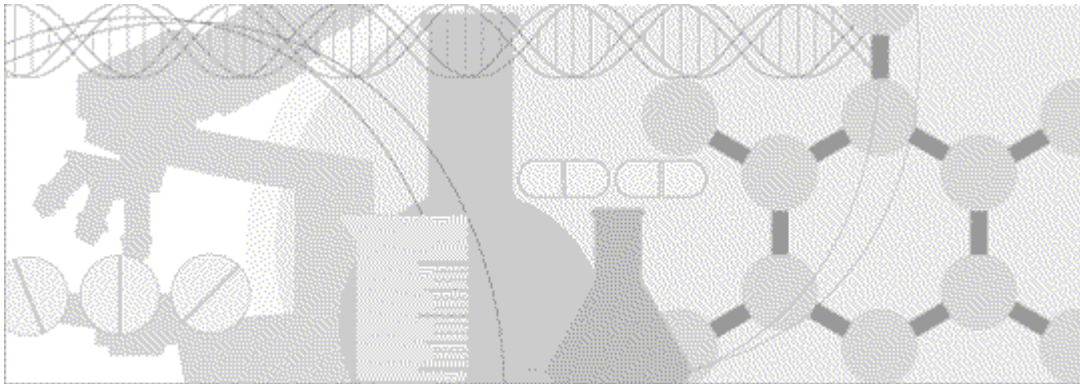


Administration Guide

Oracle[®] Health Sciences LabPas
Release 3.1



ORACLE[®]

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Contents

About this guide	ix
Overview of this guide.....	x
Audience	x
Documentation	xi
If you need assistance.....	xiii
Chapter 1 Getting started	1
The LabPas application.....	2
Users, permissions, and roles.....	3
Navigation.....	4
Main menu.....	4
Page heading.....	5
Data frame.....	5
Logging on.....	7
Logging off.....	8
Changing the contents of the data grid.....	9
Filtering grid data.....	10
Setting a home page.....	11
Creating a bookmark.....	12
Deleting a bookmark.....	13
Working with messages.....	14
Reading a message.....	14
Sending a message.....	14
Deleting a message.....	14
Adding a message group.....	15
Editing a message group.....	15
Deleting a message group.....	16
Chapter 2 Configuring the LabPas application	17
Menu items and links.....	18
Tasks: Menu Editor page.....	18
Adding an item or web link to the main menu.....	18
Renaming a menu item or link.....	19
Deleting a menu item or link.....	19
Editing the URL of an external web link.....	19
Moving a menu item or link.....	20
Terms and the term library.....	21
Tasks: Term Library page.....	21
Editing a term.....	21
Comments.....	22
Tasks: Comments page.....	22
Creating and editing a comment.....	22
Deleting a comment.....	22
Printing a list of comments.....	23
Label configuration.....	24
Tasks: Label Configuration page.....	24
Creating and editing a label configuration.....	24
Deleting a label configuration.....	25
Jobs.....	26
Tasks: Job Administration page.....	26

Preformatted jobs	26
Creating and editing a job	28
Deleting a job	29
Facilities and settings	30
Tasks: Settings pages	30
Adding and editing a facility	30
Deleting a facility	32
Specifying timeout settings	33
Specifying global settings	33
System information	36
Tasks: System Information page	36
Terminating a user session	36

Chapter 3 Setting up the LabPas application 37

Security roles and permissions	38
Security page	38
Security permissions	38
Tasks: Security page	42
Creating and editing a security role	43
Deleting a security role	43
Users, roles, and access	44
Users page	44
User authorization	44
Tasks: Users page	44
Granting user access	44
Changing a user's role	45
Locking out a user	45
Removing user access	46
Instruments	47
Tasks: Instruments page	47
Adding and editing an instrument	47
Deleting an instrument	48
Printing labels for instruments	48
Storage devices	49
Tasks: Storage Devices page	49
Adding and editing a storage device	49
Deleting a storage device	50
Printing storage device labels	51
Sample types	52
Tasks: Sample Types page	52
Adding and editing a sample type	52
Deleting a sample type	53
Vessel types	54
Tasks: Vessel Types page	54
Adding and editing a vessel type	54
Deleting a vessel type	55
Tests	56
Tests page	56
Types of tests	56
Reference values	57
Tasks: Tests page	58
Adding a Text test	58
Adding a Numeric test	59
Adding a Pos/Neg/??? test	60
Adding a Pass/Fail test	61
Adding a Double test	62

Adding a List test.....	64
Adding a Long Text test.....	66
Specifying demographic ranges.....	67
Editing a test.....	67
Deleting a test.....	68
Test panels and edit checks.....	69
Test Panels page	69
Tasks: Test Panels page.....	69
Adding a test panel.....	69
Adding a test or edit check to a test panel.....	72
Editing a test, test panel, or edit check.....	74
Deleting a test panel.....	77
Deleting a test or an edit check from a test panel	77
Forms.....	78
Tasks: Forms page.....	78
Adding a form.....	78
Adding a question to a form.....	78
Editing form properties.....	80
Deleting a form.....	81
Customers	82
Tasks: Customers page	82
Adding and editing a customer	82
Deleting a customer.....	83
Medical terms	84
Tasks: Medical Terms page.....	84
Adding and editing a medical term.....	84
Deleting a medical term.....	86

Chapter 4 Setting up the LabPas Recruiting module

87

Settings pages.....	88
Settings - Medical page	88
Medical health areas	90
Tasks: Settings - Medical - Health Area page.....	90
Adding a health area.....	90
Deleting a health area	90
Medical questions.....	91
Settings - Medical - Questions page	91
Tasks: Settings - Medical - Questions page.....	91
Adding a question.....	91
Approving medical questions.....	92
Editing a question.....	92
Deleting a question.....	93
Medical conditions.....	95
Settings - Medical - Conditions page.....	95
Tasks: Settings - Medical - Conditions page	95
Adding a condition.....	95
Approving a condition.....	96
Editing a condition.....	97
Deleting a condition.....	98
Surgical procedures.....	99
Settings - Medical - Surgical page	99
Tasks: Settings - Medical - Surgical page.....	99
Adding a surgical procedure.....	99
Approving a procedure.....	100
Editing a surgical procedure.....	100
Deleting a surgical procedure	101

Medications	102
Settings - Medical - Medications page.....	102
Tasks: Settings - Medical - Medications page	102
Adding and editing a medication	102
Deleting a medication	103
Other medical settings	104
Settings - Medical - Other page.....	104
Tasks: Settings - Medical - Other page	104
Adding and deleting a unit of measurement.....	104
Adding and deleting a frequency	105
Adding and deleting a route.....	105
Selecting Start Year Required	106
Race and Ethnicity settings	107
Settings - Volunteer - Properties page	107
Tasks: Settings - Volunteer - Properties page.....	107
Adding and deleting a race.....	107
Adding and deleting an ethnicity	108
Demographics settings.....	109
Settings - Volunteer - Demographics page	109
Tasks: Settings - Volunteer - Demographics page.....	110
Setting demographic field requirements.....	110
Adding custom demographic fields.....	110
Deleting a custom demographic field	114
Call scripts	115
Tasks: Settings - Call - Call Script page	115
Adding a call script.....	115
Approving a call script.....	116
Editing a call script.....	116
Deleting a script.....	117
Call resolutions.....	118
Tasks: Settings - Call - Resolutions page	118
Adding a call resolution.....	118
Deleting a call resolution.....	119
Study types	120
Tasks: Settings - Study - Study Types page.....	120
Adding and deleting a study type.....	120
Master Questions	121
Settings - Study - Master Questions page.....	121
About assigned numbers	121
Tasks: Settings - Study - Master Questions page	121
Adding a master question	121
Approving master questions.....	123
Editing a master question	123
Deleting a master question	125
General settings.....	126
Settings - General page.....	126
Tasks: Settings - General page	127
Setting up alert triggers	127
Requiring reasons for status assignment	128
Setting up a default email address.....	129
Adding a reason for a study status	130
Editing a reason for volunteer study statuses.....	130
Deleting a reason for volunteer study statuses.....	131
Specifying comment requirements	131

Appendix A Reports 133

Tasks: View Reports page	134
Tasks: Report Groups page	135
Report layout	136
LabPas CT reports.....	137
LabPas Recruiting reports	139
LabPas Resource Management reports.....	141
Viewing the list of available reports	142
Viewing a report.....	143
Creating a new report.....	145
Deleting a report	148
Adding and editing a report group	149
Deleting a report group	150
Printing a report	151

Appendix B Labels 153

Tasks: Labels page	154
Printing an existing barcode.....	155
Printing an auto-generated barcode.....	156

Index 157

About this guide

In this preface

Overview of this guide.....	x
Documentation	xi
If you need assistance.....	xiii

Overview of this guide

The LabPas *Administration 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.

Audience

This guide is for everyone who sets up and configures the Oracle® Health Sciences LabPas application and the LabPas Recruiting module. This audience includes the LabPas administrator, 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
<i>Release Notes</i>	The <i>Release Notes</i> document presents information about new features, enhancements, and updates for the current release.	3.1
<i>Known Issues</i>	The <i>Known Issues</i> document presents information about known issues for the current release.	3.1
<i>User Guide</i>	The <i>User Guide</i> 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 <i>User Guide</i> from the Help button in the LabPas application.	3.1
<i>Administration Guide</i>	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
<i>Clinical Trial Design and Resource Management Guide</i>	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
<i>Recruiting User Guide</i>	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
<i>Sample Management Guide</i>	This guide provides step-by-step instructions for processing and tracking samples in the lab.	3.1
<i>Clinical Data Entry Guide</i>	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
<i>Data Qualification Guide</i>	This guide provides step-by-step instructions for reviewing data that is collected in LabPas CT studies.	3.1
<i>Installation Guide</i>	This guide provides step-by-step instructions for installing the LabPas application.	3.1
<i>Secure Configuration Guide</i>	This guide provides essential secure configuration considerations for the LabPas application.	3.1
<i>Ad Hoc Reports Database Views Guide</i>	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
<i>Specification for the HL7 Lab Data Interface</i>	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
<i>Specification for the Mortara E-Scribe Interface</i>	This document provides the information needed to set up jobs and import Mortara ECG files.	3.1
<i>Third Party Licenses and Notices</i>	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>.

CHAPTER 1

Getting started

In this chapter

The LabPas application.....	2
Users, permissions, and roles.....	3
Navigation.....	4
Logging on.....	7
Logging off.....	8
Changing the contents of the data grid.....	9
Filtering grid data.....	10
Setting a home page.....	11
Creating a bookmark.....	12
Deleting a bookmark.....	13
Working with messages.....	14

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.

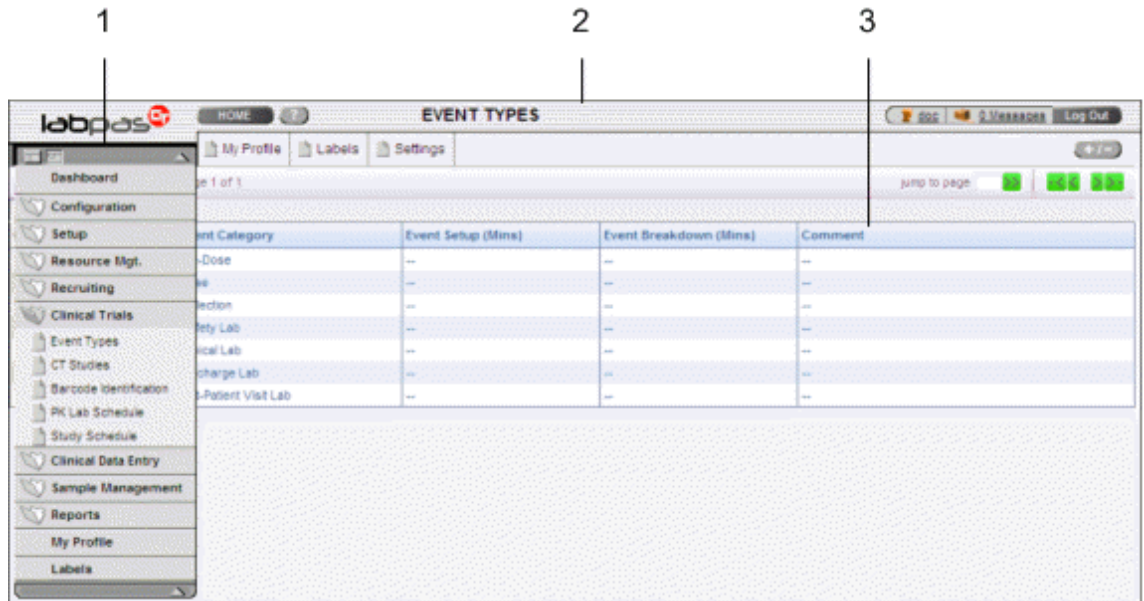
When a system administrator assigns you to a role, you are automatically assigned the permissions associated with that role.

For more information on users, security, and permissions, see *Setting up the LabPas CT module* (on page 37).

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)



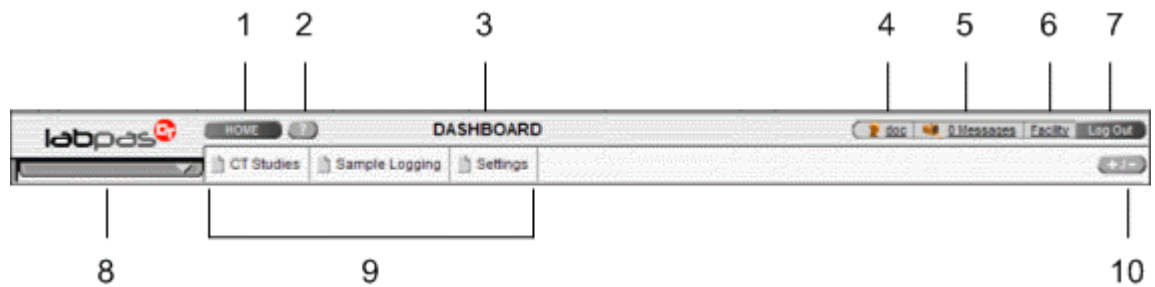
Main menu

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

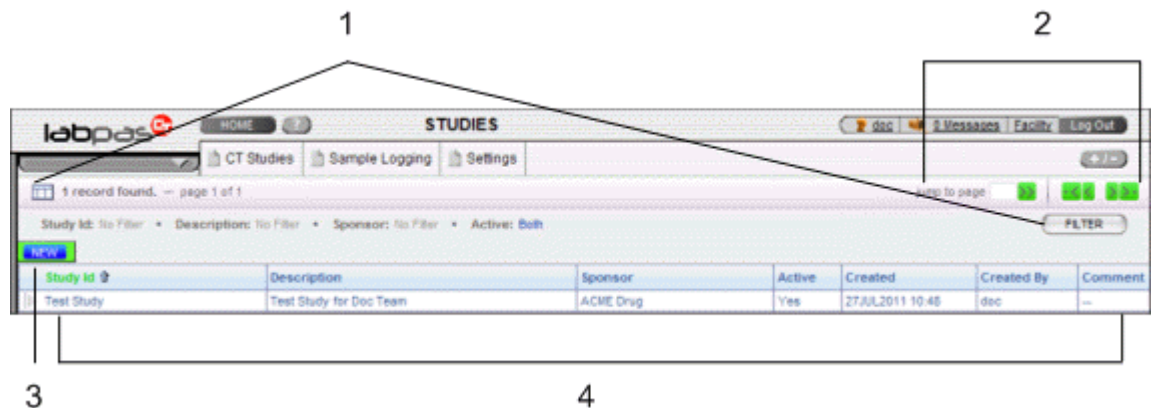
The page heading is similar on all LabPas pages.



- 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**.

CHAPTER 2

Configuring the LabPas application

In this chapter

Menu items and links.....	18
Terms and the term library.....	21
Comments.....	22
Label configuration.....	24
Jobs.....	26
Facilities and settings.....	30
System information.....	36

Menu items and links

Tasks: Menu Editor page

On the Menu Editor page, you edit the main menu and associate LabPas modules and external web pages with menu options.

The Menu Editor page has the following parts:

- **Menu tree**—Displays the components of the main menu, with items organized in folders by category and sub-category.
- **Program list**—Lists items that are not in the menu tree but that can be added.
- *Adding an item or web link to the main menu* (on page 18).
- *Renaming a menu item or link* (on page 19).
- *Deleting a menu item or link* (on page 19).
- *Editing the URL of an external web link* (on page 19).
- *Moving a menu item or link* (on page 20).

Adding an item or web link to the main menu

When you add a program or link to the main menu, the security role that is in use reflects the change. For a new item to appear on the main menu for other security roles, it must be selected on the Security page.

- 1 From the main menu, select **Configuration > Menu Editor**.
The Menu Editor page appears.
- 2 Select the Menu folder at the top of the menu tree.
- 3 To add an item to the menu:
 - a Right-click the **Menu** folder and select **Add**.
A dialog box appears.
 - b Type the name of the new menu item, and click **OK**.
The new menu item is added to the Menu folder.
- 4 To add an external web link to the menu:
 - a Right-click the **Menu** folder and select **Add Link**.
A dialog box appears.
 - b Type the name of the new link, and click **OK**.
A dialog box appears.
 - c Type the URL for the web site, and click **OK**.
The new link is added to the Menu folder.
- 5 Click **UPDATE**.

Renaming a menu item or link

If you rename menu items, consider keeping a spreadsheet with the before-and-after names so that you can reference the original names when calling Oracle for support.

- 1 From the main menu, select **Configuration > Menu Editor**.

The Menu Editor page appears.

- 2 Right-click a menu item or link, and select **Rename**.

Note: You cannot rename the Menu folder.

A dialog box appears.

- 3 Type a new name for the menu item or link, and click **OK**.

The Menu Editor page appears, with the new name for the menu item or link.

- 4 Click **UPDATE**.

Deleting a menu item or link

You can delete any menu item except the Menu folder. When you delete a program or link, the security role that is currently in use reflects the change.

- 1 From the main menu, select **Configuration > Menu Editor**.

The Menu Editor page appears.

- 2 Right-click a menu item, and select **Remove**.

- If the item is an external link, it is removed from the Menu Editor page.
- If the item is a menu item, it is deleted from the menu tree but still appears in the program list.

- 3 Click **UPDATE**.

Note: If you delete a parent category, which appears as a folder, its subcategories are removed from the menu tree but still appear in the program list. To add a subcategory back to the menu, drag the subcategory to the menu tree. To add the parent category back to the menu, you must *create a new item* (on page 18).

Editing the URL of an external web link

- 1 From the main menu, select **Configuration > Menu Editor**.

The Menu Editor page appears.

- 2 Right-click a link and select **Edit Link**.

- 3 Edit the URL as needed, and click **OK**.

The Menu Editor page appears.

- 4 Click **UPDATE**.

- 5 To test the link, from the main menu, select the link.

Moving a menu item or link

- 1 From the main menu, select **Configuration > Menu Editor**.
The Menu Editor page appears.
- 2 Select the menu item or link to move.
- 3 Drag the menu item or link to another folder in the Menu Tree.

Note: You can also move menu items from the program list to the menu tree by dragging them.

- 4 Click **UPDATE**.

Terms and the term library

Tasks: Term Library page

On the Term Library page, you view and edit the terms used in the LabPas CT module. Changes to a term are propagated throughout the user interface.

- *Editing a term* (on page 21).

Editing a term

- 1 From the main menu, select **Configuration > Term Library**.

The Term Library page appears.

The library might contain many pages of terms. Use the navigation arrows and the **Jump to page** field to go to a different page.

- 2 To filter the list of terms that appear, click **FILTER**.
- 3 Select the checkboxes for one or more terms, and click **EDIT**.

The Term Library – Edit page appears.

- 4 Fill in the fields.

Notes:

- You can enter up to 2000 characters in the Term field.
- Term IDs can represent a group of words or an entire sentence.

- 5 Click **SAVE**.

The Term Library page appears and you can view the new term. The Change Date field displays the current date and time.

- 6 After you have made all necessary changes, click **UPDATE**.

You are prompted to refresh the cache.

- 7 Click **OK**.

Comments

Tasks: Comments page

On the Comments page, you create generic comments that you can use repeatedly on many clinical data entry pages. You can also view all the comments that have been created in one or all facilities.

- *Creating and editing a comment* (on page 22).
- *Deleting a comment* (on page 22).
- *Printing a list of comments* (on page 23).

Creating and editing a comment

- 1 From the main menu, select **Configuration > Comments**.
The Comments page appears.
- 2 To create a comment, click **NEW**.
To edit a comment, select one or more comments, and click **EDIT**.
The Comments page appears.
- 3 Fill in the fields.

Field descriptions for the Comments page

Field	Description	Notes
Comment Id	Code for the new comment. The value for each comment must be unique.	REQUIRED. Maximum characters: 3. After you create a comment, this field is read-only.
Comment Type	Descriptive term.	Maximum characters: 30.
Comment	Comment text.	REQUIRED. Maximum characters: 80.

- 4 Click **SAVE**.

Deleting a comment

- 1 From the main menu, select **Configuration > Comments**.
The Comments page appears.
- 2 Select one or more comments, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

Printing a list of comments

To print comments, the Comment Label field on the *Settings - Facility page* (on page 30) must be set to Comment List.

- 1 From the main menu, select **Configuration > Comments**.

The Comments page appears.

- 2 Select one or more comments, and click **PRINT**.

The Print dialog box appears.

- 3 Click **OK**.

To the left of the comment ID is the barcode.

Label configuration

Tasks: Label Configuration page

On the Label Configuration page, you view all label configurations that have been set up. Some label configurations are preformatted.

You use labels for the following functions:

- Comment
- CT
- Default
- Device
- Generic Vessel
- Mailing
- Shipping
- Wrist

- Creating and editing a label configuration.
- *Deleting a label configuration* (on page 25).

Creating and editing a label configuration

- 1 From the main menu, select **Configuration > Label Configuration**.

The Label Configuration page appears.

- 2 To create a label configuration, click **NEW**.

To edit a label configuration, select one or more label configurations, and click **EDIT**.

The Label Configuration page appears.

- 3 Fill in the fields.

Field descriptions for the Label Configuration page

Field	Description	Notes
Name	Name of the label configuration. Must be unique.	REQUIRED. Maximum characters: 30. After you create a label configuration, this field is read-only.
Function	Available label functions. Your selection determines the Label Types that you can select.	REQUIRED.

Field	Description	Notes
Label Type	Label types associated with the Function that you selected:	REQUIRED.
Mils	Number of mils in the smallest width of the barcode bar in the label configuration.	REQUIRED. Must be a number from 7.5 to 20.0. This value is for scanner readability. One inch = 1000 mils.
2D	When selected, the barcode displayed on labels with this label configuration are two-dimensional.	

- 4 Click **SAVE**.

Deleting a label configuration

You cannot delete a label configuration that has facility settings or CT labels associated with it.

- 1 From the main menu, select **Configuration > Label Configuration**.

The Label Configuration page appears.

- 2 Select one or more label configurations, click **DELETE**.

A confirmation dialog box appears.

- 3 Click **OK**.

Jobs

Tasks: Job Administration page

On the Job Administration page, you view, create, edit, and delete the jobs that are run by the LabPas CT service, including preformatted jobs.

- *Creating and editing a job* (on page 28).
- *Deleting a job* (on page 29).

Preformatted jobs

Job	Description
CT Metrics	Prepares data for the Study - Metrics page.
Cleaner	Removes user sessions that are expired or marked for closure. Runs every minute.
Clinical Lab Export	Automatically exports clinical lab samples in a standard HL7 format.
Clinical Lab Import	Automatically imports lab results in a standard HL7 format.
SR Alerts	Generates an alert on the LabPas Recruiting Alerts page for each volunteer whose probation end date has passed.

Job	Description
PK Lab Schedule	<p>Selects sample records to display on the PK Lab Schedule page.</p> <p>Samples are selected from scheduled PK Testing events, across all active studies, according to the job parameters.</p> <p>Samples are not selected if they are:</p> <ul style="list-style-type: none"> • Cancelled. • Stored. • From a study and sample type with a Storage - Time To value of zero on the Study - Setup - PK Lab page. • Are missed. • Are failed. <p>This job includes the following required numeric parameters:</p> <ul style="list-style-type: none"> • Parameter 1—Number of minutes to display samples prior to the expected time of samples. The value must be a negative number. • Parameter 2—Number of minutes to display samples after the expected store times have passed. <p>This job includes an additional, optional numeric parameter:</p> <ul style="list-style-type: none"> • Parameter 3—Number of minutes to add to the Expected Date/Time plus tolerance to establish a delay for alerts to display. <p>Example:</p> <ul style="list-style-type: none"> • Parameter 1 = -300 • Parameter 2 = 120 <p>The PK Lab Schedule page displays:</p> <ul style="list-style-type: none"> • Samples that have not been stored but have an expected sample date in the next 5 hours (300 minutes). • PK Testing events that include a Storage - Time To value that is greater than zero and that have not been stored for 2 hours (120 minutes) past the expected store date.
PK Lab Statistics	<p>Generates statistical data to display in the header of the PK Lab Schedule page.</p> <p>This job includes the following required numeric parameters:</p> <ul style="list-style-type: none"> • Parameter 1—Type 0 to turn off statistics. Type any other number to turn on statistics. • Parameter 2—Number of days to look back from the current server date to calculate sample storage deviations.

Creating and editing a job

- 1 From the main menu, select **Configuration > Job Administration**.
The Job Administration page appears.
- 2 To create a job, click **NEW**.
To edit a job, select one or more jobs, and click **EDIT**.
The Job Administration page appears.
- 3 Fill in the fields.

Field descriptions for the Job Administration page

Field	Description	Notes
Job Name	Name of the job. Each job must have a unique name.	REQUIRED. Maximum characters: 80.
Job Module	Valid job module. A job module must be created for each new job.	REQUIRED. Case-sensitive. Maximum characters: 1024.
Active	When selected, the job is scheduled or will run after you save the job details.	The LabPas CT service runs only active jobs.
Start Time	Date and time that the job will start. You must follow the date and time format configured on the Settings - Facility page (on page 30). The date and time must be in the future. If you leave the field blank, the job begins after you save the job details.	Maximum characters: 30.
Frequency	(Available only when Active is selected.) Unit of time that, when grouped with the Interval, indicates how frequently the job runs.	REQUIRED.
Interval	(Available only when Active is selected.) Number that, when grouped with the Frequency, indicates how frequently the job runs.	REQUIRED. Must be a number from one to 9999.

Field	Description	Notes
Parameter 1-10	Program-dependent parameters for the job to allow time between when the sample appears and the PK Lab. You can specify up to 10 parameters for each job.	Maximum characters: 500. Example: Parameter 1: 300, 120.

- 4 Click **SAVE**.

Deleting a job

- 1 From the main menu, select **Configuration > Job Administration**.
The Job Administration page appears.
- 2 Select one or more jobs, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

Facilities and settings

Tasks: Settings pages

On the Settings - Facility page, you view information about facilities, one facility at a time.

- Adding and editing a facility.
- *Deleting a facility* (on page 32).

On the Settings - Application page, you view information that affects all facilities.

- *Specifying timeout settings* (on page 33).

On the Settings - Global page, you choose whether data is applicable to a single facility or is applicable to all facilities.

- *Specifying global settings* (on page 33).

Adding and editing a facility

After you add a facility, an Administrator role is created and the first available time zone that corresponds to the server is set as the default for the Facility Time Zone.

Before you create a second facility, you must *specify global settings* (on page 33) because most settings in the Global Settings box are locked after you create a second facility.

- 1 From the main menu, select **Configuration > Settings**.

The Settings page appears with the Facility tab selected.

- 2 In the upper-left corner of the page, click the right-arrow bar.

The bar expands, displaying ADD and REMOVE buttons and the facilities that you can edit.

- 3 To add a facility, click **ADD**.

To edit a facility, select a facility.

- 4 Fill in the fields.

Field descriptions for the Settings - Facility page

Setting	Description
Facility Information	
Facility Name	Address information for the site.
Code	
Address 1, Address 2	
City, State, Postal Code, Country	

Setting	Description
Time Zone	<p>Facility's time zone.</p> <p>All dates and times for the facility use the selected time zone. This field is read-only after you import clinical data for a group in the facility.</p>
Date Format	<p>Facility's formatting style for dates.</p> <p>All dates entered at the facility must use the selected format. Additionally, all dates displayed for the facility use the format.</p>
Time Format	<p>Facility's formatting style for times.</p> <p>All times entered at the facility must use the selected format. Additionally, all dates displayed for the facility use the format.</p>
Travel Unit	Unit in which distance is measured (for example, miles or kilometers).
Currency	Currency in which reimbursement is to be made.
Max. Travel Distance	Integer from 0 to 99,999.
Travel Reimbursement Rate	Valid amount, less than or equal to 100.
Max. Stipend Payment	Integer from 0 to 99,999.
CT Settings	
CT Sample Logging Required	<ul style="list-style-type: none"> • Selected—Samples must go to the Sample Logging page. • Not selected—Samples are ready to process on the Sample Processing pages for Standard PK sample processing.
Allow Recruiting Volunteers	On the Study - Participants - Candidates page, recruiting volunteers can be displayed and used in studies.
Result Import Class	External clinical lab codes for importing clinical data.
Clinical Data Entry Settings	
Require Comment	When selected, comments are required on the Clinical Data Entry - Dose, Sample, Other, and Testing pages if the actual Date/Time is outside the scheduled Date/Time, regardless of the tolerance.
Display Event Schedule After Save	<ul style="list-style-type: none"> • Selected—The Event Schedule page appears after you save. • Not selected (default)—A blank clinical data entry form appears after you save.
Auto-Populate Time After Countdown Expiration	When selected, date and time fields on clinical data entry pages are updated with the current date and time after the countdown timer expires.
Unique Barcode Settings	
Prefix	Settings are applied only if Global Barcode Uniqueness on the Global tab is not selected.
	Characters that begin each automatically generated barcode.

Setting	Description
Last Id	READ-ONLY. Last automatically generated barcode number.
Suffix	Characters that end each automatically generated barcode.
Barcode Mode	<ul style="list-style-type: none"> • Numeric—Automatically generated barcodes consist of numbers only. • Alpha-Numeric—Automatically generated barcodes consist of letters and numbers.
Label Settings	In this section, you determine the labels to use for the specified label types in the facility. Your choices depend on the labels set up on the <i>Label Configuration page</i> (on page 24). You must specify settings to print labels.
Lab Interfaces	Lab interfaces allow you to define the clinical labs that are used by a facility and associate each lab with the appropriate interface type.
ADD button	Opens the New Lab Interface dialog box. Note: To delete a lab interface, click the X to the left of the lab interface.
Lab	Name for the lab interface. This name is used as the sub folder name in the directory structure for the import and export process with external labs.
Interface Type	Type of lab interface.
Measurements	These settings are for Volunteers and Candidates. Your selections are applied to all studies at the facility.
Height	Units used to measure height. This field is read-only after a height value has been entered for a participant at the facility.
Weight	Units used to measure weight. This field is read-only after a weight value has been entered for a participant at the facility.

- 5 Click **UPDATE**.

Deleting a facility

You cannot delete a facility that has been used and that has data associated with it.

- 1 From the main menu, select **Configuration > Settings**.
The Settings page appears with the Facility tab selected.
- 2 In the upper-left corner of the page, click the right-arrow bar.

The bar expands, displaying ADD and REMOVE buttons and the facilities that you can edit.

- 3 Select the facility to remove from the list, and click **REMOVE**.

Specifying timeout settings

Only an administrator can modify this page.

- 1 From the main menu, select **Configuration > Settings**.

The Settings page appears.

- 2 Select the **Application** tab.
- 3 Fill in the fields.

Field descriptions for the Settings - Application page

Setting	Description	Notes
Inactivity Timeout Interval	Maximum number of minutes that a user can be inactive before being prompted to log on again.	REQUIRED. Must be a number from 15 to 999.
Application Timeout Interval	Maximum number of minutes that a user can be inactive before the application logs the user off.	REQUIRED. Must be a number from 15 to 1440.

- 4 Click **UPDATE**.

Specifying global settings

- 1 From the main menu, select **Configuration > Settings**.

The Settings page appears.

- 2 Select the **Global** tab.
- 3 Fill in the fields.

Field descriptions for the Settings - Global page

After you create a second facility on the *Settings - Facility page* (on page 30), all global settings are read-only and all settings are applied.

Setting	Description
Global Settings	
Global Vessel Types	Configured for all facilities.
Global Sample Types	Configured for all facilities.
Global Tests	Configured for all facilities. When not selected, Global Panels is read-only and not selected.

Setting	Description
Global Panels	Available only if Global Tests is selected. Configured for all facilities.
Global Storage Devices	Configured for all facilities.
Global Instruments	Configured for all facilities.
Global Roles	Configured for all facilities.
Global Customers	Configured for all facilities.
Global Barcode Uniqueness	When selected, barcodes across all facilities are unique.
Global Comments	Configured for all facilities.
Global Recruiting	Read-only after a study is created on the Resource Management - Studies page or when more than one facility is created. <ul style="list-style-type: none"> • Selected—Recruiting settings, studies, and volunteers are configured for all facilities. Additionally, recruiting studies apply for all CT studies in all facilities. • Not selected—Filters for selecting studies include only studies in which at least one group is associated with the current facility. Selection fields for studies, groups, and volunteers include only those options that are associated with the current facility.
Global Medical Terms	Configured for all facilities.
Global Forms	Configured for all facilities.
Mail Settings	
Host	Default email host address.
Port	Default email port address.
Authentication Required	When selected, an account name and password are required to send email messages from the LabPas Recruiting module.
Account Name/Password	(Available and required only when Authentication Required is selected.) Account name and password for sending email messages.
Unique Barcode Settings	
Prefix	If Global Barcode Uniqueness is selected, these settings override settings for individual facilities. Available only when Global Barcode Uniqueness is selected. Characters that begin each automatically generated barcode.
Last Id	READ-ONLY. Last automatically generated barcode number.

Setting	Description
Suffix	Available only when Global Barcode Uniqueness is selected. Characters that end each automatically generated barcode.
Barcode Mode	<ul style="list-style-type: none">• Numeric—Automatically generated barcodes consist of numbers only.• Alpha-Numeric—Automatically generated barcodes consist of letters and numbers.

- 4 Click **UPDATE**.

System information

Tasks: System Information page

On the System Information page, you can terminate user sessions.

- *Terminating a user session* (on page 36).

Terminating a user session

You can terminate any active session except your own.

- 1 From the main menu, select **Configuration > System Information**.

The System Information page appears.

- 2 In the Active Sessions area, click the **X** to the left of the user whose session you want to terminate.

A confirmation message appears.

- 3 Click **OK**.

The user is removed from the Active Sessions box, and the user's session is terminated.

CHAPTER 3

Setting up the LabPas application

In this chapter

Security roles and permissions	38
Users, roles, and access	44
Instruments	47
Storage devices	49
Sample types	52
Vessel types	54
Tests	56
Test panels and edit checks	69
Forms	78
Customers	82
Medical terms.....	84

Security roles and permissions

Security page

Security roles define a set of permissions that allow a user to perform certain functions or access specific pages or data.

- The Administrator role is the only security role that is installed by default.
- One administrator role must be assigned to each facility.

Users are assigned to roles on the Users page. When users are assigned to a role, they acquire the permissions associated with that role. All users assigned to the same role have the same permissions.

The Security page lists one of the following:

- The role names that are set up in a facility.
- All roles in all facilities, if Global Roles was selected when *global settings were specified* (on page 33).

Security permissions

Security permissions are assigned to a role on the Security – New page. You grant permissions in the following categories:

- *Clinical trial permissions* (on page 38)
- *Subject recruitment permissions* (on page 40)
- *DQ permissions* (on page 41)
- *Payment permissions* (on page 41)
- *Report permissions* (on page 41)
- *Application access* (on page 42)

Clinical trial permissions

Permission	Description
Study Setup	<p>User can add and edit study data on the following CT study pages:</p> <ul style="list-style-type: none"> • Study – Properties • Study – Participants – Candidates • Study – Participants – Subject • Study – Setup <p>User can add and edit study data on the following RM study pages:</p> <ul style="list-style-type: none"> • Study – Study Properties • Study – Groups • Study – Payments • Study – Setup <p>User can add and edit study data on the following SR study pages:</p> <ul style="list-style-type: none"> • Study – Setup • Study – Questionnaire
Approve Study Setup	<p>User can approve setup data on the following study pages:</p> <ul style="list-style-type: none"> • Study – Volunteers • Study – Setup – Events • Study – Participants – Candidates • Study – Participants – Subject • Study – Questionnaire
Manage Study Participants	User can manage volunteers on the Study – Volunteers pages.
Approve Study Participants	User can approve screened individuals into the study on the eligibility review form, which is accessed from the Studies – Volunteers page.
View All Studies	User can view all studies on the Studies page and in the LabPas DQ Interface.

Permission	Description
Change Study Data	<p>User can add and edit data on the following study pages:</p> <ul style="list-style-type: none"> • Study – AEs • Study – Events – Data • Study – Participants – Candidates • Study – Samples • Study – Labels <p>In addition, user can export samples and import results on the Study – Labs page.</p>
Approve Study Data	<p>User can approve, unapprove, and batch approve data on the following study pages:</p> <ul style="list-style-type: none"> • Study – AEs • CT and SR Study – Events – Data • CT and SR Study – Labs
Approve Samples	User can approve, unapprove, and batch approve samples.
Manage Study Data	<p>User can:</p> <ul style="list-style-type: none"> • Export data on the Study – Events page. • Lock and release statuses on the Study – Metrics page. • Lock and unlock studies on the Study – Properties page.
Answer Queries	User can answer queries on the Study - Labs page
Create/Modify Events	User can create, schedule, and reschedule events.
Restart Events	User can set the event status to Not Started.
Print Study Labels	<p>User is authorized to print labels on the following pages:</p> <ul style="list-style-type: none"> • Study – Events – Scheduled • Study – Participants – Subjects • Study – Participants – Candidates
Disable Status Screen Timeouts	<p>The Inactivity Timeout and Application Timeout timers are disabled on the PK Lab Schedule page for this user.</p> <p>Note: This permission applies to a special user who is configured to access only this page.</p>

Subject recruitment permissions

Permission	Description
Recruiting Setup	User can access all function buttons on the Recruiting Settings page, if you are using the Recruiting module.
View Volunteer Ids	User can view volunteer names and social security numbers in the Recruiting Volunteer pages, if you are using the Recruiting module.
Volunteer Administration	User can access all function buttons on the Recruiting Volunteer page.
Delete Clinical History	User can delete clinical history for volunteers on the Recruiting Volunteer and Incoming Calls pages, if you are using the Recruiting module.
Change Appointments	User can resolve, cancel, and reschedule volunteer appointments, if you are using the Recruiting module.
Delete Volunteer Record	User can delete a volunteer record.
Edit Volunteers	User can edit clinical history for volunteers on the Volunteer Incoming Calls and Volunteers Clinical History pages, if you are using the Recruiting module.

DQ permissions

Permission	Description
Review Study Data	User can review study data in the DQ module.
Create Queries	User can create queries in the DQ module.

Payment permissions

Permission	Description
Review Payments	User can change the review status of payments but cannot approve them.
Approve Payments	User can change the review status of payments and can approve them.

Report permissions

Permission	Description
Delete Any Report	User can delete reports created by other users.
View All Report Groups	User can view reports created by other users on the Report Groups page.

Application access permissions

The application access permissions control access to LabPas modules and to individual pages in certain modules.

Standard LabPAS access permissions

For Standard LabPas (the default), the following tabs appear.

- **Standard tab**—Displays the study pages that were configured on the *Configuration - Menu Editor page* (on page 18).

The My Profile page is selected by default and cannot be deselected.

- **RM Studies tab**—Displays the study pages that are available on the Resource Management - Studies page.

The Resource Mgt. page on the Standard tab must be selected to allow a role to have access to a page on the RM Studies tab.

- **CT Studies tab**—Displays the study pages that are available on the Clinical Trials - CT Studies page.

The Clinical Trials page on the Standard tab must be selected to allow a role to have access to a page on the CT Studies tab.

- **SR Studies tab**—Displays the study pages that are available on the Recruiting - SR Studies page.

The Recruiting page on the Standard tab must be selected to allow a role to have access to a page on the SR Studies tab.

For some menu items, individual pages can be selected. Use the arrow next to a menu item to display the pages associated with it. When you select a menu or page, the security role can view and select the page from the main menu.

If the menu item is selected, all pages associated with it are selected by default. You can select and deselect individual pages.

If a menu item is deselected, you cannot select any pages for that item.

Selecting an individual page selects the menu item it is associated with. If all pages for a menu item are deselected, the menu item is automatically deselected.

LabPAS DQ access permissions

When you select the LabPas DQ application, the security role will have full access to the LabPas DQ module.

Tasks: Security page

- *Creating and editing a security role* (on page 43).
- *Deleting a security role* (on page 43).

Creating and editing a security role

- 1 From the main menu, select **Setup > Security**.
The Security page appears.
- 2 To create a security role:
 - a Click **NEW**.
The Security – New page appears.
 - b Enter a unique name (maximum 30 characters) in the Role Name field.
 - c Select the permissions to assign to this role.
For more information, see Security permissions.
 - d Click **SAVE**.
If the role already exists, a message appears.
- 3 To edit a security role:
 - a Select one or more roles, and click **EDIT**.
The Security – Edit page appears.
 - b Edit the name and permission settings for one or more selected security roles, and click **SAVE**.
After you finish editing all selected roles, the Security page appears.

Deleting a security role

You cannot delete a role that has users associated with it.

WARNING: Do not delete the Administrator role, unless you have assigned Administrator permissions to another security role. At least one security role must have access to the Security screen at all times.

- 1 From the main menu, select **Setup > Security**.
The Security page appears.
- 2 Select one or more roles and click **DELETE**.
A confirmation message appears.
- 3 Click **OK**.

Users, roles, and access

Users page

The Users page lists all LabPas users in all facilities, along with the user ID and name, the facility to which they are assigned, and their roles.

- To appear in the User Directory, users must be registered to the server or domain with which the LabPas application is associated.
- Each user may be assigned to only one role at a time in each facility. A user may be assigned to the same role, or different roles, in other facilities.

User authorization

You use the Users – Modify page to control user access to the LabPas application. Users may be authorized to one or more facilities.

- The Authorized Users list, in the left column of the page, is a tree that is organized by the facilities configured for the application. The roles in each facility and the users in each role appear below the facility name. Users who have data associated with them appear in black; users with no associated data appear in green.
- The User Directory, in the right column of the page, consists of all users who have been registered to use the server or domain with which the LabPas application is associated.

The data source for the User Directory depends on the authentication method selected during installation:

- Windows Active Directory authentication—Users that are registered in the active directory that was specified during LabPas CT module installation.
- LDAP authentication—Users that are registered in the LDAP directory that was specified during LabPas CT module installation.

Tasks: Users page

- *Granting user access* (on page 44).
- *Changing a user's security role* (on page 45).
- *Locking out a user* (on page 45).
- *Removing user access* (on page 46).

Granting user access

Users can be authorized to only one role per facility.

- 1 From the main menu, select **Setup > Users**.
The Users page appears.
- 2 Click **MODIFY**.

The Users – Modify page appears.

- 3 In the Authorized Users list, click the icon to the left of a facility.

The roles assigned to that facility appear.

- 4 In the User Directory, select a user name and drag it to a role in the Authorized Users list.

- 5 To see the added user name, click the icon to the left of the role in the Authorized Users list.

User names appear in green when no data is associated with them, and in black when they have associated data.

The user name remains in the User Directory and can be added to other roles.

Changing a user's role

Users may be authorized to only one role per facility.

- 1 From the main menu, select **Setup > Users**.

The Users page appears.

- 2 Click **MODIFY**.

The Users – Modify page appears.

- 3 In the Authorized Users list, click the folder icon to the left of the facility to use.

The roles assigned to the facility appear.

- 4 Click the folder icon to the left of the role to which the user is currently assigned.

The user names for the role appear.

- 5 Select the name of the user and drag it to the folder for the new role.

- 6 To see the change, click the folder icon to the left of the folder the user was moved to.

Note: You can also move a user to a different role by *Granting user access* (on page 44). When the user name is added to a different role in the Authorized User list, the user is automatically removed from the original role.

Locking out a user

To block a user's access to the application, you lock out the user.

- 1 From the main menu, select **Setup > Users**.

The Users page appears.

- 2 Click **MODIFY**.

The Users – Modify page appears.

- 3 In the Authorized Users list, right-click the user name to block, and select **LOCK**.

Note: To unlock the user, click **Lock** again.

Removing user access

You can remove user access to the LabPas application. However, you cannot remove access for a user who has associate data. You cannot delete users from the user directory.

- 1 From the main menu, select **Setup > Users**.
The Users page appears.
- 2 Click **MODIFY**.
The Users – Modify page appears.
- 3 In the Authorized Users list, right-click the user name, and click **DELETE**.

Instruments

Tasks: Instruments page

The Instruments page, you view either:

- All instruments that are set up in a facility.
- All instruments in all facilities, if Global Instruments was selected when *global settings were specified* (on page 33).
- *Adding and editing an instrument* (on page 47).
- *Deleting an instrument* (on page 48).
- *Printing labels for instruments* (on page 48).

Adding and editing an instrument

- 1 From the main menu, select **Setup > Instruments**.

The Instruments page appears.

- 2 To add an instrument, click **NEW**.

To edit an instrument, select an instrument, and click **EDIT**.

The Instruments page appears.

- 3 Fill in the fields.

Field descriptions for the Instruments page

Field	Description	Notes
Instrument	Name for the instrument. The value is read-only after you create an instrument.	REQUIRED. Must be unique. Maximum characters: 30.
Barcode Id	Barcode for the instrument. Can be entered or scanned in. The value is read-only after you create an instrument.	REQUIRED. Must be unique. Case-sensitive. Maximum characters: 30.
Manufacturer	Name of the manufacturer.	
Model	Model name for the instrument.	
Serial No.	Serial number for the instrument.	

Field	Description	Notes
Device Interface Type	Device interface type of the instrument.	Required if the test result is to be automatically imported from an external instrument.
Comment	Comment about the instrument.	Maximum characters: 80.

- 4 Click **SAVE**.

Deleting an instrument

- 1 From the main menu, select **Setup > Instruments**.
The Instruments page appears.
- 2 Select one or more instruments, and click **DELETE**.
A confirmation message appears.
- 3 Click **OK**.

Printing labels for instruments

- 1 From the main menu, select **Setup > Instruments**.
The Instruments page appears.
- 2 Select one or more instruments for which you want to print labels.
- 3 Click **PRINT**.
The Print Dialog window appears on the desktop.
- 4 Select printer options, and click **OK**.

Note: Labels are formatted according to the Device Label template selected when facility settings were specified.

Storage devices

Tasks: Storage Devices page

A storage device is anything from a small refrigerator without shelves to a large walk-in freezer with multiple racks, shelves, and containers. You define the level of detail for each storage device. When you specify racks, shelves, and containers, it is easier to locate samples that are in storage.

The Storage Devices page shows either:

- All storage devices that are set up in a facility.
- All storage devices in all facilities, if Global Storage Devices was selected when *global settings were specified* (on page 33).
- *Adding and editing a storage device* (on page 49).
- *Deleting a storage device* (on page 50).
- *Printing labels for storage devices* (on page 50).

Adding and editing a storage device

When you edit a storage device, you can edit the Shelves, Racks, and Boxes fields as long as the storage device does not contain any vessels.

- 1 From the main menu, select **Setup > Storage Devices**.

The Storage Devices page appears.

- 2 To add a storage device, click **NEW**.

To edit a storage device, select a storage device, and click **EDIT**.

The Storage Devices page appears.

- 3 Fill in the fields.

Field descriptions for the Storage devices page

Field	Description	Notes
Storage Device	Name of storage device. This field is read-only after you create a storage device.	REQUIRED. Must be unique. Maximum characters: 30.
Barcode Id	Identifier for the storage device. This field is read-only after you create a storage device.	REQUIRED. Must be unique. Maximum characters: 30. Case sensitive.
Temperature Class	Temperature class associated with the storage device.	Maximum characters: 10

Field	Description	Notes
Comment	Comment about the storage device.	Maximum characters: 80
No. of Shelves	Number of shelves in the storage device.	REQUIRED. One label is printed for each shelf.
Racks	Select if the storage device has racks.	
No. of Rows	Number of rows in each rack.	Enabled and required when Racks is selected. Number from 1 to 26.
No. of Columns	Number of columns in each rack.	Enabled and required when Racks is selected. Number from 1 to 99.
Boxes	Select if the storage device has boxes.	
No. of Rows	Number of rows in each box.	Enabled and required when Boxes is selected. Number from 1 to 26.
No of Columns	Number of columns in each box.	Enabled and required when Boxes is selected. Number from 1 to 99.

- 4 Click **SAVE**.

Deleting a storage device

- 1 From the main menu, select **Setup > Storage Devices**.
The Storage Devices page appears.
- 2 Select one or more storage devices, and click **DELETE**.
A confirmation message appears.
- 3 Click **OK**.

If a storage device contains any vessels, an error message appears and the storage device is not deleted.

Printing storage device labels

- 1 From the main menu, select **Setup > Storage Devices**.
The Storage Devices page appears.
- 2 Select one or more storage devices for which you want to print labels.
- 3 Click **PRINT**.
The Print Dialog window appears on the desktop.
- 4 Select printer options, and click **OK**.

Note: Labels are formatted according to the Device Label template selected when facility settings were specified.

Sample types

Tasks: Sample Types page

You use sample types to categorize samples and their associated processes in the LabPas application. Samples generally consist of biological material such as blood, urine, or feces.

The Sample Types page lists either:

- All sample types set up in a facility.
- All sample types in all facilities, if Global Sample Types was selected when *global settings were specified* (on page 33).
- *Adding and editing a sample type* (on page 52).
- *Deleting a sample type* (on page 52).

Adding and editing a sample type

- 1 From the main menu, select **Setup > Sample Types**.

The Sample Types page appears.

- 2 To add a sample type, click **NEW**.

To edit a sample type, select one or more sample types, and click **EDIT**.

The Sample Types page appears.

- 3 Fill in the fields.

Field descriptions for the Sample types page

Field	Description	Notes
Sample Type	Name of the sample type.	REQUIRED. Must be unique. Maximum characters: 30.
Comment	Comment about the sample type.	Maximum characters: 80.

- 4 Click **SAVE**.

Deleting a sample type

You cannot delete a sample type that has samples associated with it.

- 1 From the main menu, select **Setup > Sample Types**.

The Sample Types page appears.

- 2 Select one or more sample types, and click **DELETE**.

A confirmation message appears.

- 3 Click **OK**.

Vessel types

Tasks: Vessel Types page

Vessel types describe the categories of containers that are used to hold samples. Vessel types are defined by the number of wells they contain. For example:

- A test-tube is a single-well vessel.
- A microtiter plate is a vessel with multiple wells.
- A rack is a grouping of vessels, with each sample contained in a single-well vessel (the test tube), in another vessel (the rack).

The Vessel Types page lists either:

- All vessel types set up in a facility.
- All vessel types in all facilities, if Global Vessel Types was selected when *global settings were specified* (on page 33).
- *Adding and editing a vessel type* (on page 54).
- *Deleting a vessel type* (on page 55).

Adding and editing a vessel type

If a vessel type is associated with a vessel, you cannot edit the vessel type.

- 1 From the main menu, select **Setup > Vessel Types**.

The Vessel Types page appears.

- 2 To add a vessel type, click **NEW**.

To edit a vessel type, select a vessel type, and click **EDIT**.

The Vessel Types page appears.

- 3 Fill in the fields.

Field descriptions for the Vessel Types page

Field	Description	Notes
Vessel Type	Name of the vessel type.	REQUIRED. Must be unique. Maximum characters: 30.

Field	Description	Notes
Contents	<p>Select one of the following:</p> <ul style="list-style-type: none"> • Single Well—Vessel that holds a single sample. • Multiple Wells—Vessel that holds multiple separate samples. <ul style="list-style-type: none"> ▪ Has Well Barcodes—Select if each well has its own barcode. <p>If the samples need to be separated during the workflow, they must be transferred to new single-well vessels.</p> • Grouping of Vessels—Vessel that holds other vessels. <ul style="list-style-type: none"> ▪ Contains Existing Vessels—Select when existing samples in single-well vessels are grouped into a grouping of vessels. 	REQUIRED.
Columns	Number of columns in the vessel.	<p>Enabled when either Multiple Wells or Grouping of Vessels is selected.</p> <p>Number from 1 to 26.</p>
Rows	Number of rows in the vessel.	<p>Enabled when either Multiple Wells or Grouping of Vessels is selected.</p> <p>Number from 1 to 99.</p>

- 4 Click **SAVE**.

Deleting a vessel type

You cannot delete a vessel type has vessels associated with it.

- 1 From the main menu, select **Setup > Vessel Types**.
The Vessel Types page appears.
- 2 Select one or more vessel types, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

Tests

Tests page

Tests are performed on volunteers in study recruitment and study participants in the LabPas CT module to ensure that they meet the inclusion requirements for the study or to collect study data. Tests in the LabPas application are grouped in *test panels* (on page 69).

The Tests page lists either of the following:

- All tests set up in a facility.
- All tests in all facilities, if Global Tests was selected when *global settings were specified* (on page 33).

Types of tests

Test type refers to the type of result the test requires. You can create the following test types:

- **Text**—Use to accept text input for the text result.
- **Numeric**—Use to accept numeric input for the test result.
- **Pos/Neg/???**—Use to accept a value of positive, negative, or unknown for the test result.
- **Pass/Fail**—Use to accept a value of pass or fail for the test result.
- **Double**—Use when a dual measurement is being taken (for example, blood pressure or visual acuity) or for any test in which two results are recorded.
- **List**—Includes a list of expected values that the tester can select from when the test is performed.
- **Long Text**—Use to accept text input for the text result, up to 1,000 characters.

Reference values

For Pos/Neg/???, Pass/Fail, and List tests, you can specify reference values. A reference value is the expected outcome for a test.

- When test results are recorded for a participant in a study, the application validates the results by comparing them with the reference values. If an actual test result does not match the reference value for that test, a warning message appears with instructions for the tester.
- Reference values for tests used in individual studies can be edited when you ***set up the test panels for the study*** (in the *Clinical Trial Design and Resource Management Guide*).

For Numeric and Double tests, you can specify two sets of range values:

- **Out of Range** values identify the minimum and maximum allowable values for a test result. If a test result is not within the specified range, a warning message appears with instructions for the tester.
- **Reference Ranges** identify the expected (normal) range of values for a test. You can also create demographic reference ranges, which restrict reference ranges by age and gender.
 - When test results are recorded for a participant, the LabPas application compares them with the appropriate reference range. If no demographic reference range exists that matches the participant's demographics, the default reference range is used.
 - When an actual test result is outside the reference range for a test, a warning message appears with instructions for the tester.
 - Reference ranges are optional. If no reference ranges are created for a test, no result validation occurs.
 - Reference ranges can be edited for individual studies when you ***set up the test panels for the study*** (in the *Clinical Trial Design and Resource Management Guide*).

Double tests include two sets of values for each type of range.

- Out of range values—There is one set of values for each number in the test.
 - If test result values for the first number are lower than the Out of Range - First Min or higher than the Out of Range - First Max, the entry is not allowed and an alert appears.
 - If test result values for the second number are lower than the Out of Range - Second Min or higher than the Out of Range - Second Max, the entry is not allowed and an alert appears.
- Reference ranges— There is a reference range for each number in the test. Test results are compared to the reference range, restricted by demographic reference range if available.
 - If no demographic reference range fits the participant's age and gender, the values entered in the Reference Range First/Second Min and Max fields are used as the default reference ranges for result validation.
 - If test result values are outside the appropriate reference range, an alert appears.

Tasks: Tests page

- *Adding a Text test* (on page 58).
- *Adding a Numeric test* (on page 59).
- *Adding a Pos/Neg/??? test* (on page 60).
- *Adding a Pass/Fail test* (on page 61).
- *Adding a Double test* (on page 62).
- *Adding a List test* (on page 64).
- *Adding a Long Text test.* (on page 66)
- *Editing a test* (on page 67).
- *Deleting a test* (on page 68).

Adding a Text test

- 1 From the main menu, select **Setup > Tests**.
The Tests page appears. Scroll to the right to see all the data on the page.
- 2 Click **NEW**.
The Tests – New page appears.
- 3 Select the **Text** tab.
- 4 Fill in the fields.

Field descriptions for the Text test page

Field	Description	Notes
Test	Name of the test.	REQUIRED. Must be unique. Case sensitive. Maximum characters: 60.
Units	Unit used to measure the results for the test.	Maximum characters: 30.
Abbreviation	Name to display on the Clinical Event Data pages.	REQUIRED. Maximum characters: 10.
Test Code 1	Custom text.	Used when importing results from external sources that use the MEDTOX A lab interface. Maximum characters: 30.

Field	Description	Notes
Test Code 2	Custom text.	Used when importing results from external sources that use the HL7 lab interface. Maximum characters: 30.
Data Type	Type of data recorded as the test result (for example, blood pressure, temperature, or height).	Required if the test result is to be automatically imported from an external instrument.
Comment	Comment about the test.	Maximum characters: 80.
Length	Number of characters allowed as input for a value.	REQUIRED. Number from 1 to 30.

- 5 Click **SAVE**.

Adding a Numeric test

- 1 From the main menu, select **Setup > Tests**.
The Tests page appears. Scroll to the right to see all the data on the page.
- 2 Click **NEW**.
The Tests – New page appears. The Numeric tab is selected by default.
- 3 Fill in the fields.

Field descriptions for the Numeric test page

Field	Description	Notes
Test	Name of the test.	REQUIRED. Must be unique. Case sensitive. Maximum characters: 30.
Units	Unit used to measure the results for the test.	REQUIRED. Maximum characters: 30.
Abbreviation	Name to display on the Clinical Event Data pages.	REQUIRED. Maximum characters: 10.
Test Code 1	Custom text.	Used when importing results from external sources. Maximum characters: 30.
Test Code 2	Custom text.	Used when importing results from external sources. Maximum characters: 30.

Field	Description	Notes
Data Type	Type of data recorded as the test result (for example, blood pressure, temperature, or height).	Required if the test result is to be automatically imported from an external instrument.
Comment	Comment about the test.	Maximum characters: 80.
Instructions	Directions for the tester to follow if a participant's test value violates the test's reference range.	Maximum characters: 80. Message appears in a dialog box.
Out of Range - Min	Lowest possible value for this test.	REQUIRED. -99999999 - 99999999. Must be less than the maximum value.
Out of Range - Max	Highest possible value for this test.	REQUIRED. -99999999 - 99999999.
Reference Range - Min	Minimum expected value for this test.	Must be less than the Reference Range - Max. Must be greater than or equal to the Out of Range - Min.
Reference Range - Max	Maximum expected value for this test.	Must be greater than the Reference Range - Min. Must be less than or equal to the Out of Range - Max.

- 4 Optionally, *specify one or more demographic ranges* (on page 67).
- 5 Click **SAVE**.

Adding a Pos/Neg/??? test

- 1 From the main menu, select **Setup > Tests**.
The Tests page appears. Scroll to the right to see all the data on the page.
- 2 Click **NEW**.
The Tests – New page appears.
- 3 Select the **Pos/Neg/???** tab.
- 4 Fill in the fields.

Field descriptions for the Pos/Neg??? test

Field	Description	Notes
Test	Name of the test.	REQUIRED. Must be unique. Case sensitive. Maximum characters: 30.
Units	Unit used to measure the results for the test.	Maximum characters: 30.
Abbreviation	Name to display on the Clinical Event Data pages.	REQUIRED. Maximum characters: 10.
Test Code 1	Custom text.	Used when importing results from external sources. Maximum characters: 30.
Test Code 2	Custom text.	Used when importing results from external sources. Maximum characters: 30.
Data Type	Type of data recorded as the test result (for example, blood pressure, temperature, or height).	Required if the test result is to be automatically imported from an external instrument.
Comment	Comment about the test.	Maximum characters: 80.
Instructions	Directions for the tester to follow if a participant's test value does not match the test's reference value.	Maximum characters: 80. Message appears in a dialog box.
Reference	Select the expected results for the test: <ul style="list-style-type: none"> • Pos • ??? 	Value selected is the expected result for the test. Default: Neg

- 5 Click **SAVE**.

Adding a Pass/Fail test

- 1 From the main menu, select **Setup > Tests**.
The Tests page appears. Scroll to the right to see all the data on the page.
- 2 Click **NEW**.
The Tests – New page appears.
- 3 Select the **Pass/Fail** tab.
- 4 Fill in the fields.

Field descriptions for the Pass/Fail test page

Field	Description	Notes
Test	Name of the test.	REQUIRED. Must be unique. Case sensitive. Maximum characters: 30.
Units	Unit used to measure the results for the test.	Maximum characters: 30.
Abbreviation	Name to display on the Clinical Event Data pages.	REQUIRED. Maximum characters: 10.
Test Code 1 Test Code 2	Custom text.	Used when importing results from external sources. Maximum characters: 30.
Data Type	Type of data recorded as the test result (for example, blood pressure, temperature, or height).	Required if the test result is to be automatically imported from an external instrument.
Comment	Comment about the test.	Maximum characters: 80.
Instructions	Directions for the tester to follow if a participant's test value does not match the test's reference value.	Maximum characters: 80. Message appears in a dialog box.
Reference	Select the expected results for the test: <ul style="list-style-type: none"> Pass 	Value selected is the expected result for the test. Default: Fail.

- 5 Click **SAVE**.

Adding a Double test

- 1 From the main menu, select **Setup > Tests**.
The Tests page appears. Scroll to the right to see all the data on the page.
- 2 Click **NEW**.
The Tests – New page appears.
- 3 Select the **Double** tab.
When the Double tab is highlighted, the screen displays fields relating to tests that take a dual measurement.
- 4 Fill in the fields.

Field descriptions for the Double test page

Field	Description	Notes
Test	Name of the test.	REQUIRED. Must be unique. Case sensitive. Maximum characters: 30.
Units	Unit used to measure the results for the test.	REQUIRED. Maximum characters: 30.
Abbreviation	Name to display on the Clinical Event Data pages.	REQUIRED. Maximum characters: 10.
Test Code 1	Custom text.	Used when importing results from external sources. Maximum characters: 30.
Test Code 2	Custom text.	Used when importing results from external sources. Maximum characters: 30.
Data Type	Type of data recorded as the test result (for example, blood pressure, temperature, or height).	Required if the test result is to be automatically imported from an external instrument.
Comment	Comment about the test.	Maximum characters: 80.
Instructions	Directions for the tester to follow if a participant's test value violates the test's reference range.	Maximum characters: 80. Message appears in a dialog box.
Out of Range - First Min	Lowest possible value for the first number in the test.	REQUIRED. -99999999 - 99999999. Must be less than the Out of Range - First Max value.
Out of Range - First Max	Highest possible value for the first number in the test.	REQUIRED. -99999999 - 99999999. Must be greater than the Out of Range - First Min value.
Out of Range - Second Min	Lowest possible value for the second number in the test.	REQUIRED. -99999999 - 99999999. Must be less than the Out of Range - Second Max value.

Field	Description	Notes
Out of Range - Second Max	Highest possible value for the second number in the test.	REQUIRED. -99999999 - 99999999. Must be greater than the Out of Range - Second Min value.
Reference Range - First Min	Minimum expected value for the first number in the test.	Must be less than the Reference Range - First Max number. Must be greater than or equal to the Out of Range - First Min value.
Reference Range - First Max	Maximum expected value for the first number in the test.	Must be greater than the Reference Range - First Min value. Must be less than or equal to the Out of Range - First Max value.
Reference Range - Second Min	Minimum expected value for the second number in the test.	Must be less than the Reference Range - Second Max value. Must be greater than or equal to the Out of Range - Second Min value.
Reference Range - Second Max	Maximum expected value for the second number in the test.	Must be greater than the Reference Range - Second Min value. Must be less than or equal to the Out of Range - Second Max value.

- 5 Optionally, *specify one or more demographic ranges* (on page 67).
- 6 Click **SAVE**.

Adding a List test

A list test includes a list of expected values that the tester can select from when the test is performed. You create the values list, which is populated in the drop-down list in the Reference field. If no list values are created, the Reference field is blank, meaning there is no reference range.

- 1 From the main menu, select **Setup > Tests**.
The Tests page appears. Scroll to the right to see all the data on the page.
- 2 Click **NEW**.
The Tests – New page appears.
- 3 Select the **List** tab.
- 4 Fill in the fields.

Field descriptions for the List test page

Field	Description	Notes
Test	Name of the test.	REQUIRED. Must be unique. Case sensitive. Maximum characters: 30.
Units	Unit used to measure the results for the test.	REQUIRED. Maximum characters: 30.
Abbreviation	Name to display on the Clinical Event Data pages.	REQUIRED. Maximum characters: 10.
Test Code 1	Custom text.	Used when importing results from external sources. Maximum characters: 30.
Test Code 2	Custom text.	Used when importing results from external sources. Maximum characters: 30.
Data Type	Type of data recorded as the test result (for example, blood pressure, temperature, or height).	Required if the test result is to be automatically imported from an external instrument.
Comment	Comment about the test.	Maximum characters: 80.
Instructions	Directions for the tester to follow if the test result does not match the reference value.	
Reference	List of values to select from for the test result.	Field is populated automatically from the values entered in the List Values table on the page.

- 5 Optionally, to populate the Reference field, enter values in the List Values table.

Note: To indicate no expected (normal) result for a test, leave the Reference field blank.

- a To add the first value, click the entry field and enter a test value.
The value appears in the List Values table and in the drop-down list in the Reference field.
- b To add another entry, click the + button and type a test value.
The new entry appears below the previous entry.
- c Repeat the above step until you have added all test result values.

- d If necessary, update the list of values:
 - To edit an entry in the Value List, click it and make your changes.
 - To change the order of values, select a value and click the up and down arrows to move it.
 - To delete a value, select it and click the - button.
 - e To specify the expected result for the test, on the Reference field, click the down arrow and select the value from the drop-down list.
- 6 Click **SAVE**.

Adding a Long Text test

- 1 From the main menu, select **Setup > Tests**.
The Tests page appears. Scroll to the right to see all the data on the page.
- 2 Click **NEW**.
The Tests – New page appears.
- 3 Select the **Long Text** tab.
- 4 Fill in the fields.

Field descriptions for the Long Text test page

Field	Description	Notes
Test	Name of the test.	REQUIRED. Must be unique. Case sensitive. Maximum characters: 2000.
Units	Unit used to measure the results for the test.	Maximum characters: 30.
Abbreviation	Name to display on the Clinical Event Data pages.	REQUIRED. Maximum characters: 2000.
Test Code 1	Custom text.	Used when importing results from external sources that use the MEDTOX A lab interface. Maximum characters: 2000.
Test Code 2	Custom text.	Used when importing results from external sources that use the HL7 lab interface. Maximum characters: 2000.
Comment	Comment about the test.	Maximum characters: 2000.

- 5 Click **SAVE**.

Specifying demographic ranges

Create only one demographic reference range for each set of demographics.

- From the main menu, select **Setup > Tests**.
The Tests page appears. Scroll to the right to see all the data on the page.
- In the Demographic box, click **ADD**.
The Reference Range dialog box appears.
- Fill in the fields.

Field descriptions for the Demographic reference range dialog box

Field	Description	Notes
Gender	Gender of the volunteer. <ul style="list-style-type: none"> Male Female Not Available—Range applies to both male and female. 	REQUIRED.
Age	Age of the volunteer. <ul style="list-style-type: none"> Greater than, less than, or equal to 	Age range to which validation is to be applied.
Result First Result Second Result	<ul style="list-style-type: none"> Greater than, less than, or equal to are qualifiers you enter a value for the expected test value for this demographic reference range. 	<ul style="list-style-type: none"> Restricts the demographic reference range.

- Click **SAVE**.
The Reference Range dialog box closes, and the new demographic reference range appears in the Demographics box.
- To create additional demographic reference ranges for a test, add a demographic range and fill in the fields.
Demographic reference ranges are listed in the order that they are added. If a demographic is entered for which a reference range has already been created, an error message appears.

Note: To delete a demographic reference range, click the X to the left of the range.

Editing a test

- From the main menu, select **Setup > Tests**.
The Tests page appears. Scroll to the right to see all the data on the page.
- Select one or more tests, and click **EDIT**.

The Tests – Edit page appears.

- 3 Edit the page as necessary.
 - If the test is not associated with any panel, you can edit all fields.
 - If the test is associated with a panel, you cannot change the type of test and cannot edit the Test and Abbreviation fields.
- 4 Click **SAVE**.

Deleting a test

You cannot delete a test that is associated with a panel.

- 1 From the main menu, select **Setup > Tests**.

The Tests page appears. Scroll to the right to see all the data on the page.
- 2 Select one or more tests, and click **DELETE**.

A confirm message appears.
- 3 Click **OK**.

Test panels and edit checks

Test Panels page

On the Test Panels page, you add, edit, and delete test panels set up in a facility, and you create edit checks. Panels in all facilities appear if Global Panels was selected when *global settings were specified* (on page 33).

A test panel is a grouping of tests. Each grouping organizes tests with similar characteristics. For example, a viral test panel might consist of tests for HIV, Hepatitis C, and HBsAg (Hepatitis B surface antigens). In a viral test panel, one blood sample is tested for all these viruses at one time.

When you create a test panel, you can create edit checks for it. Edit checks define relationships between the tests that require an action when test results violate the conditions of an edit check.

For example, in the viral test panel, you can create a Warn and Alert edit check for the HBsAg test for when a participant has a negative HIV test and has a high HBsAg test. If someone enters test results for a participant with these conditions, a warning message appears after results are saved, and the HBsAg result is flagged with an alert on the Study - Results page.

Tasks: Test Panels page

- *Adding a test panel.* (on page 69)
- *Adding a test or an edit check to a test panel* (on page 72)
- *Editing a test, test panel, or edit check.* (on page 74)
- *Deleting a test panel* (on page 77).
- *Deleting a test or edit check from a test panel* (on page 77).

Adding a test panel

Prerequisite: You must have at least one test.

- 1 From the main menu, select **Setup > Test Panels**.
The Test Panels page appears.
- 2 Click **NEW**.
The Test Panels – New page appears.
- 3 In the **Properties** section, fill in the fields.

Field descriptions for the Test Panels - New page

Field	Description	Notes
Panel	Name of the test panel. Each panel must have a unique name.	REQUIRED. Maximum characters: 30. This field is read-only after you create and save a test panel. Additionally, the field is read-only if you associate a panel with a study.
Panel Code 1 Panel Code 2	Custom test for the test panel. This information is used when you import results from external sources, as for example, for HL7 file configuration types.	Maximum characters: 30.
Active	Classifies the test panel as active or inactive.	
Event Types	Classifies the test panel by the event types that you select.	
Comment	Comment about the test panel.	Maximum characters: 80.

- 4 To add tests to the test panel:
 - a In the Test Selection area, click **ADD**.
A dialog box appears with a list of all tests that were created on the Tests page.
 - b Select at least one test to include in the panel, and click **UPDATE**.
The tests appear in the Test Selection area.
 - c To change the order of the tests, edit the numbers in the **Order** column. The value must be from 1 to 99. If a panel is associated with a study, this field is read-only.
- 5 To add an edit check to the test panel:
 - a In the Edit Checks area, click **ADD**.
The Edit Check - Add dialog box appears.
 - b Fill in the fields at the top of the dialog box.

Field descriptions for the Edit Check - Add dialog box - Top section

Field	Description	Notes
Test	Test to which the edit check is applied.	The drop-down list includes all tests in the panel.
Action	Action that occurs if the edit check is violated. The following table describes each action.	
Message	Custom text.	If the action that you select includes a warning message, this text is used.

Actions for edit checks			
Action	Result is flagged with an alert	A warning message appears	You can save the results
Alert	Yes	No	Yes
Prevent	No	Yes	No
Warn	No	Yes	Yes
Warn and Alert	Yes	Yes	Yes

- 6 To create a test condition in the edit check:
 - a In the Field Tests table, click **ADD**.
A new row appears in the table.
 - b Fill in the fields.

Field descriptions for the Edit Check - Add dialog box - Field Tests section

Button	Description	Notes
Field	Test to which the test condition is applied.	The drop-down list includes all tests in the panel.
Operator	Qualifier to apply to the test condition.	If the test is a Numeric or Low/High test, your options are =, <>, <, >, >=, and <=. For all others tests, your options are = and <>.

Button	Description	Notes
Value	<p>Select one:</p> <ul style="list-style-type: none"> The drop-down list with tests. The test in the Field drop-down list is compared with the test in the Value field, in the manner specified in the Operator field. The entry field, in which you type a value. The test in the Field drop-down list is compared with the value you specify, in the manner specified in the Operator field. 	
Operand	<p>(Available after you create subsequent tests.)</p> <p>Operand that links the tests.</p> <ul style="list-style-type: none"> AND—Both conditions must be met for the action to occur. OR—Only one condition must be met for the action to occur. 	

a If necessary, create additional test conditions.

7 Click **SAVE**.

The Test Panels page and the new panel appear.

A warning appears if multiple tests in a single panel have the same non-blank Test Code 2 field value set on the Setup – Tests page.

Adding a test or edit check to a test panel

You can create one edit check for each test. You can include one or more test conditions in each edit check.

1 From the main menu, select **Setup > Test Panels**.

The Test Panels page appears.

2 Select a test panel, and click **EDIT**.

The Test Panels - Edit page appears.

3 To add a test:

a In the Test Selection area, click **ADD**.

A dialog box appears with a list of all tests that were created on the Tests page.

b Select at least one test to include in the panel, and click **UPDATE**.

The tests appear in the Test Selection area.

- c To change the order of the tests, edit the numbers in the **Order** column. The value must be from 1 to 99. If a panel is associated with a study, this field is read-only.
- 4 To add an edit check:
- a In the Edit Checks area, click **ADD**.
The Edit Check - Add dialog box appears.
 - b Fill in the fields.

Field descriptions for the Edit Check - Add dialog box - Top section

Field	Description	Notes
Test	Test to which the edit check is applied.	The drop-down list includes all tests in the panel.
Action	Action that occurs if the edit check is violated. The following table describes each action.	
Message	Custom text.	If the action that you select includes a warning message, this text is used.

Actions for edit checks			
Action	Result is flagged with an alert	A warning message appears	You can save the results
Alert	Yes	No	Yes
Prevent	No	Yes	No
Warn	No	Yes	Yes
Warn and Alert	Yes	Yes	Yes

- c To create a test condition in the edit check:
 - a In the Field Tests table, click **ADD**.
A new row appears in the table.
 - b Fill in the fields.

Field descriptions for the Edit Check - Add dialog box - Field Tests section

Button	Description	Notes
Field	Test to which the test condition is applied.	The drop-down list includes all tests in the panel.
Operator	Qualifier to apply to the test condition.	If the test is a Numeric or Low/High test, your options are =, <>, <, >, >=, and <=. For all others tests, your options are = and <>.
Value	Select one: <ul style="list-style-type: none"> The drop-down list with tests. The test in the Field drop-down list is compared with the test in the Value field, in the manner specified in the Operator field. The entry field, in which you type a value. The test in the Field drop-down list is compared with the value you specify, in the manner specified in the Operator field. 	
Operand	(Available after you create subsequent tests.) Operand that links the tests. <ul style="list-style-type: none"> AND—Both conditions must be met for the action to occur. OR—Only one condition must be met for the action to occur. 	

- If necessary, create additional test conditions.
- Click **SAVE**.

Editing a test, test panel, or edit check

- From the main menu, select **Setup > Test Panels**.
The Test Panels page appears.
- Select the test panels to edit, and click **EDIT**.
The Test Panels – Edit page appears.
- To edit the test panel:
 - In the Properties section, edit the test panel as necessary.

Field descriptions for the Test Panels - Edit page

Field	Description	Notes
Panel	Name of the test panel. Each panel must have a unique name.	REQUIRED. Maximum characters: 30. This field is read-only after you create and save a test panel. Additionally, the field is read-only if you associate a panel with a study.
Panel Code 1 Panel Code 2	Custom test for the test panel. This information is used when you import results from external sources, as for example, for HL7 file configuration types.	Maximum characters: 30.
Active	Classifies the test panel as active or inactive.	
Event Types	Classifies the test panel by the event types that you select.	
Comment	Comment about the test panel.	Maximum characters: 80.

To edit the tests in the test panel:

- To add a test to the panel:
 - a In the Test Selection area, click **ADD**.
A dialog box appears with a list of all tests that were created on the Tests page.
 - b Select at least one test to include in the panel, and click **UPDATE**.
The tests appear in the Test Selection area.
- To change the order of the tests, edit the numbers in the **Order** column. The value must be from 1 to 99. If a panel is associated with a study, this field is read-only.

To edit an edit check:

- a In the Edit Checks area, click the ellipsis button (...) to the left of an edit check.
The Edit Check - Edit dialog box appears.
- b Fill in the fields.

Field descriptions for the Edit Check - Edit dialog box - Top section

Field	Description	Notes
Test	Test to which the edit check is applied.	The drop-down list includes all tests in the panel.
Action	Action that occurs if the edit check is violated. The following table describes each action.	

Field	Description	Notes
Message	Custom text.	If the action that you select includes a warning message, this text is used.

Actions for edit checks			
Action	Result is flagged with an alert	A warning message appears	You can save the results
Alert	Yes	No	Yes
Prevent	No	Yes	No
Warn	No	Yes	Yes
Warn and Alert	Yes	Yes	Yes

Field descriptions for the Edit Check - Edit dialog box - Field Tests section

Button	Description	Notes
Field	Test to which the test condition is applied.	The drop-down list includes all tests in the panel.
Operator	Qualifier to apply to the test condition.	If the test is a Numeric or Low/High test, your options are =, <>, <, >, >=, and <=. For all others tests, your options are = and <>.
Value	Select one: <ul style="list-style-type: none"> The drop-down list with tests. The test in the Field drop-down list is compared with the test in the Value field, in the manner specified in the Operator field. The entry field, in which you type a value. The test in the Field drop-down list is compared with the value you specify, in the manner specified in the Operator field. 	

Button	Description	Notes
Operand	(Available after you create subsequent tests.) Operand that links the tests.	
	<ul style="list-style-type: none"> • AND—Both conditions must be met for the action to occur. • OR—Only one condition must be met for the action to occur. 	

c Click **SAVE**.

4 Edit additional edit checks if necessary.

5 Click **SAVE**.

A warning appears if multiple tests in a single panel have the same non-blank Test Code 2 field value set on the Setup – Tests page.

Deleting a test panel

You cannot remove a test panel that is associated with a study.

1 From the main menu, select **Setup > Test Panels**.

The Test Panels page appears.

2 Select a test panel, and click **DELETE**.

A confirmation message appears.

3 Click **OK**.

Deleting a test or an edit check from a test panel

You cannot delete a test if its test panel is associated with a study, or if the test is referenced in an edit check in the test panel.

1 From the main menu, select **Setup > Test Panels**.

The Test Panels page appears.

2 Select the test panel from which to delete a test or edit check, and click **EDIT**.

3 Do one of the following:

- To delete a test—In the Test Selection area, click the **X** button to the left of the test to delete.
- To delete an edit check—In the Edit Checks area, click the **X** button to the left of the edit check to delete.

4 Click **SAVE**.

Forms

Tasks: Forms page

You use forms to screen volunteers for a study. On the Forms page, you view one of the following:

- All forms set up in a facility.
- All forms in all facilities, if Global Forms was selected when *global settings were specified* (on page 33).
- *Adding a form* (on page 78).
- *Editing form properties* (on page 80).
- *Adding a question to a form* (on page 78).
- *Deleting a form* (on page 81).

Adding a form

- 1 From the main menu, select **Setup > Forms**.
The Forms page appears.
- 2 Click **NEW**.
The New Form dialog box appears.
- 3 Fill in the fields.
 - **Form Name**—Unique name for the form.
 - **Comment**—Optional comment about the form.
- 4 Click **SAVE**.
The Form Properties page appears.
- 5 To add questions to the form, see *Adding a question to a form* (on page 78).

Adding a question to a form

- 1 From the main menu, select **Setup > Forms**.
The Forms page appears.
- 2 Click **ADD**.
The Add Question dialog box appears.
- 3 Fill in the fields.

Field descriptions for the Add Question dialog box

Field	Description	Notes
Question	Question text that appears on the form.	REQUIRED.
Gender	<ul style="list-style-type: none"> • NA • Male • Female 	
Order	Order for the question on the form.	REQUIRED.
Response Type	Format for the response to the question: <ul style="list-style-type: none"> • Checkbox • Date • List <p>If you select this option, you can enter a list of acceptable values.</p> • Number <p>If you select this option, you must enter the maximum length for the number. Optionally, you can also specify minimum and maximum acceptable values.</p> • Text <p>If you select this option, you must also enter the maximum length for the data entered.</p> • Time • Yes/No 	Depending on the response type selected, additional fields may appear.

- 4 Click **SAVE**.

The question is saved and a blank Add Question dialog box appears.

Note: The questions do not appear on the Form Properties page until you close the Add Question dialog box.

- 5 Do one of the following:

- Add another question.
- To stop adding questions, close the dialog box.

The Form Properties page appears with the questions you added.

- 6 Click **SAVE**.

Editing form properties

- 1 From the main menu, select **Setup > Forms**.
The Forms page appears.
- 2 Select one or more forms and click **Edit**.
The Form Properties page for the first selected form appears.
- 3 Edit the Form Name and Comment fields as necessary.
- 4 To add a question, see *Adding a question to a form* (on page 78).
- 5 To delete a question, click the **X** to the left of the question.
A confirmation message appears.
- 6 Click **OK**.
- 7 To edit a question:
 - a Click the ellipsis button (...) to the left of the question.
The Edit Question dialog box appears.
 - b Fill in the fields.

Field descriptions for the Edit Question dialog box

Field	Description	Notes
Question	Question text that appears on the form.	REQUIRED.
Gender	<ul style="list-style-type: none"> • NA • Male • Female 	
Order	Order for the question on the form.	REQUIRED.

Field	Description	Notes
Response Type	<p>Format for the response to the question:</p> <ul style="list-style-type: none"> • Checkbox • Date • List <p>If you select this option, you can enter a list of acceptable values.</p> • Number <p>If you select this option, you must enter the maximum length for the number. Optionally, you can also specify minimum and maximum acceptable values.</p> • Text <p>If you select this option, you must also enter the maximum length for the data entered.</p> • Time • Yes/No 	Depending on the response type selected, additional fields may appear.

The Form Properties page appears.

- 8 Click **SAVE**.

If you selected more than one form to edit, the Form Properties page for next form appears.

After you finish editing all forms, the Forms page appears.

Deleting a form

- 1 From the main menu, select **Setup > Forms**.

The Forms page appears.

- 2 Select one or more forms and click **DELETE**.

A confirmation message appears.

- 3 Click **OK**.

Customers

Tasks: Customers page

On the Customers page, you maintain customer information. You can store regularly used details about customers, and track contact names, shipping, and billing information.

The Customers page lists all customers that have been created within a facility.

The LabPas application can be configured to show all items in all facilities. For more information, see *Global Settings* (on page 33).

- *Adding and editing a customer* (on page 82).
- *Deleting a customer* (on page 83).

Adding and editing a customer

- 1 From the main menu, select **Setup > Customers**.
- 2 To add a customer, click **NEW**.
To edit a customer, select a customer, and click **EDIT**.
The Customers page appears.
- 3 Fill in the fields.

Field descriptions for the Customers page

Field	Description	Notes
Customer	Name of customer. Must be unique.	REQUIRED. Maximum characters: 80.
Telephone	Phone number of customer.	Maximum characters: 30.
Fax	Customer fax number	Maximum characters: 30.
Billing Address section		
Contact	Contact person at customer site.	Maximum characters: 30.
Address 1	Street address for customer	Maximum characters: 80.
Address 2		
City		Maximum characters: 30.
State		Maximum characters: 30.
Postal Code		Maximum characters: 30.
Country		Maximum characters: 30.

Field	Description	Notes
Shipping Address section		
Contact	Contact person at customer site.	Maximum characters: 30.
Address 1	Street address for customer	Maximum characters: 80.
Address 2		
City		Maximum characters: 30.
State		Maximum characters: 30.
Postal Code		Maximum characters: 30.
Country		Maximum characters: 30.

- 4 Click **SAVE**.

Deleting a customer

- 1 From the main menu, select **Setup > Customers**.
- 2 Select the checkboxes for the customers, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

Medical terms

Tasks: Medical Terms page

On the Medical Terms page, you view the medical terms that are set up in a specific facility. Medical terms are used for the Final Description field on the *Study - AEs page* (in the *Clinical Trial Design and Resource Management Guide*).

- *Adding and editing a medical term* (on page 84).
- *Deleting a medical term* (on page 85).

Adding and editing a medical term

- 1 From the main menu, select **Setup > Medical Terms**.
The Medical Terms page appears.
- 2 To add a medical term, click **NEW**.
To edit a medical term, select a medical term, and click **EDIT**.
The Medical Term dialog box appears.
- 3 Fill in the fields.

Field descriptions for the Medical Term dialog box

Field	Description	Notes
Medical Code	Code for the medical term. The code must be unique.	REQUIRED.
Medical Term	Name of the medical term.	REQUIRED. Medical terms are used for the Final Description field on the

Field	Description	Notes
Term Type	<p>Drop-down list in the application in which the medical term appears.</p> <ul style="list-style-type: none"> AE Final Description Terms appear in the Final Description drop-down list when you create or edit an AE form (in the <i>Clinical Trial Design and Resource Management Guide</i>). AE Conmed Terms appear in the Medication drop-down list when you create an AE observation or follow-up AE observation. Conmed Terms appear in the Medication drop-down list when you create a non-AE observation. Conmed Route Terms appear in the Route drop-down list when you create an AE observation, follow-up AE observation, or non-AE observation. Conmed Unit Terms appear in the Units drop-down list when you create an AE observation, follow-up AE observation, or non-AE observation. 	REQUIRED.
Active	Whether the term is active.	You must select Yes to use the term on the Study – AEs page (in the <i>Clinical Trial Design and Resource Management Guide</i>).
Comment	Comment about the medical term.	Maximum characters: 80.

- Click **SAVE**.
- After you finish, close the dialog box.

Deleting a medical term

- 1 From the main menu, select **Setup > Medical Terms**.
The Medical Terms page appears.
- 2 Select one or more medical terms, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

CHAPTER 4

Setting up the LabPas Recruiting module

In this chapter

Settings pages.....	88
Medical health areas.....	90
Medical questions.....	91
Medical conditions.....	95
Surgical procedures.....	99
Medications.....	102
Other medical settings.....	104
Race and Ethnicity settings.....	107
Demographics settings.....	109
Call scripts.....	115
Call resolutions.....	118
Study types.....	120
Master Questions.....	121
General settings.....	126

Settings pages

On the Settings page, you establish all settings for the LabPas Recruiting module.

You must make selections on the Settings page before you use other pages in the LabPas Recruiting module and before you design recruitment for a particular study. Choices you make on the Settings page establish many of the options and items that appear on other pages in the LabPas Recruiting module.

On the Settings - Calls page, you set up values for:

- **Call scripts** (on page 115).
- **Call script resolutions** (on page 118).

On the Settings - Volunteer page, you set up values for volunteer demographics.

- Properties—Race and Ethnicity settings.
- Demographics—Required Fields and Additional Demographic information.

On the Settings - Study page, you set Study Types and Master Questions.

- Study types are used to:
 - Differentiate between studies on the Study - Properties page.
 - Identify studies for which a volunteer should not be considered on the Volunteers - Personal - Demographics page (in the Recruiting User Guide).
- Master questions are questions of a general nature and can be asked in multiple studies. You create master questions as part of Recruitment setup and import them to individual studies as appropriate.

Settings - Medical page

Select **Recruiting > Settings**. On the Settings - Medical page, you select settings for the LabPas Recruiting module for the following categories.

Category	Description
Health area (on page 90)	Health areas are categories for medical conditions and questions. You associate health areas with questions on the following pages: <ul style="list-style-type: none"> • Settings - Medical - Questions (on page 91) • Settings - Medical - Conditions (on page 95).
Questions (on page 91)	Questions that you create on this page are used when obtaining a volunteer's medical history. Questions set up here are used on the Incoming Calls - Medical History page and the Volunteer - Clinical History - Medical page (in the <i>Recruiting User Guide</i>). They are also printed on the Recruiting Screening Appointment Report for use during in-house volunteer screening.

Category	Description
Conditions (on page 95)	On the Settings - Medical - Conditions page, you associate medical conditions with health areas so that conditions can be recorded in a volunteer's medical history.
Surgical (on page 99)	On the Settings - Medical - Surgical page, you define surgical procedures that can be selected on the Volunteers - Clinical History - Surgical page, or on the Incoming Calls - Surgical Procedures page when the medical history of a volunteer is being recorded.
Medications (on page 102)	You define medications (either prescription or non-prescription) that can be selected on the Volunteers - Concomitant Medications page or the Volunteers - Medications page when the medical history of a volunteer is being recorded.
Other (on page 104)	On the Settings - Medical - Other page, you set up values pertaining to medication distribution. The items you set up are used on the Incoming Calls - Concomitant Medications page and also on the Volunteers - Medications page when the history of medications for a volunteer is recorded.

Medical health areas

Tasks: Settings - Medical - Health Area page

Health areas are categories for medical conditions and questions. You associate health areas with questions on the following pages:

- *Settings - Medical - Questions* (on page 91)
- *Settings - Medical - Conditions* (on page 95)

- *Adding a health area* (on page 90).
- *Deleting a health area* (on page 90).

Adding a health area

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Health Area** category.
The Settings - Medical - Health Area page appears.
- 2 Click **NEW**.
The New Health Area dialog box appears.
- 3 In the **Health Area** field, type a unique name for the health area.
- 4 Type an optional **Comment**, and click **SAVE**.

Deleting a health area

You cannot delete a health area that is associated with a medical question or a medical condition.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Health Area** category.
The Settings - Medical - Health Area page appears.
- 2 Select one or more health areas, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

Medical questions

Settings - Medical - Questions page

Questions that you create on this page are used when obtaining a volunteer's medical history. Questions set up here are used on the *Incoming Calls - Medical History page* and the *Volunteer - Clinical History - Medical page* (in the *Recruiting User Guide*). They are also printed on the Recruiting Screening Appointment Report for use during in-house volunteer screening.

The LabPas Recruiting module provides a number of questions. You can add, edit, or delete conditions. You can restrict data that is displayed on the page by using the FILTER button.

Tasks: Settings - Medical - Questions page

- *Adding a question* (on page 91).
- *Approving a question* (on page 92).
- *Editing a question* (on page 92).
- *Deleting a question* (on page 93).

Adding a question

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Questions** category.
The Settings - Medical - Questions page appears.
- 2 Click **NEW**.
The New Question dialog box appears.
- 3 Fill in the fields.

Field descriptions for the New Question dialog box

Field	Description	Notes
Id	Question ID.	Required for a new question. Must be unique. Read-only if you are editing an existing question.
Health Area	<ul style="list-style-type: none"> • A health area—Make a selection. • No Selection—Select this option if no specific health area can be associated with the question. During volunteer screening, if a volunteer answers Yes, you are prompted for a Date and Comment. 	Options in the drop-down list are created on the <i>Settings - Medical - Health Area page</i> (on page 90).
Question	Text of the question.	REQUIRED.

Field	Description	Notes
Phone Screening Question	When selected, the question is listed on the <i>Incoming Calls - Medical History page</i> (in the <i>Recruiting User Guide</i>).	
Comment	Custom text.	

- 4 Click **SAVE**.
The new question is created and assigned a version number of 1.
- 5 You must ***approve the question*** (on page 92) to make it available for use on other pages.

Approving medical questions

You approve questions on the Settings - Medical - Questions page at one time.

If you add new questions or revise existing questions after approval, you must repeat the approval process to make the new or revised questions available to other pages.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Questions** category.
The Settings - Medical - Questions page appears.
- 2 Click **APPROVAL**.
The Approval dialog box appears.
- 3 Type your User ID, password, and an optional comment, and click **APPLY**.
All questions on the page are approved.

Editing a question

You cannot edit an approved question if it has been deleted or revised, or if there is a more recent version of the question.

You can make any number of edits to an unapproved question without creating a new version.

If you edit and save a question that has been approved, a new version of the question is created. The old version can no longer be edited.

Edited questions must be approved before they are available for use on other pages.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Questions** category.
The Settings - Medical - Questions page appears.
- 2 Select one or more questions, and click **EDIT**.
The Edit Question dialog box appears for the first question.
- 3 Fill in the fields.

Field descriptions for the Edit Question dialog box

Field	Description	Notes
Id	Question ID.	Required for a new question. Must be unique. Read-only if you are editing an existing question.
Health Area	<ul style="list-style-type: none"> • A health area—Make a selection. • No Selection—Select this option if no specific health area can be associated with the question. During volunteer screening, if a volunteer answers Yes, you are prompted for a Date and Comment. 	Options in the drop-down list are created on the <i>Settings - Medical - Health Area page</i> (on page 90).
Question	Text of the question.	REQUIRED.
Phone Screening Question	When selected, the question is listed on the <i>Incoming Calls - Medical History page</i> (in the <i>Recruiting User Guide</i>).	
Comment	Custom text.	

- Click **SAVE**.
 - Previously unapproved questions are saved in the current version.
 - For previously approved questions:
 - A new version is created, and you cannot edit the former version. Status of the former version is changed to Revised.
 - A message appears, indicating that any existing volunteer responses to the former version of the question are now associated with the new version.
- You must **approve the question** (on page 92) to make it available on other pages in the LabPas Recruiting module.

Deleting a question

After you delete a question, it is no longer available for selection on the *Incoming Calls - Medical History page* and the *Volunteers - Clinical History - Medical page* (in the *Recruiting User Guide*).

If a deleted question has already been associated with any volunteers, it continues to be displayed (in red text) and reported for those volunteers.

- From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Questions** category.
The Settings - Medical - Questions page appears.
- Select one or more questions, and click **DELETE**.

The Deletion dialog box appears.

- 3 Type your User ID, password, and an optional comment, and click **APPLY**.

One of the following results occurs:

- If you deleted a question after it has been approved, the question remains on the grid, but it is disabled and displays a status of Deleted.
- If the question has not yet been approved, it is removed completely.

Medical conditions

Settings - Medical - Conditions page

On the Settings - Medical - Conditions page, you associate medical conditions with health areas so that conditions can be recorded in a volunteer's medical history.

The LabPas Recruiting module provides several preconfigured conditions. You can add, edit, or delete conditions. You can restrict the data that appears on the page by using the FILTER button.

Conditions must be approved before they are available for use on other pages.

Tasks: Settings - Medical - Conditions page

- *Adding a condition* (on page 95).
- *Approving a condition* (on page 96).
- *Editing a condition* (on page 97).
- *Deleting a condition* (on page 98).

Adding a condition

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Conditions** category.
The Settings - Medical - Conditions page appears.
- 2 Click **NEW**.
The Condition dialog box appears.
- 3 Fill in the fields.

Field descriptions for the New Condition dialog box

Field	Description	Notes
Medical Term	Medical name for the condition.	Required for a new condition. Must be unique. If you are editing a condition, this field is read only.
Common Name	Common name for the medical condition.	REQUIRED.

Field	Description	Notes
Static Condition checkbox	When selected, the condition is not associated with a health area. (The Health Area drop-down list is read-only.)	Static conditions are always available for selection whenever a medication must be associated with a condition on the <i>Volunteers - Medications</i> or <i>Incoming Calls - Concomitant Medications pages</i> (in the <i>Recruiting User Guide</i>).
Health Area	Health Area associated with the condition.	Available if the Static Condition checkbox is deselected. Options are created on the <i>Settings - Medical - Health Area page</i> (on page 90).
Comment	Custom text.	

- 4 Click **SAVE**.
The new condition is assigned a version number of 1 and is initially unapproved.
- 5 You must *approve the condition* (on page 96) to make it available for use on other pages.

Approving a condition

You approve all conditions on the Settings - Medical - Conditions page at one time.

If you add new conditions or revise existing conditions after approval, you must repeat the approval process to make the new or revised questions available to other pages.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Conditions** category.

The Settings - Medical - Conditions page appears.

- 2 Click **APPROVAL**.

The Approval dialog box appears.

- 3 Type your User ID, password, and an optional comment, and click **APPLY**.

All conditions are approved at one time.

- Previously unapproved conditions have their status set to Approved.
- Earlier versions of edited conditions have their status set to Revised, and can no longer be edited.

Editing a condition

You cannot edit an approved condition if it has been deleted or revised, or if there is a later version of the condition.

You can edit an unapproved condition without creating a new version.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Conditions** category.
The Settings - Medical - Conditions page appears.
- 2 Select one or more conditions, and click **EDIT**.
The Edit Condition dialog box appears.
- 3 Fill in the fields.

Field descriptions for the Edit Condition dialog box

Field	Description	Notes
Medical Term	Medical name for the condition.	Required for a new condition. Must be unique. If you are editing a condition, this field is read only.
Common Name	Common name for the medical condition.	REQUIRED.
Static Condition checkbox	When selected, the condition is not associated with a health area. (The Health Area drop-down list is read-only.)	Static conditions are always available for selection whenever a medication must be associated with a condition on the <i>Volunteers - Medications</i> or <i>Incoming Calls - Concomitant Medications pages</i> (in the <i>Recruiting User Guide</i>).
Health Area	Health Area associated with the condition.	Available if the Static Condition checkbox is deselected. Options are created on the <i>Settings - Medical - Health Area page</i> (on page 90).
Comment	Custom text.	

- 4 Click **SAVE**.
 - Previously unapproved conditions are saved in the current version.
 - For previously approved conditions, a new version is created, and the former version cannot be edited. Status of the former version is changed to Revised.
- 5 You must **approve the condition** (on page 96) to make it available on other pages.

Deleting a condition

After a condition is deleted, it is no longer available for selection on the Incoming Calls - Medical History page and the Volunteers - Clinical History - Medical page.

If a deleted question has already been associated with any volunteers, it continues to be displayed (in red text) and reported for those volunteers.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Conditions** category.

The Settings - Medical - Conditions page appears.

- 2 Select one or more conditions, and click **DELETE**.

The Deletion dialog box appears.

- 3 Type your User ID, password, and an optional comment, and click **APPLY**.

- If the condition was previously approved, it remains listed on the SETTINGS - Medical - Conditions page, but is disabled and shows a status of Deleted.
- If the condition has not yet been approved, it is completely removed.

Surgical procedures

Settings - Medical - Surgical page

On the Settings - Medical - Surgical page, you define surgical procedures that can be selected on the Volunteers - Clinical History - Surgical page, or on the Incoming Calls - Surgical Procedures page when the medical history of a volunteer is being recorded. For more information, see ***Volunteers*** and ***Incoming Calls*** (in the *Recruiting User Guide*).

The LabPas Recruiting module provides pre-configured surgical procedures. You can add, edit, or delete conditions. You can restrict the data that appears on the Settings - Medical - Surgical page, by using the FILTER button.

Surgical procedures must be approved before they are available for use on other pages in the LabPas application.

Tasks: Settings - Medical - Surgical page

- *Adding a surgical procedure* (on page 99).
- *Approving a surgical procedure* (on page 100).
- *Editing a surgical procedure* (on page 100).
- *Deleting a surgical procedure* (on page 101).

Adding a surgical procedure

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Surgical** category. The Settings - Medical - Surgical page appears.
- 2 Click **NEW**. The New Procedure dialog box appears.
- 3 Fill in the fields.

Field descriptions for the New Procedure dialog box

Field	Description	Notes
Medical Term	Medical name for the surgical procedure (for example, Appendectomy).	Required if you are creating a new procedure. Must be unique. Read-only if you are editing a surgical procedure.
Common Name	Common name for the surgical procedure.	REQUIRED.
Comment	Custom text.	

- 4 Click **SAVE**.

- The new surgical procedure is assigned a number of 1.
- 5 You must **approve the procedure** (on page 100) for it to be available on other pages.

Approving a procedure

All surgical procedures that are listed on the Settings - Medical - Surgical page are approved at one time.

If you add new surgical procedures or revise existing procedures after approval, you must repeat the approval process to make the new or revised procedures available to other pages in the LabPas application.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Surgical** category.
The Settings - Medical - Surgical page appears.
- 2 Click **APPROVAL**.
The Approval dialog box appears.
- 3 Type your User ID, password, and an optional comment, and click **APPLY**.
All procedures are approved at one time.

Editing a surgical procedure

You cannot edit an approved surgical procedure if it has been deleted or revised, or if there is a later version of the procedure.

You can make any number of edits to an unapproved surgical procedure without creating a new version.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Surgical** category.
The Settings - Medical - Surgical page appears.
- 2 Select one or more procedures, and click **EDIT**.
The Edit Procedure dialog box appears.
- 3 Fill in the fields.

Field descriptions for the Edit Procedure dialog box

Field	Description	Notes
Medical Term	Medical name for the surgical procedure (for example, Appendectomy).	Required if you are creating a new procedure. Must be unique. Read-only if you are editing a surgical procedure.
Common Name	Common name for the surgical procedure.	REQUIRED.
Comment	Custom text.	

- 4 Click **SAVE**.
 - Previously unapproved surgical procedures are saved in the current version.
 - For previously approved surgical procedures, a new version is created, and the former version cannot be edited. Status of the former version is changed to Revised.
- 5 You must *approve the procedure* (on page 100) for it to be available on other pages.

Deleting a surgical procedure

After a surgical procedure is deleted, it is no longer available for selection on the *Volunteers - Clinical History - Surgical page* or the *Incoming Calls - Surgical Procedures page* (in the *Recruiting User Guide*).

If a deleted procedure has already been associated with any volunteers, it continues to be displayed and reported for those volunteers.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Surgical** category.
The Settings - Medical - Surgical page appears.
- 2 Select one or more surgical procedures, and click **DELETE**.
The Deletion dialog box appears.
- 3 Type your User ID, password, and an optional comment, and click **APPLY**.
 - If the surgical procedure was previously approved, the procedure remains listed on the Settings - Medical - Surgical page, but is disabled and shows a status of Deleted.
 - If the surgical procedure has not yet been approved, it will be completely removed.

Medications

Settings - Medical - Medications page

You define medications (either prescription or non-prescription) that can be selected on the Volunteers - Concomitant Medications page or the Volunteers - Medications page when the medical history of a volunteer is being recorded. For more information, see *Volunteers* (in the *Recruiting User Guide*).

The medications that you designate as active are available for selection when adding a medication to a volunteer record.

You can restrict the data that appears on the page, by using the FILTER button.

The LabPas Recruiting module does not provide any preconfigured lists of medications. You must add medications using this page.

Tasks: Settings - Medical - Medications page

- *Adding and editing a medication* (on page 102).
- *Deleting a medication* (on page 103).

Adding and editing a medication

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Medications** category. The Settings - Medical - Medications page appears.
- 2 To add a medication, click **NEW**.
To edit a medication, select a medication, and click **EDIT**.
The Medication dialog box appears.
- 3 Fill in the fields.

Field descriptions for the Medication dialog box

Field	Description	Notes
Medication	Medical name for the medication (for example, Acetaminophen).	Required if you are adding a medication. Read-only if you are editing a medication.
Common Name	Common name for the medication (for example, Tylenol).	
Active	Yes —The medication is available for selection on other pages. No —The medication is not available for selection on other pages.	Default: Yes.

Field	Description	Notes
Condition Required	<p>Yes—A condition is required when this medication is associated with a volunteer on the Volunteers - Medications page or the Incoming Calls - Concomitant Medications page.</p> <p>No— A condition is not required when this drug is associated with a volunteer.</p>	<p>REQUIRED.</p> <p>Default: No.</p>
Prescription	<p>Yes—The medication is categorized as a prescription drug.</p> <p>No— The medication is categorized as an over the counter (OTC) drug.</p>	<p>REQUIRED.</p> <p>Default: No.</p> <p>The LabPas Recruiting module differentiates between prescription and OTC (over the counter) drugs, for use when calculating medication washout requirements for study eligibility, as configured on the Study - Restrictions page (in the <i>Clinical Trial Design and Resource Management Guide</i>).</p>
Hormonal	<p>Yes—Any volunteer who is currently taking the drug is ineligible for any studies that do not allow hormonal medications.</p> <p>No— Any volunteer who is currently taking the drug is eligible for any studies that do not allow hormonal medications.</p>	<p>REQUIRED.</p> <p>Default: No.</p> <p>The condition for hormonal drugs is configured on the Study - Setup - General page (in the <i>Clinical Trial Design and Resource Management Guide</i>).</p>
Type	Study type.	
Comment	Custom text.	

- 4 Click **SAVE**.

Deleting a medication

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Medications** category. The Settings - Medical - Medications page appears.
- 2 Select one or more medications, and click **DELETE**. A confirmation dialog box appears.
- 3 Click **OK**.

Other medical settings

Settings - Medical - Other page

On the Settings - Medical - Other page, you set up values pertaining to medication distribution. The items you set up are used on the Incoming Calls - Concomitant Medications page and also on the Volunteers - Medications page when the history of medications for a volunteer is recorded. For more information, see *Volunteers* and *Incoming Calls* (in the *Recruiting User Guide*).

A number of values are preconfigured in the LabPas Recruiting module. You can add additional units, frequencies, and routes, and delete existing ones.

The Settings - Medical - Other page includes the following information.

Table	Description
Unit	Unit of measurement. Examples: Caps, Tabs, Sprays, Mg, and MCG.
Frequency	Frequency of use. Examples: once daily, twice daily, and as needed.
Route	Method of distribution. Examples: oral, inhaled, and ophthalmic.
Conditions and Medications	Checkbox for Start Year Required. Selected —The Start Year is required for adding and editing volunteer Condition and Medication records. Not selected —There is no requirement for the Start Year field when adding or editing volunteer Condition and Medication records.

Tasks: Settings - Medical - Other page

- *Adding and deleting a unit of measurement* (on page 104).
- *Adding and deleting a frequency* (on page 105).
- *Adding and deleting a route* (on page 105).
- *Selecting Start Year Required* (on page 106).

Adding and deleting a unit of measurement

You cannot delete a unit of measurement if it has already been used to record a volunteer's medication history on the Incoming Calls - Concomitant Medications page or the Volunteers - Medications page.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Other** category.

- The Settings - Medical - Other page appears.
- 2 To add a unit of measurement:
 - a In the Unit table, click **ADD**.
The New Unit dialog box appears.
 - b In the Unit field, type a unit of measurement.
 - c Click **SAVE**.
 - 3 To delete a unit of measurement:
 - a In the Unit table, click the **X** next to the unit of measurement you want to delete.
A confirmation dialog box appears.
 - b Click **OK**.

Adding and deleting a frequency

You cannot delete a frequency if it has already been used to record a volunteer's medication history on either the Incoming Calls - Concomitant Medications page or the Volunteers - Medications page.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Other** category.
The Settings - Medical - Other page appears.
- 2 To add a frequency:
 - a In the Frequency table, click **ADD**.
The New Frequency dialog box appears.
 - b In the Frequency field, type a unique frequency.
 - c Click **SAVE**.
- 3 To delete a frequency:
 - a In the Frequency table, click the **X** for frequency.
A confirmation dialog box appears.
 - b Click **OK**.

Adding and deleting a route

You cannot delete a route if it has already been used for recording a volunteer's medication history on either the Incoming Calls - Concomitant Medications page or the Volunteers - Medications page.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Other** category.
The Settings - Medical - Other page appears.
- 2 To add a route:
 - a In the Route table, click **ADD**.
The New Route dialog box appears.
 - b In the Route field, type a unique method of distribution.
- 3 To delete a route:

- a In the Route table, click the **X** for a route.
A confirmation dialog box appears.
 - b Click **OK**.
- 4 Click **SAVE**.

Selecting Start Year Required

- 1 From the main menu, select **Recruiting > Settings**. Click the **Medical** tab > **Other** category.
The Settings - Medical - Other page appears.
- 2 Select the checkbox for **Start Year Required**.

For more information, see the *Settings - Medical - Other page* (on page 104).

Race and Ethnicity settings

Settings - Volunteer - Properties page

On the Settings - Volunteer - Properties page, you set up values pertaining to volunteer demographics.

Table	Examples
Race	Asian, White, Black or African American.
Ethnicity	Hispanic or Latino, Not Hispanic or Latino.

The settings from this page are used on the Volunteers - Personal - Demographics page, the Incoming Calls - New Volunteer page, and the Incoming Calls - Existing Volunteer page when demographic information for volunteers is being recorded. For more information, see ***Volunteers*** and ***Incoming Calls*** (in the *Recruiting User Guide*).

The LabPas Recruiting module provides preconfigured values. You can add additional values and edit or delete existing ones.

Tasks: Settings - Volunteer - Properties page

- *Adding and deleting a race* (on page 107).
- *Adding and deleting an ethnicity* (on page 108).

Adding and deleting a race

You cannot delete a race if it has been associated with any volunteers on the Volunteers - Personal - Demographics page or the Incoming Calls - New Volunteer or Incoming Calls - Existing Volunteer pages.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Volunteer** tab > **Properties** category.
The Settings - Volunteer - Properties page appears.
- 2 To add a race:
 - a In the Race table, click **ADD**.
The New Race dialog box appears.
 - b In the Race field, type a race.
 - c In the Category field, select a race category from the drop-down menu.
 - d Click **SAVE**.
- 3 To delete a race:
 - a In the Race table, click the **X** for a race.
A confirmation dialog box appears.
 - b Click **OK**.

Adding and deleting an ethnicity

You cannot delete an ethnicity if it has already been associated with any volunteers on the Volunteers - Personal - Demographics page or the Incoming Calls - New Volunteer or Incoming Calls - Existing Volunteer pages.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Volunteer** tab > **Properties** category.
The Settings - Volunteer - Properties page appears.
- 2 To add an ethnicity:
 - a In the Ethnicity table, click **ADD**.
The New Ethnicity dialog box appears.
 - b In the Ethnicity field, type an ethnicity.
 - c In the Category field, select a race category from the drop-down menu.
 - d Click **SAVE**.
- 3 To delete an ethnicity:
 - a In the Ethnicity table, click the **X** for an ethnicity.
A confirmation dialog box appears.
 - b Click **OK**.

Demographics settings

Settings - Volunteer - Demographics page

On the Settings - Volunteer - Demographics page, you select settings for the following areas.

Table	Description
Required Fields	<p>List of fields that pertain to the identity, current address, and emergency contact information of the volunteer.</p> <p>Your selections appear on the following pages when information about the volunteer is collected:</p> <ul style="list-style-type: none"> • Volunteers - Personal - Demographics. • Volunteers - Personal - Contact. • Incoming Calls - New Volunteer. • Incoming Calls -Existing Volunteer. • Incoming Calls - Volunteer Details. <p>For more information, see <i>Volunteers</i> and <i>Incoming Calls</i> (in the <i>Recruiting User Guide</i>).</p>
Additional Demographics	<p>You can add custom demographic fields to collect data.</p> <p>Fields can be in the form of:</p> <ul style="list-style-type: none"> • Checkbox. • Display. • Entry—For text entry. • Radio—For radio buttons, one of which must be selected. • Selection—For a drop-down list. <p>The custom fields you create appear on the following pages in the LabPas Recruiting module when information about the volunteer is collected:</p> <ul style="list-style-type: none"> • Volunteers - Personal - Other. • Incoming Calls - Additional Demographics. <p>For more information, see <i>Volunteers</i> and <i>Incoming Calls</i> (in the <i>Recruiting User Guide</i>).</p>

Tasks: Settings - Volunteer - Demographics page

For a description of the tables, see the *Settings - Volunteer - Demographics page* (on page 109).

- *Setting demographic field requirements* (on page 110).
- *Adding custom demographic fields* (on page 110).
- *Deleting a custom demographic field* (on page 114).

Setting demographic field requirements

Selections you make on this page appear on the following pages when information is collected for the volunteer:

- Volunteer - Personal - Demographics.
- Volunteer - Personal - Contact.
- Incoming Calls - New Volunteer.
- Incoming Calls - Existing Volunteer.
- Incoming Calls - Volunteer Details.

For more information, see *Volunteers* and *Incoming Calls* (in the *Recruiting User Guide*).

- 1 From the main menu, select **Recruiting > Settings**. Click the **Volunteer** tab > **Demographics** tab.

The Settings - Volunteer - Demographics page appears.

In the **Required Fields** table, fields that appear by default on Demographic or Contact information collection pages are already selected and disabled.

- 2 In the Required Fields table, select the checkboxes for fields that you want to appear as required fields on pages in the LabPas Recruiting module for recording information about the volunteer.

Required fields appear for users with a red asterisk (*) to indicate that they are required.

- 3 Click **UPDATE**.

Adding custom demographic fields

Custom demographic fields appear on the following pages when information is recorded for the volunteer:

- Volunteers - Personal - Other.
- Incoming Calls - Additional Demographics

For more information, see *Volunteers* and *Incoming Calls* (in the *Recruiting User Guide*).

- 1 From the main menu, select **Recruiting > Settings**. Click the **Volunteer** tab > **Demographics** tab.

The Settings - Volunteer - Demographics page appears.

- 2 In the Additional Demographics table, click **ADD**.

A new row appears.

- 3 Fill in the fields.

Field descriptions for a new custom field

Field	Description	Notes
Name	Name of the field that appears on the page that is used to record information. Custom text.	Must be unique. Default: Field_# . The # value is the default order number. If the corresponding field number already exists, A is appended to the number.
Order	Indicates the order in which the custom field should appear on page.	Must be unique. Default: highest previous existing order number, plus 1.
Active	When selected, the field appears on the Volunteers - Personal - Other page and the Incoming Calls - Additional Demographics page.	
Type drop-down box	Type of data field. Select the type, and then fill in the Properties field to specify details about the field type. Fields can be in the form of: <ul style="list-style-type: none"> • Checkbox. • Display. • Entry—For text entry. • Radio—For radio buttons, one of which must be selected. • Selection—For a drop-down list. 	Default: Entry.

- 4 In the **Properties** column, click the ellipsis button (...).

The dialog box appears for the type of field you are adding.

- 5 Fill in the fields.

Checkbox field properties

Field	Description	Notes
Default value	Selection of the checkbox on the form.	Default: Unchecked.

Display field properties

Field	Description	Notes
Rows	Number of rows to appear in the display field. Represents the length of the custom text box.	Default: 1.
Columns	Number of columns to appear in the display field. Represents the width of the custom text box.	Default: 30.
Default value	Read-only text to appear in the field on the page where volunteer data is collected.	

Entry field properties

Field	Description	Notes
Required	When selected, the field is required on the page for collecting volunteer data.	Default: 1.
Size drop-down list	Size of the custom field: Small —Approximately 1 inch. Medium —Approximately 2 inches. Large —Approximately 3 inches.	Default: Medium.
Length	Number of characters that can be entered in the field.	REQUIRED. Default: 30. Maximum is 500.
Data Type	Type of data that can be entered into the field on the page for collecting volunteer data.	Default: Text.
Min	Lowest numeric value that can be entered in the field.	Required if Data Type is Numeric Default: 0.
Max	Highest numeric value that can be entered in to the field.	Required if Data Type is Numeric. Default: 0.
Default value	Custom text to appear in the field.	Default: blank.

Radio field properties

- a Click in the **Value List** field.
An entry box appears.

- b Enter text for the first radio button.
- c Click the plus sign (+) button.
The entry is saved, and a new entry box appears.
- d Enter text for the next radio button.
- e To add additional radio buttons, click the plus sign (+) button and type the value in the entry field.
 - To edit any button value, click in the entry field and make changes.
 - To remove a button from the list, click in the field and then click the minus sign (-) button.
 - To change the order of the radio buttons, put the cursor in the entry field and click the up or down arrow buttons located on the right side of the Value List field.
- f After you finish adding radio buttons and arranging them in the order you want, use the **Default Value** drop-down list to select the radio button that is selected by default on the page where data is collected for the volunteer.

Selection field properties

- a In the **Size** drop-down list, select the size of the field.
 - **Small**—approximately 1 inch.
 - **Medium**—approximately 2 inches. (Default)
 - **Large**—approximately 3 inches.
- b Click in the **Value List** field.
An entry box appears.
- c Enter text for the first selection on the selection list you are creating.
- d Click the plus sign (+) button.
The entry is saved, and a new entry box appears.
- e Enter text for the next selection.
- f To add additional selections, click the plus sign (+) button, and type the value in the entry field.
 - To edit any selection value, click in the entry field and make changes.
 - To remove a selection from the list, click in the field and then click the minus sign (-) button.
 - To change the order of the selections, select the entry field and click the up or down arrow buttons located on the right side of the **Value List** field.
- g After you finish adding selections and arranging them in the order you want them to appear, use the **Default Value** drop-down list to choose the default selection that appears on the page where data is collected for the volunteer.

- 6 Click **SAVE**.

Deleting a custom demographic field

You cannot delete a custom demographic field if it has been associated with any study restrictions or volunteers on the Volunteers - Personal - Other or the Incoming Calls - Additional Demographics pages.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Volunteer** tab > **Demographics** tab.

The Settings - Volunteer - Demographics page appears.

- 2 In the Additional Demographics table, click the **X** next to a field name.

The field deleted from the table and no longer appears on the Volunteers - Personal - Other and the Incoming Calls - Additional Demographics pages.

Call scripts

Tasks: Settings - Call - Call Script page

On the Settings - Calls - Call scripts page, you create call scripts that appear on the **Incoming Calls pages** (in the Recruiting User Guide). Call scripts appear at the top of the Operator's page, giving the operator instructions to follow while speaking with potential volunteers over the phone.

- *Adding a call script* (on page 115).
- *Approving a call script* (on page 116).
- *Editing a call script* (on page 116).
- *Deleting a call script* (on page 117).

Adding a call script

- 1 From the main menu, select **Recruiting > Settings**. Click the **Calls** tab > **Call Script** tab.
The Settings - Calls - Call Script page appears.
- 2 Click **NEW**.
The New Script dialog box appears.
- 3 Fill in the fields.

Field descriptions for the New Script dialog box

Field	Description	Notes
Id	Page in the Incoming Calls pages on which the script appears. Select from a drop-down list of pages in the Incoming Calls section of the LabPas Recruiting module.	Required for a new script. Must be unique. Read-only if you are editing the script. Default: Advertising.
Script	Text of the script that the operator reads over the phone to the caller or prospective volunteer. The text you enter here appears in the header of the page you selected in the Id field.	REQUIRED.
Comment	Custom text.	

- 4 Click **SAVE**.
The new script is assigned a version number of 1.
- 5 You must *approve the script* (on page 116) to make it available on other pages.

Approving a call script

If you add new call scripts or revise existing scripts after the initial approval, you must repeat the approval process to make the new or revised scripts available on other pages.

All questions are approved at one time when the approval is complete.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Calls** tab > **Call Script** tab.
The Settings - Calls - Call Script page appears.
- 2 Click **APPROVAL**.
The Approval dialog box appears.
- 3 Type your User ID, password, and an optional comment, and click **APPLY**.
 - Previously unapproved call scripts have their statuses set to Approved.
 - Previously approved scripts are saved to a new version number. The previous version of the script has its status set to Revised, and is no longer editable.

Editing a call script

You cannot edit an approved call script if it has been deleted or revised, or if there is a more recent version of the script.

You can make any number of edits to an unapproved call script without creating a new version.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Calls** tab > **Call Script** tab.
The Settings - Calls - Call Script page appears.
- 2 Select one or more scripts, and click **EDIT**.
The Edit Script dialog box appears.

Note: If you selected multiple call scripts the Edit Scripts dialog box appears for each record.

- 3 Fill in the fields.

Field descriptions for the Edit Script dialog box

Field	Description	Notes
Id	Page in the Incoming Calls pages on which the script appears.	Required for a new script. Must be unique.
	Select from a drop-down list of pages in the Incoming Calls section of the LabPas Recruiting module.	Read-only if you are editing the script. Default: Advertising.

Field	Description	Notes
Script	Text of the script that the operator reads over the phone to the caller or prospective volunteer. The text you enter here appears in the header of the page you selected in the Id field.	REQUIRED.
Comment	Custom text.	

- 4 Click **SAVE**.
 - If the call script has not been approved, the edits are saved in the current version
 - For previously approved call scripts, a new version is created, and the former version cannot be edited. Status of the former version is changed to Revised.
- 5 You must *approve the call scripts* (on page 116) to make them available for use on other pages.

Deleting a script

- 1 From the main menu, select **Recruiting > Settings**. Click the **Calls** tab > **Call Script** tab.
The Settings - Calls - Call Script page appears.
- 2 Select one or more scripts, and click **DELETE**.
The Deletion dialog box appears.
- 3 Type your User ID, password, and an optional comment, and click **APPLY**.
One of the following results occurs:
 - Scripts that have not yet been approved are removed completely.
 - If a call script has been previously approved, it remains on the Settings - Calls - Call Scripts page, but is disabled and shows a status of Deleted. The script no longer appears on the Incoming Calls pages of the LabPas Recruiting module.

Call resolutions

Tasks: Settings - Call - Resolutions page

Call resolutions are required when completing an outgoing call and when prematurely ending an incoming call to volunteers. The LabPas Recruiting module does not provide call resolutions; you must set them up on the Settings - Calls - Resolutions page.

You can restrict data that appears on the page by using the FILTER button.

You can select the **Reschedule Call** option only for outgoing calls. If you select the **Reschedule Call** option for a resolution, then whenever that resolution is applied to a call, a new outgoing call is scheduled for the next day, to the same volunteer.

- *Adding a call resolution* (on page 118).
- *Deleting a call resolution* (on page 119).

Adding a call resolution

You cannot use the same resolution for both incoming and outgoing calls. For the same text to appear in a resolution for both types of calls, you must add a character to make them different (for example, **Hang up** and **Hang-up**).

- 1 From the main menu, select **Recruiting > Settings**. Click the **Calls** tab > **Resolutions** tab.

The Settings - Calls - Call Resolutions page appears.

- 2 Click **NEW**.

The New Resolution dialog box appears.

- 3 Fill in the fields.

Field description for the New Resolutions dialog box

Field	Description	Notes
Resolution	Custom text to describe how the call should be completed.	REQUIRED. Must be unique.
Direction	Type of call to which the resolution pertains: In Coming or Out Going.	
Reschedule Call	When selected after this resolution is applied to the call, a new outgoing call is scheduled to the same volunteer for the following day.	Enabled if the selection for Direction is Out Going. Default: not selected.
Call Type	Type of call.	For reference only.
Comment	Custom text.	

- 4 Click **SAVE**.

Deleting a call resolution

You cannot delete a resolution that has been used in the processing of a call.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Calls** tab > **Resolutions** tab.
The Settings - Calls - Call Script page appears.
- 2 Select one or more resolutions, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

Study types

Tasks: Settings - Study - Study Types page

Study types are used to:

- Differentiate between studies on the Study - Properties page.
- Identify studies for which a volunteer should not be considered on the Volunteers - Personal - Demographics page (in the Recruiting User Guide).

You must define at least one study type before you can open a study for recruiting.

- *Adding and deleting a study type* (on page 120).

Adding and deleting a study type

You cannot delete a study type that has been associated with a study, study restriction, or volunteer.

- 1 From the main menu, select **Recruiting > Settings**. Click **Study > Study Types**.

The Study Types list appears.

- 2 To add a study type:

- a Click **ADD**.

The New Study Type dialog box appears.

- b Provide a unique name for the study type.
- c Click **SAVE**.

- 3 To delete a study type:

- a Click the **X** next to a study type.

A confirmation dialog box appears.

- b Click **OK**.

Master Questions

Settings - Study - Master Questions page

Master questions are questions of a general nature and can be asked in multiple studies. You create master questions as part of Recruitment setup and import them to individual studies as appropriate.

Master questions that you create are available for selection on the *Study - Questionnaire page* (in the *Clinical Trial Design and Resource Management Guide*). On this page, you choose study-specific screening questions.

You can restrict data that is displayed on the page by using the FILTER button.

The LabPas Recruiting module does not provide master questions; you must create them. Master questions must be approved before they are available for use on other pages.

About assigned numbers

When you add a new master question to the LabPas Recruiting module, you assign a number to the question. The questions later appear on the *Study - Questionnaire page* (in the *Clinical Trial Design and Resource Management Guide*). On this page, the questions are listed in the order of their assigned numbers.

It is recommended that you assign numbers that are not consecutive, so that new questions that are subsequently added can be assigned numbers that allow them to appear before or after the previously-created questions as needed.

For example, if you create three questions that have numbers 10, 20, and 30, a subsequent question can be created with the number 15 to appear between the first two questions.

Tasks: Settings - Study - Master Questions page

- *Adding a master question* (on page 121).
- *Approving a master question* (on page 123).
- *Editing a master question* (on page 123).
- *Deleting a master question* (on page 125).

Adding a master question

Numbers that you assign to master questions determine the order that the questions appear on the *Study - Questionnaire page* (in the *Clinical Trial Design and Resource Management Guide*). For more information, see *About assigned numbers* (on page 121).

- 1 From the main menu, select **Recruiting > Settings**. Click the **Study** tab > **Master Questions** category.
The Settings - Study - Master Questions page appears.
- 2 Click **NEW**.

The New Question dialog box appears.

- 3 Fill in the fields.

Field descriptions for the New Question dialog box

Field	Description	Notes
Id	ID used to identify the question.	REQUIRED. Must be unique. After the Master Question has been created, this field cannot be edited.
Number	Number that is assigned to each question to determines the order in which the question appears during phone screening.	REQUIRED. Must be unique. Questions on this page and on the Study - Questionnaire page appear in the order of the assigned number. It is recommended that you assign non-consecutive numbers, such as 10, 20, 30, so that if you subsequently add more master questions, each new question can be inserted between existing questions. For example, you can insert question 15 between questions 10 and 20.
Qualifier	Drop-down list selection of None, Male, and Female.	Default: None.
Question	Question that is read to the caller or volunteer.	REQUIRED.
Question Type	Type of question. Radio button selection of Phone Screening and Eligibility Review.	Default: Phone Screening.
Required	When selected, the Question is required on the S - Questionnaire page.	Disabled and cleared if Question Type is set to Eligibility Review.
Disqualify When	Answer to the question that disqualifies the caller from the study.	Default: Blank. A selection of Yes or No is required if Question Type is set to Phone Screening.
Comment	Custom text.	

- 4 Click **SAVE**.

The new question is saved and assigned a version number of 1.

Approving master questions

If you add new questions or revise existing questions after approval, you must repeat the approval process to make the new or revised questions available to other pages.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Study** tab > **Master Questions** category.

The Settings - Study - Master Questions page appears.

- 2 Click **APPROVAL**.

The Approval dialog box appears.

- 3 Type your User ID, password, and an optional comment, and click **APPLY**.

- Previously unapproved master questions have their status set to Approved.
- Earlier approved versions of edited questions have their status changed to Revised, and can no longer be edited.

Once the approval is complete, all questions are approved at the same time.

Editing a master question

You cannot edit an approved master question that has been deleted or revised, or if there is a more recent version of the question.

You can make any number of edits to an unapproved question without creating a new version.

If you edit and save a question that has been approved, a new version of the question is created. The old version can no longer be edited.

Edited questions must be approved before they are available for use on other pages.

- 1 From the main menu, select **Recruiting > Settings**. Click the **Study** tab > **Master Questions** category.

The Settings - Study - Master Questions page appears.

- 2 Click **EDIT**.

- 3 The Edit Question dialog box appears.

Note: If you selected multiple master questions, the Edit Scripts dialog box appears for each record, one at a time.

- 4 Fill in the fields.

Field descriptions for the Edit Question dialog box

Field	Description	Notes
Id	ID used to identify the question.	REQUIRED. Must be unique. After the Master Question has been created, this field cannot be edited.
Number	Number that is assigned to each question to determines the order in which the question appears during phone screening.	REQUIRED. Must be unique. Questions on this page and on the Study - Questionnaire page appear in the order of the assigned number. It is recommended that you assign non-consecutive numbers, such as 10, 20, 30, so that if you subsequently add more master questions, each new question can be inserted between existing questions. For example, you can insert question 15 between questions 10 and 20.
Qualifier	Drop-down list selection of None, Male, and Female.	Default: None.
Question	Question that is read to the caller or volunteer.	REQUIRED.
Question Type	Type of question. Radio button selection of Phone Screening and Eligibility Review.	Default: Phone Screening.
Required	When selected, the Question is required on the S - Questionnaire page.	Disabled and cleared if Question Type is set to Eligibility Review.
Disqualify When	Answer to the question that disqualifies the caller from the study.	Default: Blank. A selection of Yes or No is required if Question Type is set to Phone Screening.
Comment	Custom text.	

- 5 Click **SAVE**.

Deleting a master question

- 1 From the main menu, select **Recruiting > Settings**. Click the **Study** tab > **Master Questions** category.

The Settings - Study - Master Questions page appears.

- 2 Select one or more questions, and click **DELETE**.

The Deletion dialog box appears.

- 3 Type your User ID, password, and a comment, and click **APPLY**.

One of the following results occurs:

- If you deleted a master question after it has been approved, the question remains on the grid, but it is disabled and displays a status of Deleted.
- If the master question has not yet been approved, it is completely removed.

Deleted questions are no longer available for selection in the Study - Questionnaire pages.

General settings

Settings - General page

On the General tab of the Settings page you select settings for the following areas.

Table	Description
<i>Alert Triggers</i> (on page 127)	Specify the maximum number of times a volunteer can cancel within a given period of time. Alerts appear on the <i>Alerts page</i> (in the <i>Recruiting User Guide</i>) when a volunteer reaches the number of maximum cancellations per the period of months you specify.
<i>Mail settings</i> (on page 128)	Specify the default email address of the sender, to be used when sending emails to volunteers from the <i>Volunteer Lookup page</i> (in the <i>Recruiting User Guide</i>). You can send a test email to confirm that the settings are working correctly.
<i>Volunteer Study Status</i> (on page 128)	Specify whether a status, when selected for a volunteer, requires a reason to be associated with it.
<i>Reasons</i> (on page 130)	Create and activate reasons that relate to volunteer study statuses and any related alerts. The LabPas Recruiting module provides preconfigured reasons. You can add additional reasons, and edit or delete existing reasons. Reasons are available in a drop-down list on the following pages: <ul style="list-style-type: none"> • <i>Study - Volunteers page</i> (in the <i>Clinical Trial Design and Resource Management Guide</i>). • <i>Volunteers - Studies page</i> (in the <i>Recruiting User Guide</i>). • <i>Appointments page</i> (in the <i>Recruiting User Guide</i>).
<i>Volunteer Data Settings</i> (on page 131)	Indicate whether a comment is required when volunteer data is changed.

Tasks: Settings - General page

For descriptions of the tables, see the *Settings - General page* (on page 126).

- *Setting up alert triggers* (on page 127).
- *Requiring reasons for study assignment* (on page 128).
- *Setting up and testing a default email address* (on page 128).
- *Adding reasons pertaining to volunteer study statuses* (on page 130).
- *Editing reasons pertaining to volunteer study statuses* (on page 130).
- *Deleting reasons pertaining to volunteer study statuses* (on page 131).
- *Indicating if a comment is required when volunteer data is changes* (on page 131)

Setting up alert triggers

You use the Alert Triggers table to set alert parameters relating to volunteer cancellations, and to note a general probation period of time. Alerts are generated by the LabPas Recruiting module and appear on the *Alerts page* (in the *Recruiting User Guide*) when a volunteer reaches the number of maximum cancellations per the period of months specified.

For example, if the settings are 1 in the **Appt. Cancellation** fields and 12 in the **Months** field, then if a volunteer cancels one time in a 12-month period, an alert is generated on the Alerts page for that volunteer.

- 1 From the main menu, select **Recruiting > Settings**. Click the **General** tab.
The Settings - General page appears.
- 2 In Alert Triggers table, fill in the fields.

Field description for the Alert Triggers table

Field	Description	Notes
Appt. Cancellations	Maximum number of times a volunteer can cancel in the number of months you specify in the Months field. If blank, no alerts are issued.	When a volunteer reaches the maximum number of cancellations in the specified number of months, an alert appears on the Alerts page.
Months	Number of months for the maximum number of cancellations. If blank, no alerts are issued.	
Probation Length [] Months	Length of probation period. You can consult this field when determining the Probation End Date for a specific volunteer who is on probation, on the Volunteers - Personal - Demographics page.	Reference only.

- 3 Click **SAVE**.

Requiring reasons for status assignment

In the **Volunteer Study Status** table you specify whether a status requires a reason when it is assigned to a volunteer on the Study - Volunteers page or Volunteers - Study History page, or when resolving appointments on the Appointments page.

- 1 From the main menu, select **Recruiting > Settings**. Click the **General** tab.

The Settings - General page appears.

The Volunteer Study Status table lists the statuses that are preconfigured in the LabPas Recruiting module.

- 2 For each status, select or deselect the **Reason Required** checkbox.

- **Selected**—A reason is required when the status is assigned.
- **Note selected**—A reason is not required.

- 3 Click **SAVE**.

Note: Setting parameters for a sample type is not required for clinical lab processing in the LabPas Recruiting module. In fact, it is not a common process in this context. We recommend that you contact Oracle for guidance in implementation if this process is important for your facility.

Setting up a default email address

Specify the default email address to be used when sending emails to volunteers from the Volunteer Lookup page. You can also send a test email.

Prerequisite: Before you can send emails through the LabPas application, you must first configure mail settings in the *global settings for the LabPas application* (on page 33).

Note: This page is used only to create email settings and to send test emails. To send *actual* emails to study volunteers, use the Volunteer Lookup email page.

- 1 From the main menu, select **Recruiting > Settings**. Click the **General** tab.

The Settings - General page appears.

- 2 In the Mail Settings table, fill in the fields.

Field descriptions for the Mail Settings table

Field	Description	Notes
Sender	Email address of the person who is sending the email.	REQUIRED.
Cc	Email addresses of others to receive a copy of the email.	
BCc	Email addresses of others to receive a copy of the email.	This address is not visible to recipients in the CC field.

- 3 To send a test email, click **TEST**.

The Mail dialog box appears.

Field descriptions for the Mail dialog box

Field	Description	Notes
Format	Format of the email message.	
To	Email address to which the test email will be sent.	REQUIRED.
Subject	Subject of the email. Type the subject in the field.	REQUIRED.
Message	Content of the message.	

- 4 Fill in the fields and click **SAVE**.

The test email is sent.

If there are any technical issues with the email recipient's email address, an error message is sent to the Sender email address and to the **Cc** and **Bcc** email addresses, if provided.

Adding a reason for a study status

You use the Reasons table to create and activate reasons relating to volunteer study statuses, and also to determine if and when alerts should be generated in association with the reasons.

The LabPas Recruiting module provides a number of reasons.

- 1 From the main menu, select **Recruiting > Settings**. Click the **General** tab.

The Settings - General page appears.

- 2 In the Reasons table, click **ADD**.

A new row appears in the table.

- 3 Fill in the fields.

Field descriptions for the Reason table

Field	Description	Notes
Reason	Name for a reason (for example, Positive Urine Drug Screen for Alcohol).	
Active	When selected, the reason is made available for selection in other pages.	
Generate Alert	When selected, an alert is generated on the Alerts page when this reason is associated with a volunteer (according to the parameters in the Occurrences/Months field).	If selected, you must also specify Occurrences and Months .
Occurrences	Maximum number of times the reason can be given.	Required if you select the Generate Alert checkbox.
Months	Number of months in which the number you specified in Occurrences can occur.	Required if you select the Generate Alert checkbox.

- 4 Click **SAVE**.

Editing a reason for volunteer study statuses

- 1 From the main menu, select **Recruiting > Settings**. Click the **General** tab.

The Settings - General page appears.

- 2 In the Reasons table, click in a row and fill in the fields.

Field descriptions for the Reason table

Field	Description	Notes
Reason	Name for a reason (for example, Positive Urine Drug Screen for Alcohol).	
Active	When selected, the reason is made available for selection in other pages.	
Generate Alert	When selected, an alert is generated on the Alerts page when this reason is associated with a volunteer (according to the parameters in the Occurrences/Months field).	If selected, you must also specify Occurrences and Months .
Occurrences	Maximum number of times the reason can be given.	Required if you select the Generate Alert checkbox.
Months	Number of months in which the number you specified in Occurrences can occur.	Required if you select the Generate Alert checkbox.

- 3 Click **SAVE**.

Deleting a reason for volunteer study statuses

You cannot delete a reason if it has been associated with an alert or a volunteer.

- 1 From the main menu, select **Recruiting > Settings**. Click the **General** tab.
The Settings - General page appears.
- 2 In the Reasons table, click the **X** next to a reason.

Specifying comment requirements

Specify whether a comment is required when volunteer data is changed.

- 1 From the main menu, select **Recruiting > Settings**. Click the **General** tab.
The Settings - General page appears.
- 2 In the Volunteer Data Settings table, select **Change Comment Required**.

APPENDIX A

Reports

In this appendix

Tasks: View Reports page.....	134
Tasks: Report Groups page.....	135
Report layout	136
LabPas CT reports.....	137
LabPas Recruiting reports	139
LabPas Resource Management reports	141
Viewing the list of available reports.....	142
Viewing a report.....	143
Creating a new report.....	145
Deleting a report	148
Adding and editing a report group.....	149
Deleting a report group.....	150
Printing a report	151

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.
- *Viewing the list of available reports* (on page 142)
- *Viewing a report* (on page 143)
- *Creating a new report* (on page 145)
- *Deleting a report* (on page 148)

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 149).
- *Deleting a report group* (on page 150).

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 143).

- 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 143). 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 the Sample Processing pages. 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 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	<p>Includes metrics for each user authorized to use the Incoming Calls and Outgoing Calls pages in the selected study.</p> <p>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.</p>
Recruiting Change Log	<p>Includes modifications made to previously recorded data (for example, volunteers, study setup, and study properties) on the Volunteer pages.</p> <p>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.</p>
Recruiting Media Campaigns	<p>Tracks volunteer response, scheduling, and study participation based on an ad campaign and displays descriptive information about the campaign.</p>
Recruiting Screening Appointment	<p>Includes appointment information for the selected volunteer, including demographic, medical, and testing data.</p> <p>If the Global Recruiting application setting is not selected:</p> <ul style="list-style-type: none"> • 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	<p>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.</p> <p>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.</p>
Recruiting Volunteer Data	<p>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.</p>

Report	Description
Study Recruitment	<p data-bbox="667 212 1354 243">Includes recruitment details for the selected study, including:</p> <ul data-bbox="667 264 1471 604" style="list-style-type: none"><li data-bbox="667 264 1414 327">• Number of subjects goal, percent of subjects goal, number of subjects needed to reach subjects goal.<li data-bbox="667 348 1425 453">• Number of backup (alternate) subjects goal, current percent of backup (alternate) subjects goal, current number of backup (alternate subjects needed to reach backup goal).<li data-bbox="667 474 1471 604">• 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	<p data-bbox="667 625 1471 688">Provides details of collection labels that have been printed or reprinted in the current facility.</p>

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. 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.	REQUIRED. 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: <ul style="list-style-type: none"> • 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. 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.	REQUIRED. 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: <ul style="list-style-type: none"> • 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.	

- 4 Click **SAVE**.

The Save Report As dialog box appears.

- 5 In the **Report Name** field, type a name for the new report.
- 6 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.
- 7 Click **APPLY**.

Deleting a report

You must have the Delete Any Report permission to delete reports that are associated with a user other than yourself.

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 must have the Delete Any Report permission to delete report groups that are associated with a user other than yourself.

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 145), or *view an existing report* (on page 143).
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	154
Printing an existing barcode.....	155
Printing an auto-generated barcode	156

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 155).
- *Printing an auto-generated barcode* (on page 156).

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.

Index

A

- access • 44
 - granting • 44
 - removing • 46

B

- barcode
 - printing an auto-generated • 156
 - printing an existing • 155
- bookmark
 - creating • 12
 - deleting • 13

C

- call resolution • 118
 - adding • 118
 - deleting • 119
 - settings • 118
- call script • 115
 - adding • 115
 - approving • 116
 - deleting • 117
 - editing • 116
 - settings • 115
- comment • 22
 - creating • 22
 - deleting • 22
 - editing • 22
 - printing • 23
- condition
 - adding • 95
 - approving • 96
 - deleting • 98
 - editing • 97
 - settings • 95
- customer • 82
 - adding • 82
 - deleting • 83
 - editing • 82

D

- data frame • 5
 - configuring • 9
 - filtering • 10
- demographic
 - adding a custom field • 110
 - deleting a custom field • 114
 - setting field requirements • 110
 - settings • 109, 110
- demographic range

- specifying for a test • 67

E

- edit check • 69
 - adding to a test panel • 72
 - deleting from a test panel • 77
- ethnicity
 - adding • 108
 - deleting • 108
 - settings • 107

F

- facility
 - deleting • 32
 - working with • 30
- form • 78
 - adding • 78
 - adding a question • 78
 - deleting • 81
 - editing properties • 80
- frequency
 - adding • 105
 - deleting • 105

G

- general settings • 126, 127
 - adding a reason for a study status • 130
 - deleting a reason for volunteer study statuses • 131
 - editing a reason for a volunteer study status • 130
 - setting a default email address • 129
 - setting up alert triggers • 127
 - specifying comment requirements • 131
 - specifying whether a status requires a reason • 128

H

- home page
 - setting • 11

I

- instrument • 47
 - adding • 47
 - deleting • 48
 - editing • 47
 - printing label • 48

J

- job • 26
 - administrating • 26
 - creating • 28
 - deleting • 29

editing • 28

L

label • 154

label configuration • 24

deleting • 25

LabPas application • 2

configuring • 17

getting started • 1

setting up • 37

LabPas Recruiting module

setting up • 87

link • 18

adding an external web link to the menu • 18

deleting • 19

editing the URL for an external web link • 19

moving • 20

renaming • 19

logon

logging off • 8

logging on • 7

M

main menu • 4

master question • 121

adding • 121

approving • 123

assigning numbers • 121

deleting • 125

editing • 123

settings • 121

measurement

adding a unit of • 104

deleting a unit of • 104

medical condition • 95

adding • 95

approving • 96

deleting • 98

editing • 97

settings • 95

medical health areas • 90

adding • 90

deleting • 90

settings • 90

medical question • 91

adding • 91

approving • 92

deleting • 93

editing • 92

settings • 91

medical settings • 104

adding a frequency • 105

adding a route • 105

adding a unit of measurement • 104

deleting a frequency • 105

deleting a route • 105

deleting a unit of measurement • 104

Selecting Start Year Required • 106

medical term • 84

adding • 84

deleting • 86

editing • 84

medication • 102

adding • 102

deleting • 103

editing • 102

settings • 102

menu

editing • 18

menu item • 18

adding • 18

deleting • 19

moving • 20

renaming • 19

message

deleting • 14

reading • 14

working with • 14

message group

adding • 15

deleting • 16

N

navigation • 4

P

page heading • 5

permission • 3, 38

application access permission • 42

procedure

approving • 100

Q

question

adding • 91

deleting • 93

editing • 92

R

race

adding • 107

deleting • 107

settings • 107

reference value • 57

report • 133, 141

creating • 145

layout aaa • 136

printing • 151

viewing • 134, 142, 143

report group • 135

adding • 149

editing • 149

role • 3, 44

changing • 45

route

adding • 105

deleting • 105

S

- sample type • 52
 - adding • 52
 - deleting • 53
 - editing • 52
- security role • 38, 42
 - creating • 43
 - deleting • 43
 - editing • 43
- settings • 30, 88
 - pages • 88
 - specifying global settings • 33
 - specifying timeout settings • 33
 - working with • 30
- storage device • 49
 - adding • 49
 - deleting • 50
 - editing • 49
 - printing label • 51
- study statuses
 - adding a reason • 130
 - deleting a reason for volunteer study status • 131
 - editing a reason for a volunteer study status • 130
- study type • 120
 - adding • 120
 - deleting • 120
 - settings • 120
- surgical procedure • 99
 - adding • 99
 - approving • 100
 - deleting • 101
 - editing • 100
 - settings • 99
- system information • 36
 - terminating a user session • 36

T

- term • 21
 - editing • 21
- term library • 21
- test • 56
 - adding a Double test • 62
 - adding a List test • 64
 - adding a Numeric test • 59
 - adding a Pass/Fail test • 61
 - adding a Pos/Neg/??? test • 60
 - adding a Text test • 58
 - deleting • 68
 - editing • 67
- test panel • 69
 - adding a test • 72
 - adding an edit check • 72
 - deleting • 77
 - deleting a test • 77
 - deleting an edit check • 77

U

- user • 3, 44
 - authorizing • 44

- changing role • 45
- granting access • 44
- locking out • 45
- removing access • 46

V

- vessel type • 54
 - deleting • 55