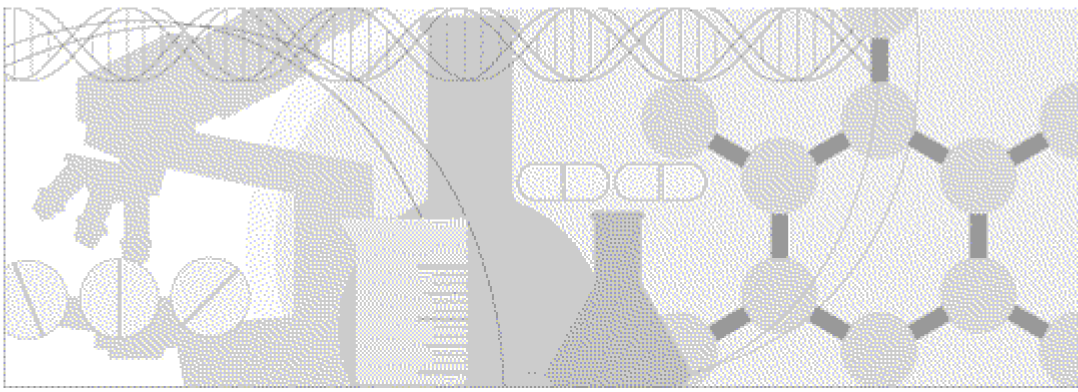
Recruiting User Guide

Oracle® Health Sciences LabPas
Release 3.1



Part Number: E48673-01

Contents

About this guide

In this preface

Overview of this guide

The LabPas *Recruiting 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.

Audience

This guide is for everyone who uses the Oracle® Health Sciences LabPas application to manage recruiting efforts for clinical trials. This audience includes principal investigators, recruiting managers, recruiters, study coordinators, study managers, and other staff who work on recruitment functions.

Documentation

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

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

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

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

If you need assistance

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

CHAPTER 1
Getting started

In this chapter

The LabPas application

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

- **LabPas CT module**—Use the LabPas CT module to establish the elements, settings, and properties on which a study is built. You can set up and configure:
  - Users
  - Facilities
  - Instruments
  - Storage devices
  - Sample and vessel types
  - Test panels
  - Global settings
- **LabPas Resource Management**—Use the LabPas Resource Management module to create and manage clinics, studies, and staff assignments.
- **LabPas Recruiting module**—Use the LabPas Recruiting module to manage volunteer recruitment. You can:
  - Develop study-specific call scripts.
  - Define study inclusion and exclusion criteria.
  - Search the recruiting database for potential volunteers.
  - Receive calls from potential volunteers.
  - Manage advertising campaigns.
  - Schedule outgoing phone calls.
  - Track caller responses.
  - Record volunteer information.
  - Create a schedule of events.
  - Schedule and process screening events.
  - Assign volunteers to studies.
- **LabPas DQ module**—Use the LabPas DQ module to review the data that is collected in LabPas CT studies.

Users, permissions, and roles

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

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

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

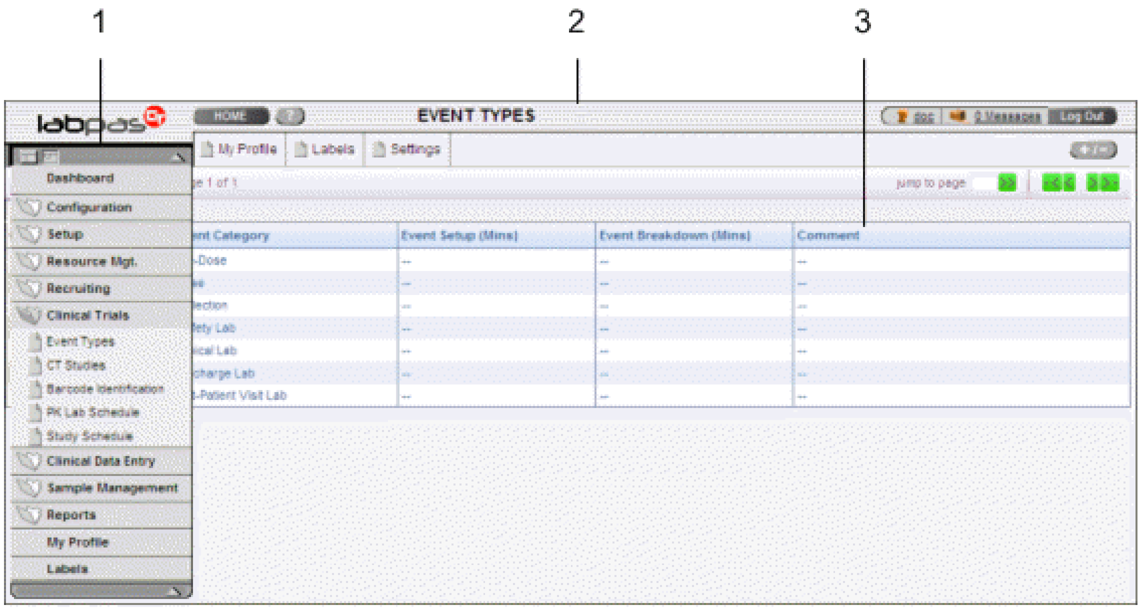
Navigation

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

1 *Main menu* (on page 4)

2 *Page heading* (on page 5)

3 *Data frame* (on page 5)



Main menu

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

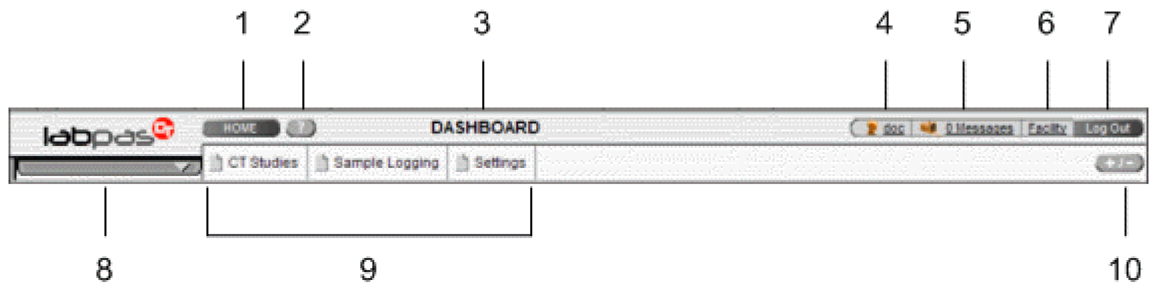
- To expand the collapsed main menu, click the down arrow.

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

- To keep the main menu expanded, click the page icon ( ).
- To navigate through the application, expand the main menu, click a folder, and select a page in the folder.

Page heading

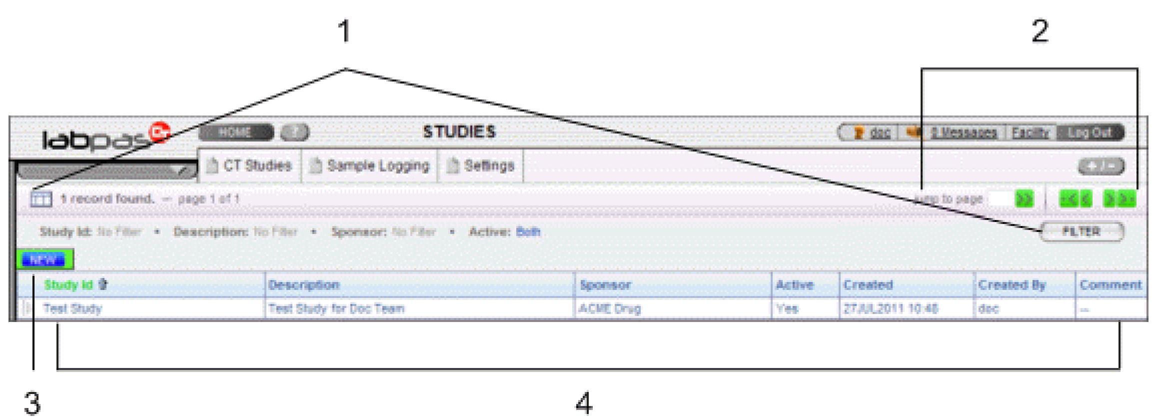
The page heading is similar on all LabPas pages.



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

Data frame

The data frame contains one or more of the following.



1 **Grid tools**—Use the grid setup and filter options to limit and order your selections.

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

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

- Buttons with white backgrounds function only when items in the grid are checked.
- Buttons with green backgrounds do not require any items to be checked to function.

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

Logging on

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

1 To log on, do one of the following:

- In the address field of your browser, type http://<*server name*>/LabPAS and press **Enter**.
- In the address field of your browser, type http://<*server IP address*>/LabPAS and press **Enter**.
- From the desktop, double-click the shortcut for the LabPas CT module.

The User Logon page appears.

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

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

Your home page appears.

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

Logging off

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

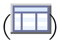
If your session times out, log back on and then log off to exit securely from the application.

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

Changing the contents of the data grid

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

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

1 Click the grid setup icon ().

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

2 Select each column to display.

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

4 Click **APPLY**.

Filtering grid data

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

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

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

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

Setting a home page

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

   The Configure User Profile page appears.

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

3. Click **UPDATE**.

   The selected page is now your home page.

Creating a bookmark

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

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

The Bookmarks dialog box appears.

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

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

3 Select one or more menu items.

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

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

Deleting a bookmark

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

The Bookmarks dialog box appears.

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

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

3 Deselect the menu items that do not require bookmarks.

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

5 Click **APPLY**.

Working with messages

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

Reading a message

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

The Inbox dialog box appears.

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

Message details appear. You can do the following:

- Reply to the message.
- Forward the message.
- Using the navigation arrows, view next and previous selected messages.

3 Click **DONE**.

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

Sending a message

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

The Inbox dialog box appears.

2 Click **NEW**.

The New Message dialog box appears.

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

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

The Address Book dialog box appears.

b Select one or more users or groups.

c Click **SAVE**.

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

5 Click **SEND**.

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

Deleting a message

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

The Inbox dialog box appears.

2 Select one or more messages.

3 Click **DELETE**.

A confirmation dialog box appears.

4 Click **OK**.

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

Adding a message group

You can set up groups of users as message recipients.

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

The Inbox dialog box appears.

2 Click **NEW**.

The New Message dialog box appears.

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

The Address Book dialog box appears.

4 Click **EDIT GROUPS**.

The Groups dialog box appears.

5 Click **NEW**.

The New Group dialog box appears.

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

7 Click **SAVE**.

Editing a message group

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

The Inbox dialog box appears.

2 Click **NEW**.

The New Message dialog box appears.

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

The Address Book dialog box appears.

4 Click **EDIT GROUPS**.

The Groups dialog box appears.

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

The Edit Group Details dialog box appears.

6 Edit the group information and member list.

7 Click **SAVE**.

Deleting a message group

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

The Inbox dialog box appears.

2 Click **NEW**.

The New Message dialog box appears.

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

The Address Book dialog box appears.

4 Click **EDIT GROUPS**.

The Groups dialog box appears.

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

A confirmation message appears.

6 Click **OK**.

CHAPTER 2

Schedule

In this chapter

Schedule pages

On the Schedule pages, you view available appointment sessions for volunteers to come to the current facility for in-house screening. To work with another facility's recruiting schedule, you must log on to the facility.

Page	Description
Schedule - Day page	View all in-house screening sessions in a specific day. You can ***add*** (on page 20), ***edit*** (on page 22), and ***delete*** (on page 24) screening sessions only on this page.
Schedule - Week page	View all in-house screening sessions in a specific week.
Schedule - Month page	View all in-house screening sessions in a specific month.

Note: You cannot assign volunteers to screening sessions on the Schedule pages. You assign or remove volunteers from screening sessions on the *Incoming Calls* (on page 63) and the *Appointments* (on page 97) pages.

Tasks: Schedule pages

- *Adding a session* (on page 20).
- *Editing a session* (on page 22).
- *Deleting a session* (on page 24).
- *Viewing all sessions in a day, week, or month* (on page 25).
- *Approving a session* (on page 26).
- *Approving all sessions in a week or month* (on page 27).

Adding a session

A session is a screening appointment that is scheduled for a specific day.

1 From the main menu, select **Recruiting > Schedule**.

The Schedule - Day page appears, showing today's schedule.

2 To view a different day, click the calendar button and select the date, or click the **Next** or **Previous** arrow buttons on either side of the calendar.

3 Click **ADD**.

A new session row appears in the table.

4 Fill in the fields.

Field descriptions for the Schedule - Day page

Field	Description	Notes
Session	Session number. This value must be unique.	Default: The highest previous existing order number plus 1, beginning with 1.
Time	Scheduled start time of the session.	Default: The next consecutive hour, beginning with 08:00 AM.
Duration	Duration, in hours, of the session.	Value must be an integer from 1 to 168.
Openings	Number of screening appointments available during the session.	Default for the first session: 1. Subsequent sessions default to the same value as the previous session.
Filled	Number of volunteers who have been scheduled for the session, through the ***Incoming Calls page*** (on page 63) or the ***Appointments page*** (on page 97).	READ-ONLY.
Clinic	Clinic where the session takes place. Click the ellipsis button (**...**) and select a Clinic from the list.	Default: Blank.

Field	Description	Notes
Reservation	Study ID of the study for which the screening session is used. To assign the session to a specific study, click the ellipsis button (**...**) and select a study from the list.	Default: Blank. Blank indicates that the session is not reserved for a specific study and is available to schedule volunteers for screening in any study. You must provide a value in order to use the Group Lookup or Visit Lookup buttons. When you schedule screening appointments for a volunteer through the Incoming Calls page or Appointments page, all sessions reserved for the study as well as sessions that have no reservations are available.
Group	Group in which the volunteer is scheduled in the clinic lab.	Default: Blank. The Study Lookup button appears if this field is not blank.
Visit	Visit in which the volunteer performs the screening events or follow-up screening events. Click the ellipsis button (**...**) and select a Visit from the list.	Default: Blank. The Visit selection button is disabled if the Reservation field is blank.
Approved	Date and time that the session was approved.	READ-ONLY. Empty if the session was not approved.
Canceled	Date and time that the session was canceled.	READ-ONLY. Empty if the session was not canceled.

Note: Before you can schedule volunteers to a session, you must ***approve the session*** (on page 26).

Editing a session

Prerequisite: You must have Recruiting Setup security permissions.

A session is a screening appointment that is scheduled for a specific day. You can edit both approved and unapproved sessions.

1 From the main menu, select **Recruiting > Schedule**.

The Schedule - Day page appears, showing today's schedule.

2 To view a different day, click the calendar button and select the date, or click the **Next** or **Previous** arrow buttons on either side of the calendar.

3 Fill in the fields.

Field descriptions for the Schedule - Day page

Field	Description	Notes
Session	Session number. This value must be unique.	Default: The highest previous existing order number plus 1, beginning with 1.
Time	Scheduled start time of the session.	Default: The next consecutive hour, beginning with 08:00 AM.
Duration	Duration, in hours, of the session.	Value must be an integer from 1 to 168.
Openings	Number of screening appointments available during the session.	Default for the first session: 1. Subsequent sessions default to the same value as the previous session.
Filled	Number of volunteers who have been scheduled for the session, through the ***Incoming Calls page*** (on page 63) or the ***Appointments page*** (on page 97).	READ-ONLY.
Clinic	Clinic where the session takes place. Click the ellipsis button (**...**) and select a Clinic from the list.	Default: Blank.

Field	Description	Notes
Reservation	Study ID of the study for which the screening session is used. To assign the session to a specific study, click the ellipsis button (**...**) and select a study from the list.	Default: Blank. Blank indicates that the session is not reserved for a specific study and is available to schedule volunteers for screening in any study. You must provide a value in order to use the Group Lookup or Visit Lookup buttons. When you schedule screening appointments for a volunteer through the Incoming Calls page or Appointments page, all sessions reserved for the study as well as sessions that have no reservations are available.
Group	Group in which the volunteer is scheduled in the clinic lab.	Default: Blank. The Study Lookup button appears if this field is not blank.
Visit	Visit in which the volunteer performs the screening events or follow-up screening events. Click the ellipsis button (**...**) and select a Visit from the list.	Default: Blank. The Visit selection button is disabled if the Reservation field is blank.
Approved	Date and time that the session was approved.	READ-ONLY. Empty if the session was not approved.
Canceled	Date and time that the session was canceled.	READ-ONLY. Empty if the session was not canceled.

Deleting a session

Prerequisite: You must have Recruiting Setup security permissions.

A session is a screening appointment that is scheduled for a specific day.

If you cancel a session that already has volunteers assigned to it, reminder calls associated with the session are automatically removed, and a cancellation call is scheduled on the *Outgoing Calls page* (on page 133) for the following day, for each volunteer.

1 From the main menu, select **Recruiting > Schedule**.

   The Schedule - Day page appears, showing today's schedule.

2 To view a different day, click the calendar button and select the date, or click the **Next** or **Previous** arrow buttons on either side of the calendar.

3 Click the **X** for a session.

   If the session has not been approved, it is removed completely.

   If the session has been approved, the Cancel Session Approval dialog box appears.

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

   The session remains on the Schedule - Day page, with all its fields disabled and buttons removed. The Cancelled field displays the date and time of the cancellation.

Viewing all sessions in a day, week, or month

Prerequisite: You must have Recruiting Setup security permissions.

A session is a screening appointment that is scheduled for a specific day.

1. From the main menu, select **Recruiting > Schedule**.

   The Schedule - Day page appears, showing today's schedule.

2. To view a different day, click the calendar button and select the date, or click the **Next** or **Previous** arrow buttons on either side of the calendar.

3. To view all sessions for a given week:

   a. Click the **Week** tab.

      The page displays the schedule for the current week.

   b. To view a different week, click the calendar button and select the date, or click the **Next** or **Previous** arrow buttons on either side of the calendar.

4. To view all sessions for a given month:

   a. Click the **Month** tab.

      The schedule for the current month appears.

   b. To view a different month, click the calendar button and select the date, or click the **Next** or **Previous** arrow buttons on either side of the calendar.

Approving a session

Prerequisite: You must have Recruiting Setup security permissions.

A session is a screening appointment that is scheduled for a specific day.

You must approve sessions before you can schedule any volunteers to them. If you add new sessions after the initial approval, you must repeat the approval process to make new sessions available for scheduling. You can edit approved sessions without repeating their approval.

1 From the main menu, select **Recruiting > Schedule**.

   The Schedule - Day page appears, showing today's schedule.

2 To view a different day, click the calendar button and select the date, or click the **Next** or **Previous** arrow buttons on either side of the calendar.

3 Click **APPROVE**.

   The Approve Schedule dialog box appears.

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

   The session is approved, and the approval date and time appear as read-only text in the Approved field.

Approving all sessions in a week or month

Prerequisite: You must have Recruiting Setup security permissions.

Before you can assign volunteers to a session, you must approve the session. Unapproved sessions are highlighted in yellow. Approved sessions are highlighted in green only if all sessions are approved for that day. Canceled sessions do not appear, regardless of their state of approval.

1 From the main menu, select **Recruiting > Schedule**.

   The Schedule - Day page appears, showing today's schedule.

2 To approve all sessions in a week:

   a Click the **Week** tab.

      The page displays the schedule for the current week.

   b To view a different week, click the calendar button and select the date, or click the **Next** or **Previous** arrow buttons on either side of the calendar.

   c Click **APPROVE**.

      The Approve Schedule dialog box appears.

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

      All previously unapproved sessions in the week are approved, and the yellow highlighting is removed from them. Approval dates and times appear for each session.

3 To approve all sessions in a month:

   a Click the **Month** tab.

      The schedule for the current month appears.

   b To view a different month, click the calendar button and select the date, or click the **Next** or **Previous** arrow buttons on either side of the calendar.

   c Click **APPROVE**.

      The Approve Schedule dialog box appears.

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

      All previously unapproved sessions in the month are approved.

CHAPTER 3

Volunteers

In this chapter

Volunteers page

The Volunteers page lists all volunteers in the LabPas Recruiting module. On the Volunteers page you can select a volunteer record to work with, or create a new volunteer record.

You must have the Volunteer Administration permission to add a volunteer record.

Tasks: Volunteers page

- *Creating a new volunteer record.* (on page 30)
- *Selecting a volunteer for updating or deletion* (on page 31).

Creating a new volunteer record

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Click **NEW**.

The New Volunteer dialog box appears.

3 Fill in the fields.

Field descriptions for the New Volunteer page

Field	Description	Notes
Title	Title of the volunteer (for example, Mr., Ms., or Dr.).	Required or optional, depending on how the study was set up.
First Name	First name of the volunteer.	REQUIRED.
Last Name	Last name of the volunteer.	REQUIRED. Maximum length is 50 characters.
Middle Initial	Middle initial of the volunteer.	Required or optional, depending on how the study was set up.
Birth Date	Date of birth for the volunteer. Type the date in the field, or click the calendar icon and select a date.	REQUIRED.
Gender	Gender of the volunteer.	REQUIRED.

4 Click **APPLY**.

The Volunteer - Personal - Demographics page for the volunteer appears. The volunteer is assigned a Volunteer Record Number (VRN), which appears above the tabs on the page.

Volunteer - Personal page

When you select a volunteer from the Volunteers page, the Volunteer - Personal - Demographics page for the volunteer appears. It contains the following tabs, from which you can add and update volunteer information, and delete the volunteer:

- **Personal**—Contains demographic, contact, and other information for a volunteer.
- **Clinical History**—Contains Medical, Surgical, Medications, and Physician tabs.
- **Studies**—Displays a table that lists the studies that the volunteer is associated with.
- **Appointment Log**—Lists the appointments for the volunteer.
- **Notes**—Lists the notes for the volunteer.

The page header for all the volunteer pages includes the following.

- **Volunteers button**—Click to return to the Volunteers page from any page you can access from the Volunteers page.
- **Volunteer Record Number (VRN) for the selected volunteer**—Assigned by the LabPas application when you create the volunteer.
- **Name of the selected volunteer**—Volunteer name. If you do not have the View Volunteer Ids security permission, the Name field is populated with asterisks ******.
- **NOTE button**—Click to add a note regarding the volunteer.
- **Number of notes that exists for the volunteer**—The number of notes less than two weeks old appears in blue text, followed by the total number of notes.

Demographic information

Tasks: Volunteer - Personal - Demographics page

The demographic information that you enter on the Volunteer - Personal - Demographics page is used both for reference purposes and to determine volunteer eligibility for studies, based on the qualification requirements defined for the study.

- You must have the Volunteer Administration permission to edit the volunteer demographics information.
- You must have the Delete Volunteer Record permission to delete a volunteer.

> **Note:** If a volunteer previously participated in a phone-screening interview on the Incoming Calls page, you view data collected during that call on this page.

- *Editing identification information for a volunteer.* (on page 32)
- *Excluding a volunteer from studies associated with a study type* (on page 33).
- *Deleting a study type exclusion* (on page 34).
- *Editing characteristics for a volunteer* (on page 34).
- *Adding a tobacco record.* (on page 37)
- *Editing a tobacco record* (on page 38).
- *Deleting a tobacco record* (on page 39).
- *Adding a photo for a volunteer* (on page 39).
- *Deleting a volunteer's record* (on page 40).

Editing identification information for a volunteer

1. From the main menu, select **Recruiting > Volunteers**.

   The Volunteers page appears.
2. Select a volunteer.

   The Volunteer – Personal page appears.
3. Select the **Demographics** tab.

   The Volunteer - Personal - Demographics page appears.
4. In the **Identity** section, fill in the fields.

Field descriptions for the Identity section

Field	Description	Notes
Identity		
Name (F)	First name of the volunteer.	
Name (L)	Last name of the volunteer.	Maximum length is 50 characters.
Name (MI)	Middle initial of the volunteer.	Required or optional, depending on how the study was set up.
Title	Title of the volunteer (for example, Mr., Ms., Dr.).	Required or optional, depending on how the study was set up.
Status	Overall status for the volunteer across all studies.	If the volunteer has a status of Probation, the Probation End field below might be populated with the date when the volunteer is allowed to participate in trials.
Location Pref.	Volunteer preference for the location of the study facility.	
Probation End	End date of the probation period for the volunteer. Type the date in the field, or click the calendar icon and select a date.	If the LabPas application is configured so that SR Alerts are active, an alert is generated for the volunteer on the ***Alerts page*** (on page 149) when the Probation End date has passed.
Travel Distance	Distance that the volunteer travels to reach the facility.	Integer from 0 to 99,999.
Availability	Times when the volunteer is available for a study.	
Gender	Gender of the volunteer.	
Race	Race of the volunteer.	
Marital Status	Marital status of the volunteer.	
Ethnicity	Ethnicity of the volunteer.	Default: blank.
Soc. Sec. No.	Social security number for the volunteer.	Required or optional, depending on how the study was set up.

5 Click **SAVE.**

The volunteer information is updated on the volunteer - Personal - Demographics page.

Excluding a volunteer from studies associated with a study type

Prerequisite: Study types must be defined for the LabPas Recruiting module on the Settings - Study - Study page.

You can add one study type at a time. Repeat this procedure until you have added all study types from which to exclude the volunteer.

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Demographics** tab.

The Volunteer - Personal - Demographics page appears.

4 In the Study Type Exclusions section, click **ADD**.

A list of study types appears.

5 Select the study type from which to exclude the volunteer.

Deleting a study type exclusion

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Demographics** tab.

The Volunteer - Personal - Demographics page appears.

4 In the Study Type Exclusions section, click the **X** for a study type.

A confirmation dialog box appears.

5 Click **OK**.

Editing characteristics for a volunteer

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Demographics** tab.

The Volunteer - Personal - Demographics page appears.

4 In the **Characteristics** section, fill in the fields.

Field descriptions for the Characteristics section

Field	Description	Notes
Characteristics		
Birth Date	Volunteer date of birth. Type the date in the field, or click the calendar icon and select a date.	REQUIRED. Default: Date entered when the volunteer record was created.
Age	Age of the volunteer.	READ-ONLY. Calculated using the volunteer birth date and the current date.
Last Study	Name of the last study in which the volunteer participated.	READ-ONLY.
Frame	Description of the physical build of the volunteer.	
BMI	Volunteer Body Mass Index.	Calculated to two decimal places if the volunteer height and weight are provided. If Facility Settings are configured for standard measurements, the converts to metric for this calculation.
Dose Date	Date that the volunteer was given the initial dose. Type the date in the field, or click the calendar icon and select a date.	
Height Ft	Volunteer height in feet.	
Height In	Remainder of volunteer height in inches.	

Field	Description	Notes
% IBW	Percentage of ideal body weight.	READ-ONLY. Calculated if the height, weight, frame and gender for the volunteer are provided. Men (medium frame): IBW = 48 kg + (1.1 kg * (Height cm - 150 cm)). Women (medium frame): IBW = 45 kg + (.9 kg * (Height cm - 150 cm)). % IBW = Weight (kg)/IBW * 100 For both men and women, subtract 10% for small frame, and add 10% for large frame.
Exit Date	The date that the volunteer ended participation in the study. Type the date in the field, or click the calendar icon and select a date.	
Weight Lbs	Weight of the volunteer.	
CrCl	Measurement of creatinine clearance for the volunteer.	Measured in mg/dL. Read only field that is populated if the volunteer serum creatinine, gender, age and weight are provided. CrCl is calculated to three decimal places using the Cockgroft-Gault formula: Men: CrCl (mL/min) = ((140-age) * Weight kg / (72 * serum creatinine mg/dL). Women: CrCl (mL/min) = .85 * ((140-age) * Weight kg / (72 * serum creatinine mg/dL).
Serum Creatinine	Measurement of the volunteer serum creatinine.	Measured in mg/dL.

Field	Description	Notes
GFR	Measurement of the volunteer GFR.	READ-ONLY. Populated if the Serum Creatinine, Age, Race, and Gender for the volunteer are provided. GFR is calculated using the following formula: GFR (mL/min/1.73 m^2) = 175 x Serum Creatinine$^{-1.154}$ x Age$^{-0.203}$ x (1.212 if Race Category is African American) x (0.742 if Gender is Female).
Tobacco History	Whether the volunteer has used tobacco: • Never. • Quit or Current.	If you select Quit or Current, you must add information to the Tobacco History table.

5 Click **SAVE**.

Adding a tobacco record

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Demographics** tab.

The Volunteer - Personal - Demographics page appears.

4 Select **Quit or Current** in the Tobacco History Records table.

5 In the Tobacco History Records table, click **ADD**.

The Add Tobacco dialog box appears.

6 Fill in the fields.

Field descriptions for the Add Tobacco dialog box

Field	Description	Notes
Quantity	Number of tobacco products that the volunteer uses.	Required when editing a candidate.
Type	Type of tobacco products that the volunteer uses.	Required when editing a candidate.
Frequency	How often the volunteer uses tobacco products.	Required when editing a candidate.

Field	Description	Notes
Start Date	Date that the volunteer first started using tobacco.	The Start Date year value is required. If the month and day values are left blank, xx or xxx appear instead.
End Date	Date that the volunteer stopped using tobacco.	The End Date year value is required. If the month and day values are left blank, xx or xxx appear instead.
Ongoing	Selected if the volunteer is still using tobacco.	
Comment	Custom text.	

7 Click **SAVE.**

The new tobacco record appears in the Tobacco History Records table, and the Tobacco History radio buttons are read-only.

8 To add additional tobacco records, click **ADD** and repeat the procedure.

Click **SAVE**.

The volunteer information is updated on the Volunteer - Personal - Demographics page.

Editing a tobacco record

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Demographics** tab.

4 The Volunteer - Personal - Demographics page appears.

5 In the Tobacco History Records table, click the ellipsis button (**...**) next to a record.

The Edit Tobacco dialog box appears.

6 Fill in the fields.

Field descriptions for the Edit Tobacco dialog box

Field	Description	Notes
Quantity	Number of tobacco products that the volunteer uses.	Required when editing a candidate.
Type	Type of tobacco products that the volunteer uses.	Required when editing a candidate.
Frequency	How often the volunteer uses tobacco products.	Required when editing a candidate.

Field	Description	Notes
Start Date	Date that the volunteer first started using tobacco.	
End Date	Date that the volunteer stopped using tobacco.	
Ongoing	Selected if the volunteer is still using tobacco.	
Comment	Custom text.	

7 Click **SAVE**.

Deleting a tobacco record

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Demographics** tab.

The Volunteer - Personal - Demographics page appears.

4 In the Tobacco History Records table, click the **X** button next to a record.

A confirmation message appears.

5 Click **OK**.

Adding a photo for a volunteer

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Demographics** tab.

The Volunteer - Personal - Demographics page appears.

4 Click **PHOTO**.

The Volunteer Photo dialog box appears.

5 Click **UPLOAD**.

The Upload Photo dialog box appears.

6 Click **Browse,** select a photo to upload, and click **APPLY**.

A confirmation dialog box appears.

7 Click **OK**.

The selected volunteer photo appears in the Volunteer Photo dialog box.

Deleting a volunteer's record

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Demographics** tab.

The Volunteer - Personal - Demographics page appears.

4 Click **DELETE**.

A message appears, confirming the deletion.

5 Enter a comment and click **APPLY.**

The volunteer's personal, clinical history, studies, appointments, and notes pages are deleted.

If the volunteer signed a consent form, any data associated with the study is not deleted, but the association between the volunteer and the study is deleted.

Contact information

Tasks: Volunteer - Personal - Contact page

On the Volunteer - Personal - Contact page, you enter the contact and emergency contact information for a volunteer.

You must have the Volunteer Administration permission to edit the volunteer contact information.

> **Note:** If a volunteer previously participated in a phone-screening interview on the Incoming Calls page, you view data collected during that call on this page.

- *Editing contact information for a volunteer* (on page 41).
- *Editing emergency contact information for a volunteer* (on page 42).

Editing contact information for a volunteer

Some fields might be required, depending on how the LabPas Recruiting module was set up.

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Contact** tab.

The Contact page appears.

4 In the Current Address section, fill in the fields.

Field descriptions for the Contact Information section

Field	Description	Notes
Name	Name of volunteer.	READ-ONLY.
Address 1, Address 2 City, State, Postal Country	Address of volunteer.	
Telephone	Telephone number of volunteer.	
Cell	Cellular phone number of volunteer.	
Addl	Additional phone number for the volunteer.	
Email	Email address of volunteer.	
Marital Status	Marital status of the volunteer.	Default: Single.
Soc. Sec. No.	Social security number of volunteer.	

Field	Description	Notes
Race	Race of the volunteer.	
Ethnicity	Ethnicity of the volunteer.	

5 Click **SAVE**.

Editing emergency contact information for a volunteer

Some fields might be required, depending on how the LabPas Recruiting module was set up.

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Contact** tab.

The Contact page appears.

4 In the **Emergency Contact** section, fill in the fields.

Field descriptions for the Emergency Contact section

Field	Description	Notes
Relationship	Relationship of the emergency contact to the volunteer.	
Name (F)	First name of the emergency contact.	
Name (L)	Last name of the emergency contact.	
Name (MI)	Middle initial of the emergency contact.	
Title	Title of the emergency contact (for example, Mr. Ms., Dr.).	
Address 1 Address 2	Address of the emergency contact.	
Note: If a volunteer previously participated in a phone-screening interview on the Incoming Calls page, you view data collected during that call on this page.		

5 Click **SAVE**.

Additional demographic information

Tasks: Volunteer - Personal - Other page

The Volunteer - Personal - Other page contains additional demographics about a volunteer. The fields that appear depend on how the LabPas application and the specific study were set up.

You must have the Volunteer Administration permission to edit this page.

> **Note:** If a volunteer previously participated in a phone-screening interview on the Incoming Calls page, you view data collected during that call on this page.

- *Editing additional demographic information for a volunteer* (on page 43).

Editing additional demographic information for a volunteer

1. From the main menu, select **Recruiting > Volunteers**.

   The Volunteers page appears.
2. Select a volunteer.

   The Volunteer – Personal page appears.
3. Select the **Other** tab.

   The Volunteer – Personal – Other page appears.
4. Fill in the fields that appear depending on how the study was set up.
5. Click **SAVE**.

   The updated additional demographic information appears on the page.

Medical history

Volunteer - Clinical History - Medical page

On the Volunteer - Clinical History - Medical page, you record Yes or No answers to medical history questions for a volunteer.

Questions are associated with specific health areas on the Settings - Medical - Questions page, and conditions are associated with specific health areas on the Settings - Medical - Conditions page.

To use these pages, you must have:

- Volunteer Administration permission to add information.
- Edit Volunteer permission to update existing information.
- Delete Clinical History permission to delete medical conditions.

If you edit or delete a condition, an entry is logged in the Recruiting Change Log.

> **Note: If a volunteer previously participated in a phone-screening interview on the Incoming Calls page, you view data collected during that call on this page.**

If you select Yes for a question, and any conditions are associated with the question, a table of medical and non-medical conditions appears, with two or more of the following fields depending on the type of condition: Condition, Start Date, End Date, Ongoing, and Comment.

Start Date, End Date, and Date year values are required. If the month and day values are left blank, xx or xxx appear instead.

Tasks: Volunteer - Clinical History - Medical page

- *Adding a medical condition to the medical history for a volunteer* (on page 44).
- *Adding a non-medical condition to the medical history for a volunteer* (on page 46).
- *Editing a medical condition in the medical history for a volunteer* (on page 46).
- *Editing a non-medical condition in the medical history for a volunteer* (on page 48).
- *Deleting a condition from the medical history for a volunteer* (on page 49).

Adding a medical condition to the medical history for a volunteer

You can add up to of three conditions at one time. The conditions you add must be associated with the same health area as the question.

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Medical** tab.

The Volunteer - Clinical History - Medical page appears.

5 Select **Yes** for a question to which to add a condition.

If the question is associated with a specific health area, the Add Medical Condition dialog box appears.

The conditions that you enter must be associated with the same health area as the question.

6 Fill in the fields.

Field descriptions for the Add Medical Condition dialog box

Field	Description	Notes
Condition	Medical condition, illness, disease, or disorder.	REQUIRED. Includes a search function that allows you to choose from a list of approved medical conditions. Read-only if you are editing a medical condition.
Start Month	Month that the condition started.	
Start Day	Day that the condition started.	
Start Year	Year that the condition started.	REQUIRED.
Ongoing	When selected, the condition is still occurring.	Required if End Year is not specified.
End Month	Month that the condition ended.	
End Day	Day that the condition ended.	
End Year	Year that the condition ended.	REQUIRED.
Comment	Custom text to further explain condition.	Required or optional, depending on how the study was set up.

7 Click **SAVE**.

The condition is saved, and the fields clear so that you can add another condition.

8 Click **X** to close the Add Medical Conditions dialog box.

A table with the new condition appears below the question in the Volunteer - Clinical History - Medical page.

> **Note:** After you associate a condition with a question, you cannot select No for the question until all conditions are removed from the table below the question.

Adding a non-medical condition to the medical history for a volunteer

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Medical** tab.

The Volunteer - Clinical History - Medical page appears.

5 Select **Yes** for a question to which to add a condition.

If the question is not associated with a specific health area, the Add Other Conditions dialog box appears.

6 Fill in the fields.

Field descriptions for the Add Other Conditions dialog box

Field	Description	Notes
[Condition Question]	Medical history question.	
Month	Month that the condition occurred.	
Day	Day that the conditions occurred.	
Year	Year that the condition occurred.	REQUIRED.
Comment	Custom text to explain the condition.	REQUIRED.

7 Click **SAVE**.

The condition is saved, and the fields clear so that you can add another condition.

8 Click **X** to close the Add Other Conditions dialog box.

A table displaying the new condition appears below the question in the Volunteer - Clinical History - Medical page.

> **Note:** After you associate a condition with a question, you cannot select No for the question until all conditions are removed from the table below the question.

Editing a medical condition in the medical history for a volunteer

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Medical** tab.

The Volunteer - Clinical History - Medical page appears.

5 Click the ellipsis button (**...**) for the condition to edit.

The Edit Medical Condition dialog box appears.

6 Fill in the fields.

Field descriptions for the Edit Medical Conditions dialog box

Field	Description	Notes
Condition	Medical condition, illness, disease, or disorder.	REQUIRED. Includes a search function that allows you to choose from a list of approved medical conditions. Read-only if you are editing a medical condition.
Start Month	Month that the condition started.	
Start Day	Day that the condition started.	
Start Year	Year that the condition started.	REQUIRED.
Ongoing	When selected, the condition is still occurring.	Required if End Year is not specified.
End Month	Month that the condition ended.	
End Day	Day that the condition ended.	
End Year	Year that the condition ended.	REQUIRED.
Comment	Custom text to further explain condition.	Required or optional, depending on how the study was set up.

7 Click **SAVE**.

The changes to the condition appear in the table on the Volunteer - Clinical History - Medical page.

Changes appear in the Recruiting Change Log report, with following source listed for each change:

- **Volunteer Medical History** if you made changes in the table.
- **Volunteer** if you changed the answer to the question.

Note: After you associate a condition with a question, you cannot select No for the question until all conditions are removed from the table below the question.

Editing a non-medical condition in the medical history for a volunteer

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Medical** tab.

The Volunteer - Clinical History - Medical page appears.

5 Click the ellipsis button (**...**) for the condition to edit.

The Edit Medical Condition dialog box appears.

6 Fill in the fields.

Field descriptions for the Edit Other Conditions dialog box

Field	Description	Notes
[Condition Question]	Medical history question.	
Month	Month that the condition occurred.	
Day	Day that the conditions occurred.	
Year	Year that the condition occurred.	REQUIRED.
Comment	Custom text to explain the condition.	REQUIRED.

7 Click **SAVE**.

The changes to the condition appear in the table on the Volunteer - Clinical History - Medical page.

Changes appear in the Recruiting Change Log report, with following source listed for each change:

- **Volunteer Medical History** if you made changes in the table.
- **Volunteer** if you changed the answer to the question.

> **Note:** After you associate a condition with a question, you cannot select No for the question until all conditions are removed from the table below the question.

Deleting a condition from the medical history for a volunteer

1. From the main menu, select **Recruiting > Volunteers**.

   The Volunteers page appears.
2. Select a volunteer.

   The Volunteer – Personal page appears.
3. Select the **Clinical History** tab.

   The Volunteer - Clinical History page appears.
4. Select the **Medical** tab.

   The Volunteer - Clinical History - Medical page appears.
5. Click the **X** button for the condition to delete.

   The Delete Condition dialog box appears.
6. Type your User ID, password, and an optional comment, and click **APPLY**.

   The condition no longer appears in the table on the Volunteer - Clinical History - Medical page.

   Changes made to conditions are logged in the Recruiting Change Log report on the Reports page.

Surgical history

Volunteer - Clinical History - Surgical page

Use the Volunteer - Clinical History - Surgical page to record surgical history for a volunteer.

The page consists of one question followed by a radio button selection of Yes or No (default). If you select Yes, any surgical procedures that are added appear in the table beneath the question. After a surgical procedure is added, you cannot select No for the question until all surgical procedures are removed from the table.

To use these pages, you must have:

- Volunteer Administration permission to add information.
- Edit Volunteer permission to update existing information.
- Delete Clinical History permission to delete surgical procedures.

If you edit or delete a surgical procedure, an entry is logged in the Recruiting Change Log.

> **Note:** If a volunteer previously participated in a phone-screening interview on the Incoming Calls page, you view data collected during that call on this page.

Tasks: Volunteer - Clinical History - Surgical page

- *Recording and editing a surgical procedure* (on page 50).
- *Deleting a surgical procedure* (on page 51).

Recording and editing a surgical procedure

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Surgical** tab.

The Volunteer - Clinical History - Surgical page appears.

5 To record a surgical procedure, select **Yes** to the question.

To edit a surgical procedure, click the ellipsis button (**...**) for a surgical procedure.

The Surgical Procedures dialog box appears.

6 Fill in the fields.

Field descriptions for the Surgical Procedures dialog box

Field	Description	Notes
Procedure	Type of surgical procedure.	REQUIRED. Includes a search function that retrieves both medical and common names of procedures. Read-only if you are editing a surgical procedure.
Month	Month that the surgical procedure occurred.	
Day	Day that the surgical procedure occurred.	
Year	Year that the surgical procedure occurred.	REQUIRED.
Comment	Custom text to explain the surgical procedure.	Required or optional, depending on how the study was set up.

7 Click **SAVE**.

If you added a surgical procedure, the dialog box remains open so that you can add another procedure. Close the dialog box after you finish adding procedures.

If you edited a surgical procedure, the dialog box closes.

Deleting a surgical procedure

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Surgical** tab.

The Volunteer - Clinical History - Surgical page appears.

5 Click the **X** button for a surgical procedure.

The Delete Surgical Procedures dialog box appears.

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

The procedure is removed from the table on the Volunteer - Clinical History - Surgical page.

An entry is created in the Recruiting Change Log with a source of Volunteer Surgical History.

After all surgical procedures are removed from the table, the No button is enabled.

Concomitant medications

Volunteer - Clinical History - Medications page

You use the Volunteer - Clinical History - Medication page to record medication history for a volunteer.

To use these pages, you must have:

- Volunteer Administration permission to add information.
- Edit Volunteer permission to update existing information.
- Delete Clinical History permission to delete information.

> **Note:** If a volunteer previously participated in a phone-screening interview on the Incoming Calls page, you view data collected during that call on this page.

Medication records Start Year and End Year values are required. If the month and day values are left blank, xx or xxx appear instead.

Changes that you make to a medication record are logged in the Recruiting Change Log report.

Tasks: Volunteer - Medications page

- *Adding and editing a concomitant medication.* (on page 52)
- *Deleting a concomitant medication* (on page 54).

Adding and editing a concomitant medication

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Medications** tab.

The Volunteer - Clinical History - Medication page appears.

5 To add a concomitant medication, click **ADD**.

To edit a concomitant medication, click the ellipsis button (**...**) for a medication.

The Concomitant Medications dialog box appears.

6 Fill in the fields.

Field descriptions for the Concomitant Medications dialog box

Field	Description	Notes
Medication	Name of the medication.	REQUIRED. The search retrieves both medical and common names of medicines. Read-only if you are editing a concomitant medication.
Condition	Medical conditions or surgical procedures.	REQUIRED. • If the caller already has a volunteer record, the field displays a list of medical conditions or surgical conditions associated with the volunteer. • If the caller is taking the medication for a condition that does not appear in the drop-down list, then you must go back to the Medical tab and record the newly-disclosed condition.
Dose	Dose of the medication.	Reference only. Field can contain alphanumeric text.
Unit	Physical format of medication. For example, pill or capsule.	REQUIRED.
Frequency	How often the dose is taken.	REQUIRED.
Method	How the dose is taken. For example, oral, auricular.	REQUIRED.
Start Month	Month that the volunteer first started taking the medication.	
Start Day	Day that the volunteer first started taking the medication.	
Start Year	Year that the volunteer first started taking the medication.	REQUIRED.
Ongoing	When selected, the volunteer is still taking the medication.	
End Month	Month that the volunteer stopped taking the medication.	
End Day	Day that the volunteer stopped taking the medication.	

Field	Description	Notes
End Year	Year that the volunteer stopped taking the medication.	REQUIRED.
Comment	Custom text explaining the medications.	Required or optional, depending on how the study was set up.

7 Click **SAVE**.

If you added a medication, the dialog box remains open. You can add as many as three concomitant medications at one time. Close the dialog box when you are finished.

If you edited a medication, the dialog box closes.

Deleting a concomitant medication

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Medications** tab.

The Volunteer - Clinical History - Medication page appears.

5 Click the **X** button for a medication.

The Delete Medication dialog box appears.

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

The Edit Concomitant Medications dialog box closes, and the updated medication information appears in the table on the Volunteer - Medications page.

Changes that you make to a medication record are logged in the Recruiting Change Log report.

Physician information

Tasks: Volunteer - Clinical History - Physician page

On the Volunteer - Clinical History - Physician page, you record contact information about the primary care physician or general practitioner for a volunteer. The information collected in this page can be used when you print labels and export data from the ***Study - GP page*** (in the *Clinical Trial Design and Resource Management Guide*).

You must have the Volunteer Administration permission to edit the data on these pages.

- ***Recording contact information for the primary physician for a volunteer*** (on page 55).
- ***Recording GP Questionnaire send and receive dates for the primary physician for a volunteer*** (on page 56).

Recording contact information for the primary physician for a volunteer

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Physician** tab.

The Volunteer - Clinical History - Physician page appears.

5 Fill in the fields.

Field descriptions for the Primary Physician section

Field	Description
Primary Physician	
Name (F)	First name of primary physician.
Name (L)	Last name of primary physician.
Name (MI)	Middle initial of primary physician.
Title	Title of primary physician.
Facility	Facility where the primary physician is located.
Address 1, Address 2 City, State, Postal Country	Street address of primary physician.
Telephone	Telephone number of primary physician.

Field	Description
Cell	Cellular phone number of primary physician.
Addl.	Additional phone number of primary physician.
Fax	Fax number of primary physician.
Email	Email address of primary physician.

6 Click **SAVE**.

The updated information appears on the Volunteer - Clinical History - Physician page.

Recording GP Questionnaire send and receive dates for the primary physician for a volunteer

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Clinical History** tab.

The Volunteer - Clinical History page appears.

4 Select the **Physician** tab.

The Volunteer - Clinical History - Physician page appears.

5 Fill in the fields.

Field descriptions for the GP Questionnaire section

Field	Description
Sent	Date that the GP (general practitioner or primary physician) questionnaire was sent. Type the date in the field or click the calendar icon and select a date.
Received	Date that the GP (general practitioner or primary physician) questionnaire was received. Type the date in the field or click the calendar icon and select a date.

6 Click **SAVE**.

The updated information appears on the Volunteer - Clinical History - Physician page.

Studies and study status

Volunteer - Studies page

Use the Volunteer - Studies page to view or update study questions and volunteer answers.

The Group selection field on the New Study and Edit Volunteer dialog boxes displays groups that are defined for the study in the Resource Management module.

If Global Recruiting has not been configured:

- The Group selection field on the Select Volunteer and Edit Volunteers dialog boxes is restricted to groups that are associated with the current facility.
- The Volunteers table is restricted to volunteers assigned to groups that are associated with the current facility.

Tasks: Volunteer - Studies page

- *Viewing and editing answers to study questions* (on page 57).

Viewing and editing answers to study questions

1. From the main menu, select **Recruiting > Volunteers**.

   The Volunteers page appears.
2. Select a volunteer.

   The Volunteer – Personal page appears.
3. Select the **Studies** tab.

   The Volunteer – Studies page appears.
4. Select the checkboxes for the study IDs for the study questions to view or edit.
5. Click **QUESTIONS**.

   The Study Questions dialog box appears with a list of questions.

   If you select multiple volunteers, the Study Questions dialog box appears for each record, one at a time.

   Field descriptions for the Study Questions dialog box

Field	Description	Notes
Study	Study Id.	READ-ONLY.
Number	Question number.	READ-ONLY. Questions are listed in numerical order.

Field	Description	Notes
Question	Study-specific question.	READ-ONLY. Created in the Study - Questionnaire page.
Answer	Answers to study questions.	If the volunteer previously answered any of the questions, either on this page or on the Incoming Calls - Study Questions page, the answers to the questions appear in the Answer field. If any of the questions are not answered, none of the radio buttons are selected in the Answer field. This field is disabled if the status of the volunteer in the CT study is Accepted, Approved, or Dropped.

6 To answer or change an answer to a study question, select the radio button.

7 Click **SAVE**.

The updated information appears in the Volunteer - Study page.

If the volunteer had a status of Accepted, Approved, or Completed, the status is changed to Revised.

Appointment information

Volunteer - Appointment Log page

On the Volunteer - Appointment Log page, you view appointment information for a volunteer. All appointments that are scheduled for a volunteer, both past and present, appear on this page. The information is read-only.

Tasks: Volunteer - Appointment Log page

- *Viewing appointment information for a volunteer* (on page 59).

Viewing appointment information for a volunteer

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Appointment Log** tab.

The Volunteer – Appointment Log page appears.

4 View appointment information.

Field descriptions for the Volunteer - Appointment Log page

Field	Description	Notes
Study Id	Study ID for the scheduled appointment.	READ-ONLY.
Appt Date	Date of the appointment.	READ-ONLY.
Session	Number given to the session for the specific date.	READ-ONLY.
Appt Status	Appointment status.	READ-ONLY. Field is blank if the appointment is still active. Appointments that are not active can have a status of one of the following: Complete, No Show, Canceled, CRO Canceled, or Vol Canceled. You update appointment statuses only on the *Appointments page* (on page 97).

Field	Description	Notes
Approval Date	Date on which the appointment was approved.	READ-ONLY.
Approved By	User name of the person who approved the appointment.	READ-ONLY.

5 To exit the page, select another tab.

Notes

Volunteer - Notes page

You use the Volunteer - Notes page to add and delete notes for a volunteer. The notes you add on this page do not appear in Screening notes.

You must have the Volunteer Administration permission to add or delete notes.

Tasks: Volunteer - Notes page

- *Adding and deleting a note* (on page 61).

Adding and deleting a note

1 From the main menu, select **Recruiting > Volunteers**.

The Volunteers page appears.

2 Select a volunteer.

The Volunteer – Personal page appears.

3 Select the **Notes** tab.

The Volunteer - Notes page appears.

4 To add a note:

a Click **NEW**.

The New Note dialog box appears.

b Type the note and click **SAVE**.

> **Note:** To add a note from any of the tabbed pages on the Volunteers page, click the NOTE button above the tabs. The notes you add on this page do not appear in screening notes.

5 To delete a note:

a Select a note, and click **DELETE**.

A confirmation dialog box appears.

b Click **OK**.

CHAPTER 4

Incoming calls

In this chapter

Tasks: Incoming Calls page

On the Incoming Calls pages, you collect information from a person who is interested in volunteering for a study.

Note: Tabs for pages that are missing required data appear in red.

Receiving an incoming call

- *Step 1: Starting an incoming call* (on page 66).
- *Step 2: Selecting a media campaign* (on page 66).
- *Step 3: Identifying a caller.* (on page 66)
- *Step 4: Recording demographic information about a new volunteer.* (on page 70)
- *Step 5a: Recording whether a caller has a known medical condition* (on page 73).
  - *Step 5b: Recording the medical history for a caller* (on page 73).
- *Step 6a: Recording whether a caller had a surgical procedure* (on page 75).
  - *Step 6b: Recording a surgical procedure for a caller* (on page 76).
- *Step 7a: Recording whether a caller has current or past medications* (on page 77).
  - *Step 7b: Recording a medication for a caller* (on page 77).

- *Step 8: Recording contact information for a caller.* (on page 79)
- *Step 9: Recording additional demographics about a caller* (on page 80).
- *Step 10: Selecting a study and recording answers to study questions* (on page 81).
- *Step 11: Selecting an appointment for a caller* (on page 84).
- *Step 12: Viewing a selected screening appointment prior to confirmation* (on page 84).
- *Step 13: Ending a call* (on page 85).

Editing and deleting information for a caller or volunteer

For medical conditions, surgical procedures, and medications:

- You must have the Edit Volunteers permission to update information.
- You must have the Delete Clinical History permission to delete information.

To reschedule and cancel appointments, you must have the Change Appointments permission.

- *Editing demographic information for a volunteer.* (on page 87)
- *Editing a medical condition for a caller* (on page 90).
- *Editing a non-medical condition for a caller* (on page 91).
- *Deleting a condition for a caller* (on page 92).
- *Editing a surgical procedure for a caller* (on page 92).
- *Deleting a surgical procedure for a caller* (on page 93).
- *Editing a medication for a caller* (on page 93).
- *Deleting a medication for a caller* (on page 95).
- *Editing a caller's answer to a study question* (on page 95).
- *Rescheduling an existing appointment* (on page 86).
- *Canceling an existing appointment* (on page 86).

Receiving an incoming call

Step 1: Starting an incoming call

1 From the main menu, select **Recruiting > Incoming Calls**.

The Incoming Calls page appears.

> **Note:** If you did not complete a previous call, a message prompts you to resolve the incomplete call before starting a new call. The page where the call stopped appears when you access the Incoming Calls page.

2 Click **NEXT**.

3 Do one of the following:

- If advertising campaigns exist, continue to ***Step 2: Selecting a media campaign*** (on page 66).
- If advertising campaigns do not exist, continue to ***Step 3: Identifying a caller*** (on page 66).

Step 2: Selecting a media campaign

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

1 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

2 From the **Campaign** drop-down list, select the media campaign to which the caller is responding.

3 To provide a comment about the caller's response, type it in the **Comment** field.

4 Click **NEXT**.

The Volunteer Identification page appears.

5 Continue to ***Step 3: Identifying a caller*** (on page 66).

Step 3: Identifying a caller

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Previous step: ***Step 2: Selecting a media campaign*** (on page 66)

1 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

2 Fill in the fields.

Field descriptions for the Incoming Calls - Volunteer Identification page

To find identify an existing caller, you must complete at least one of the following fields: VRN, Title, First Name, Last Name, Middle Initial, or Birth Date.

Field	Description
VRN	Volunteer Record Number.
Title	Title for the caller (for example, Mr., Ms., Dr.).
First Name	First name of the caller.
Last Name	Last name of the caller. Maximum length is 50 characters.
Middle Initial	Middle initial of the caller.
Birth Date	Caller date of birth. Select the birth date from a drop-down calendar.

If the caller is a volunteer who is associated with a study, the read-only fields at the top of the page display information for the caller.

3 Click **NEXT**.

The next step depends on whether the data you entered matches a volunteer:

- If the data does not match an existing volunteer, the New Volunteer page appears. Continue to ***Step 4: Recording demographic information about a new volunteer*** (on page 70).
- If the data matches a volunteer, the Volunteer Lookup dialog box appears.

  Field descriptions for the Volunteer Lookup dialog box

Field	Description
Name	Name of volunteer.
Address 1	Volunteer's street address.
Address 2	Volunteer's street address.
City	Volunteer's address: City.
State	Volunteer's address: State.
Postal	Volunteer's address: Postal or Zip code.
Telephone	Volunteer's telephone number.
Birth Date	Volunteer's date of birth.
SSN	Volunteer's social security number.

a Select the volunteer.

The Existing Volunteer - Demographics page appears.

b Fill in the fields. You can also ***reschedule*** (on page 86) or ***cancel*** (on page 86) an appointment for the caller.

Field descriptions for the Incoming Calls - Existing Volunteer - Demographics page

Field	Description	Notes
Title	Title of the caller (for example, Mr., Ms., Dr.).	
Age	Age of the volunteer.	READ-ONLY. Automatically calculated based on the date of birth for the volunteer.
BMI	Volunteer's body mass index.	Automatically calculated if the volunteer height and weight are provided. BMI is calculated to two decimal places.
% IBW	Volunteer's percentage of ideal body weight.	
CrCl	Measurement of the Creatinine Clearance for the volunteer.	READ-ONLY. Measured in mg/dL. A value appears if the volunteer serum creatinine, gender, age and weight are provided. CrCl is calculated to three decimal places using the Cockgroft-Gault formula: Men: CrCl (mL/min) = ((140-age) * Weight kg / (72 * serum creatinine mg/dL). Women: CrCl (mL/min) = .85 * ((140-age) * Weight kg / (72 * serum creatinine mg/dL).
GFR	Measurement of the GFR for the volunteer.	Read-only field, which is only populated if the volunteer Serum Creatinine, Age, Race and Gender are provided. GFR is calculated using the following formula: GFR (mL/min/1.73 m^2) = 175 x Serum Creatinine$^{-1.154}$ x Age$^{-0.203}$ x (1.212 if Race Category is African American) x (0.742 if Gender is Female).
First Name	First name of volunteer.	REQUIRED.

Field	Description	Notes
Last name	Last name of volunteer.	REQUIRED. Maximum length is 50 characters.
Middle Initial	Middle initial of volunteer.	REQUIRED.
Gender	Gender of the volunteer.	REQUIRED.
Birth Date	Date of birth for the volunteer. Type the date in the field, or click the calendar icon and select a date.	REQUIRED.
Frame	Description of volunteer physical build in a drop-down list of Small, Medium, and Large.	Men (medium frame): IBW = 48 kg + (1.1 kg * (Height cm - 150 cm)). Women (medium frame): IBW = 45 kg + (.9 kg * (Height cm - 150 cm)). % IBW = Weight (kg)/IBW * 100 (For both men and women, subtract 10% for small frame, and add 10% for large frame).
Height Ft	Height of the volunteer in feet.	Values are based on settings on the Configuration - Settings - Facility page.
Height In	Remainder of the height of the volunteer in inches.	Values are based on settings on the Configuration - Settings - Facility page.
Weight	Weight of the volunteer.	Values are based on settings on the Configuration - Settings - Facility page.
Serum Creatinine	Measurement of volunteer serum creatinine.	Measured in mg/dL.
Availability	Times when the volunteer is available for a study.	
Location Pref.	Volunteer preference for location of the study facility.	Choose from all facilities defined on the Configuration - Settings - Facilities page.
Travel Distance	Distance that the volunteer travels to reach the facility.	Integer from 0 to 99,999.

Field	Description	Notes
Tobacco History	Whether the volunteer has used tobacco. • Never • Quit or Current	• If you select Never, the ADD button with the Tobacco History Records table is disabled. • If you select Quit or Current, the Add button is enabled. The year value is required for Tobacco History records. If the month and day values are left blank, xx or xxx appear instead. For more information, see ***Adding a tobacco record*** (on page 37).

c Click **NEXT** and continue to ***Step 5a: Recording whether a caller has a known medical condition*** (on page 73).

Step 4: Recording demographic information about a new volunteer

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Previous step: ***Step 3: Identifying a caller*** (on page 66).

1 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

2 Fill in the fields.

Field descriptions for the Incoming Calls - New Volunteer page

Field	Description	Notes
Title	Title of the caller (for example, Mr., Ms., Dr.).	
Age	Age of the volunteer.	READ-ONLY. Automatically calculated based on the date of birth for the volunteer.
BMI	Volunteer's body mass index.	Automatically calculated if the volunteer height and weight are provided. BMI is calculated to two decimal places.
% IBW	Volunteer's percentage of ideal body weight.	

Field	Description	Notes
CrCl	Measurement of the Creatinine Clearance for the volunteer.	READ-ONLY. Measured in mg/dL. A value appears if the volunteer serum creatinine, gender, age and weight are provided. CrCl is calculated to three decimal places using the Cockgroft-Gault formula: Men: CrCl (mL/min) = ((140-age) * Weight kg / (72 * serum creatinine mg/dL). Women: CrCl (mL/min) = .85 * ((140-age) * Weight kg / (72 * serum creatinine mg/dL).
GFR	Measurement of the GFR for the volunteer.	Read-only field, which is only populated if the volunteer Serum Creatinine, Age, Race and Gender are provided. GFR is calculated using the following formula: GFR (mL/min/1.73 m^2) = 175 x Serum Creatinine$^{-1.154}$ x Age$^{-0.203}$ x (1.212 if Race Category is African American) x (0.742 if Gender is Female).
First Name	First name of volunteer.	REQUIRED.
Last name	Last name of volunteer.	REQUIRED. Maximum length is 50 characters.
Middle Initial	Middle initial of volunteer.	REQUIRED.
Gender	Gender of the volunteer.	REQUIRED.
Birth Date	Date of birth for the volunteer. Type the date in the field, or click the calendar icon and select a date.	REQUIRED.

Field	Description	Notes
Frame	Description of volunteer physical build in a drop-down list of Small, Medium, and Large.	Men (medium frame): IBW = 48 kg + (1.1 kg * (Height cm - 150 cm)). Women (medium frame): IBW = 45 kg + (.9 kg * (Height cm - 150 cm)). % IBW = Weight (kg)/IBW * 100 (For both men and women, subtract 10% for small frame, and add 10% for large frame).
Height Ft	Height of the volunteer in feet.	Values are based on settings on the Configuration - Settings - Facility page.
Height In	Remainder of the height of the volunteer in inches.	Values are based on settings on the Configuration - Settings - Facility page.
Weight	Weight of the volunteer.	Values are based on settings on the Configuration - Settings - Facility page.
Serum Creatinine	Measurement of volunteer serum creatinine.	Measured in mg/dL.
Availability	Times when the volunteer is available for a study.	
Location Pref.	Volunteer preference for location of the study facility.	Choose from all facilities defined on the Configuration - Settings - Facilities page.
Travel Distance	Distance that the volunteer travels to reach the facility.	Integer from 0 to 99,999.

Field	Description	Notes
Tobacco History	Whether the volunteer has used tobacco. • Never • Quit or Current	• If you select Never, the ADD button with the Tobacco History Records table is disabled. • If you select Quit or Current, the Add button is enabled. The year value is required for Tobacco History records. If the month and day values are left blank, xx or xxx appear instead. For more information, see ***Adding a tobacco record*** (on page 37).

If the caller is a volunteer who is associated with a study, the read-only fields at the top of the page display information for the caller.

3 Click **NEXT**.

The Medical History page appears.

4 Continue to ***Step 5a: Recording whether a caller has a known medical condition*** (on page 73).

Step 5a: Recording whether a caller has a known medical condition

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Previous step: ***Step 4: Recording demographic information about a new volunteer*** (on page 70).

If the caller previously provided a medical history, the Medical List Leading Question does not appear.

1 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

2 Select **Yes** or **No** for the question, indicating whether the caller has a known medical condition.

- If you selected **Yes**, the Medical History page appears.

  Continue to ***Step 5b: Recording the medical history for a caller*** (on page 73).

- If you selected **No**, the Surgical Procedures page appears.

  Continue to ***Step 6a: Recording whether a caller had a surgical procedure*** (on page 75).

Step 5b: Recording the medical history for a caller

Where to start: *Step 1: Starting an incoming call* (on page 66).

Previous step: *Step 5a: Recording whether a caller has a known medical condition* (on page 73).

If the responses to the questions for a volunteer appear on the Volunteer - Clinical History - Medical page or were recorded during a previous incoming call, the Incoming Calls - Medical History page includes the previously collected data. If you answer Yes to a question and any conditions are associated with the question, a table appears and displays the conditions.

1 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

2 Select either **Yes** or **No**.

> **Note:** You cannot answer No to a question that lists any associated conditions.

The next step depends on the answer:

- If you selected **Yes**, depending on the question and whether it is associated with a specific health area or medical procedure, a dialog box appears for you to add the condition or procedure.

  a Fill out the fields for the dialog box that appears.

  Field descriptions for the Add Medical Conditions dialog box

Field	Description	Notes
Condition	Medical condition, illness, disease, or disorder.	REQUIRED. Includes a search function that allows you to choose from a list of approved medical conditions. Read-only if you are editing a medical condition.
Start Month	Month that the condition started.	
Start Day	Day that the condition started.	
Start Year	Year that the condition started.	REQUIRED.
Ongoing	When selected, the condition is still occurring.	Required if End Year is not specified.
End Month	Month that the condition ended.	
End Day	Day that the condition ended.	
End Year	Year that the condition ended.	REQUIRED.

Field	Description	Notes
Comment	Custom text to further explain condition.	Required or optional, depending on how the study was set up.

Field descriptions for the Add Other Conditions dialog box

Field	Description	Notes
[Condition Question]	Medical history question.	
Month	Month that the condition occurred.	
Day	Day that the conditions occurred.	
Year	Year that the condition occurred.	REQUIRED.
Comment	Custom text to explain the condition.	REQUIRED.

The Existing Volunteer - Medical page appears.

b Click **Next**.

The Surgical List Leading Question page appears.

- If you selected **No**, the Surgical List Leading Question page appears.

3 Continue to ***Step 6a: Recording whether a caller had a surgical procedure*** (on page 75).

Step 6a: Recording whether a caller had a surgical procedure

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Prerequisite: ***Step 4: Recording demographic information about a new volunteer*** (on page 70).

Previous step (one of the following):

- ***Step 5a: Recording whether a caller has a known medical condition*** (on page 73).
- ***Step 5b: Recording the medical history for a caller*** (on page 73).

If the caller previously provided surgical procedures, the Surgical List Leading Question does not appear.

1 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears. The approved script is created on the Settings - Call - Call Script page.

2 Select either **Yes** or **No**.

- If you selected **Yes**, the Add Surgical Procedures dialog box appears.

  Continue to ***Step 6b: Recording a surgical procedure for a caller*** (on page 76).

- If you selected **No**, one of the following pages appears:
  - Concomitant Medication Leading Question page—Continue to ***Step 7a: Recording whether a caller has current or past medications*** (on page 77).
  - Concomitant Medications page—Continue to ***Step 7b: Recording a medication for a caller*** (on page 77).

Step 6b: Recording a surgical procedure for a caller

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Previous step: ***Step 6a: Recording whether a caller had a surgical procedure*** (on page 75).

1 Fill in the fields.

Field descriptions for the Add Surgical Procedures dialog box

Field	Description	Notes
Procedure	Type of surgical procedure.	REQUIRED. Includes a search function that retrieves both medical and common names of procedures. Read-only if you are editing a surgical procedure.
Month	Month that the surgical procedure occurred.	
Day	Day that the surgical procedure occurred.	
Year	Year that the surgical procedure occurred.	REQUIRED.
Comment	Custom text to explain the surgical procedure.	Required or optional, depending on how the study was set up.

2 Click **SAVE**.

3 Add additional surgical procedures as necessary.

4 After you finish adding surgical procedures, close the dialog box.

The surgical procedure information appears in a table.

5 Click **Next**.

The Concomitant Medications Leading Questions page appears.

6 Continue to ***Step 7a: Recording whether a caller has current or past medications*** (on page 77).

Step 7a: Recording whether a caller has current or past medications

Where to start: *Step 1: Starting an incoming call* (on page 66).

Previous step (one of the following):

- *Step 6a: Recording whether a caller had a surgical procedure* (on page 75).
- *Step 6b: Recording a surgical procedure for a caller* (on page 76).

1 Read the approved script in the gray box to the caller.

  If the page does not have an approved script, Question Input appears. The approved script is created on the Settings - Call - Call Script page.

2 Select either **Yes** or **No**.

  - If you selected **Yes**, the Concomitant Medications page appears.

    Continue to *Step 7b: Recording a medication for a caller* (on page 77).

  - If you selected **No**, the Volunteer Details page appears.

    Continue to *Step 8: Recording contact information for a caller* (on page 79).

Step 7b: Recording a medication for a caller

Where to start: *Step 1: Starting an incoming call* (on page 66).

Previous step: *Step 7a: Recording whether a caller has current or past medications* (on page 77).

If a volunteer's answers to any of the questions were recorded on the Volunteers - Clinical History - Medical page, or during a previous incoming call, this page includes the previously collected data.

1 Read the approved script in the gray box to the caller.

2 Fill in the fields.

  Field descriptions for the Incoming Calls - Concomitant Medications page

Field	Description	Notes
Medication	Name of the medication.	REQUIRED. The search retrieves both medical and common names of medicines. Read-only if you are editing a concomitant medication.

Field	Description	Notes
Condition	Medical conditions or surgical procedures.	REQUIRED. • If the caller already has a volunteer record, the field displays a list of medical conditions or surgical conditions associated with the volunteer. • If the caller is taking the medication for a condition that does not appear in the drop-down list, then you must go back to the Medical tab and record the newly-disclosed condition.
Dose	Dose of the medication.	Reference only. Field can contain alphanumeric text.
Unit	Physical format of medication. For example, pill or capsule.	REQUIRED.
Frequency	How often the dose is taken.	REQUIRED.
Method	How the dose is taken. For example, oral, auricular.	REQUIRED.
Start Month	Month that the volunteer first started taking the medication.	
Start Day	Day that the volunteer first started taking the medication.	
Start Year	Year that the volunteer first started taking the medication.	Required or optional, depending on how the study was set up.
Ongoing	When selected, the volunteer is still taking the medication.	
End Month	Month that the volunteer stopped taking the medication.	
End Day	Day that the volunteer stopped taking the medication.	
End Year	Year that the volunteer stopped taking the medication.	
Comment	Custom text explaining the medications.	Required or optional, depending on how the study was set up.

3 Click **ADD**

The medication appears in the Concomitant Medication History table.

4 Add additional medications as necessary.

5 After you finish adding medications, click **NEXT**.

The Volunteer Details page appears.

6 Continue to *Step 8: Recording contact information for a caller* (on page 79).

Step 8: Recording contact information for a caller

Where to start: *Step 1: Starting an incoming call* (on page 66).

Previous step (one of the following):

- *Step 7a: Recording whether a caller has current or past medications* (on page 77).
- *Step 7b: Recording a medication for a caller* (on page 77).

1 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

2 Fill in the fields.

Field descriptions for the Incoming Calls - Volunteer Details page

Field	Description	Notes
Title	Title of the caller (for example, Mr., Ms., or, Dr.).	
First Name	First name.	REQUIRED.
Last Name	Last name.	REQUIRED. Maximum length is 50 characters.
Middle Initial	Middle initial.	
Address 1 Address 2 City State Postal Country	Street address.	
Tel.	Telephone number.	
Cell	Cellular phone number.	
Addl	Additional phone number.	
Email	Email address.	
Marital Status	Marital status.	Default: Single.
Soc. Sec. No.	Social security number.	

Field	Description	Notes
Race	Race.	Values are created on the Settings - Volunteer-Properties page.
Ethnicity	Ethnicity.	Values are created on the Settings - Volunteer-Properties page.
Emergency Contact		
Relationship	Relationship of the emergency contact to the caller.	
Name (F)	First name of the emergency contact.	
Name (L)	Last name of the emergency contact.	
Name (MI)	Middle initial of the emergency contact person.	
Title	Title of the emergency contact (for example, Mr. Ms., Dr.).	
Address 1 Address 2	Address of the emergency contact.	

3 Click **NEXT**.

The Additional Demographics page appears.

4 Continue to ***Step 9: Recording additional demographics about a caller*** (on page 80).

Step 9: Recording additional demographics about a caller

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Prerequisite: ***Step 4: Recording demographic information about a new volunteer*** (on page 70).

Previous step: ***Step 8: Recording contact information for a caller*** (on page 79).

1 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

2 Fill in the fields.

> **Note: The actual fields that appear on this page are set up during configuration of the LabPas Recruiting module. The fields listed here are examples.**

Field descriptions for the Incoming Calls - Additional Demographics page

Field	Description	Notes
U.S. Citizen	When selected, the caller is a citizen of the United States of America.	Field created on the Settings - Volunteer - Demographics page.
Disclaimer		Field created on the Settings - Volunteer - Demographics page.
Occupation	Occupation.	Field created on the Settings - Volunteer - Demographics page.
Age Group	Age group.	Select a radio button for the appropriate age group. Field created on the Settings - Volunteer - Demographics page.

3 Click **NEXT**.

The Study Questions page appears.

4 Continue to ***Step 10: Selecting a study and recording answers to study questions*** (on page 81).

Step 10: Selecting a study and recording answers to study questions

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Prerequisites:

- ***Step 9: Recording additional demographics about a caller*** (on page 80).
- Verify whether a study is selected for a caller.

1 Click **STUDIES**.

The Select Study dialog box appears.

Field descriptions for the Select Study dialog box

Field	Description	Notes
Volunteer Location Pref.	Volunteer preference for study location.	• Recorded on the ***Volunteer - Personal - Demographics page*** (on page 32). • READ-ONLY.

Field	Description	Notes
Study Type Exclusions		• Recorded on the ***Volunteer - Personal - Demographics page*** (on page 32) • READ-ONLY.
Available Studies		
	All available studies with which the volunteer is not yet associated.	• Studies for which the volunteer's entered data does not qualify are displayed in red. • Studies for which the volunteer's entered data meets all inclusion/exclusion criteria are displayed in green. • All data entered so far meets study inclusion/exclusion criteria are displayed in blue. • If Global Recruiting has not been configured, only active studies appear.
Study ID		Displays the values defined for each study on the Study - Properties page.
Rank		Displays the values defined for each study on the Study - Properties page.
Type		Displays the values defined for each study on the Study - Properties page.
Start Date		Corresponds to the settings created for each specific group on the Study - Setup - General page.
End Date		Corresponds to the settings created for each specific group on the Study - Setup - General page.
Description		Displays the values defined for each study on the Study - Properties page.
Group	Groups to which the volunteer is assigned.	Corresponds to the settings created for each specific group on the Study - Setup - General page. If the LabPas application is not configured for Global Recruiting, the only groups that appear are associated with the current facility.

Field	Description	Notes
Location		Corresponds to the settings created for each specific group on the Study - Setup - General page.

2 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

3 To view more details about a study, click the ellipsis button (**...**) to the left of the study ID.

The Study Details dialog box appears. The two fields, **Synopsis** and **Outline**, contain custom text that was entered on the Study - Setup - General page.

4 To select the study group that the caller is screened for during the rest of the phone call, click the row for the study group in the Select Study dialog box.

The Select Study dialog box closes. On the Incoming Calls - Study Questions page, the fields in the page header are populated with data for the selected study. The text box below the script contains questions for you to read to the caller.

Field descriptions for the Incoming Calls - Study Questions page

Field	Description	Notes
Selected Study	Study code.	
Location	Study location.	
Group	Group number.	
Qualifies	• **Yes**—The caller is qualified for the study. • **No**—The caller is not qualified for the study.	Not updated until all study questions specified as **Required** on the Study - Questionnaire page have been answered.
Reason	If the caller does not qualify for the study, red text appears in the **Reason** field, explaining why he or she does not qualify.	Not updated until all study questions specified as **Required** on the Study - Questionnaire page have been answered.

5 Select the **Yes** or **No** radio button for each question.

As each question is answered, it appears in the Completed Questions table.

After you answer all questions for the study, **Study questions complete** appears below the script.

After you answer all required questions, the Appointment tab is enabled.

6 Click **NEXT**.

The Appointment page appears.

7 Continue to ***Step 11: Selecting an appointment for a caller*** (on page 84).

Step 11: Selecting an appointment for a caller

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Previous step: ***Step 10: Selecting a study and recording answers to study questions*** (on page 81).

Prerequisite: ***Step 4: Recording demographic information about a new volunteer*** (on page 70).

1. Read the approved script in the gray box to the caller.

   If the page does not have an approved script, Question Input appears.

2. Select an in-house screening appointment.

   The Schedule Appointment page appears.

3. Continue to ***Step 12: Viewing a selected screening appointment prior to confirmation*** (on page 84).

Step 12: Viewing a selected screening appointment prior to confirmation

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Prerequisites:

- ***Step 4: Recording demographic information about a new volunteer*** (on page 70).
- ***Step 11: Selecting an appointment for a caller*** (on page 84).

1. Review information about the appointment
2. Read the approved script in the gray box to the caller.

   If the page does not have an approved script, Question Input appears.

3. Verify the information in the fields with the caller.

   Field descriptions for the Incoming Calls - Schedule Appointment page

Field	Description	Notes
Date/Time	Date and time of the appointment.	READ-ONLY.
Session	Session number.	READ-ONLY.
Clinic	Name of the clinic where the visit will occur.	READ-ONLY.
Visit	Type of visit (for example, screening).	READ-ONLY.
Openings	Number of openings for the appointment.	READ-ONLY.
Filled	The number of filled time slots.	READ-ONLY.
Available	Number of available appointments.	READ-ONLY.

4 Click **NEXT**.

The Appointment Confirmation page appears.

5 Continue to *Step 13: Ending a call* (on page 85).

Step 13: Ending a call

Where to start: *Step 1: Starting an incoming call* (on page 66).

Prerequisites:

- Define a call resolution on the Settings - Call Resolution page.
- *Step 4: Recording demographic information about a new volunteer* (on page 70).
- *Step 11: Selecting an appointment for a caller* (on page 84).
- *Step 12: Viewing a selected screening appointment prior to confirmation* (on page 84).

1 Verify the screening appointment with the caller.

2 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

3 Click **DONE**.

Editing and deleting information for a caller or volunteer

Rescheduling an existing appointment

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Prerequisites: ***Step 2: Selecting a media campaign*** (on page 66) and ***Step 3: Identifying a caller*** (on page 66).

1 Select the **Rescheduling** tab.

2 In the Appointments table, select the checkbox for the appointment.

3 Click **RESCHEDULE**.

The Reschedule Appointment - Select Appointment dialog box appears. This dialog box displays a table of approved sessions that are available in the same facility as the original appointment.

If no appointments are available, **No Appointments** appears instead of the session table.

4 Click the appointment that you want to select as the rescheduled appointment.

The Reschedule Appointment - Schedule Appointment dialog box appears. It displays a summary of the new appointment information.

5 Type your User ID, password, and an optional comment.

The Reschedule Appointment - Confirm Appointment dialog box appears. It displays any instructions that were set up for the study on the Study - Setup - General page.

6 Click **DONE**.

The original appointment session becomes available for scheduling other volunteers. The **Filled** value associated with the new appointment session is incremented by one, and the **Available** value associated with the appointment session is decremented by one. The Volunteer - Appointment Log page displays the new appointment information.

Canceling an existing appointment

Where to start: ***Step 1: Starting an incoming call*** (on page 66).

Previous step: ***Step 3: Identifying a caller*** (on page 66).

1 Select the **Demographics** tab.

The Incoming Calls - Demographics page appears.

2 In the Appointments table, select the checkbox for the appointment to cancel.

3 Click **CANCEL**.

The Cancel Appointment - Cancel Appointment dialog box appears and displays a summary of the appointment being canceled.

4 Fill in the fields.

5 Type your User ID, password, and an optional comment.

Field descriptions for the Cancel Appointment dialog box

Field	Description	Notes
Canceled By	Whether the appointment is canceled by the CRO or volunteer.	
Call Volunteer	• **Selected**—The outgoing call is automatically scheduled to go out to the volunteer whose appointment was canceled, on the day following the appointment cancelation. • **Cleared**—No outgoing call is scheduled.	You can view cancelation calls in the Outgoing Calls page.

6 Click **DONE**.

The appointment is removed from the Appointments table. The cancelled appointment becomes available again for scheduling other volunteers. If the volunteer status for the specific study was previously Scheduled, it resets to Unscheduled. A reminder call might be scheduled in Outgoing Calls, depending on how appointments are configured during study setup.

Editing demographic information for a volunteer

Prerequisites:

- ***Step 1: Starting an incoming call*** (on page 66).
- ***Step 2: Selecting a media campaign*** (on page 66) (if an advertising campaign does not yet exist).
- ***Step 3: Identifying a caller*** (on page 66).

1 Select the volunteer for whom to edit demographic information.

2 Click **Next**.

The Incoming Calls - Existing Volunteer page appears.

3 Read the approved script in the gray box to the caller.

If the page does not have an approved script, Question Input appears.

4 Fill in the fields.

If the caller is a volunteer who is associated with a study, the read-only fields at the top of the page display information for the caller.

Field descriptions for the Incoming Calls - Existing Volunteer page

Field	Description	Notes
Title	Title of the caller (for example, Mr., Ms., Dr.).	
Age	Age of the volunteer.	READ-ONLY. Automatically calculated based on the date of birth for the volunteer.
BMI	Volunteer's body mass index.	Automatically calculated if the volunteer height and weight are provided. BMI is calculated to two decimal places.
% IBW	Volunteer's percentage of ideal body weight.	
CrCl	Measurement of the Creatinine Clearance for the volunteer.	READ-ONLY. Measured in mg/dL. A value appears if the volunteer serum creatinine, gender, age and weight are provided. CrCl is calculated to three decimal places using the Cockgroft-Gault formula: Men: CrCl (mL/min) = ((140-age) * Weight kg / (72 * serum creatinine mg/dL). Women: CrCl (mL/min) = .85 * ((140-age) * Weight kg / (72 * serum creatinine mg/dL).
GFR	Measurement of the GFR for the volunteer.	Read-only field, which is only populated if the volunteer Serum Creatinine, Age, Race and Gender are provided. GFR is calculated using the following formula: GFR (mL/min/1.73 m^2) = 175 x Serum Creatinine$^{-1.154}$ x Age$^{-0.203}$ x (1.212 if Race Category is African American) x (0.742 if Gender is Female).
First Name	First name of volunteer.	REQUIRED.

Field	Description	Notes
Last name	Last name of volunteer.	REQUIRED. Maximum length is 50 characters.
Middle Initial	Middle initial of volunteer.	REQUIRED.
Gender	Gender of the volunteer.	REQUIRED.
Birth Date	Date of birth for the volunteer. Type the date in the field, or click the calendar icon and select a date.	REQUIRED.
Frame	Description of volunteer physical build in a drop-down list of Small, Medium, and Large.	Men (medium frame): IBW = 48 kg + (1.1 kg * (Height cm - 150 cm)). Women (medium frame): IBW = 45 kg + (.9 kg * (Height cm - 150 cm)). % IBW = Weight (kg)/IBW * 100 (For both men and women, subtract 10% for small frame, and add 10% for large frame).
Height Ft	Height of the volunteer in feet.	Values are based on settings on the Configuration - Settings - Facility page.
Height In	Remainder of the height of the volunteer in inches.	Values are based on settings on the Configuration - Settings - Facility page.
Weight	Weight of the volunteer.	Values are based on settings on the Configuration - Settings - Facility page.
Serum Creatinine	Measurement of volunteer serum creatinine.	Measured in mg/dL.
Availability	Times when the volunteer is available for a study.	
Location Pref.	Volunteer preference for location of the study facility.	Choose from all facilities defined on the Configuration - Settings - Facilities page.
Travel Distance	Distance that the volunteer travels to reach the facility.	Integer from 0 to 99,999.

Field	Description	Notes
Tobacco History	Whether the volunteer has used tobacco. • Never • Quit or Current	• If you select Never, the ADD button with the Tobacco History Records table is disabled. • If you select Quit or Current, the Add button is enabled. The year value is required for Tobacco History records. If the month and day values are left blank, xx or xxx appear instead. For more information, see ***Adding a tobacco record*** (on page 37).

5 Click **NEXT**.

Editing a medical condition for a caller

1 From the main menu, select **Recruiting > Incoming Calls**.

The Incoming Calls page appears.

2 Select the **Medical** tab.

The Incoming Calls - Medical History page appears.

3 Click the ellipsis button (**...**) for the condition name.

The Edit Medical Conditions dialog box appears.

4 Fill in the fields.

Field descriptions for the Edit Medical Conditions dialog box

Field	Description	Notes
Condition	Medical condition, illness, disease, or disorder.	REQUIRED. Includes a search function that allows you to choose from a list of approved medical conditions. Read-only if you are editing a medical condition.
Start Month	Month that the condition started.	
Start Day	Day that the condition started.	
Start Year	Year that the condition started.	REQUIRED.

Field	Description	Notes
Ongoing	When selected, the condition is still occurring.	Required if End Year is not specified.
End Month	Month that the condition ended.	
End Day	Day that the condition ended.	
End Year	Year that the condition ended.	REQUIRED.
Comment	Custom text to further explain condition.	Required or optional, depending on how the study was set up.

5 Click **SAVE**.

The changes are updated in the table on the Incoming Calls - Medical History page.

Changes made to conditions are logged in the Recruiting Change Log report, which you view on the Reports page.

Editing a non-medical condition for a caller

1 From the main menu, select **Recruiting > Incoming Calls**.

The Incoming Calls page appears.

2 Select the **Medical** tab.

The Incoming Calls - Medical History page appears.

3 Click the ellipsis button (**...**) to the left of the condition name.

The Edit Other Conditions dialog box appears.

4 Fill in the fields.

Field descriptions for the Edit Other Conditions dialog box

Field	Description	Notes
Question	Question about other condition.	Depends on selected condition.
Month	Month in which the condition occurred.	
Day	Day on which the condition occurred.	
Year	Year on which the condition occurred.	
Comment	Custom text.	REQUIRED.

5 Click **SAVE**.

The changes are updated in the table on the Incoming Calls - Medical History page.

Changes made to conditions are logged in the Recruiting Change Log report, which can be viewed on the Reports page.

Deleting a condition for a caller

1 From the main menu, select **Recruiting > Incoming Calls**.

The Incoming Calls page appears.

2 Select the **Medical** tab.

The Incoming Calls - Medical History page appears.

3 Click the **X** button for a condition.

The Delete Condition dialog box appears.

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

The condition is removed from the table on the Incoming Calls- Medical History page.

Changes to conditions are logged in the Recruiting Change Log report, which can be viewed on the Reports page.

Editing a surgical procedure for a caller

1 From the main menu, select **Recruiting > Incoming Calls**.

The Incoming Calls page appears.

2 Select the **Surgical** tab.

The Incoming Calls - Surgical Procedures page appears.

3 Click the ellipsis button (**...**) for the surgical procedure to edit.

The Edit Surgical Procedures dialog box appears.

4 Fill in the fields.

Field descriptions for the Edit Surgical Procedures dialog box

Field	Description	Notes
Procedure	Type of surgical procedure.	REQUIRED. Includes a search function that retrieves both medical and common names of procedures. Read-only if you are editing a surgical procedure.
Month	Month that the surgical procedure occurred.	
Day	Day that the surgical procedure occurred.	

Field	Description	Notes
Year	Year that the surgical procedure occurred.	REQUIRED.
Comment	Custom text to explain the surgical procedure.	Required or optional, depending on how the study was set up.

5 Click **SAVE**.

The changes are updated in the table on the Incoming Calls - Surgical Procedures page.

Changes made to surgical procedures are logged in the Recruiting Change Log report, which can be viewed on the Reports page.

Deleting a surgical procedure for a caller

1 From the main menu, select **Recruiting > Incoming Calls**.

The Incoming Calls page appears.

2 Select the **Surgical** tab.

The Incoming Calls - Surgical Procedures page appears.

3 Click the **X** button for a procedure.

The Delete Volunteer Surgical Procedure dialog box appears.

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

The procedure is removed from the table on the Incoming Calls- Surgical Procedures page.

Changes to surgical procedures are logged in the Recruiting Change Log report, which can be viewed on the Reports page.

Editing a medication for a caller

1 From the main menu, select **Recruiting > Incoming Calls**.

The Incoming Calls page appears.

2 Select the **Medications** tab.

The Incoming Calls - Concomitant Medications page appears.

3 Click the ellipsis button (**...**) for the medication to edit.

The Edit Concomitant Medication dialog box appears.

4 Fill in the fields.

Field descriptions for the Edit Concomitant Medication dialog box

Field	Description	Notes
Medication	Name of the medication.	REQUIRED. The search retrieves both medical and common names of medicines. Read-only if you are editing a concomitant medication.
Condition	Medical conditions or surgical procedures.	REQUIRED. • If the caller already has a volunteer record, the field displays a list of medical conditions or surgical conditions associated with the volunteer. • If the caller is taking the medication for a condition that does not appear in the drop-down list, then you must go back to the Medical tab and record the newly-disclosed condition.
Dose	Dose of the medication.	Reference only. Field can contain alphanumeric text.
Unit	Physical format of medication. For example, pill or capsule.	REQUIRED.
Frequency	How often the dose is taken.	REQUIRED.
Method	How the dose is taken. For example, oral, auricular.	REQUIRED.
Start Month	Month that the volunteer first started taking the medication.	
Start Day	Day that the volunteer first started taking the medication.	
Start Year	Year that the volunteer first started taking the medication.	Required or optional, depending on how the study was set up.
Ongoing	When selected, the volunteer is still taking the medication.	
End Month	Month that the volunteer stopped taking the medication.	
End Day	Day that the volunteer stopped taking the medication.	

Field	Description	Notes
End Year	Year that the volunteer stopped taking the medication.	
Comment	Custom text explaining the medications.	Required or optional, depending on how the study was set up.

5 Click **SAVE**.

The changes are saved and appear in the Concomitant Medication History table.

Deleting a medication for a caller

1 From the main menu, select **Recruiting > Incoming Calls**.

The Incoming Calls page appears.

2 Select the **Medications** tab.

The Incoming Calls - Concomitant Medications page appears.

3 Click the **X** button for a medication.

The Delete Medication dialog box appears.

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

The medication is removed from the Concomitant Medication History table.

Editing a caller's answer to a study question

1 From the main menu, select **Recruiting > Incoming Calls**.

The Incoming Calls page appears.

2 Select the **Study Questions** tab.

The Incoming Calls - Study Questions page appears.

3 Click the ellipsis button (**...**) for the question number to edit.

The Edit Question Response dialog box appears.

4 Select the **Yes** or **No** radio button.

5 Click **SAVE**.

The Edit Question Response dialog box closes.

CHAPTER 5

Appointments

In this chapter

Tasks: Appointments page

On the Appointments page, you schedule, cancel, and reschedule appointments in the LabPas Recruiting module.

You must have the Change Appointments permission to perform these activities.

- *Scheduling an appointment.* (on page 99)
- *Rescheduling an appointment* (on page 101).
- *Canceling an appointment* (on page 103).
- *Changing a volunteer's appointment status to No Show* (on page 105).

You can also use the Appointments page to print volunteer screening labels to use in screening appointments.

You must have the Volunteer Administration permission to print volunteer labels.

- *Printing volunteer appointment labels* (on page 107).

Scheduling an appointment

1 From the main menu, select **Recruiting > Appointments**.

The Appointments page appears.

Field descriptions for the Appointments page

Field	Description	Notes
Study ID	ID of the study for which the volunteer will be screened during the selected appointment.	READ-ONLY.
Facility	Facility where the screening appointment will occur.	• READ-ONLY. • Only displayed if Global Recruiting has been selected on the Configuration - Settings - Global page • Settings were defined on the Schedule page.
Name	Name of the volunteer.	Read-only.
VRN	Volunteer record number.	Read-only.
Appt. Date	Date of the appointment.	Settings were defined on the Schedule page. READ-ONLY.
Session	Session number.	Settings were defined on the Schedule page. READ-ONLY.
Clinic	Name of the clinic.	READ-ONLY.
Visit	Type of visit.	READ-ONLY.
Appt. Status	Status of appointment.	READ-ONLY. Blank if the appointment is still active. Appointments that are not active can have a status of one of the following: Complete, No Show, Canceled, CRO Canceled, or Vol Canceled.
Approval Date	Approval date of appointment.	READ-ONLY.
Approved by	Person who approved the appointment.	READ-ONLY.

The data that appears on the page is restricted to the selected day. To change the day, click the calendar and select a date, or use the arrow buttons to navigate to the previous or next days.

2 Click **NEW**.

The New Appointment - Select Volunteer dialog box appears, listing all volunteers who are associated with a study, but who are not yet scheduled for an appointment or assigned a study status.

Only one row is displayed for a single study and volunteer, even if the volunteer has been added to a study multiple times through the Recruiting – SR Studies – Volunteers – Volunteers – Select Volunteer page. If selected, an appointment is scheduled for only the most recent study participant record created for the volunteer.

3 Filter the volunteer list:

- To filter the volunteer list by study, type a study ID in the **Study Id** field, and click **APPLY**.

  Only the volunteers associated with the selected study appear.

- To remove the filter, delete the text from the **Study Id** field and click **APPLY**.

  All volunteers appear.

4 Select a volunteer.

The New Appointment - Select Appointment dialog box appears, listing all approved sessions for the facility group to which the volunteer is assigned, and that has available appointments.

If no sessions exist, **No Appointments** appears.

5 Select an appointment.

The New Appointment - Schedule Appointment dialog box appears.

6 In the Approval area, type your User ID, password, and a comment, and click **NEXT**.

The New Appointment - Confirm Appointment dialog box appears and displays information about the scheduled appointment.

7 Click **DONE**.

The appointment is scheduled and appears on the Appointments page.

Rescheduling an appointment

You can reschedule appointments that have not yet been resolved or that have a status of Cancelled or CRO Canceled. You can reschedule only one appointment at a time.

1 From the main menu, select **Recruiting > Appointments**.

The Appointments page appears.

Field descriptions for the Appointments page

Field	Description	Notes
Study ID	ID of the study for which the volunteer will be screened during the selected appointment.	READ-ONLY.
Facility	Facility where the screening appointment will occur.	• READ-ONLY. • Only displayed if Global Recruiting has been selected on the Configuration - Settings - Global page • Settings were defined on the Schedule page.
Name	Name of the volunteer.	Read-only.
VRN	Volunteer record number.	Read-only.
Appt. Date	Date of the appointment.	Settings were defined on the Schedule page. READ-ONLY.
Session	Session number.	Settings were defined on the Schedule page. READ-ONLY.
Clinic	Name of the clinic.	READ-ONLY.
Visit	Type of visit.	READ-ONLY.
Appt. Status	Status of appointment.	READ-ONLY. Blank if the appointment is still active. Appointments that are not active can have a status of one of the following: Complete, No Show, Canceled, CRO Canceled, or Vol Canceled.
Approval Date	Approval date of appointment.	READ-ONLY.
Approved by	Person who approved the appointment.	READ-ONLY.

The data that appears on the page is restricted to the selected day. To change the day, click the calendar and select a date, or use the arrow buttons to navigate to the previous or next days.

2 Select the checkbox for the appointment to reschedule.

3 Click **RESCHEDULE**.

The Reschedule Appointment - Select Appointment dialog box appears, listing approved sessions that are available in the same facility as the original appointment.

If no sessions exist, **No Appointments** appears.

4 Select an appointment.

The Reschedule Appointment - Schedule Appointment dialog box appears.

5 In the Approval area, type your User ID, password, and a comment, and click **NEXT**.

The Reschedule Appointment - Confirm Appointment dialog box appears, and displays confirmation information about the scheduled appointment and any final instructions.

If the study was configured to include reminder calls, then the **Reminder Date** field displays the date when a reminder call will be made to the volunteer.

6 Click **DONE**.

The rescheduled appointment appears on the Appointments page.

Cancelling an appointment

1 From the main menu, select **Recruiting > Appointments**.

The Appointments page appears.

Field descriptions for the Appointments page

Field	Description	Notes
Study ID	ID of the study for which the volunteer will be screened during the selected appointment.	READ-ONLY.
Facility	Facility where the screening appointment will occur.	• READ-ONLY. • Only displayed if Global Recruiting has been selected on the Configuration - Settings - Global page • Settings were defined on the Schedule page.
Name	Name of the volunteer.	Read-only.
VRN	Volunteer record number.	Read-only.
Appt. Date	Date of the appointment.	Settings were defined on the Schedule page. READ-ONLY.
Session	Session number.	Settings were defined on the Schedule page. READ-ONLY.
Clinic	Name of the clinic.	READ-ONLY.
Visit	Type of visit.	READ-ONLY.
Appt. Status	Status of appointment.	READ-ONLY. Blank if the appointment is still active. Appointments that are not active can have a status of one of the following: Complete, No Show, Canceled, CRO Canceled, or Vol Canceled.
Approval Date	Approval date of appointment.	READ-ONLY.
Approved by	Person who approved the appointment.	READ-ONLY.

The data that appears on the page is restricted to the selected day. To change the day, click the calendar and select a date, or use the arrow buttons to navigate to the previous or next days.

2 Select one or more checkboxes for the appointments to cancel.

3 Click **CANCEL**.

The Cancel Appointments dialog box appears.

4 Fill in the fields.

Field descriptions for the Cancel Appointment dialog box

Field	Description	Notes
Canceled By	Whether the appointment is canceled by the CRO or volunteer.	
Call Volunteer	• **Selected**—The outgoing call is automatically scheduled to go out to the volunteer whose appointment was canceled, on the day following the appointment cancelation. • **Cleared**—No outgoing call is scheduled.	You can view cancelation calls in the Outgoing Calls page.

5 In the Approval area, type your User ID, password, and a comment, and click **NEXT**.

6 Click **DONE**.

Changing a volunteer's status to No Show

1 From the main menu, select **Recruiting > Appointments**.

The Appointments page appears.

Field descriptions for the Appointments page

Field	Description	Notes
Study ID	ID of the study for which the volunteer will be screened during the selected appointment.	READ-ONLY.
Facility	Facility where the screening appointment will occur.	• READ-ONLY. • Only displayed if Global Recruiting has been selected on the Configuration - Settings - Global page • Settings were defined on the Schedule page.
Name	Name of the volunteer.	Read-only.
VRN	Volunteer record number.	Read-only.
Appt. Date	Date of the appointment.	Settings were defined on the Schedule page. READ-ONLY.
Session	Session number.	Settings were defined on the Schedule page. READ-ONLY.
Clinic	Name of the clinic.	READ-ONLY.
Visit	Type of visit.	READ-ONLY.
Appt. Status	Status of appointment.	READ-ONLY. Blank if the appointment is still active. Appointments that are not active can have a status of one of the following: Complete, No Show, Canceled, CRO Canceled, or Vol Canceled.
Approval Date	Approval date of appointment.	READ-ONLY.
Approved by	Person who approved the appointment.	READ-ONLY.

The data that appears on the page is restricted to the selected day. To change the day, click the calendar and select a date, or use the arrow buttons to navigate to the previous or next days.

2 Select one or more checkboxes for the appointments.

3 Click **NO SHOW**.

The No Show Appointments dialog box appears.

4 In the Approval area, type your User ID, password, and a comment, and click **APPLY**.

Printing volunteer appointment labels

You use volunteer labels during a screening appointment. You can print more than one label at a time.

1 From the main menu, select **Recruiting > Appointments**.

The Appointments page appears.

Field descriptions for the Appointments page

Field	Description	Notes
Study ID	ID of the study for which the volunteer will be screened during the selected appointment.	READ-ONLY.
Facility	Facility where the screening appointment will occur.	• READ-ONLY. • Only displayed if Global Recruiting has been selected on the Configuration - Settings - Global page • Settings were defined on the Schedule page.
Name	Name of the volunteer.	Read-only.
VRN	Volunteer record number.	Read-only.
Appt. Date	Date of the appointment.	Settings were defined on the Schedule page. READ-ONLY.
Session	Session number.	Settings were defined on the Schedule page. READ-ONLY.
Clinic	Name of the clinic.	READ-ONLY.
Visit	Type of visit.	READ-ONLY.
Appt. Status	Status of appointment.	READ-ONLY. Blank if the appointment is still active. Appointments that are not active can have a status of one of the following: Complete, No Show, Canceled, CRO Canceled, or Vol Canceled.
Approval Date	Approval date of appointment.	READ-ONLY.
Approved by	Person who approved the appointment.	READ-ONLY.

The data that appears on the page is restricted to the selected day. To change the day, click the calendar and select a date, or use the arrow buttons to navigate to the previous or next days.

2 Select the checkbox for an appointment, and click **LABELS**.

The printer dialog box appears.

3 Select printer options and click **OK**.

CHAPTER 6

Looking up volunteers

In this chapter

Tasks: Volunteer Lookup page

On the Volunteer Lookup page, you:

- Search the LabPas database for potential study volunteers.
- Filter the list of existing volunteers in the LabPas Recruiting module by demographic, medical, surgical, and medication criteria.
- For the filtered group of volunteers:
  - Schedule outgoing calls.
  - Send an email.
  - Generate labels.
  - Export the list of volunteers as a CSV (comma-separated values) file.

- *Filtering volunteers* (on page 113).
- *Scheduling an outgoing call to volunteers* (on page 125).
- *Exporting a list of volunteers* (on page 127).
- *Emailing a list of volunteers* (on page 129).
- *Printing volunteer labels* (on page 131).

Demographic criteria - conditional fields

Demographic Criteria—Conditional Fields		
Criteria selection	Changes in the When field	Other
• Age • BMI • Height (and height is measured in meters) • Weight • Washout-Dose (Days) • Washout-Exit (Days) • Washout - Prescription Meds (Days) • Washout-OTC Meds (Days) • % Ideal Body Weight • CrCl or GFR	• First entry field is preceded by a drop-down selection of >=, >, or =. • Second entry field is preceded by a drop-down selection of <=, < or =. • At least one of the two entry fields must be populated to create a new restriction.	Default selections are >= and <=.
Washout-Tobacco (Days)	Two entry fields used to create a range.	Default selections: >= and <=.
Height (measured in feet and inches)	The field comprises two sets of entry fields (each for ft and in) used to create a range.	At least one of the two sets of entry fields must be populated to create a new restriction
Frame	Frame of the volunteer.	Default: Small.
Availability	Availability of the volunteer.	Default: Anytime.
Location Preference	Location preference of the volunteer.	Default: first facility listed.
Study Type Exclusions	The field provides a drop-down selection of all study types configured on the Settings - Study-Study Types page, listed in alphabetical order.	Default: first study type listed.
Additional Demographics	Additional demographics for the volunteer.	Drop-down selection of any of the fields that were created on the Settings - Volunteer - Demographics page, if any.

Demographic Criteria—Conditional Fields		
Criteria selection	**Changes in the When field**	**Other**
Tobacco History	Tobacco history of the volunteer.	If Quit or Ongoing is selected, then a Type drop-down field appears with a selection of Any, Not Specified, Cigarettes, Smokeless Tobacco, or Other Tobacco. Default: Never.
Tobacco Usage (Daily)	The field consists of two entry fields used to create a range of daily tobacco use.	A Type drop-down field appears with a selection of Any, Not Specified, Cigarettes, Smokeless Tobacco, and Other Tobacco. Default: Any.
Status	Status of the volunteer.	Default: Active.
Gender	Gender of the volunteer.	Default: Male.
Scheduled for Study	Whether the volunteer is scheduled for a study.	Default: Yes.

Filtering volunteers

1 From the main menu, select **Recruiting > Volunteer Lookup**.

The Volunteer Lookup page appears.

Field descriptions for the Volunteer Lookup page

Field	Description	Notes
VRN	Volunteer record number listing.	
Name	Name of the volunteer.	
Gender	Gender of the volunteer.	
Birth Date	Date of birth for the volunteer.	
Age	Age of the volunteer.	
Frame	Physical build of the volunteer.	Small, Medium, or Large.
Height	Height of the volunteer.	
Weight	Weight of the volunteer.	
BMI	Body mass index for the volunteer.	
%IBW	Percentage of ideal body weight for the volunteer.	
Washout-Dose	Filters by the range of days that have passed since the volunteer's Dose Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Exit	Filters by the range of days that have passed since the volunteer's Exit Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Tobacco	Filters by the range of days that have passed since the specified tobacco end date.	
Status	Study status of the volunteer.	
Telephone	Telephone number of the volunteer.	
Cell	Cellular phone number of the volunteer.	
Other Phone	Other phone number of the volunteer.	
Email	Email address of the volunteer.	

2 To filter volunteers by criteria, click the ellipsis button (**...**) for the Demographics field.

The Demographic Criteria dialog box appears.

3 Fill in the fields in the top area of the dialog box.

Field descriptions for the Demographic Criteria dialog box

Field	Description	Notes
Qualifier	Restricts information by None, Male, or Female.	Default: None. If you select Male or Female, then the Gender option is not available in the **Criteria** field. If you select a Qualifier, then the remaining restrictions (Type, Criteria and When) are applied only to the gender selected. All volunteers of the opposite gender still appear in the list of volunteers.
Type	**Inclusion**—Volunteers who meet the criteria you specify are included. **Exclusion**—Volunteers who meet the criteria you specify are excluded.	
Criteria	Restriction criteria that is applied to each volunteer's demographic data.	Default: Scheduled for Study.
When	One or more values that are used as restrictions.	

Note: The option you select in the Criteria filter affects the options that appear in the When filter. For more information, see ***Demographic Criteria - Conditional Fields*** (on page 111).

Filter Table

Lists one row for each filter you add for the criteria.

Column	Description	Notes
X button	Indicates that the filter is included. To remove the filter, click the X.	
Qualifier Type Criteria When	Lists the criteria you specified for the filter in the upper area of this dialog box.	

Column	Description	Notes
Operand	Specifies how to process multiple filters. **AND**—(Default). Volunteer must satisfy criteria in the filter that contains the AND operand, and the next filter in the list. The AND operand is always satisfied first, before OR is considered. **OR**—Volunteer must satisfy criteria in either the filter that contains the OR operand, or the next filter in the list.	If you add 2 or more filters, an operand appears in all rows except the last. AND takes precedence. For exclusion criteria, the operand is applied to the results returned for each criteria. For examples of using both AND and OR operands, see ***Using multiple criteria to filter*** (on page 120).and ***Specifying criteria in multiple categories*** (on page 122).

4 Click **ADD**.

The filter appears in the first row of the table.

5 To delete a filter, click the **X** button for the filter.

6 To specify additional criteria by which to filter, perform the following steps and repeat as necessary:

a Make selections at the top of the dialog box and click **ADD**.

The new filter appears in the next row of the table. In the previous row, a qualifier appears in the Operand column. The default operand is AND.

b Select the qualifier.

For more information, see ***Using multiple criteria to filter*** (on page 120).

7 Click **APPLY**.

The filters are applied to the volunteer list on the Volunteer Lookup page.

8 To apply filters for other areas, click the ellipsis button (**...**) for the Medical History, Surgical History, and Demographics fields and repeat the procedure.

Field descriptions for the Medical History Criteria dialog box

Field	Description	Notes
Qualifier	Restrict by None, Male, or Female.	Default: None.
Type	**Inclusion**—Volunteers who meet the criteria you specify are included. **Exclusion**—Volunteers who meet the criteria you specify are excluded.	
Criteria	Restriction criteria used for each volunteer's medical history data. Other fields that appear correspond to your selection: • **Medical Question** • **Medical Condition**	

Field	Description	Notes
Medical Question	Click the ellipsis button (**...**) and select a question.	Appears if **Criteria** selection is **Medical Question**.
Medical Condition	Click the ellipsis button (**...**) and select a condition.	Appears if **Criteria** selection is **Medical Condition**.
When	The volunteer's answer to the medical question. • **Yes—**Volunteer answered Yes to the Medical Question. • **No—**Volunteer answered No to the Medical Question.	Appears if **Criteria** selection is **Medical Question**. Depending on the Type selection, volunteer is included or excluded based on the answer.
Ongoing Start, End	• **Ongoing** Selected—The condition is active. • **Start, End** Used to isolate a date range.	Appears if **Criteria** selection is **Medical Condition**. **Note:** To calculate a condition washout, or calculate durations, you might need to create ***multiple criteria*** (on page 120). You can specify a combination of Ongoing and Start and End dates to include or exclude past or ongoing medical conditions. For more information, see **Examples of specifying medical history using Ongoing, Start, and End dates** later in this topic.

Filter Table

Lists one row for each filter you add for the criteria.

Column	Description	Notes
X button	Indicates that the filter is included. To remove the filter, click the X.	
Qualifier Type Criteria When	Lists the criteria you specified for the filter in the upper area of this dialog box.	

Column	Description	Notes
Operand	Specifies how to process multiple filters. **AND**—(Default). Volunteer must satisfy criteria in the filter that contains the AND operand, and the next filter in the list. The AND operand is always satisfied first, before OR is considered. **OR**—Volunteer must satisfy criteria in either the filter that contains the OR operand, or the next filter in the list.	If you add 2 or more filters, an operand appears in all rows except the last. AND takes precedence. For exclusion criteria, the operand is applied to the results returned for each criteria. For examples of using both AND and OR operands, see ***Using multiple criteria to filter*** (on page 120).and ***Specifying criteria in multiple categories*** (on page 122).

Examples of specifying medical history using Ongoing, Start, and End dates

To	Do this
Exclude or include a volunteer who has any history of a specific condition.	Unselect **Ongoing**, and leave Start and End dates blank.
Exclude or include a volunteer who actively has a condition.	Select **Ongoing**, and leave Start and End dates blank.
Include or exclude a volunteer who has had a condition within the last *n* number of years.	Specify date range as **Start**—*n* years ago, **End**—the current date. This range returns volunteers who actively have the condition and those who have been cured recently.
Include a volunteer who actively has a condition and who has had it for *n* number of years.	Specify two separate criteria for the condition, and use the AND operand: • An **Inclusion** criteria, using the same Start date and End date, *n* years in the past; leave Ongoing unselected • An **Inclusion** criteria, with Ongoing selected, and Start and End dates blank. **Note:** If Ongoing is selected, Start and End dates are ignored for that criteria.
Include a volunteer who had a condition but not within the last *n* number of years.	Specify two separate criteria for the condition: • An **Inclusion** criteria with End Date n years in the past, Start date blank, and Ongoing unselected. • An **Exclusion** criteria with Start Date *n* years in the past, End date blank, and Ongoing unselected.

Field descriptions for the Surgical History Criteria dialog box

Field	Description	Notes
Qualifier	Restrict by None, Male, or Female.	Default: None.
Type	**Inclusion**—Volunteers who meet the criteria you specify are included. **Exclusion**—Volunteers who meet the criteria you specify are excluded.	
Surg Procedure	Click the ellipsis button (**...**) and select an approved surgical procedure.	
When	Restriction value for the answer to the Surgical Procedure.	Default: Yes.

Filter Table

Lists one row for each filter you add for the criteria.

Column	Description	Notes
X button	Indicates that the filter is included. To remove the filter, click the X.	
Qualifier Type Criteria When	Lists the criteria you specified for the filter in the upper area of this dialog box.	
Operand	Specifies how to process multiple filters. **AND**—(Default). Volunteer must satisfy criteria in the filter that contains the AND operand, and the next filter in the list. The AND operand is always satisfied first, before OR is considered. **OR**—Volunteer must satisfy criteria in either the filter that contains the the OR operand, or the next filter in the list.	If you add 2 or more filters, an operand appears in all rows except the last. AND takes precedence. For exclusion criteria, the operand is applied to the results returned for each criteria. For examples of using both AND and OR operands, see ***Using multiple criteria to filter*** (on page 120).and ***Specifying criteria in multiple categories*** (on page 122).

Field descriptions for the Concomitant Medications Criteria dialog box

Field	Description	Notes
Qualifier	Restrict by None, Male, or Female.	Default: none.
Type	**Inclusion**—Volunteers who meet the criteria you specify are included. **Exclusion**—Volunteers who meet the criteria you specify are excluded.	
Medication	You can select an active or inactive medication that was defined on the Settings - Medical - Medications page.	
Ongoing	**Selected**—To limit the search to only volunteers who are currently taking the medication. **Deselected**—Volunteers who have taken the medication in the past and volunteers who are currently taking the medication are included in the search.	

Filter Table

Lists one row for each filter you add for the criteria.

Column	Description	Notes
X button	Indicates that the filter is included. To remove the filter, click the X.	
Qualifier Type Criteria When	Lists the criteria you specified for the filter in the upper area of this dialog box.	
Operand	Specifies how to process multiple filters. **AND**—(Default). Volunteer must satisfy criteria in the filter that contains the AND operand, and the next filter in the list. The AND operand is always satisfied first, before OR is considered. **OR**—Volunteer must satisfy criteria in either the filter that contains the OR operand, or the next filter in the list.	If you add 2 or more filters, an operand appears in all rows except the last. AND takes precedence. For exclusion criteria, the operand is applied to the results returned for each criteria. For examples of using both AND and OR operands, see ***Using multiple criteria to filter*** (on page 120).and ***Specifying criteria in multiple categories*** (on page 122).

> **Note:** When you exit the Volunteer Lookup page, the filter criteria is not saved.

Using multiple criteria to filter

Each criteria is used independently to narrow the pool of volunteers.

- Multiple criteria can be separated by or AND or OR operands. If you specify two or more criteria, the operand field appears in all rows except the last.
- AND returns the volunteers who meet both criteria.
- OR returns the volunteers who meet either criteria.
- Within a category, if you specify multiple criteria and use both AND and OR, the AND operand is satisfied first (that is, AND takes precedence).
- If you specify criteria in multiple categories:
    - First, the conditions in each category are satisfied.
    - Next, the AND operand is applied between the results of each category. For more information, see ***Specifying criteria in more than one category*** (on page 122).

Example 1—Multiple criteria in a single category, inclusions

Include all males with a small or medium frame.

- In the Demographics category, create the following search criteria in the order shown in the table.

Criteria	Qualifier	Type	Criteria	When	Operand
A	None	Inclusion	Gender	Male	AND
B	None	Inclusion	Frame	Small	OR
C	None	Inclusion	Gender	Male	AND
D	None	Inclusion	Frame	Medium	(none)

Expressed mathematically, the criteria are satisfied this way:

(A **AND** B) **OR** (C **AND** D)

The AND operands take precedence, so those criteria are satisfied first. Then using those results, the OR operand is satisfied.

- All volunteers who meet criteria A and criteria B: males with small frame.

  OR

- All volunteers who meet criteria C and D: males with medium frame.

Results: Volunteers returned include males with small frame and males with medium frame.

Example 2—Multiple criteria in a single category, exclusions

Exclude volunteers who have taken either aspirin or acetaminophen.

For exclusions, the operand you select applies against the volunteers *who remain* after the exclusions are applied.

Criteria	Qualifier	Type	Concomitant Medications	Ongoing	Operand
A	None	Exclusion	Aspirin	Not checked	AND
B	None	Exclusion	Acetaminophen	Not checked	(none)

Expressed mathematically, the criteria are satisfied this way:

(A. Never taken aspirin) **AND** (B. Never taken acetaminophen)

Note that the operand in this case is AND.

Using OR in this example would have returned the wrong result, because:

- Criteria A excludes volunteers who took aspirin, but does not exclude those who took acetaminophen.
- Criteria B excludes volunteers who took acetaminophen, but does not exclude those who took aspirin.

Determining use of AND and OR

The next examples use the following pool of volunteers. The Scenario table shows examples of how using AND and OR affect the volunteers returned.

Volunteer	Medications
101	No medications.
102	Acetaminophen only.
103	Aspirin only.
104	Acetaminophen and Aspirin.

The table shows volunteers returned in each scenario.

Scenario	Volunteers meeting A	Volunteers meeting B	Volunteers returned
A. Inclusion: Med—Acetaminophen OR B. Inclusion: Med—Aspirin	102, 104	103, 104	102, 103, 104 Volunteers who meet either criteria.
A. Inclusion: Med—Acetaminophen AND B. Inclusion: Med—Aspirin	103, 104	103, 104	104 Volunteers who meet both criteria.
A. Exclusion: Med—Acetaminophen OR B. Exclusion: Med—Aspirin	101, 103	101, 102	101, 102, 103 Volunteers who meet either criteria.
A. Exclusion: Med—Acetaminophen AND B. Exclusion: Med—Aspirin	101, 103	101, 102	101 Volunteers who meet both criteria.

Specifying criteria in more than one category

You can use criteria in more than one category (Demographics, Medical History/Medical Questions, Surgical History, and Medications). Volunteers who meet criteria in one category are connected to those that meet criteria in other categories by AND.

Expressed mathematically:

(Volunteers returned in the first category) **AND** (Volunteers returned in the second category)

Example 3—Criteria in more than one category, with inclusions

Include all males who have one of the following conditions: dermatitis, acne, dandruff.

This lookup uses two categories: Demographics and Medical History.

- In **Demographics**, create the following.

Criteria	Qualifier	Type	Criteria	When	Operand
A	None	Inclusion	Gender	Male	(none)

- In **Medical History**, create the following criteria in this order.

Criteria	Qualifier	Type	Criteria	Medical Condition	Ongoing	Operand
B	None	Inclusion	Medical Condition	Acne	selected	OR
C	None	Inclusion	Medical Condition	Dermatitis	selected	OR
D	None	Inclusion	Medical Condition	Dandruff	selected	(none)

Expressed mathematically, the criteria are satisfied this way:

(A. Demographics: Males) AND (Medical History, volunteers with B. Acne OR C. Dermatitis OR D. Dandruff)

Results: Volunteers returned include all of the following:

Males with acne.

Males with dermatitis.

Males with dandruff.

Example 4—Criteria in more than one category, with exclusions

Include females who have one of the following conditions: dog allergy, tree allergy, who are not on one of the following medications: fexofenadine, diphenhydramine.

This lookup uses three categories: Demographics, Medical History, and Medication.

- In Demographics, create the following.

Criteria	Qualifier	Type	Criteria	When	Operand
A	None	Inclusion	Gender	Female	(none)

This category returns all females.

- In Medical History, create the following criteria.

Criteria	Qualifier	Type	Criteria	Medical Condition	Ongoing	Operand
B	None	Inclusion	Medical Condition	Dog Allergy	selected	OR
C	None	Inclusion	Medical Condition	Tree Allergy	selected	(none)

This category returns volunteers who have dog allergies and volunteers who have tree allergies (volunteers who satisfy one of the criteria).

> **Note: Qualifier is not used in this example. Using the qualifier Female would have returned females with dog allergies, females with tree allergies, and all males. A qualifier applies the criteria to only the gender you select, and leaves all other volunteers in the list.**

- In Medications, create the following criteria.

Criteria	Qualifier	Type	Medication	Ongoing	Operand
D	None	Exclusion	Fexofenadine	selected	AND
E	None	Exclusion	Diphenhydramine	selected	(none)

This category returns volunteers who are not taking fexofenadine or diphenhydramine. The AND operand is used because each exclusion returns volunteers who have not taken the specified medication.

Results: The results of all the categories are connected with AND.

Expressed mathematically:

(All female volunteers) **AND** (volunteers with dog allergies and volunteers with tree allergies) **AND** (volunteers who are not taking fexofenadine or diphenhydramine).

The final result includes those volunteers who appear in all three sets of results:

Females with dog allergies or tree allergies, who are not taking fexofenadine or diphenhydramine.

Scheduling an outgoing call to volunteers

1 From the main menu, select **Recruiting > Volunteer Lookup**.

The Volunteer Lookup page appears.

Field descriptions for the Volunteer Lookup page

Field	Description	Notes
VRN	Volunteer record number listing.	
Name	Name of the volunteer.	
Gender	Gender of the volunteer.	
Birth Date	Date of birth for the volunteer.	
Age	Age of the volunteer.	
Frame	Physical build of the volunteer.	Small, Medium, or Large.
Height	Height of the volunteer.	
Weight	Weight of the volunteer.	
BMI	Body mass index for the volunteer.	
%IBW	Percentage of ideal body weight for the volunteer.	
Washout-Dose	Filters by the range of days that have passed since the volunteer's Dose Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Exit	Filters by the range of days that have passed since the volunteer's Exit Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Tobacco	Filters by the range of days that have passed since the specified tobacco end date.	
Status	Study status of the volunteer.	
Telephone	Telephone number of the volunteer.	
Cell	Cellular phone number of the volunteer.	
Other Phone	Other phone number of the volunteer.	
Email	Email address of the volunteer.	

2 Select the checkboxes for the volunteers, and click **SCHEDULE**.

The Schedule Outgoing Calls dialog box appears.

3 Fill in the fields.

Field descriptions for the Schedule Outgoing Calls dialog box

Field	Description	Notes
Call Date	The date that the call will be made. Either type the date in the field or click the calendar icon and select the date.	REQUIRED. Default: the current date.
Study Id	Study Id. Click the Lookup icon and select a reference study for the outgoing call. Optionally, to restrict data by either Study Id or Description, click **FILTER**.	
Message	Custom text that appears if the call is selected from the Outgoing Calls page.	

4 Click **SAVE**.

Exporting a list of volunteers

Before you can export a list of volunteers, you must create the restriction criteria needed to filter the volunteer list.

1 From the main menu, select **Recruiting > Volunteer Lookup**.

The Volunteer Lookup page appears.

Field descriptions for the Volunteer Lookup page

Field	Description	Notes
VRN	Volunteer record number listing.	
Name	Name of the volunteer.	
Gender	Gender of the volunteer.	
Birth Date	Date of birth for the volunteer.	
Age	Age of the volunteer.	
Frame	Physical build of the volunteer.	Small, Medium, or Large.
Height	Height of the volunteer.	
Weight	Weight of the volunteer.	
BMI	Body mass index for the volunteer.	
%IBW	Percentage of ideal body weight for the volunteer.	
Washout-Dose	Filters by the range of days that have passed since the volunteer's Dose Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Exit	Filters by the range of days that have passed since the volunteer's Exit Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Tobacco	Filters by the range of days that have passed since the specified tobacco end date.	
Status	Study status of the volunteer.	
Telephone	Telephone number of the volunteer.	
Cell	Cellular phone number of the volunteer.	
Other Phone	Other phone number of the volunteer.	
Email	Email address of the volunteer.	

2 ***Filter the volunteer list*** (on page 113).

3 Click **EXPORT**.

The File Download dialog box appears.

4 Click **Save**.

The Save As dialog box appears.

5 Type the file name and specify the location to save the file.

6 Click **Save**.

A CSV (comma-separated values) file is saved to the specified location.

Each exported row includes the volunteer's home phone number, cell phone number, email address, and location preference.

Emailing a list of volunteers

Prerequisites:

- Create the restriction criteria needed to filter the volunteer list.
- Define global email settings on the Configuration - Settings - Global page.

You can email a list of volunteers who provided valid email addresses on the Volunteers - Personal - Contact page or the Incoming - Volunteer Details page.

1 From the main menu, select **Recruiting > Volunteer Lookup**.

The Volunteer Lookup page appears.

Field descriptions for the Volunteer Lookup page

Field	Description	Notes
VRN	Volunteer record number listing.	
Name	Name of the volunteer.	
Gender	Gender of the volunteer.	
Birth Date	Date of birth for the volunteer.	
Age	Age of the volunteer.	
Frame	Physical build of the volunteer.	Small, Medium, or Large.
Height	Height of the volunteer.	
Weight	Weight of the volunteer.	
BMI	Body mass index for the volunteer.	
%IBW	Percentage of ideal body weight for the volunteer.	
Washout-Dose	Filters by the range of days that have passed since the volunteer's Dose Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Exit	Filters by the range of days that have passed since the volunteer's Exit Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Tobacco	Filters by the range of days that have passed since the specified tobacco end date.	
Status	Study status of the volunteer.	
Telephone	Telephone number of the volunteer.	
Cell	Cellular phone number of the volunteer.	
Other Phone	Other phone number of the volunteer.	

Field	Description	Notes
Email	Email address of the volunteer.	

2 ***Filter the volunteer list*** (on page 113).

3 Click **EMAIL**.

The Mail dialog box appears.

4 Fill in the fields.

Field descriptions for the Mail dialog box

Field	Description	Notes
Study Id	Study ID. Select a reference study for the email.	Default: No Selection. This field is for your reference only; it does not appear in the email message that is sent to volunteers.
Template Name	Drop-down list of approved email templates.	Default: No selection.
Subject	Subject line from the selected email template.	Cannot be changed.
Email text	Body text from the selected email template.	Cannot be changed.

5 Click **SAVE**.

Printing volunteer labels

Before you can print volunteer labels, you must create the restriction criteria needed to filter the volunteer list.

1 From the main menu, select **Recruiting > Volunteer Lookup**.

The Volunteer Lookup page appears.

Field descriptions for the volunteer lookup page

Field	Description	Notes
VRN	Volunteer record number listing.	
Name	Name of the volunteer.	
Gender	Gender of the volunteer.	
Birth Date	Date of birth for the volunteer.	
Age	Age of the volunteer.	
Frame	Physical build of the volunteer.	Small, Medium, or Large.
Height	Height of the volunteer.	
Weight	Weight of the volunteer.	
BMI	Body mass index for the volunteer.	
%IBW	Percentage of ideal body weight for the volunteer.	
Washout-Dose	Filters by the range of days that have passed since the volunteer's Dose Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Exit	Filters by the range of days that have passed since the volunteer's Exit Date (entered on the Volunteer - Personal - Demographics page).	
Washout-Tobacco	Filters by the range of days that have passed since the specified tobacco end date.	
Status	Study status of the volunteer.	
Telephone	Telephone number of the volunteer.	
Cell	Cellular phone number of the volunteer.	
Other Phone	Other phone number of the volunteer.	
Email	Email address of the volunteer.	

2 ***Filter the volunteer list*** (on page 113).

3 Click **LABELS**.

The Print dialog box appears.

4 Select the printer options and click **OK**.

CHAPTER 7

Outgoing calls

In this chapter

Tasks: Outgoing Calls page

On the Outgoing Calls page, you view all calls that are scheduled to be made to volunteers.

You must have the Change Appointments permission to update volunteer records with call information.

> **Note:** If Global Recruiting was not selected when the LabPas application was configured, only calls in the current facility appear.

- ***Making a recruitment call*** (on page 135).
- ***Ending a call*** (on page 136).
- ***Making a cancelation call*** (on page 137).
- ***Rescheduling a canceled appointment*** (on page 138).
- ***Making a reminder call*** (on page 139).
- ***Rescheduling an appointment from a reminder call*** (on page 140).
- ***Canceling an appointment from a reminder call*** (on page 141).
- ***Making a notification call*** (on page 142).
- ***Rescheduling an appointment from a notification call*** (on page 143).
- ***Making a call back call*** (on page 144).

Making a recruitment call

You make recruitment calls to attempt to recruit existing volunteers for participation in a study.

Recruitment calls are generated on the Volunteer Lookup page.

1 From the main menu, select **Recruiting > Outgoing Calls**.

   The Outgoing Calls page appears.

   If you do not have the Change Appointments permission, the data on the page is read-only.

2 Click a call with a call type of **Recruitment**.

   The Outgoing Call - Existing Volunteer page appears with a message box containing the volunteer's phone number and the message.

3 Call the volunteer.

4 Read the approved script in the gray box to the caller.

5 Click **OK**.

Ending a call

1 If a call ends before you collect data, on the Outgoing Calls page, click **END CALL**.

The End Call dialog box appears.

2 From the **Resolution** drop-down list, select a call resolution.

3 To add custom text about the ended call, type the text in the **Comment** field.

4 Click **SAVE**.

The End Call dialog box closes and the call is removed from the call list.

If the Resolution selection was configured to automatically reschedule the call on the Settings - Calls - Resolutions page, a new recruitment call to the same volunteer appears in the call list for the next day.

Making a cancellation call

Cancellation calls let volunteers know that their appointments have been canceled.

> **Note:** Cancellation calls are generated from the Schedule page if a session in the schedule is cancelled, or from the Appointments page if the Call Volunteer option is selected when an appointment is cancelled.

1 From the main menu, select **Recruiting > Outgoing Calls**.

The Outgoing Calls page appears.

2 Click a call with a call type of **Cancelation**.

The Cancelation Call dialog box appears.

3 From the **Resolution** field, select a resolution for the cancellation call.

4 To provide a comment, type your comment in the **Comment** field.

5 Click **SAVE**.

The call no longer appears on the Outgoing Calls page.

Rescheduling a cancelled appointment

1 From the main menu, select **Recruiting > Outgoing Calls**.

The Outgoing Calls page appears.

2 Select a call with a call type of **Cancelation**.

The Cancellation Call dialog box appears.

3 Click **RESCHEDULE**.

The Cancellation - Select Appointment dialog box appears. This dialog box contains a table of approved sessions that are available in the same facility as the original appointment.

If no sessions are available, **No Appointments** appears.

4 Select an appointment.

The Cancellation Call - Schedule Appointment dialog box appears.

5 Fill in the fields.

Field descriptions for the Cancellation Call - Schedule Appointment dialog box

Field	Description	Notes
User ID	Your user ID.	REQUIRED.
Password	Your password.	REQUIRED.
Comment	Custom text.	
Resolution	Method of resolving outgoing calls.	REQUIRED.
Comment	Custom text.	

6 Click **NEXT**.

The Cancellation Call - Confirm Appointment dialog box appears.

7 Click **DONE**.

The call no longer appears on the Outgoing Calls page.

If the volunteer study status is Unscheduled or Consent Refused, the Volunteer Study Status changes to Scheduled. If the volunteer's Eligibility Review was Completed, it changes to Pending.

The Check-In and Check-Out events scheduled for the appointment being rescheduled are associated with the new appointment.

Making a reminder call

Reminder calls remind volunteers of an upcoming appointment. If a study is designed to include screening calls, the LabPas Recruiting module generates reminder calls for volunteers in that study.

1 From the main menu, select **Recruiting > Outgoing Calls**.

The Outgoing Calls page appears.

2 Select a call with a call type of **Reminder**.

The Reminder Call dialog box appears.

3 Call the volunteer and read from the script.

4 From the **Resolution** drop-down list, select a call resolution.

5 To add custom text about the resolution, type your comment in the **Comment** field.

6 Click **SAVE**.

The call is removed from the call list.

If the volunteer's status was Scheduled, it is set to Unscheduled.

If the Resolution selection was configured to automatically reschedule the call on the Settings - Calls - Resolutions page, a new reminder call to the same volunteer appears in the call list for the next day.

Rescheduling an appointment from a reminder call

1 From the main menu, select **Recruiting > Outgoing Calls**.

The Outgoing Calls page appears.

2 Select a call with a call type of **Reminder**.

The Reminder Call dialog box appears.

3 Click **RESCHEDULE**.

The Reminder Call - Select Appointment dialog box appears. This dialog box contains a table of approved sessions that are available in the same facility as the original appointment.

If no sessions are available, **No Appointments**.

4 Select an appointment.

The Reminder Call - Schedule Appointment dialog box appears.

5 Fill in the fields, and click **NEXT**.

Field descriptions for the Reminder Call - Schedule Appointment dialog box

Field	Description	Notes
User ID	Your user ID.	REQUIRED.
Password	Your password.	REQUIRED.
Comment	Custom text.	
Resolution	Method of resolving outgoing calls.	REQUIRED.
Comment	Custom text.	

6 Click **DONE**.

Cancelling an appointment from a reminder call

1 From the main menu, select **Recruiting > Outgoing Calls**.

The Outgoing Calls page appears.

2 Select a call with a call type of **Reminder**.

The Reminder Call dialog box appears.

3 Click **CANCEL**.

The Reminder Call - Cancel Appointment dialog box appears.

4 Fill in the fields, and click **NEXT**.

Field descriptions for the Reminder Call - Cancel Appointment dialog box

Field	Description	Notes
User ID	Your user ID.	REQUIRED.
Password	Your password.	REQUIRED.
Comment	Custom text.	
Resolution	Method of resolving outgoing calls.	REQUIRED.
Comment	Custom text.	

5 Click **DONE**.

The call no longer appears on the Outgoing Calls page.

Making a notification call

On the Notification Call page, you communicate the outcome of a screening appointment to a volunteer, record the resolution to an outgoing call, and ***reschedule appointments*** (on page 143).

1 From the main menu, select **Recruiting > Outgoing Calls**.

  The Outgoing Calls page appears.

2 Select a call with a call type of **Notification**.

  The Notification Call dialog box appears.

3 Call the volunteer and read from the script.

4 From the **Resolution** drop-down list, select a call resolution.

5 To add custom text about the resolution, type your comment in the **Comment** field.

6 Click **SAVE**.

  The call is removed from the call list.

  If the volunteer's study status was Scheduled, it is set to Unscheduled.

Rescheduling an appointment from a notification call

1 From the main menu, select **Recruiting > Outgoing Calls**.

The Outgoing Calls page appears.

2 Select a call with a call type of **Notification**.

The Notification Call dialog box appears.

3 Click **RESCHEDULE**.

The New Appointment - Select Appointment dialog box appears. It displays a list of approved sessions for the facility in which the volunteer is participating.

If no sessions are available, **No Appointments** appears.

4 Select an appointment.

The New Appointment - Schedule Appointment dialog box appears.

5 Fill in the fields, and click **NEXT**.

Field descriptions for the New Appointment - Schedule Appointment dialog box

Field	Description	Notes
User ID	Your user ID.	REQUIRED.
Password	Your password.	REQUIRED.
Comment	Custom text.	
Resolution	Method of resolving outgoing calls.	REQUIRED.
Comment	Custom text.	

6 To confirm an appointment, click **DONE**.

If the volunteer's study status was Unscheduled or Consent Refused, it is changed to Scheduled.

Making a call back call

When a caller leaves a phone message, that message is recorded on the Message Call Back page. The Outgoing Calls page then generates a call back call for the recorded message.

1. From the main menu, select **Recruiting > Outgoing Calls**.

   The Outgoing Calls page appears.

2. Click a call with a call type of **Call Back**.

   The Outgoing Calls - Start New Call page appears.

3. Follow the procedures for ***processing an incoming call*** (on page 66).

CHAPTER 8

Call back messages

In this chapter

Tasks: Message Call Back page

On the Message Call Back page, you record phone messages left by volunteers who want a return call. You set a date for making an outgoing call. As each message is recorded, a Call Back call is generated on the Outgoing Calls page for the date selected.

The Message Call Back page also displays a list of outgoing Call Back calls to be made to people who left phone messages.

- *Adding and editing a call back message* (on page 147).

Adding and editing a Call Back message

1 From the main menu, select **Recruiting > Message Call Back**.

The Message Call Back page appears.

2 To restrict data that appears on the page by first or last name, use the **FILTER** button.

3 To add a message, click **NEW**.

4 To edit a message, select a message, and click **EDIT**.

The Callback dialog box appears.

5 Fill in the fields.

Field descriptions for the Callback dialog box

Field	Description	Notes
First Name Last Name	First and last name of the caller who left the message.	REQUIRED.
Tel.	Telephone number of the caller who left the message.	REQUIRED.
Call Date	Date for the caller to receive a return call. Type the date in the field, or click the calendar icon and select a date.	REQUIRED. Default: Today's date.
Comment	Custom text that references the caller’s message.	REQUIRED.

6 Click **SAVE**.

CHAPTER 9

Alerts

In this chapter

Tasks: Alerts page

On the Alerts page, you view and acknowledge alerts, and edit volunteer status in response to an alert. An alert appears when a volunteer cancels too many appointments or when a volunteer study status is associated with a reason to generate an alert.

You must have the Volunteer Administration permission to edit and acknowledge alerts.

- *Acknowledging an alert* (on page 151).
- *Editing the status of a volunteer based on an alert* (on page 152).

Acknowledging an alert

1. From the main menu, select **Recruiting > Alerts**.

   The Alerts page appears.

2. Select the checkboxes for one of more alerts, and click **ACKNOWLEDGE**.

   The Acknowledge Alerts dialog box appears.

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

   The updated information appears on the Alerts page, with the following information:

   - In the **Acknowledged** field, the date and time that the alerts were acknowledged.
   - In the **Acknowledged By** field, your user name.

Editing the status of a volunteer based on an alert

1. From the main menu, select **Recruiting > Alerts**.

   The Alerts page appears.

2. Select one or more alerts, and click **EDIT**.

   The Edit Alerts dialog box appears.

3. Fill in the fields.

   Field descriptions for the Edit Alerts dialog box

Field	Description	Notes
Status	The status for the volunteer, across all studies.	
Probation End	The date that the probation for the volunteer ends. Type the date in the field, or click the calendar icon and select a date.	If a new date is selected, a new alert is generated. The current date appears by default.
Acknowledge Alert	When selected, acknowledges the alert.	REQUIRED.

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

CHAPTER 10
Advertising

In this chapter

Media sources and advertising campaigns

Media sources

Media sources designate the advertising medium that is used for a campaign. You must create at least one media source for each campaign. The LabPas Recruiting module does not provide preconfigured media sources.

Advertising campaigns

Advertising campaigns are referenced on the Incoming Calls - Advertising page, where you ask callers if they are calling in response to advertising. This page is optional in the LabPas Recruiting module. The page does not appear during incoming calls or if there are no active campaigns.

If Global Recruiting is not configured for the study, the selection of studies is restricted to studies in which at least one group in the study is associated with the current facility.

There are no preconfigured campaigns in the LabPas Recruiting module.

Tasks: Advertising page

On the Advertising page, you use two tabs, Media and Campaigns, to displays all advertising information in the LabPas Recruiting module.

You must have the Recruiting Setup security permission to perform the following advertising functions:

- *Adding a media source* (on page 155).
- *Deleting a media source* (on page 155).
- *Adding and editing an advertising campaign* (on page 156).
- *Deleting an advertising campaign* (on page 157).

Adding a media source

1 From the main menu, select **Recruiting > Advertising**.

The Advertising page appears.

2 Select the **Media** tab.

The Advertising - Media page appears.

3 Click **NEW**.

The New Media dialog box appears.

4 Fill in the fields.

Field descriptions for the New Media dialog box

Field	Description	Notes
Media	Type of media source to add.	REQUIRED.
Comment	Custom text about the media source.	

5 Click **SAVE**.

Deleting a media source

You cannot delete a media source that is associated with an advertising campaign.

1 From the main menu, select **Recruiting > Advertising**.

The Advertising page appears.

2 Select the **Media** tab.

The Advertising - Media page appears.

3 Select one or more media sources, and click **DELETE**.

A confirmation dialog box appears.

4 Click **OK**.

Adding and editing an advertising campaign

To add a campaign, at least one ***media source*** (on page 155) must exist.

1 From the main menu, select **Recruiting > Advertising**.

The Advertising page appears.

2 Select the **Campaigns** tab.

The Advertising - Campaigns page appears.

3 To add a campaign, click **NEW**.

To edit a campaign, select a campaign, and click **EDIT**.

The Ad Campaign dialog box appears.

4 Fill in the fields.

Field descriptions for the Ad Campaign dialog box

Field	Description	Notes
Id	Unique ID number for the campaign.	REQUIRED.
Active	Whether the campaign is active.	If the campaign is active, it is available for selection on the Incoming Calls - Advertising page.
Campaign Start	Date that the campaign begins. Type the date, or click the calendar icon and select a date.	
Campaign End	Date that the campaign ends. Type the date, or click the calendar icon and select a date.	
Media	Media source. Select from a drop-down list of all media sources that appear on the Advertising - Media page.	
Source	Location for the media campaign.	REQUIRED. Alphanumeric text.
Total Cost	Total cost of the media campaign.	Alphanumeric text.
Study Id	Study ID. Select from a drop-down list of all studies set up on the Studies page.	Default: **(No Selection)**. If no study is selected, the advertising campaign is not restricted to a specific study.

5 Click **SAVE**.

Deleting an advertising campaign

You cannot delete an advertising campaign that is associated with an active incoming call.

1. From the main menu, select **Recruiting > Advertising**.

   The Advertising page appears.

2. Select the **Campaigns** tab.

   The Advertising - Campaigns page appears.

3. Select one or more advertising campaigns, and click **DELETE**.

   A confirmation dialog box appears.

4. Click **OK**.

CHAPTER 11

Screening volunteers

In this chapter

Screening page

In the Screening section, you use four categories of pages:

- **Screening**—You screen volunteers. After the volunteer is identified, the Screening Appointment page lists the tasks that you must complete.
- **Screening - Other**—You work with all events with an event type of Other, such as informed consent, volunteer demographics and medical history, and forms that are specific to the study.
- **Screening - Sample**—You record the time and date of the clinical testing event.
- **Screening - Testing**—You record the time and date of the testing event.

The events in the Screening section use the colors blue, green, yellow, and red to show the progress of a task.

- **Blue events**—Not started.
- **Green events**—Completed.
- **Yellow events**—Partially completed.
- **Red events**—Incomplete.

Note: Events can be completed, partially completed, and not started due to prerequisites.

Tasks: Screening page

On the Screening page, you screen volunteers. After the volunteer is identified, the Screening Appointment page lists the tasks that you must complete.

- *Screening a volunteer* (on page 162).
- *Checking in a volunteer for screening* (on page 163).
- *Obtaining informed consent* (on page 164).
- *Performing screening tasks* (on page 165).
- *Updating volunteer information* (on page 166).
- *Recording an Other event for screening* (on page 167).
- *Recording a clinical testing event for screening* (on page 169).
- *Recording a testing event for screening* (on page 170).
- *Checking out a volunteer* (on page 168).

Screening a volunteer

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

2 The Screening page appears.

3 Identify the volunteer who is being screened using one of the following methods:

- In the **Id** field, type a valid VRN or Screening number that is scheduled for an appointment, and click **DONE**.
- Click the ellipsis button (**...**) next to the **Id** field.

  The Volunteer Lookup page appears. Select the volunteer.
- Scan the barcode of the volunteer.

The Screening Appointment dialog box appears with the volunteer's information. Color-coded buttons appear at the bottom of the page :

- A Check-In event button.
- A button for each visit, in the order of the visits.
- A Check-Out event.

4 Do one of the following actions, as appropriate:

- If this is the first time the volunteer has presented for screening, click the **Check-In** button. Continue to ***Checking in a volunteer for screening*** (on page 163).
- If the **Check-In** button is green, click the first button in the list that represents a Not Started event or visit, Repeat Visit, or Incomplete visit. Continue to ***Performing Screening Tasks*** (on page 165).

Checking in a volunteer for screening

Where to start: ***Screening a volunteer*** (on page 162).

1 In the Event: Check-In area at the bottom of the page, click the clock icon.

The current date and time appear in the fields.

2 If necessary, use the green arrows to specify the time when the volunteer checked in.

If you adjust the time, you must provide a comment.

If the volunteer arrives late to the appointment, select the **Late** checkbox.

3 After check-in is complete, select the **Yes** radio button next to Complete.

4 Click **SAVE**.

The Screening Appointment page appears. The Check In button is green.

5 Click the next button in the button list. Continue to ***Performing screening tasks*** (on page 165).

Obtaining informed consent

Where to start: ***Screening a volunteer*** (on page 162).

Previous step: ***Checking in a volunteer*** (on page 163).

1 Click the event button for Informed Consent.

 The Enter Other Details page appears, with the volunteer information in the top section.

2 In the Event area, click the clock icon.

 The date and time appear in the fields.

3 Read the informed consent to the volunteer and ask for a signature.

4 Select the **Signed** radio button as appropriate.

5 If a copy of the informed consent was given to the volunteer, select the checkbox.

6 Enter a screening number, the volunteer's initials, and, if necessary, a comment.

 Your clinic might require unique initials for each study. If volunteers have the same initials, you could use first and last name initials for one, and first, middle, and last initials for the other.

7 Click **SAVE**.

 Volunteers with a status of Scheduled are automatically updated to either Pending Volunteer (if informed consent was agreed to) or Consent Refused.

Performing screening tasks

Where to start: *Screening a volunteer* (on page 162).

Previous step: *Checking in a volunteer* (on page 163).

After you check in the volunteer and click the next visit or event button, the pages that appear are determined by the way screening events were set up for the study.

1 Click one of the following:

- A not started visit or event.
- An incomplete visit or event.
- A repeat visit.

The page for the visit opens. Buttons representing events for the visit appear at the bottom of the page.

You can click the events in any order. If an event has a prerequisite event, a message appears with the name of the prerequisite event.

2 Continue with the events as appropriate. Events might include any of the following:

- *Updating volunteer information* (on page 166).
- *Obtaining informed consent* (on page 164).
- *Recording a Clinical Testing event* (on page 169).
- *Recording a Testing event* (on page 170).
- *Recording an Other event* (on page 167).

3 When all events are completed, check out the volunteer.

Updating volunteer information

Screening events can include events for updating volunteer demographics and updating volunteer medical history.

You can update volunteer demographics and volunteer medical history information from the Screening - Other page if the volunteer you are screening has one of the following study statuses: Unscheduled, Scheduled, Pending Volunteer, or Consent Refused.

If the volunteer has any other study status, you must update the demographics and medical history in the LabPas CT module from the ***Study - Participants - Candidates page*** (in the *Clinical Trial Design and Resource Management Guide*).

Where to start: ***Screening a volunteer*** (on page 162).

Previous step: ***Checking in a volunteer for screening*** (on page 163).

1. Click the button for the event to update volunteer information.

   If the volunteer study status is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused, the page for updating the volunteer information appears.

   These pages are the same pages that appeared when a new volunteer is interviewed, with the addition of a Screening button to return you to the screening page for the volunteer.

2. Fill in the fields, and click **SAVE**.

3. Click **SCREENING.**

   The Screening page for the volunteer appears. If you completed the update of information, the button for the event appears green.

Recording an Other event for screening

Events of type Other include:

- *Check In.* (on page 163)
- *Check Out* (on page 168).
- *Informed Consent* (on page 164).
- *Updating volunteer information* (on page 166).
- Study-specific events, such as a form.

Checking out a volunteer

1 On the Screening page, click the button for the Check Out event.

The Enter Other Details page appears, with the volunteer information in the top section.

2 Click the clock icon.

The date and time appear in the fields.

3 Use the arrows to adjust the time, if necessary.

If you change the time, you must provide a comment.

4 Select the **Complete** radio button as appropriate.

5 Provide a comment.

6 Click **SAVE**.

Recording a clinical testing event for screening

Where to start: *Screening a volunteer* (on page 162).

Previous step: *Checking in a volunteer* (on page 163).

1 Click the button that represents the clinical testing event.

A message appears if a prerequisite event, such as *informed consent* (on page 164), has not been signed by the volunteer.

The Enter Sample Details page appears, with the volunteer information in the top section.

2 In the bottom area, follow the instructions for the event.

3 Scan the vessel barcodes.

4 Click the clock icon.

The time and date appear in the fields.

5 Use the arrows to adjust the time.

If you change the time, you must also provide a comment.

6 Fill in the fields for any form that are associated with the event.

7 Click **SAVE**.

The visit page appears and the button for the event you completed is green.

Recording a testing event for screening

Where to start: ***Screening a volunteer*** (on page 162).

Previous step: ***Checking in a volunteer*** (on page 163).

1 Click the button that represents the testing event.

 A message appears if a prerequisite event, such as ***informed consent*** (on page 164), has not been signed by the volunteer.

 The Enter Testing Details page appears, with the volunteer information in the top section.

2 In the bottom section, follow the instructions for the event.

3 Click the clock icon.

 The time and date appear in the fields.

4 Use the arrows to adjust the time.

 If you change the time, you must also provide a comment.

5 Fill in the fields.

 The fields that appear depend on the test and how it was set up for the study. If a form is attached to the event, those fields also appear.

 If reference ranges and edit checks have been configured for event fields, the allowed ranges and values are compared as you enter data.

 - A result that violates an Out of Range value is not allowed, and a warning appears.
 - If a test result is outside the reference range, you must provide a comment.

 Edit checks that have been defined are applied. If data is in violation of an edit check, the following actions occur.

Action defined for edit check	Result
Prevent	The test name and associated message for each edit check appears. Saving is cancelled. No further edit checks are processed.
Either of the following: • Warn • Warn and Alert	The test name and associated message for each edit check appears. A new line is started for each message.
Either of the following: • Alert • Warn and Alert	The message for each relevant edit check is saved as an alert against the result that generated the alert.

 If all fields are not completed, you must provide a comment.

6 Click **SAVE**.

APPENDIX A
Reports

In this appendix

Tasks: View Reports page

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

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

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

- *Viewing the list of available reports* (on page 180)
- *Viewing a report* (on page 181)
- *Creating a new report* (on page 183)
- *Deleting a report* (on page 186)

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 187).
- *Deleting a report group* (on page 188).

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 181).

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

Report	Description
Study Recruitment	Includes recruitment details for the selected study, including: • Number of subjects goal, percent of subjects goal, number of subjects needed to reach subjects goal. • Number of backup (alternate) subjects goal, current percent of backup (alternate) subjects goal, current number of backup (alternate subjects needed to reach backup goal). • Numbers of volunteers with the following statuses: Promoted that are not an alternate, Promoted that are an alternate, Completed, Scheduled, Revised, Pending, DNQ, CRO, Dropped, and Volunteer Dropped.
SR Label Audit	Provides details of collection labels that have been printed or reprinted in the current facility.

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: • 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: • 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 183), or *view an existing report* (on page 181).

   The report appears in an Adobe Reader window.

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

   The report prints to the default printer.

APPENDIX B

Labels

In this appendix

Tasks: Labels page

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

- *Printing an existing barcode* (on page 193).
- *Printing an auto-generated barcode* (on page 194).

Printing an existing barcode

Prerequisite: At least one default label must exist.

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

The Labels page appears.

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

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

4 Fill in the fields.

Field descriptions for the Labels page

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

5 Click **PRINT**.

The Print dialog box appears.

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

Printing an auto-generated barcode

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

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

The Labels page appears.

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

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

4 Fill in the fields.

Field descriptions for the Labels page

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

5 Click **PRINT**.

The Print dialog box appears.

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

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

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

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