed By	User name of the person who made the change.
Comment	Comment that was entered for approval.
Change	Descriptive information about the changed item, including the new data entered. Old data appears in brackets.

Reviewing data

Prerequisites:

- You must have the Monitor Review permission (for external users) or the Review Study Data permission (for internal users).

- The data item must be a reviewable item, and must have a status of Approved.

Participants (Subjects or Candidates), Adverse Events, and Event Data are reviewable items:

- Participants are considered approved when they are in a final state (Approved, Screen Fail, Consent Withdrawn, Dropped, or Completed).

- For events that have an associated sample to be considered approved, both the event and the sample must have the Approval Status set to Approved.

To review data, select a node in the Event Tree. You can use the Filter Criteria bar to limit the data that appears in the tree. You can filter study data by various fields. If you do not set a filter, the selection defaults to all. By default, the LabPas DQ module displays previously made selection criteria in an unlocked study.

1. In the Filter Criteria bar, click **FILTER**.

   The Selection Criteria dialog box appears.

2. From the **Study Id** drop-down list, select a study.

3. Fill in the fields.

   Field descriptions for the Selection Criteria dialog box

Field	Description	Notes
Study Id	Study for which to view data.	REQUIRED. Only unlocked studies to which you have access appear.
Period	Period for which to view data.	
Group	Group number for which to view data.	
Screening Visit	Screening visit for which to view data.	
Adverse Events	• **Yes**—AE forms appear. • **No**—AE forms do not appear.	
Subject No.	Subject number for which to view data.	
Screening No.	Screening number for which to view data.	
Time Point	Time point for which to view data.	

Field	Description	Notes
Screening Event	Screening event for which to view data.	
Event Type	Event types for which to view data.	

4   Click **APPLY**.

The filter selections are applied, and your selections appear in the Filter Criteria bar.

5   To view detailed data for a specific study, subject, or event, click its node in the Event Tree.

For more information, see *Event Tree* (on page 21).

The Item Details section of the page is populated with the relevant data. For more information, see Item Details.

If queries exist for the selected node, the Queries section is also populated. For more information, see *Queries* (on page 25).

When you view data items:

- Click **REVIEW** to set the Monitor Review Status of the current data item to Reviewed. A green check mark is displayed for the reviewed data item in the Event Tree after the screen is refreshed.

- Click **UNREVIEW** to set the Monitor Review Status of the current data item to Not Reviewed. The green check mark is not displayed with the data item in the Event Tree when the screen is refreshed.

Modifying the Monitor Review Status for a data item generates an audit trail entry with the source Study Data Approval.

- Monitor Review Status changes for Participants, Adverse Events, and Clinical Events are written to the CT Change Log.

- Monitor Review Status changes for Screening Events are written to the Recruiting Change Log.

Opening a query in the LabPas DQ module

Prerequisites:

- You must have the Create Query permission.

- Item Details must display at least one data item node that includes at least one item detail.

Note: Queries can be answered only on the Study - Queries page.

You can open a query on a blank item.

1 In **Item Details**, click the row of data in question.

The Open Query dialog box appears.

2 Type your text in the **Query** field, and click **SAVE**.

The new query thread appears in Queries with a status of Open, and any collapsed queries are expanded. The new query thread also appears on the Study - Queries page.

Editing a query in the LabPas DQ module

Prerequisites:

- You must have the Create Query permission.

- Item Details must display at least one data item node that includes at least one item detail.

> **Note:** Queries can be answered only on the Study - Queries page.

You can edit the queries with the status of Open or Re-Issued.

1   Click the ellipsis button (**...**) to the left of the query.

   The Edit Query dialog box appears.

2   Edit the **Query** field and click **SAVE**.

   The edited query appears in Queries with the updated Entry Date/Time, and any collapsed queries are expanded. The edited query also appears on the Study - Queries page.

Closing a query in the LabPas DQ module

Prerequisites:

- You must have the Create Query permission.

- Item Details must display at least one data item node that includes at least one item detail.

Note: Queries can be answered only on the Study - Queries page.

Only query threads that have a status of Open, Re-Issued, or Answered can be closed.

1   Click the Close button (**X**) to the left of the query.

    The Close Query dialog box appears.

2   Fill in the **Query** field, and click **SAVE**.

    A new query thread appears in Queries with a status of Closed, and any collapsed queries are expanded. The new query thread also appears on the Study - Queries page.

Re-issuing a query in the LabPas DQ module

Prerequisites:

- You must have the Create Query permission.

- Item Details must display at least one data item node that includes at least one item detail.

Note: Queries can be answered only on the Study - Queries page.

Only query threads that have a status of Answered or Closed can be re-issued.

1   Click the Repeat button ( ) to the left of the query.

The Re-Issue Query dialog box appears.

2   Fill in the **Query** field, and click **SAVE**.

A new query thread appears in the Queries box with a status of Re-Issued, and any collapsed queries are expanded. The new query thread also appears on the Study - Queries page.

Reports

In this appendix

Tasks: View Reports page

On the View Reports page, you view a list of available reports. Reports are arranged by groups, and only one group of reports appears on the page at one time. You can use the **FILTER** button to select groups.

The Standard Reports group is provided with the LabPas CT module and is the default group selected for viewing on the View Reports page. The following reports are provided with the LabPas CT module:

- **LabPas Report**—For use with all modules.
- **Change Log**—Describes security and user additions and modifications.

Tasks: Report Groups page

On the Report Groups page, you view a list of report groups available in the LabPas CT module and maintain the report groups created by all users to categorize their reports.

- *Adding and editing a report group* (on page 49).
- *Deleting a report group* (on page 50).

Report layout

All reports display data that is associated with the current facility only.

All reports are based on the currently selected facility and include a cover page, unless you select the Suppress Cover Page option. For more information, see *Viewing a report* (on page 43).

- Each report cover page includes the following information:
    - Facility Name.
    - Study ID (if relevant).
    - Selection criteria specific to each report (for example, group, period, and sample types).
    - Date (selection or range).

        > Note: Not all reports include the date.

    - Time zone of the facility.
    - Sorting criteria, if relevant.
    - Date the report was printed.
    - User who created the report.
- All reports also include a cover page and a standard header on each page of the report.
- Each report page header includes the following information:
    - Report title.
    - Facility name.
    - Selection criteria specific to each report (for example, group, period, and sample types).
    - Date (selection or range).

        > Note: Not all reports include the date.

    - Time zone of the facility.
- Each report has a standard footer on each page, unless you select the Suppress Page Footer option. For more information, see *Viewing a report* (on page 43). The footer for each report includes the following information:
    - Date the report was printed.
    - Page number/total.

LabPas CT reports

The following reports are available from the LabPas CT module only.

Report	Description
CT Change Log	Includes changes made to study data in the selected study, including any individual components requiring an authorized user's approval.
CT Clinical Data Report	Includes all study data collected for individual subjects, including medical history taken in the LabPas Recruiting module and the most recent sample and test results processed in the LabPas CT module. This report can be restricted to exclude certain data if desired.
CT Clinical Event Deviation	Includes events processed in LabPas CT module or on the Sample Logging page for the selected study that have deviated from the Expected Time. The lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility.
CT Data Queries	Includes all active and closed queries for a study in the current facility.
CT Feces Log	Includes all feces samples that have been processed through the Feces Info task for the selected study.
CT Inventory History	Includes storage details for all ad hoc PK samples and aliquots in the selected study. The report tracks samples as they are moved into and out of specified storage devices.
CT Lab Summary	Includes data for the selected study that is entered as samples and processed through Sample Processing pages and the Worklist. Includes ad hoc PK samples and aliquots.
CT Label Audit	Includes all collection and transfer labels that are created in the selected study, and the printing history of each label.
CT PK Sample Processing Deviation	Includes details of PK samples when processing deviates from the Centrifuge - Time To, Storage - Time To, or Aliquots - Quantity settings defined on the Study - Setup - PK Lab page. Tracks the deviations from Centrifuge Time, Aliquot Number, and Storage Time.
CT PK Sample Processing Instructions	Includes instructions, by sample type, as defined on the Study - Setup - PK Lab page for the selected study. The lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility.
CT PK Sample Processing Log	Includes sample processing instructions and details for all ad hoc PK samples processed in the current facility. Includes comments that are entered on the Sample page or the Sample Logging page, and in the Sample Centrifuge, Sample Aliquoting, and Sample Storage pages. Comments entered on the LabPas CT module Draw page can be overridden on the Sample Logging page.
CT Sample Information	Includes information collected in the Sample Information page, including the Sample Information instructions that are configured for the study and sample type and details of all ad hoc PK samples.

Report	Description
CT Sample Inventory	Includes details of all aliquots and ad hoc PK samples in the selected study, including all sample processing information.
CT Scheduled Events	Includes basic information for all scheduled events in the selected study.
CT Shipments	Includes all cartons, broken down by box and box contents, that are processed through the sample shipping for the selected study. Lists the ad hoc PK samples and aliquots packed in boxes that are associated with the shipment.
CT Shipments 2	Includes all cartons processed through the sample shipping for the selected study. This report can be sorted by shipping criteria. Lists the ad hoc PK samples and aliquots packed in boxes that are associated with the shipment.
CT Urine Log	Includes details of all samples processed through the Urine Info task for the selected study.
CT Worklist History	Includes worklist task step details for samples as they are processed through the Worklist, by participant, for the selected study.
CT Clinical Lab Results	Includes details of all scheduled and ad hoc clinical lab samples for a study.

LabPas Recruiting reports

The following reports are available from the LabPas Recruiting module only.

Report	Description
Recruiter Metrics	Includes metrics for each user authorized to use the Incoming Calls and Outgoing Calls pages in the selected study.
	If the Global Recruiting application setting is not selected, the lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility.
Recruiting Change Log	Includes modifications made to previously recorded data (for example, volunteers, study setup, and study properties) on the Volunteer pages.
	If the Global Recruiting application setting is not selected, the lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility.
Recruiting Media Campaigns	Tracks volunteer response, scheduling, and study participation based on an ad campaign and displays descriptive information about the campaign.
Recruiting Screening Appointment	Includes appointment information for the selected volunteer, including demographic, medical, and testing data.
	If the Global Recruiting application setting is not selected:
	• The lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility.
	• The data in the report is restricted to appointments associated with the current facility.
Recruiting Screening Schedule	Includes the schedule of all approved appointments for volunteers, in order of date and time, including available openings and filled appointments for each time slot.
	If the Global Recruiting application setting is not selected, the lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility.
Recruiting Volunteer Data	Includes a subset of the Recruiting Screening Appointment report. Includes the sections Demographic Information, Emergency Contact, Tobacco History, Medical History, Surgical History, and Concomitant Medications. The Demographic Information section contains a photo of the volunteer.

Report	Description
Study Recruitment	Includes recruitment details for the selected study, including:
	• Number of subjects goal, percent of subjects goal, number of subjects needed to reach subjects goal.
	• Number of backup (alternate) subjects goal, current percent of backup (alternate) subjects goal, current number of backup (alternate subjects needed to reach backup goal).
	• Numbers of volunteers with the following statuses: Promoted that are not an alternate, Promoted that are an alternate, Completed, Scheduled, Revised, Pending, DNQ, CRO, Dropped, and Volunteer Dropped.
SR Label Audit	Provides details of collection labels that have been printed or reprinted in the current facility.
Bio Bank	Used only with the LabPas Bio Banking module.
	Includes two **Bio Bank** Reports:
	• Change Log
	• Bank Shipments
EM Reports	Used only with the LabPas Environmental Monitoring module.
	Includes four **EM Reports:**
	• Audit History.
	• Daily Reading Chart.
	• Readings by Vessel.
	• Readings by Storage Device.

LabPas Resource Management reports

The following reports are available from the LabPas Resource Management application only.

Report	Description
RM Administrative Staff Assignment	Includes details about work shifts and staff assigned to events in a study.
RM Change Log	Includes changes made to clinics, studies, and staff assignment in the LabPas Resource Management application.
RM Staff Schedule	Includes details of events that are assigned to specific users.

Viewing the list of available reports

1   From the main menu, select **Reports > View**.

The View Reports page appears, displaying a list of all available reports.

2   Review the list of reports.

Viewing a report

1   From the main menu, select **Reports > View**.

The View Reports page appears, displaying a list of all available reports.

2   In the Report Name column, click the report type.

The View Reports - Edit page appears. The criteria and fields on this page differ for each report.

> **Note:** Most report types have a criteria choice of either Date Interval or Date Range.

3   Fill in the fields, and click **VIEW**.

The report appears in an Adobe Reader window.

Field descriptions for the View Reports - Edit page

Field	Description	Notes
Study	Study ID.	REQUIRED.
	Either type the Study ID in the field, or click the Lookup icon and select the study from the list in the Study Lookup dialog box.	The Study Lookup dialog box displays only studies to which you have been granted access (on the Study - Properties page.) If you have been granted permission to view all studies on the Security page, the dialog box displays all studies.
Report-specific criteria	Displays different criteria fields depending on the report type. Fields that might appear: • Storage Device • Vessel Barcode • Rack • Box	Most of the report-specific fields appear under the **Study** field and above the **Date Interval** and **Range** fields.
Date Interval	Time interval (for example, Month to Date or Year to Date) used to filter the report.	The selected date choice is the date criteria by which the report is filtered. If you select **Date Interval**, a drop-down field is enabled. If you select **Date Range**, two calendar fields are enabled. You must select either Storage Date Interval or Date Range.

Field	Description	Notes
Date Interval	Time interval (for example, Month to Date or Year to Date) used to prepare the report. If you selected the Date Interval radio button, select a date interval from the drop-down menu.	
Date Range	Used to prepare the report. Filters the report by Date Range.	The selected date choice is the date criteria by which the report is filtered. If you select **Date Interval**, a drop-down field is enabled. If you select **Date Range**, two calendar fields are enabled. You must select either Storage Date Interval or Date Range. Default: Month to Date.
Date Range	Date range for the report. If you selected the Date Range radio button, either type the dates in the **From** and **To** fields, or click the calendar icons and select the dates.	
Report Date Format	Format (for example, MM/DD/YYYY or YYYY/MM/DD) of all dates in the report.	
Sort By Then By Then By	Additional sorting criteria.	Not applicable for all report types.
Suppress Cover Page	When selected, the cover page is not included when you view the report in Adobe Reader.	
Suppress Page Breaks	When selected, page breaks are not inserted when you view the report in Adobe Reader.	For the CT Clinical Data Report, you can select **Suppress Page Breaks**, but page breaks are not inserted in the report.
Suppress Page Footer	When selected, page footers are removed when you view the report in Adobe Reader.	

Creating a new report

1   From the main menu, select **Reports > View**.

The View Reports page appears, displaying a list of all available reports.

2   In the Report Name column, click the report type.

The View Reports - Edit page appears. The criteria and fields on this page differ for each report.

> **Note:** Most report types have a criteria choice of either Date Interval or Date Range.

3   Fill in the fields.

Field descriptions for the View Reports - Edit page

Field	Description	Notes
Study	Study ID.	REQUIRED.
	Either type the Study ID in the field, or click the Lookup icon and select the study from the list in the Study Lookup dialog box.	The Study Lookup dialog box displays only studies to which you have been granted access (on the Study - Properties page.) If you have been granted permission to view all studies on the Security page, the dialog box displays all studies.
Report-specific criteria	Displays different criteria fields depending on the report type. Fields that might appear: • Storage Device • Vessel Barcode • Rack • Box	Most of the report-specific fields appear under the **Study** field and above the **Date Interval** and **Range** fields.
Date Interval	Time interval (for example, Month to Date or Year to Date) used to filter the report.	The selected date choice is the date criteria by which the report is filtered. If you select **Date Interval**, a drop-down field is enabled. If you select **Date Range**, two calendar fields are enabled. You must select either Storage Date Interval or Date Range.

Field	Description	Notes
Date Interval	Time interval (for example, Month to Date or Year to Date) used to prepare the report. If you selected the Date Interval radio button, select a date interval from the drop-down menu.	
Date Range	Used to prepare the report. Filters the report by Date Range.	The selected date choice is the date criteria by which the report is filtered. If you select **Date Interval**, a drop-down field is enabled. If you select **Date Range**, two calendar fields are enabled. You must select either Storage Date Interval or Date Range. Default: Month to Date.
Date Range	Date range for the report. If you selected the Date Range radio button, either type the dates in the **From** and **To** fields, or click the calendar icons and select the dates.	
Report Date Format	Format (for example, MM/DD/YYYY or YYYY/MM/DD) of all dates in the report.	
Sort By Then By Then By	Additional sorting criteria.	Not applicable for all report types.
Suppress Cover Page	When selected, the cover page is not included when you view the report in Adobe Reader.	
Suppress Page Breaks	When selected, page breaks are not inserted when you view the report in Adobe Reader.	For the CT Clinical Data Report, you can select **Suppress Page Breaks**, but page breaks are not inserted in the report.
Suppress Page Footer	When selected, page footers are removed when you view the report in Adobe Reader.	

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5 Click **SAVE**.

The Save Report As dialog box appears.

6 In the **Report Name** field, type a name for the new report.

7 In the **Group Name** field, make a selection:

- **Existing** to add the report to an existing group.

   A list of existing groups appears for you to select the group.

   > **Note:** Standard Reports, which might not have reports added to or deleted from it, might be excluded from the list.

- **New** to create a new report group. Type a group name.

8 Click **APPLY**.

Deleting a report

You cannot delete a report that is a member of the Standard Reports group.

1   From the main menu, select **Reports > View**.

    The View Reports page appears, displaying a list of all available reports.

2   In the Report Name column, click the report type.

    The View Reports - Edit page appears. The criteria and fields on this page differ for each report.

> **Note:** Most report types have a criteria choice of either Date Interval or Date Range.

3   Click **DELETE**.

    A confirmation message appears.

4   Click **OK**.

Adding and editing a report group

1   From the main menu, select **Reports > Groups**.

    The Report Groups page appears.

2   To add a report group, click **NEW**.

    To edit a report group, select a report group, and click **EDIT**.

    The Report Groups page appears.

3   In the **Report Group** field, type a unique name with a maximum of 30 characters.

4   Optionally, in the **Comment** field, type a comment with a maximum of 80 characters.

5   Click **SAVE**.

Deleting a report group

You cannot delete a report group that has reports associated with it.

1   From the main menu, select **Reports > Groups**.

    The Report Groups page appears.

2   Select the checkboxes for the report groups, and click **DELETE**.

    A confirmation dialog box appears.

3   Click **OK**.

Printing a report

1   *Create a report* (on page 45), or *view an existing report* (on page 43).

    The report appears in an Adobe Reader window.

2   In the Adobe Reader window, click the printer icon, or select **File > Print**.

    The report prints to the default printer.

APPENDIX B
Labels

In this appendix

Tasks: Labels page

On the Labels page, you print default labels. This page is comparable to a personal label maker and does not affect or interact with any of the other pages. Information that you enter on the page is not saved.

- *Printing an existing barcode* (on page 55).

- *Printing an auto-generated barcode* (on page 56).

Printing an existing barcode

Prerequisite: At least one default label must exist.

1   From the main menu, select **Labels**.

The Labels page appears.

2   From the **Label** drop-down list, select a default label.

3   In the **Barcode Mode** field, select **Use Existing**.

4   Fill in the fields.

Field descriptions for the Labels page

Field	Description	Notes
Label	Type of label to print. All default labels appear.	
Barcode Mode	Type of barcode: **Use Existing** or **Auto-Generate**.	If you select **Use Existing**, the Barcode Id field is required. If you select **Auto-Generate**, the No. of Barcodes field is required.
Barcode Id	Barcode ID of the existing label.	Maximum characters: 30. Required if Barcode Mode is **Existing**.
No. of Barcodes	Number of barcodes for an auto-generated label.	Required if Barcode Mode is **Auto-Generate**.
Line (1 - 5)	Custom text that appears on the label.	Maximum characters per line: 30.

5   Click **PRINT**.

The Print dialog box appears.

6   Select the printer options, and click **OK**.

Printing an auto-generated barcode

Use the auto-generated barcode selection to print ad hoc collection labels prior to a study.

1   From the main menu, select **Labels**.

The Labels page appears.

2   In the **Label** drop-down list, click a default label.

3   In the **Barcode Mode** field, select **Auto-Generate**.

4   Fill in the fields.

Field descriptions for the Labels page

Field	Description	Notes
Label	Type of label to print.	
	All default labels appear.	
Barcode Mode	Type of barcode: **Use Existing** or **Auto-Generate**.	If you select **Use Existing**, the Barcode Id field is required.
		If you select **Auto-Generate**, the No. of Barcodes field is required.
Barcode Id	Barcode ID of the existing label.	Maximum characters: 30.
		Required if Barcode Mode is **Existing**.
No. of Barcodes	Number of barcodes for an auto-generated label.	Required if Barcode Mode is **Auto-Generate**.
Line (1 - 5)	Custom text that appears on the label.	Maximum characters per line: 30.

5   Click **PRINT**.

The Print dialog box appears.

6   Select the printer options, and click **OK**.

The labels are generated based on the value in the No. of Barcodes field, starting with the last Barcode Id that was generated.

> **Note:** You can save unused labels for other studies.

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