Clinical Data Entry Guide

Oracle® Health Sciences LabPas
Release 3.1

Contents

Oracle® Health Sciences LabPas 3.1

About this guide

In this preface

Overview of this guide

The LabPas *Clinical Data Entry 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.

Audience

This guide is for everyone who uses the Oracle® Health Sciences LabPas application to capture data about subjects, samples, tests, and adverse events. This audience includes clinic floor staff, clinicians, pharmacists, and study coordinators who are charged with gathering subject data during a clinical trial.

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.

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)
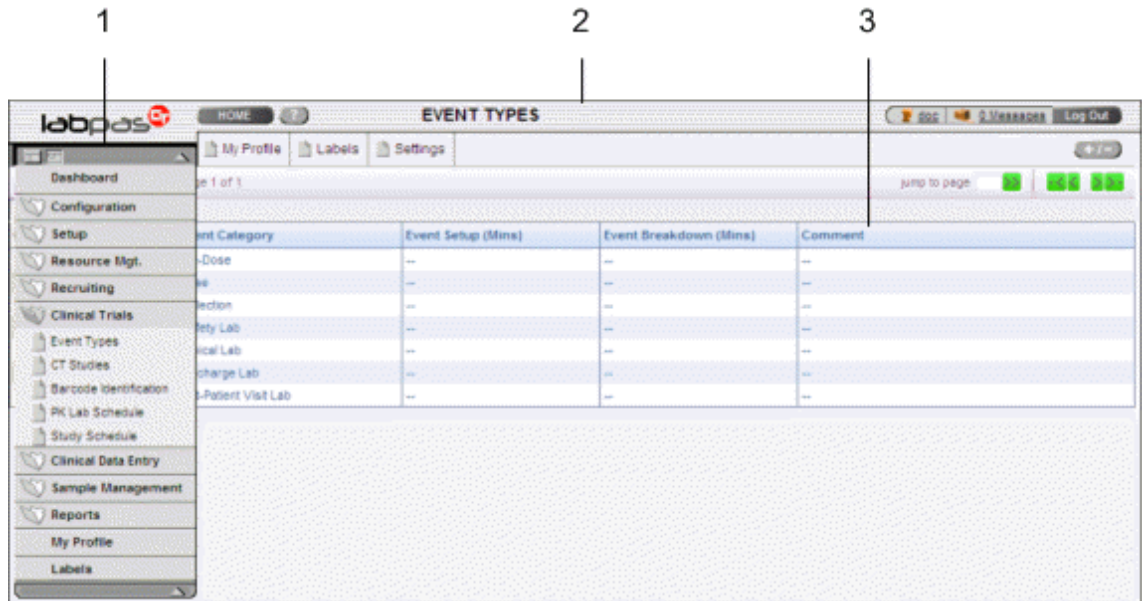
Main menu

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.
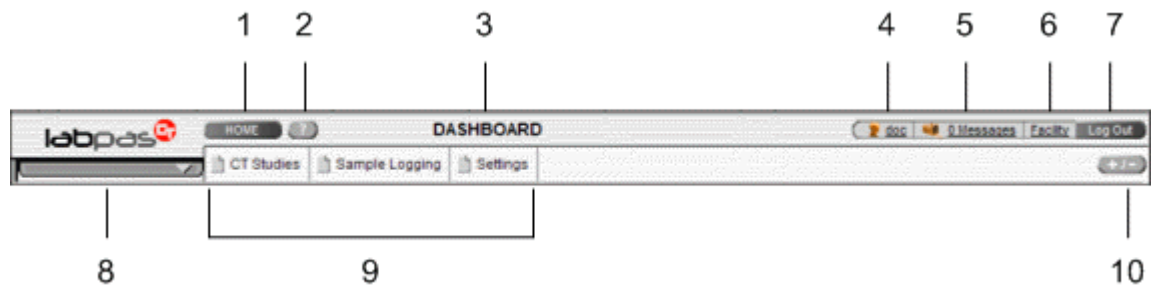
1—Home button	Open your home page, as configured on the My Profile page.
2—Help button	Open the *User Guide*, in a separate window, to the section that corresponds to the current page.
3—Page name	Name of the currently selected page.
4—User name	Your user name. Opens your My Profile page.
5—Message indicator	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.
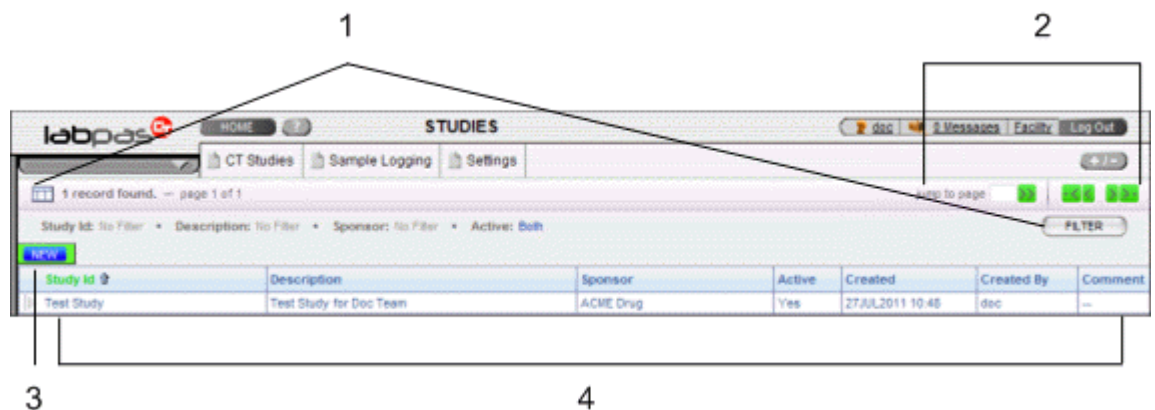
1   **Grid tools**—Use the grid setup and filter options to limit and order your selections.

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
Working from your own schedule

In this chapter

My Schedule page

On the My Schedule page, you view the studies and events that are assigned to you for the day. You can also view all events in the facility for a specific day on the *Event Schedule page* (on page 26).

On the My Schedule page:

- Only events associated with the current facility are listed.

- The current day appears by default.

- Late events appear in red.

The schedule lists hours vertically on the left, beginning with the start time of the earliest study for each day and ending with the latest time of the last study for the day.

Each study assigned to you is in a different column organized by the Study ID. The LabPas application *calculates the start and end time for the event* (on page 23) and creates a colored bar to show the time and duration of the event.

- When the My Schedule page appears, you see only the colored bars for the events to which you are assigned.

- Each study is assigned a different color so you can see which events belong to that study. Up to five colors are used at one time, but the colors are recycled if you are assigned to more than five studies at one time.

> **Note:** An error occurs if the My Schedule page has not been filtered to a specific study, group, and period.

Tasks: My Schedule page

- *Viewing events assigned to you* (on page 20).

- *Viewing the schedule for a different day* (on page 22).

Viewing events assigned to you

1. From the main menu, select **Clinical Data Entry > My Schedule**.

   The My Schedule page appears.

2. Select the colored bar for an event.

   The My Schedule Details dialog box appears.

   Field descriptions for the My Schedule Details dialog box

Field	Description	Notes
Study Id	Unique identifier for the study.	
Group	Study group to which the subject has been assigned.	
Period	Time period to which the event has been assigned.	
Time Point	Increment of time between events.	Examples: • 0h—Start time for the event. • .25h—Increment of one-half hour after the previous event. Seconds are not displayed in the Start Time and End Time fields, even for events that have the Consider Seconds field checked on the CT Studies – Setup – Events page.
Expected Time	Time the event is scheduled to begin.	
Event Type	Type of event, such as Dose, Testing, or PK Testing.	
Category	Category of event, such as Dose, Vitals, or Collection.	
Panels	Test entry linked to the sample as sequenced in the Test Panel.	When you select a panel, the test fields associated with the panel appears. The details of the panel depend on the type of test.
Assigned With	Other users who are also assigned to the event, regardless of subject or candidate restrictions.	

Field	Description	Notes
Sub/Screen	Subjects and candidates to whom the user is assigned. Select **All** if the user is assigned to all subjects and candidates.	For more information, see *Rules for entering Sub/Screening numbers* (on page 45).

3   Review the details of the event.

4   Do one of the following:

- To return to the My Schedule page, click **CANCEL**.

- To close My Schedule Details dialog box and go to the Event Schedule, click **SCHEDULE**.

Viewing the schedule for a different day

1 From the main menu, select **Clinical Data Entry > My Schedule**.

The My Schedule page appears.

Field descriptions for the My Schedule page

Field	Description	Notes
Hour	Hours for the time period.	The hours begin with the start time of the earliest study for the time period and end with the end time of the last study for the time period.
Study ID	Unique identifier for the study.	Each study that has been assigned to you appears in a different column, with the Study ID at the top of each column.
Colored bars	Time periods in which you are assigned to one or more events for a study.	The LabPas application *calculates the start and end time for the event* (on page 23), and represents the duration of the event with the colored bar. Each bar shows the following information: • Start time for each event. • End time for each event. • The Location associated with the event. A different color is used for each study. Five colors are used and then recycled if more than five studies appear.

2 Click the Calendar icon, located in the upper-right corner of the page, and select a day from the calendar.

or

Click the forward and backward arrow buttons ( ) to navigate to a different day.

Calculations for the start and end times of events

Events are calculated by their start and end times.

The start time of an event is calculated by subtracting the value in the **Event Setup (Mins)** field for the event category from the earliest schedule time with a status of Not Started for the event.

The end time for an event is calculated in one of the following ways:

- **Post-dose events:** The end time for each bar is calculated by adding the value in the **Event Breakdown (Mins)** field for the event category to the latest schedule time with a status of Not Started for the event.

- **Pre-dose events**: The end time for each bar is calculated as the greater of the following values:

  - Add the value in the **Event Breakdown (Mins)** field for the event category to the latest schedule time with a status of Not Started for the event.

  - Add the value in the **Event Breakdown (Mins)** field for the event category to the earliest schedule time with a status of Not Started for the event. This time is then added to the result of the formula:

    (Number of Not Started events / Number of parallel subjects for the study) * Offset interval

C H A P T E R 3
Working from the facility schedule

In this chapter

Event Schedule page

On the Event Schedule page, you view the following information for studies in the current facility:

- A list of scheduled events that have not been started.

- Details of individual events.

Late events appear in red.

If you open the Event Schedule page from the My Schedule page:

- The information is sorted by **Expected Date** in ascending order.

- Only your events, rather than events for the entire facility, appear.

Note: An error occurs if the Event Schedule page has not been filtered to a specific study, group, and period.

Tasks: Event Schedule page

- *Viewing the events on the schedule* (on page 28).

- *Viewing the schedule for a different day* (on page 22).

- *Viewing events that are assigned to you* (on page 32).

- *Changing the columns on the event schedule* (on page 34).

Viewing the events on the schedule

Prerequisites:

- At least one event must be scheduled.

- The Lab Status of the scheduled event must be Not Started.

1   From the main menu, select **Clinical Data Entry > Event Schedule**.

The Event Schedule page appears.

Field descriptions for the Event Schedule page

Field	Description	Notes
Study	Unique identifier for the study.	The study ID associated with the event, followed by the unique alphanumeric identifier for the study in parenthesis. Example: S102(0002)
Group	The group associated with the event.	
Period	The period associated with the event.	
Time Point	Increment of time between events.	Examples: • 0h—Start time for the event. • .25h—Increment of one-half hour after the previous event.
Expected Time	Time the event is scheduled to occur.	Seconds are not displayed in the Start Time and End Time fields, even for events that have the Consider Seconds field checked on the CT Studies – Setup – Events page.
Event Type	Type of event, such as Dose, Testing, or PK Testing.	
Event Category	Category of event, such as Dose, Vitals, or Collection.	
Sample Type	Type of sample being collections, such as blood or urine.	

Field	Description	Notes
Subject	Unique identifier for the subject whose information you are collecting.	For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Screening	Unique screening identifier for the subject whose information you are collecting.	For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Initials	Initials of the person who set up the event.	
Vessel Type	Type of vessel that should be used to collect the sample.	
Barcode	Barcode of the vessel used to collect the sample.	
No. Tubes	Number of tubes used to collect the dose or sample.	
Assignment	List of user IDs assigned to the event, delimited by a comma.	You cannot sort by the Assignment column. When filtering by the Assigned status, options are: • To Me. Only displays the events assigned to the current user. • To Anyone. Displays all assigned events. • Specific Users. Only displays events assigned to the entered user.

2   To see details about an event, select it.

Viewing the schedule for a different day

Prerequisites:

- At least one event must be scheduled.

- The Lab Status of the scheduled event must be Not Started.

1   From the main menu, select **Clinical Data Entry > Event Schedule**.

The Event Schedule page appears.

Field descriptions for the Event Schedule page

Field	Description	Notes
Study	Unique identifier for the study.	The unique alphanumeric identifier for the study is in parentheses after the Study ID. Example: S102(0002)
Group	Study group to which the subject has been assigned.	
Period	Time period to which the event has been assigned.	
Time Point	Increment of time between events.	Examples: • 0h—Start time for the event. • .25h—Increment of one-half hour after the previous event.
Expected Time	Time the event is scheduled to occur.	
Event Type	Type of event, such as Dose, Testing, or PK Testing.	
Event Category	Category of event, such as Dose, Vitals, or Collection.	
Sample Type	Type of sample being collections, such as blood or urine.	
Subject	Unique identifier for the subject whose information you are collecting.	For more information, see *Rules for entering Sub/Screening numbers* (on page 45).

Field	Description	Notes
Screening	Unique screening identifier for the subject whose information you are collecting.	For more information, see ***Rules for entering Sub/Screening numbers*** (on page 45).
Initials	Initials of the person who set up the event.	
Vessel Type	Type of vessel that should be used to collect the sample.	
Barcode	Barcode of the vessel used to collect the sample.	
No. Tubes	Number of tubes used to collect the dose or sample.	

2   Click the Calendar icon, located in the upper-right corner of the page, and select a day from the calendar.

or

Click the forward and backward arrow buttons (◄ ►) to navigate to a different day.

Viewing events that are assigned to you

Prerequisites:

- At least one event must be scheduled.
- The Lab Status of the scheduled event must be Not Started.

1 From the main menu, select **Clinical Data Entry > Event Schedule**.

The Event Schedule page appears.

Field descriptions for the Event Schedule page

Field	Description	Notes
Study	Unique identifier for the study.	The unique alphanumeric identifier for the study is in parentheses after the Study ID. Example: S102(0002)
Group	Study group to which the subject has been assigned.	
Period	Time period to which the event has been assigned.	
Time Point	Increment of time between events.	Examples: - 0h—Start time for the event. - .25h—Increment of one-half hour after the previous event.
Expected Time	Time the event is scheduled to occur.	
Event Type	Type of event, such as Dose, Testing, or PK Testing.	
Event Category	Category of event, such as Dose, Vitals, or Collection.	
Sample Type	Type of sample being collections, such as blood or urine.	
Subject	Unique identifier for the subject whose information you are collecting.	For more information, see *Rules for entering Sub/Screening numbers* (on page 45).

Field	Description	Notes
Screening	Unique screening identifier for the subject whose information you are collecting.	For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Initials	Initials of the person who set up the event.	
Vessel Type	Type of vessel that should be used to collect the sample.	
Barcode	Barcode of the vessel used to collect the sample.	
No. Tubes	Number of tubes used to collect the dose or sample.	

2   Click **FILTER**.

3   For **Assigned**, select **To Me**.

4   Click **APPLY**.

Changing the columns on the Event Schedule

1   From the main menu, select **Clinical Data Entry > Event Schedule**.

    The Event Schedule page appears.

2   Click the **Grid Setup** button ( ).

    The Column Selection dialog box appears.

    Field descriptions for the Column Selection dialog box

Field	Description
Select columns to display	Columns that you can include on the Event Schedule.
Sort Column	Column that controls the sort order of the event schedule.
	The selected column has a green heading.
Asc, Desc	Order in which events are sorted: Asc (ascending) or Desc (descending).

3   Select the columns to display on the event schedule, and deselect the columns to remove.

4   To sort the columns:

    a   From the Sort Column list, select the column that controls how the events are sorted.

    b   Select Asc or Desc to control the order of the list.

5   Click **APPLY**.

C H A P T E R 4

Recording doses

In this chapter

Dose page

On the Dose page, you record dosing information for a candidate or subject.

> **Note:** After you complete and save the dose information for an event, the subject/candidate association is created. The initial dose permanently links the candidate to the subject for the duration of the study.

The information you enter must correspond to:

- A valid scheduled event in the current Facility.
- The Study Id, Group, and Period settings defined on the My Profile page.

Tasks: Dose page

- *Recording dose information* (on page 38).

Recording dose information

Prerequisites:

- At least one Dose event for the study must exist.

- The Event Status of the scheduled event must be Not Started.

After you complete and save the dose information for an event, the subject/candidate association is created. The initial dose permanently links the candidate to the subject for the duration of the study.

> **Note:** If an event does not start by the expected time, the LabPas application can automatically reschedule the event. For more information, see *Rules for rescheduling Non Started events* (on page 46).

1   From the main menu, select **Clinical Data Entry > Dose**.

or

From the main menu, select **Clinical Data Entry > Event Schedule**, and select a **Dose** event.

The Dose page appears.

2   Scan or type the barcode of the vessel that contains the dose in the **Vessel BC** field.

If the Vessel BC field is related to a valid scheduled event, the Time Point, Tolerance, Scheduled, Consider Seconds, and Instructions fields display the information from the scheduled event.

Values set for Negative Tolerance Seconds and Positive Tolerance Seconds fields appear if the Consider Seconds option for the event is selected on the CT Studies – Setup – Events page.

An error message appears if the barcode is not associated with a scheduled dose.

3   If the expected time has not been reached, wait for the countdown time to reach zero, and click the green bar to enter the current time and date.

or

If the time has been reached, take the dose, and then click the Clock icon to enter the date and time.

For more information, see *About updating the date and time for an event.* (on page 41)

4   In the first **Sub/Screen No**. field, scan the barcode or enter the ID number of the subject or candidate who receives the dose.

An error message appears if:

- The ID is not associated with a scheduled dose.

- The Eligibility Review for the subject/candidate has been set to Pending.

If the event is associated with a form on the CT Studies – Setup – Events screen, all fields in the form appear above the Comment and Missed Event fields and are in the sequence set in the Order field. When you click SAVE, a warning appears if any form fields are empty.

For more information, see *Rules for entering Sub/Screen numbers* (on page 45).

5   In the second **Sub/Screen No**. field, scan the barcode or enter the ID number of the subject or candidate who receives the second dose.

If the eligibility review for the subject/candidate is pending, a message appears. Click **Cancel** to clear the page.

If a subject/candidate connection already exists, a warning message appears to link the subject to another candidate.

6   Fill in the other fields on the page, and click **SAVE**.

Field descriptions for the Dose page

Field	Description	Notes
Vessel BC	Barcode of the vessel for this dose.	REQUIRED.
		Maximum characters: 30.
		If you scan the barcode, this field is filled in. Otherwise, you must type the barcode.
		If the Vessel Barcode is associated with a locked study, group, and period, an error occurs, and all buttons and entry fields are read-only.
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	REQUIRED.
		Maximum characters: 30.
		For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Date/Time	Date and time of the event.	REQUIRED.
		Click the clock to update the time and date after you have taken the dose.
		Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page.
		For more information, see *About updating the date and time for an event.* (on page 41)
Countdown Timer	Clock that counts down the time that is displayed on the Dose Clinic floor page after a valid Vessel Barcode and both Sub/Screen fields are entered.	For more information, see *About updating the date and time for an event.* (on page 41)
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.

Field	Description	Notes
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

When you select Missed Event, a warning message appears. If you cancel, the Missed Event option is unchecked. If you continue, the Comment field is required.

When you click **SAVE**, if the Missed Event field is checked:

- The event status is changed to Missed.

- The event is counted as a deviation.

- The event schedule is not adjusted.

- The event is saved with a blank Actual Sample Date.

When you click **SAVE**, if the Missed Event field is unchecked:

- The event status is changed to Completed.

- If the Consider Seconds option for the event is not selected on the CT Studies – Setup – Events page, the seconds entered in Date/Time field are not saved in the Actual Sample Date.

- If the dose Date and Time do not match the Expected Time of the event, scheduled events (up to the first anchor event) with a status of Not Started and a PK time greater than the PK time of the current event are rescheduled when one of the following is true:

  - Adjust Schedule is selected for the event, and Use Tolerance for Adjust is deselected.

  - Both Adjust Schedule and Use Tolerance for Adjust are selected for the event, and the date and time are outside the tolerance for the event.

  - Adjust Schedule (Restricted) is selected for the event, Adjusted By for the event being rescheduled is set to the current event, and Use Tolerance for Adjust is deselected.

  - Both Adjust Schedule (Restricted) and Use Tolerance for Adjust are selected for the event, Adjusted By for the event being rescheduled is set to the current event, and the date and time is outside the tolerance for the event.

If all information is valid, the data is saved and all fields are cleared so that you can record a new event.

For the facility associated with the Dose event, if **Display Event Schedule After Save** is selected on the Facility Settings page, the Event Schedule page appears. Otherwise, the Clinic Floor page is refreshed and all fields are cleared.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

About updating the date and time of an event

You can update the time on the Clinical Data Entry pages in one of the following ways:

- **If you are administering a dose, accept the time from the Countdown Timer dialog box.**

  A counter dialog box indicates the amount of time remaining before the scheduled Dose event if the expected time of the Dose event occurs in the next 99 hours.

  When the countdown time reaches zero, click the green bar to close the Countdown dialog box and update the Date/Time fields with the server's current date and time.

  If the Countdown dialog box closes before the count is complete, click the Countdown button to the right of the Clock icon to open the Countdown Timer dialog box.

- **Click the clock icon to the right of the date and time fields.**

  The current date and time appear in the fields. Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page.

  To adjust the time value for an event:

  - Click the Time field up arrow to increment the time by one minute and change the seconds count to 0.

  - Click the Time field down arrow to set the seconds counter to 0 and leave the minute value unchanged when the seconds count is not set to 0.

  - Click the Time field down arrow to decrement the time by one minute when the seconds count is set to 0.

  If the page has a countdown timer:

  - As the countdown timer approaches zero, an alert sounds. When the countdown time reaches zero, the Countdown Timer dialog box closes.

  - If you complete an event after the expected time has been reached, you can click the Clock icon to apply the current date and time.

  - If the Auto-Populate Time After Countdown Expiration option is selected on the Facility Settings page for the facility associated with the event, the Date/Time field is updated with the current date and time.

  Use the green up and down arrows to adjust the time. For some pages, if you adjust the time in this way, you must add a comment.

> **Note:** If a field has both a date and time field, you must provide both or neither.

About adding comments

In most cases, the Comment field consists of two parts:

- **Comment ID:** A one- to three-digit identifier for a preconfigured Comment Id, as defined on the *Comments page* (in the *Administration Guide*).

> **Note:** On some pages, this field is not available. In these cases, enter a free-form comment in the Comment text area.

- **Comment text:** A preconfigured comment as defined by the Comment Id, or custom text (maximum characters: 800).

You must enter a comment if:

- The actual date and time for the dose are outside the tolerance for the Expected Date/Time.

- All events scheduled to take place after the dose have an adjusted PK time so that appropriate time intervals are still met. Events resume their originally scheduled PK times at the next anchor.

- If **Require Comment** is selected on the Settings - Facility page and the **Date/Time** field is outside of the scheduled date/time, regardless of the tolerance.

You can enter comments in one of the following ways:

- You enter a predefined Comment Id, which updates the Comment Text field.

  If you do not have a list of predefined comments, speak with your Study Monitor, who set up the list of comments.

- You can also type text manually in the Comment Text field.

Viewing nearby and historical events

When you perform clinical data entry, you can view nearby and historical events for the event type with which you are working.

1   Start at one of the following places:

- Recording dose information.

- Recording sample information.

- Recording test data.

- Recording other information.

- Drawing an Adhoc - PK sample.

- Drawing an Adhoc - Lab sample.

- Recording Adhoc - Testing data.

- Recording an Adhoc - Other sample.

- Recording an AE observation.

- Recording a follow-up AE observation.

- Recording a non-AE observation.

- Pooling a sample.

2   Type or scan a valid Sub/Screen No., and click **EVENTS**.

The Event History dialog box appears.

Description of the Event History dialog box

Nearby tab

The Nearby tab displays a table of events that have a status of Not Started, Missed, Failed, Completed, or In Progress for the same study, group, and period as the current event, including:

- The last five ad hoc or scheduled events that were saved for the subject or candidate.

- The current event, for scheduled events only.

- The next five scheduled events following the current event for the subject or candidate.

Events saved on the Clinical Data Entry - Pooling page do not appear.

Events are color-coded:

- The current event is orange.

- Completed and in progress events are green.

- Missed events are red.

Each event appears only once.

Seconds appear in the Expected Time and Actual Time fields for events with the Consider Seconds fields selected on the CT Studies – Setup – Events page.

History tab

Current event	What appears in the table
Dose PK Clinical Testing Testing Other	In progress and completed events that have the same values as the current event for the following information: • Event type • Event category • Study • Candidate • Group • Period
Pooling	All pooling events associated with the current pool barcode (only if opened from the Pooling page).

Observation	• For non-AE observations:
	
	  ▪ All non-AE observations associated with the same study, candidate, group, period, and event category as the current event.
	
	• For new AE observations:
	
	  ▪ No events. [A new AE observation does not have any historical data associated with it.]
	
	• For AE follow-up observations:
	
	  ▪ All AE observations that are in the same observation group or that are associated with the same AE form, across all periods in the study.

Seconds appear in the Expected Time and Actual Time fields for events with the Consider Seconds fields selected on the CT Studies – Setup – Events page.

Rules for entering Sub/Screening numbers

Many data-entry pages include fields for viewing and entering Subject and Screening numbers. In most cases, you collect this information by scanning the barcode on a subject's wristband. However, at times you might need to type this information manually, such as for an ad hoc or adverse event.

The Sub/Screen No. must:

- Match a valid Subject number or Screening number in the current Facility.

- Match the Study Id, Group, and Period settings defined on the My Profile page.

- Be linked to a candidate.

Follow these additional rules:

- If the Sub/Screen No. entered corresponds to a subject or is linked to a subject, the subject must be approved.

- If the unique study identifier and period are included, they are removed when the Sub/Screen No. field loses focus.

- If the unique study identifier and period are not included, an error message appears if the value does not uniquely identify a subject or candidate in an active study.

- If the Sub/Screen No. is associated with a locked study, group, and period, an error is generated, and all buttons and entry fields are disabled.

- If a Sub/Screen No. is entered on a Testing page that is associated with a locked study, group, and period, an error occurs and the Sub/Screen No. field clears.

When you enter a valid Sub/Screen No, the LabPas application searches for the next scheduled event for the subject or candidate that is scheduled to occur in the next 10 minutes, including tolerance. The LabPas application uses the current system date and time for the search. If any scheduled events have been missed, a Prior Event dialog box appears, where you can complete the missed event. If no prior events have been missed, the next scheduled event appears.

If you type the subject number, you must prefix the ID with a unique alphanumeric identifier for the study and a period. For example, to enter the subject number for subject 00001 for Study 013, type **0001.013**.

Rules for rescheduling Not Started events

Event conditions	Result
• The event is saved on a Clinic Floor page. • **Adjust Schedule** is selected for the event on the ***Study - Setup - Events page*** (in the *Clinical Trial Design and Resource Management Guide*). • The Date/Time field is outside the tolerance for the event.	The LabPas application reschedules each **Not Started** event in the schedule with a PK time greater than the PK time of the saved event so that the appropriate time intervals are still met. Only events up to the first anchor event following the current event are rescheduled. Events resume their originally scheduled PK Times at the next anchor.
• The event that is saved on a Clinic Floor page. • **Adjust Schedule (Restricted)** is selected for the event on the ***Study - Setup - Events page*** (in the *Clinical Trial Design and Resource Management Guide*). • The Event Date is outside the tolerance for the event.	The LabPas application reschedules each Not Started event in the schedule that has a PK time greater than the PK time of the saved event if one of the following conditions are true: • The event being rescheduled has an Adjusted By setting set to Previous Event, and the saved event precedes the event that is being rescheduled. • The event being rescheduled has its Adjusted By setting set to the event that is being saved. Only events up to the first anchor event following the current event are rescheduled.

Calculating the tolerance for an event

An event is considered outside tolerance range when either of the following is true:

- The Date and Time entered are earlier than the Expected Time for the event, and the time by which the event is early is greater than the Negative Tolerance configured for the event.

- The Date and Time entered are later than the Expected Time for the event, and the time by which the event is late is greater than the Positive Tolerance configured for the event.

If the event is configured with the Consider Seconds field selected on the CT Studies – Setup – Events page, then:

- Seconds are considered when determining if the event is outside tolerance range.

- Seconds are considered when adjusting the Expected Time for future events that are also configured with the Consider Seconds field selected.

- Seconds are not considered when adjusting the Expected Time for future events that are not configured with the Consider Seconds field selected.

C H A P T E R 5
Recording samples

In this chapter

Tasks: Sample page

On the Sample page, you record data about a sample as it is taken from a candidate or subject.

The information you enter must correspond to:

- A valid scheduled event in the current facility.

- The Study ID, Group, and Period settings on the My Profile page.

After the event is completed and updated, the sample is marked as In Progress and is removed from the Event Schedule page.

- *Recording sample information* (on page 51).

Recording sample information

Prerequisites:

- At least one PK Testing or Clinical Testing event for the study must exist.

- The Event Status of the scheduled event must be Not Started.

- The event type must be PK Testing or Clinical Testing.

- You must complete any scheduled PK Testing or Clinical Testing events that have been missed for this participant.

  In this case, a Prior Event dialog appears where you can complete the missed event. If you select CANCEL from the Prior Event dialog, the **Vessel BC** field is cleared, and you can scan or enter the sample barcode for the missed event.

> **Note:** If an event has not been started by the expected time, the LabPas application can automatically reschedule the event. For more information, see *Rules for rescheduling Non Started events* (on page 46).

1   From the main menu, select **Clinical Data Entry > Sample**.

   or

   From the main menu, select **Clinical Data Entry > Event Schedule**, and select a PK Testing or Clinical Testing event.

   The SAMPLE page appears.

2   In the **Vessel BC** field, scan or type the barcode of the vessel for the sample.

   If the Vessel BC field is related to a valid scheduled event, the Time Point, Tolerance, Scheduled, Consider Seconds, and Instructions fields display the information from the scheduled event.

   Values set for Negative Tolerance Seconds and Positive Tolerance Seconds fields appear if the Consider Seconds option for the event is selected on the CT Studies – Setup – Events page.

   If the event is associated with a form on the CT Studies – Setup – Events screen, all fields in the form appear above the Comment and Missed Event fields and are in the sequence set in the Order field. When you click SAVE, a warning appears if any form fields are empty.

   If the event is not associated with a form on the CT Studies – Setup – Events screen, additional Vessel BC fields appear for each PK Testing or Clinical Testing event that:

   - Is associated with the subject.

   - Has the same PK time.

   - Is not associated with a form.

3   If the expected time has not been reached, wait for the countdown time to reach zero, and then click the green bar to enter the current time and date.

   or

   If the time has been reached, take the PK Testing or Clinical Testing Sample, then click the Clock icon to enter the date and time.

   For more information, see *About updating the date and time for an event.* (on page 41)

4   In the first **Sub/Screen No**. field, scan the barcode or enter the ID number of the subject or candidate whose sample you are taking.

5   In the second **Sub/Screen No**. field, scan the barcode or enter the ID number of the subject or candidate whose sample you are taking.

6   Fill in the other fields on the page, and click **SAVE**.

Field descriptions for the Sample page

Field	Description	Notes
Vessel BC	Barcode of the vessel for this sample. The barcode must be associated with a scheduled dose.	REQUIRED. Maximum characters: 30. If you scan the barcode, this field is filled in. Otherwise, you must type the barcode. Multiple barcodes display if: • More than one sample is scheduled at the same time point. • The event has a quantity of greater than one on the Setup - Events page. If the Vessel Barcode is associated with a locked study, group, and period, an error occurs, and all buttons and entry fields are read-only.
Sub/Screen No.	Subject and screening number for the subject whose information you have entered. The subject must be associated with a scheduled PK Testing or Clinical Testing event.	REQUIRED. Maximum characters: 30. For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Date Time	Date and time of the event.	REQUIRED. Click the clock to update the time and date after you have taken the sample. Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page. For more information, see *About updating the date and time for an event.* (on page 41)

Field	Description	Notes
Countdown Timer	Clock that counts down the time that is displayed on the Sample Clinic floor page after a valid Vessel Barcode and both Sub/Screen fields are entered.	The Countdown Timer for compound draws on the Clinical Data Entry pages begins automatically only after all of the Vessel BC fields are populated.
		For more information, see *About updating the date and time for an event.* (on page 41)
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

When you select Missed Event, a warning message appears. If you cancel, the Missed Event field is unchecked. If you continue:

- The Comment field is required.

- The Date and Time fields are cleared and disabled.

- The clock icon, Time field up and down arrows, and countdown timer are disabled.

When you click **SAVE**, if the Missed Event field is checked:

- The event status is changed to Missed.

- The event is counted as a deviation.

- The event schedule is not adjusted.

- The event is saved with a blank Actual Sample Date.

- If Sample Logging is not required, a new sample is not created.

- If Sample Logging is required, a new sample cannot be logged.

When you click **SAVE**, if the Missed Event field is unchecked:

- The event status is changed to In Progress.

- If the Consider Seconds option for the event is not selected on the CT Studies – Setup – Events page, the seconds entered in the Time field are not saved in the Actual Sample Date.

- The event is considered on time if the Date and Time field values are within the scheduled date and time tolerance range.

- If the sample Date and Time do not match the Expected Time of the event, scheduled events (up to the first anchor event) with a status of Not Started and a PK time greater than the PK time of the current event are rescheduled when one of the following is true:

  - Adjust Schedule is selected for the event, and Use Tolerance for Adjust is deselected.

  - Both Adjust Schedule and Use Tolerance for Adjust are selected for the event, and the date and time are outside the tolerance for the event.

  - Adjust Schedule (Restricted) is selected for the event, Adjusted By for the event being rescheduled is set to the current event, and Use Tolerance for Adjust is deselected.

  - Both Adjust Schedule (Restricted) and Use Tolerance for Adjust are selected for the event, Adjusted By for the event being rescheduled is set to the current event, and the date and time is outside the tolerance for the event.

If all information is valid, the data is saved and all fields are cleared so that you can record a new event.

For the facility associated with the Dose event, if **Display Event Schedule After Save** is selected on the Facility Settings page, the Event Schedule page appears. Otherwise, the Clinic Floor page is refreshed and all fields are cleared.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

C HAPTER 6
Recording test data

In this chapter

Testing page

On the Testing page, you record test data for a candidate or subject.

When the Testing page initially opens, the Study ID, Group, and Period fields are blank. These fields are updated after you enter a valid Sub/Screen No.

Testing events are associated with test panels. These panels contain the specific tests that are appropriate for the panel. For example, some panels contain tests with out of range testing. In these cases, as you enter test results, they are compared to:

- The **Out of Range** limits defined when *reference values were specified for the test* (in the *Administration Guide*). If a result violates the **Out of Range** limits, an error message appears.

- The reference range (or reference value) *defined for the test in a specific study* (in the *Clinical Trial Design and Resource Management Guide*). If a test has demographic reference ranges defined and the gender or age for the participant is known, the appropriate demographic reference range is used. If a result violates the reference range, a warning appears.

Tasks: Testing page

- *Recording test data* (on page 58).

Recording test data

Prerequisites:

- At least one Testing event for the study must exist.

- The Event Status of the scheduled event must be Not Started.

- The event type must be Testing.

1   From the main menu, select **Clinical Data Entry > Testing**.

or

From the main menu, select **Clinical Data Entry > Event Schedule**, and select a Testing event.

The Testing page appears.

2   To import test data, click **IMPORT**.

Data is imported. The source of an imported value is set to the device interface type associated with the instrument barcode. Imported values are read-only.

The instrument serial number that is provided by the device when you click IMPORT must match the Serial No. configured for the instrument on the Setup – Instruments page. If serial numbers do not match, an error message appears and the results are not imported.

To manually enter test data:

a   In the **Sub/Screen No.** field, scan or type the barcode of the subject or candidate.

The LabPas application searches all scheduled Testing events for the subject that are expected to occur in the next 10 minutes (including tolerance).

The current system date and time are used for the search:

- If any scheduled Testing events were missed, a Prior Event dialog box appears. Multiple dialog boxes appear if multiple events were missed.

  To select the late event, click **OK**.

  To skip the late event, click **CANCEL**.

- If no prior events have been missed, the next scheduled event appears. Test fields appear specific to the scheduled test panel. The read-only Time Point, Tolerance, Scheduled, Panel and Instructions fields display the appropriate information from the scheduled event.

> **Note:** If the **Sub/Screen No.** entered is not associated with a scheduled event, or if the next event's Scheduled time (including tolerance) is more than **10 minutes in the future, an error message appears.**

b   If the expected time has not been reached, wait for the countdown time to reach zero, and then click the green bar to enter the current time and date.

or

If the time has been reached, complete the Testing event and click the Clock icon.

If the Vessel BC field is related to a valid scheduled event, the Time Point, Tolerance, Scheduled, Consider Seconds, and Instructions fields display the information from the scheduled event.

Values set for Negative Tolerance Seconds and Positive Tolerance Seconds fields appear if the Consider Seconds option for the event is selected on the CT Studies – Setup – Events page.

If the event is associated with a form on the CT Studies – Setup – Events screen, all fields in the form appear above the Comment and Missed Event fields and are in the sequence set in the Order field. When you click SAVE, a warning appears if any form fields are empty.

For more information, see *About updating the date and time for an event.* (on page 41)

c   Fill in the rest of the fields on the page, and click **SAVE**.

Field descriptions for the Testing page

Testing input fields are based on the panels associated with the event during configuration (on the Study - Setup - Events page).

Field	Description	Notes
Vessel BC	Barcode of the vessel for this dose.	REQUIRED.
		Maximum characters: 30.
		If you scan the barcode, this field is filled in. Otherwise, you must type the barcode.
		If a Vessel Barcode is entered on a page that is associated with a study and group from a different facility, an error occurs, and the field is cleared.
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	REQUIRED.
		Maximum characters: 30.
		For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Date/Time	Date and time of the event.	REQUIRED.
		Click the Clock icon to update the time after you take the test sample.
		Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page.
		For more information, see *About updating the date and time for an event.* (on page 41)

Field	Description	Notes
Countdown Timer	Clock that counts down the time that is displayed on the Testing Clinic floor page after a valid Sub/Screen field value was entered.	For more information, see *About updating the date and time for an event.* (on page 41)
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
Panel	Test entry linked to the sample as sequenced in the Test Panel.	
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

As the page updates, edit checks created for the panels are applied:

- If any edit checks with an action of **Warn** or **Warn and Alert** have been violated, a warning message appears.

- If any edit checks with an action of **Alert** or **Warn and Alert** have been violated, the test in violation is flagged with an alert when test data is viewed or edited in the Study - Results page.

- If any edit checks with an action of **Prevent** have been violated, a warning message appears, and you cannot save until you correct the result in violation.

The source of a record that you create manually is LabPas.

> **Note:** When the Actual Sample Date has a value, the Event Status on the Study - Events - Schedule page for the sample changes to Completed.

If the save is successful:

- The entry includes seconds entered into the Time field even if seconds are not saved with the Actual Sample Date.

- The Approval Status for the event is set to Not Approved.

- The Monitor Review Status for the event is set to Not Reviewed.

If you select Missed Event, a warning appears. If you cancel, the Missed Event field is unchecked. If you continue:

- The Comment field is required.

- The Date field and Time field are cleared and disabled.

- The clock icon, Time field up and down arrows, and countdown timer are disabled.

- The Instrument BC field is cleared and disabled.

- All result entry fields are cleared and disabled.

- The IMPORT button is disabled.

When you click **SAVE**, if the Missed Event field is checked:

- The event status is changed to Missed.

- The event is counted as a deviation.

- The event schedule is not adjusted.

- The event is saved with a blank Actual Sample Date.

- No result records are created, even for non-optional tests.

When you click **SAVE**, if the Missed Event field is not checked:

- The status of the scheduled event is changed to Completed.

- If the Consider Seconds field for the event is not selected on the CT Studies – Setup – Events page, the seconds entered in the Time field are not saved in the Actual Sample Date.

- If the Date/Time field does not match the Expected Time of the event, scheduled events (up to the first anchor event) with a status of not started and a PK time greater than the PK time of the current event are rescheduled when one of the following is true:

  - Adjust Schedule is selected for the event, and Use Tolerance for Adjust is deselected.

  - Both Adjust Schedule and Use Tolerance for Adjust are selected for the event, and the date and time are outside the tolerance for the event.

  - Adjust Schedule (Restricted) is selected for the event, Adjusted By for the event being rescheduled is set to the current event, and Use Tolerance for Adjust is deselected.

  - Both Adjust Schedule (Restricted) and Use Tolerance for Adjust are selected for the event, Adjusted By for the event being rescheduled is set to the current event, and the date and time is outside the tolerance for the event.

- Edit checks created for the panels are applied:

  - If any edit checks with an action of Warn or Warn and Alert have been violated, a warning message appears.

  - If any edit checks with an action of Alert or Warn and Alert have been violated, the test in violation is flagged with an alert when test data is viewed or edited in the Study - Results page.

  - If any edit checks with an action of Prevent have been violated, a warning message appears, and you cannot save until you correct the result in violation.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

C H A P T E R 7

Recording other data

In this chapter

Tasks: Other page

On the Other page, you record any other type of data for a candidate or subject.

Values appear in the Study Id, Group, and Period fields after you enter a valid Sub/Screen No.

- *Recording other information* (on page 65).

Recording other data

Prerequisites:

- At least one Other event must exist for the study.

- The Event Status of the scheduled event must be Not Started.

The event type must be Other.

> **Note:** If an event has not been started by the expected time, the LabPas application can automatically reschedule the event. For more information, see *Rules for rescheduling Non Started events* (on page 46).

1   From the main menu, select **Clinical Data Entry > Other**.

   The Other page appears.

   - In the **Sub/Screen No.** field, scan or type the barcode of the subject or candidate.

   The LabPas application searches all scheduled Other events that are expected to occur in the next 10 minutes (including tolerance) for the ID entered.

   The current system date and time are used for the search:

   - If any scheduled events were missed, a Prior Event dialog box appears. Additional dialog boxes appear if multiple events were missed.

      - To select the late event, click **OK**.

      - To skip the late event, click **CANCEL**.

   - If no prior events have been missed, the next scheduled event is displayed. Test fields appear specific to the scheduled test panel.

   If the Vessel BC field is related to a valid scheduled event, the Time Point, Tolerance, Scheduled, Consider Seconds, and Instructions fields display the information from the scheduled event.

   Values set for Negative Tolerance Seconds and Positive Tolerance Seconds fields appear if the Consider Seconds option for the event is selected on the CT Studies – Setup – Events page.

   If the event is associated with a form on the CT Studies – Setup – Events screen, all fields in the form appear above the Comment and Missed Event fields and are in the sequence set in the Order field. When you click SAVE, a warning appears if any form fields are empty.

   > **Note:** If the Sub/Screen No. entered is not associated with a scheduled event, or if the Date/Time value is before the event's scheduled time and tolerance, an error message appears.

2   If the expected time has not been reached, wait for the countdown time to reach zero, and then click the green bar to enter the current time and date.

   or

   If the time has been reached, complete the Other event and click the Clock icon.

   For more information, see *About updating the date and time for an event.* (on page 41)

3   Fill in the other fields on the page, and click **SAVE**.

Field descriptions for the Other page

Field	Description	Notes
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Date/Time	Date and time of the event.	Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page. For more information, see *About updating the date and time for an event.* (on page 41)
Countdown Timer	Clock that counts down the time that is displayed on the Other Clinic floor page after a valid Sub/Screen field value was entered.	For more information, see *About updating the date and time for an event.* (on page 41)
Outcome	Whether the event has been started.	Default: No. If you select No, you must add a comment.
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

If the save is successful:

- The entry includes seconds entered into the Time field even if seconds are not saved with the Actual Sample Date.

- The Approval Status for the event is set to Not Approved.

- The Monitor Review Status for the event is set to Not Reviewed.

If all information is valid, the data is saved and all fields are cleared so that you can record a new event.

> **Note:** When the Actual Sample Date has a value, the Event Status on the Study - Events - Schedule page for the sample is set to Completed.

If you select Missed Event, a warning appears. If you cancel, the Missed Event field is unchecked. If you continue:

- The Comment field is required.

- The Date field and Time field are cleared and disabled.

- The clock icon, Time field up and down arrows, and countdown timer are disabled.

- The Outcome field is disabled.

When you click **SAVE**, if the Missed Event field is checked:

- The event status is changed to Missed.

- The event is counted as a deviation.

- The event schedule is not adjusted.

- The event is saved with a blank Actual Sample Date.

- A blank value is saved in the Outcome field. The field is also disabled.

When you click **SAVE**, if the Missed Event field is not checked:

- If all information is valid, the data is saved and all fields are cleared so that you can record a new event.

- The event order status changes to Completed.

- If the Consider Seconds field for the event is not selected on the CT Studies – Setup – Events page, the seconds entered in the Time field are not saved in the Actual Sample Date.

- The event is considered on time if the Date and Time field values are within the scheduled date and time tolerance range.

- If the Date/Time field does not match the Expected Time of the event, scheduled events (up to the first anchor event) with a status of not started and a PK time greater than the PK time of the current event are rescheduled when one of the following is true:

  - Adjust Schedule is selected for the event, and Use Tolerance for Adjust is deselected.

  - Both Adjust Schedule and Use Tolerance for Adjust are selected for the event, and the date and time are outside the tolerance for the event.

  - Adjust Schedule (Restricted) is selected for the event, Adjusted By for the event being rescheduled is set to the current event, and Use Tolerance for Adjust is deselected.

  - Both Adjust Schedule (Restricted) and Use Tolerance for Adjust are selected for the event, Adjusted By for the event being rescheduled is set to the current event, and the date and time is outside the tolerance for the event.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

Recording ad hoc lab events and observations

In this chapter

Tasks: Adhoc - Lab page

On the Adhoc - Lab page, you collect unscheduled samples for clinical analysis.

- *Drawing an Adhoc - Lab sample* (on page 71).

Recording an Adhoc - Lab sample

Prerequisites:

- At least one Subject or Candidate must be associated with the study.

- At least one sample type must be associated with Clinical Lab events in the study.

- At least one single-well vessel must exist.

- At least one panel must be associated with a Clinical Lab event.

1   From the main menu, select **Clinical Data Entry > Adhoc - Lab**.

    The Adhoc - Lab page appears.

2   In the **Vessel BC** field, scan or type the barcode of the vessel in which the sample is stored.

3   In the **Sub/Screen No.** field, scan or type the barcode of the subject or candidate from whom the ad hoc sample is drawn.

    If the Sub/Screen No. entered is associated with a candidate that is not linked to a subject, the candidate must have a study status of Accepted, Approved, Completed, Dropped, Screen Fail, Consent Withdrawn, or Pending Candidate.

    The Period field defaults to the period associated with the last event saved for the Sub/Screen No. If no events have been saved, the Period field defaults to blank.

    The Form field does not display any forms when the Sub/Screen No. field is blank. After a valid Subject No. or Screening No. is entered, all forms associated with the study are available for selection and form input fields appear for the selected form. Form fields appear above the Comment field.

    After you select a form in the Form field, a warning appears if you click the SAVE button and any form fields are empty.

4   Fill in the other fields on the page, and click **SAVE**.

    Field descriptions for the Adhoc - Lab page

Field	Description	Notes
Vessel BC	Barcode of the vessel for this dose. If you scan the barcode, this field is filled in. Otherwise, you must type the barcode. The barcode must: • Be unique. • Belong to a vessel that is not allocated to any scheduled events.	REQUIRED. Maximum characters: 30. If a Vessel Barcode is entered on a page that is associated with a study and group from a different facility, an error occurs, and the field is cleared. If the Vessel Barcode is associated with a locked study, group, and period, an error occurs, and all buttons and entry fields are read-only.

Field	Description	Notes
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	REQUIRED. Maximum characters: 30. For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Date/Time	Date and time of the event.	REQUIRED. Update the time after you have taken the test sample. Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page. For more information, see *About updating the date and time for an event.* (on page 41)
Countdown Timer	Not used.	Ad hoc events are not scheduled.
Sample	Type of sample that is taken from the participant.	REQUIRED. Sample types available for selection are based on the settings created in the Study - Setup - PK Lab page.
Vessel	Type of vessel used to collect the sample.	REQUIRED.
Panel	Panel that is assigned to the sample. Choose from all panels associated with the study.	REQUIRED.
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

If the save is successful:

- The entry includes seconds entered into the Time field even if seconds are not saved with the Actual Sample Date.

- The Approval Status for the event is set to Not Approved.

- The Monitor Review Status for the event is set to Not Reviewed.

If all information is valid, the data is saved and all fields are cleared so that you can record a new event.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

Recording ad hoc PK events and observations

In this chapter

Tasks: Adhoc - PK page

On the Adhoc - PK page, you collect unscheduled samples to support the PK process. This page is intended primarily to support non-blood samples such as urine and feces when unscheduled collections are required.

Ad hoc PK samples are not scheduled to a service.

- *Drawing an Adhoc - PK sample* (on page 77).

Drawing an Adhoc - PK sample

Prerequisites:

- At least one subject or candidate must be associated with the study.
- At least one sample type must be associated with PK Lab events in the study.
- At least one single-well vessel must exist.
- At least one panel must be associated with a PK Lab event.

1   From the main menu, select **Clinical Data Entry > Adhoc-PK**.

The Adhoc - PK page appears.

2   In the **Vessel BC** field, scan or type the barcode of the vessel in which the sample is stored.

3   In the **Sub/Screen No.** field, scan or type the barcode of the subject or candidate from whom the ad hoc sample is drawn.

If the Sub/Screen No. entered is associated with a candidate that is not linked to a subject, the candidate must have a study status of Accepted, Approved, Completed, Dropped, Screen Fail, Consent Withdrawn, or Pending Candidate.

The Period field defaults to the period associated with the last event saved for the Sub/Screen No. If no events have been saved, the Period field defaults to blank.

The Form field does not display any forms when the Sub/Screen No. field is blank. After a valid Subject No. or Screening No. is entered, all forms associated with the study are available for selection and form input fields appear for the selected form. Form fields appear above the Comment field.

After you select a form in the Form field, a warning appears if you click the SAVE button and any form fields are empty.

4   Fill in the other fields on the page, and click **SAVE**.

Field descriptions for the Adhoc - PK page

Field	Description	Notes
Vessel BC	Barcode of the vessel for this dose. If you scan the barcode, this field is filled in. Otherwise, you must type the barcode. The barcode must: - Be unique. - Belong to a vessel that is not allocated to any scheduled events.	REQUIRED. Maximum characters: 30. If a Vessel Barcode is entered on a page that is associated with a study and group from a different facility, an error occurs, and the field is cleared. If the Vessel Barcode is associated with a locked study, group, and period, an error occurs, and all buttons and entry fields are read-only.

Field	Description	Notes
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	REQUIRED. Maximum characters: 30. For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Date/Time	Date and time of the event.	REQUIRED. Update the time after you take the test sample. Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page. For more information, see About updating the date and time for an event.
Countdown Timer	Not used.	Ad hoc events are not scheduled.
Sample	Type of sample that is taken from the participant.	REQUIRED. Sample types available for selection are set up during configuration.
Vessel	Type of vessel used to collect the sample.	REQUIRED.
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

If the save is successful:

- The entry includes seconds entered into the Time field even if seconds are not saved with the Actual Sample Date.

- The Approval Status for the event is set to Not Approved.

- The Monitor Review Status for the event is set to Not Reviewed.

If all information is valid, the data is saved and all fields are cleared so that you can record a new event.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

C H A P T E R   1 0

Recording ad hoc testing events and observations

In this chapter

Tasks: Adhoc - Testing

On the Adhoc - Testing page, you collect unscheduled Testing events data. The fields that appear depend on the tests that are associated with the panel on the *Test Panels page* (in the *Administration Guide*).

- *Recording Adhoc - Testing data* (on page 83).

Recording Adhoc - Testing data

Prerequisites: At least one subject or candidate and at least one panel with the Event Type of Testing must be associated with the study.

1 From the main menu, select **Clinical Data Entry > Adhoc-Testing**.

The Adhoc - Testing page appears.

2 In the **Sub/Screen No.** field, scan or type the barcode of the subject or candidate from whom the ad hoc sample is drawn.

If the Sub/Screen No. entered is associated with a candidate that is not linked to a subject, the candidate must have a study status of Accepted, Approved, Completed, Dropped, Screen Fail, Consent Withdrawn, or Pending Candidate.

The Period field defaults to the period associated with the last event saved for the Sub/Screen No. If no events have been saved, the Period field defaults to blank.

The Form field does not display any forms when the Sub/Screen No. field is blank. After a valid Subject No. or Screening No. is entered, all forms associated with the study are available for selection and form input fields appear for the selected form. Form fields appear above the Comment field.

After you select a form in the Form field, a warning appears if you click the SAVE button and any form fields are empty.

The instrument serial number that is provided by the device when you click IMPORT must match the Serial No. configured for the instrument on the Setup – Instruments page. If serial numbers do not match, an error message appears and the results are not imported.

3 To manually enter data, fill in the fields on the page.

Field descriptions for the Adhoc - Testing page

Field	Description	Notes
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	REQUIRED. Maximum characters: 30. For more information, see *Rules for entering Sub/Screening numbers* (on page 45).

Field	Description	Notes
Date/Time	Date and time of the event.	REQUIRED.
		Update the time after you take the test sample.
		Seconds are not displayed in the Start Time and End Time fields, even for events that have the Consider Seconds field checked on the CT Studies – Setup – Events page.
		For more information, see *About updating the date and time for an event.* (on page 41)
Countdown Timer	Not used.	Ad hoc events are not scheduled.
Panel	Test entry linked to the sample as sequenced in the Test Panel.	REQUIRED.
		When you select a panel, the test fields associated with the panel appears. The details of the panel depend on the type of test.
Comment	Preconfigured or freeform comment about the entry.	The comment is saved with the event, not with any result records.
		For more information, see About adding comments.

Field	Description	Notes
Instrument Barcode	Barcode of the instrument used to collect the sample.	Some test panels include an **Instrument Barcode** field. This field has two parts: the Barcode ID and the description.
		If the **Instrument Barcode** field was configured to have a Device Interface Type value, an IMPORT button appears on the page. Click this button to import test values from the instrument that you connected to the computer.
		If the test values are not imported, you can manually enter the information. This might occur, for example, if there are connection issues to the instrument.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

or

To import data, click **IMPORT**.

The first time you import data from a medical device using a serial connection, you are prompted to select a serial prompt.

4   Click **UPDATE**.

As you enter test results, they are compared to the Out of Range limits defined for the test in the *Tests page* (in the *Administration Guide*). If a result violates the Out of Range limits, an error message appears, and the entry is not allowed.

If the save is successful:

- The entry includes seconds entered into the Time field even if seconds are not saved with the Actual Sample Date.

- The Approval Status for the event is set to Not Approved.

- The Monitor Review Status for the event is set to Not Reviewed.

After you save, edit checks for the panels are applied:

- If edit checks with an action of Warn or Warn and Alert have been violated, a warning message appears.

- If edit checks with an action of Alert or Warn and Alert have been violated, the test in violation appears in red on the Study - Sample Results page.

- If edit checks with an action of Prevent have been violated, a warning message appears, and you cannot save until you correct the result in violation.

The source of an imported value is set to the device interface type associated with the instrument barcode. Imported values are read-only.

The source of a record that you create manually is LabPas.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

Recording other ad hoc events and observations

In this chapter

Tasks: Adhoc - Other page

On the Adhoc - Other page, you collect data for other unscheduled events that are not logged on the specialized sample collection pages. These events might include:

- Check-in or check-out.

- Follow-up visit.

- Informed consent.

- Volunteer demographics or medical history.

- Mouth check.

- Other uncategorized events that are important to the study.

When the page first appears, the Study Id, Group and Period fields display values as defined on the My Profile page.

- *Recording an Adhoc - Other sample* (on page 89).

Recording an Adhoc - Other sample

Prerequisites:

- At least one Subject or Candidate must be associated with the study.

- At least one category in the event type **Other** must exist.

1 From the main menu, select **Clinical Data Entry > Adhoc - Other**.

The Adhoc - Other page appears.

2 In the **Sub/Screen No.** field, scan or type the barcode of the subject or candidate from whom the ad hoc sample is drawn.

If the Sub/Screen No. entered is associated with a candidate that is not linked to a subject, the candidate must have a study status of Accepted, Approved, Completed, Dropped, Screen Fail, Consent Withdrawn, or Pending Candidate.

The Period field defaults to the period associated with the last event saved for the Sub/Screen No. If no events have been saved, the Period field defaults to blank.

The Form field does not display any forms when the Sub/Screen No. field is blank. After a valid Subject No. or Screening No. is entered, all forms associated with the study are available for selection and form input fields appear for the selected form. Form fields appear above the Comment field.

After you select a form in the Form field, a warning appears if you click the SAVE button and any form fields are empty.

3 Fill in the other fields on the page, and click **SAVE**.

Field descriptions for the Adhoc - Other page

Field	Description	Notes
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	REQUIRED. Maximum characters: 30. For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Date/Time	Date and time of the event.	REQUIRED. The date and time of the server appear if Default Time was selected when *facility settings were configured* (in the *Administration Guide*). Update the time after you have taken the test sample. For more information, see *About updating the date and time for an event.* (on page 41)

Field	Description	Notes
Countdown Timer	Not used.	Ad hoc events are not scheduled.
Category	Category of event that is being recorded	REQUIRED.
Outcome	Whether the event was completed successfully.	REQUIRED. If you select No, you must provide a comment.
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

If the save is successful:

- The entry includes seconds entered into the Time field even if seconds are not saved with the Actual Sample Date.

- The Approval Status for the event is set to Not Approved.

- The Monitor Review Status for the event is set to Not Reviewed.

If all information is valid, the data is saved and all fields are cleared so that you can record a new event.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

C H A P T E R   1 2
Recording AE observations

In this chapter

Tasks: AE Observations page

On the AE Observations page, you view AE forms and AE observation groups that are associated with the current facility, and you record new AE observations from the clinic floor. An AE observation is a record of an adverse event.

Each row in the table represents one of the following:

- AE form.
- AE observation group.

    A group consists of one or more AE observations, including follow-up AE observations. Every observation in the group has the same study, screening number, description, and onset date and time.

Each observation group can be associated with an AE form.

An AE observation is always associated with a candidate. If the link between the candidate and subject is altered, the data remains with the candidate.

The following table describes the differences between AE observations and non-AE observations.

Functionality	AE observation	Non-AE observation
Has an onset date	Yes	No
Has a resolution date	Yes	No
You specify an indication	No	Yes
You specify an event category	No	Yes
		You choose from the options defined on the Clinical Trials - Event Types page. Only the event categories that are defined for the Observation event type are visible.

Viewing a list of AE observations and AE forms

You must select a study in the filtering dialog box. If (No Selection) is selected in the Study filter, no rows appear, and the NEW EVENT button is not visible.

1   From the main menu, select **Clinical Data Entry > AE Observations**.

The AE Observations page appears.

2   Review the list of AE observations and AE forms.

Field descriptions for the AE Observations page

Field	Description	Notes
Study	Unique identifier for the study.	The unique alphanumeric identifier for the study is in parentheses after the Study ID. Example: S102(0002).
Group	Study group to which the subject has been assigned.	
Period	• **For an AE form or AE observation group associated with an AE form**—The period of the AE form. • **For an AE observation group not associated with an AE form**—The period associated with the oldest AE observation in the AE observation.	
Subject	Unique identifier for the subject whose information you are collecting.	For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Screening	Unique screening identifier for the subject whose information you are collecting.	For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Description	• **For an AE form or AE observation group associated with an AE form**—The description of the AE form. • **For an AE observation group not associated with an AE form**—The description of the AE observation group.	

Field	Description	Notes
Onset	• **For an AE form or AE observation group associated with an AE form**—The onset date for the AE form. • **For an AE observation group not associated with an AE form**—The onset date and time of the AE observation group.	
Resolution	• **For an AE form or AE observation group associated with an AE form**—The resolution date of the AE form. • **For an AE observation group not associated with an AE form**—The latest resolution date associated with the group of observations.	
AE Form	• **Yes**—If at least one observation in the group is attached to an AE Form. • **No**—The row is not an AE form.	

If the record selected from the AE Observations table has a non-blank Resolution date and time, then, for that record:

- All fields default to the most recent observation in the selected observation group or AE Form.

- All fields are disabled.

- The SAVE button does not appear.

- The Sub/Screen No. field does not appear.

- The Reported time field does not display seconds.

- The Onset time field does not display seconds.

- The Resolution time field does not display seconds.

If the record selected from the AE Observations table has a blank Resolution date and time, then, for that record:

- The Description field defaults to the Description from the record selected in the AE Observations table.

- The Onset date and Onset time fields default to the Onset date and time from the record selected in the AE Observations table.

- The Onset time field does not display seconds.

Recording an AE observation

An AE observation is not automatically associated with an AE form. You must manually add an AE form and associate an AE observation with it. For more information, see Adding an AE form.

To record an AE observation with the same study, screening number, description, and onset date and time as an existing AE observation, record a follow-up AE observation.

1   From the main menu, select **Clinical Data Entry > AE Observations**.

    The AE Observations page appears.

2   Click **NEW EVENT**.

> **Note:** You must select a study in the filtering dialog box. If (No Selection) is selected in the Study filter, no rows appear, and the NEW EVENT button is not visible.

    The Enter New AE Observation Details page appears.

3   In the **Sub/Screen No.** field, scan or type the barcode of the subject or candidate who experienced the adverse event.

    If the Sub/Screen No. entered is associated with a candidate that is not linked to a subject, the candidate must have a study status of Accepted, Approved, Completed, Dropped, Screen Fail, Consent Withdrawn, or Pending Candidate.

4   Fill in the fields on the page.

Field descriptions for the Enter New AE Observation Details page

Field	Description	Notes
Sub/Screen No.	Subject and screening number for the subject who experienced the adverse event.	REQUIRED. Maximum characters: 30. For more information, see *Rules for entering Sub/Screening numbers* (on page 45).
Description	Free-form description of the adverse event.	
Reported Date/Time	Date and time the adverse event was reported.	REQUIRED. For more information, see *About updating the date and time for an event.* (on page 41)
Onset Date/Time	Date and time the adverse event first occurred.	REQUIRED. For more information, see *About updating the date and time for an event.* (on page 41)

Field	Description	Notes
Resolution Date/Time	Date and time the adverse event was resolved. You can provide a resolution date and time when you create the adverse event.	• Must be later than the onset date and time. • An AE observation with a resolution date and time is read-only. To make changes, edit the AE observation on the Clinical Trials - CT Studies - Events - Data page and delete the resolution date and time. Each observation group can have only one resolution date and time.For more information, see *About updating the date and time for an event.* (on page 41)
Severity	Severity of the adverse event.	
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.
Medication Given		
Medication	A type-ahead list containing all active medications with a term type of AE Conmed from the Setup - Medical Terms page.	If you provide a Dose, Unit, or Route, you must provide a Medication. The conmeds that you add to an observation appear on the Conmeds tab when you view an AE form (Clinical Trials - CT Studies - AEs tab).
Indication	AE always appears.	READ-ONLY
Dose	Amount of the medication that was dispensed.	
Units	A drop-down list with all active units with a term type of Conmed Unit from the Setup - Medical Terms page.	

Field	Description	Notes
Route	A drop-down list with all active routes with a term type of Conmed Route from the Setup - Medical Terms page.	

5   Click **SAVE**.

If all information is valid, the data is saved and all fields are cleared so that you can record a new observation.

The AE observation is created with the Adverse Event event category.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

Recording a follow-up AE observation

A follow-up AE observation is an AE observation that is grouped with an existing AE observation or AE form. If the existing AE observation group is associated with an AE form, the follow-up observation is associated with the form, too. Otherwise, the follow-up observation is not associated with an AE form.

A follow-up AE observation has the same description and onset date as the AE observation group that you select.

If the observation has a non-blank Resolution Date, the follow-up AE observation Period field defaults to the period with the most recent observation that is associated with the selected group from the AE Observations page. If the observation has a blank Resolution Date, the Period field defaults to the period with the last event saved for the same Sub/Screen No.

You cannot create a follow-up observation for a resolved AE observation group or AE form.

Follow-up AE observations are recorded in the CT Change Log report with a source of AE Observations.

You must select a study in the filtering dialog box. If (No Selection) is selected in the Study filter, no rows appear, and the NEW EVENT button is not visible.

1   From the main menu, select **Clinical Data Entry > AE Observations**.

    The AE Observations page appears.

2   Select an AE observation group or AE form.

    The Enter AE Observation Follow Up Details page appears for the selected event.

3   In the **Sub/Screen No.** field, scan or type the barcode of the subject or candidate who experienced the adverse event.

4   Fill in the fields.

    Field descriptions for the Enter AE Observation Follow Up Details page

Field	Description	Notes
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	
Description	Description of the selected observation.	READ-ONLY
Reported Date/Time	Date and time the event was reported.	For more information, see *About updating the date and time for an event.* (on page 41)
Onset Date/Time	Date and time the event was reported.	

Field	Description	Notes
Resolution Date/Time	Date and time the event was resolved.	For more information, see *About updating the date and time for an event.* (on page 41)
		• Must be later than the onset date and time.
		• An AE observation with a resolution date and time is read-only. To make changes, edit the AE observation on the Clinical Trials - CT Studies - Events - Data page and delete the resolution date and time.
		• Each observation group can have only one resolution date and time.
Severity	Severity of the observation.	
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.
Medication Given		
Medication	A type-ahead list containing all active medications with a term type of AE Conmed from the Setup - Medical Terms page.	If you provide a Dose, Unit, or Route, you must provide a Medication. The conmeds that you add to an observation appear on the Conmeds tab when you view an AE form (Clinical Trials - CT Studies - AEs tab).
Indication	AE always appears.	READ-ONLY
Dose	Amount of the medication that was dispensed.	
Route	A drop-down list with all active routes with a term type of Conmed Route from the Setup - Medical Terms page.	

5   Click **SAVE**.

A follow up observation is automatically attached to an AE Form when the observation group selected in the AE Observations table is associated with an AE Form, and all events in the observation group are attached to the same AE Form

The follow-up AE observation is created. Because the follow-up observation is grouped with the existing AE observation group or AE form, a new row does not appear.

The AE Observation event is saved to the same period that appears in the Period field.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

Resolving an AE observation

You can resolve an AE observation by creating a follow-up AE observation and entering a resolution date. When the final AE observation in an AE observation group is resolved, the entire group is considered to be resolved.

If you forgot to enter a resolution date when you created an AE observation, you can *edit the AE observation* on the Study - Events - Data page (in the *Clinical Trial Design and Resource Management Guide*).

You must select a study in the filtering dialog box. If (No Selection) is selected in the Study filter, no rows appear, and the NEW EVENT button is not visible.

1   From the main menu, select **Clinical Data Entry > AE Observations**.

The AE Observations page appears.

2   Select an AE observation or AE observation group.

The Enter AE Observation Follow Up Details page appears.

3   In the **Sub/Screen No.** field, scan or type the barcode of the subject or candidate who experienced the adverse event.

4   Enter a Reported Date and Time and a Resolution Date and Time, and fill in additional fields if necessary.

Field descriptions for the Enter AE Observation Follow Up Details page

Field	Description	Notes
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	
Description	Description of the selected observation.	READ-ONLY
Reported Date/Time	Date and time the event was reported.	For more information, see *About updating the date and time for an event.* (on page 41)
Onset Date/Time	Date and time the event was reported.	

Field	Description	Notes
Resolution Date/Time	Date and time the event was resolved.	For more information, see *About updating the date and time for an event.* (on page 41)
		• Must be later than the onset date and time.
		• An AE observation with a resolution date and time is read-only. To make changes, edit the AE observation on the Clinical Trials - CT Studies - Events - Data page and delete the resolution date and time.
		• Each observation group can have only one resolution date and time.
Severity	Severity of the observation.	
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.
Medication Given		
Medication	A type-ahead list containing all active medications with a term type of AE Conmed from the Setup - Medical Terms page.	If you provide a Dose, Unit, or Route, you must provide a Medication. The conmeds that you add to an observation appear on the Conmeds tab when you view an AE form (Clinical Trials - CT Studies - AEs tab).
Indication	AE always appears.	READ-ONLY
Dose	Amount of the medication that was dispensed.	
Route	A drop-down list with all active routes with a term type of Conmed Route from the Setup - Medical Terms page.	

5   Click **SAVE**.

CHAPTER 13

Recording non-AE observations

In this chapter

Tasks: Observations page

On the Observations page, you view non-AE observations associated with the current facility and create new, non-AE observations, including adding the concomitant medications (conmeds) given in response to the observation.

The following table describes the differences between a non-AE observation and an AE observation.

Functionality	AE observation	Non-AE observation
Has an onset date	Yes	No
Has a resolution date	Yes	No
You specify an indication	No	Yes
You specify an event category	No	Yes You choose from the options defined on the Clinical Trials - Event Types page. Only the event categories that are defined for the Observation event type are visible.

- *Viewing non-AE observations* (on page 107).
- *Recording a non-AE observation* (on page 108).

Viewing non-AE observations

1   From the main menu, select **Clinical Data Entry > Observations**.

The Observations page appears, displaying all non-AE observations in the study.

2   To view details for an individual non-AE observation, select the observation.

Recording a non-AE observation

An observation is always associated with a candidate.

1   From the main menu, select **Clinical Data Entry > Observations**.

The Observations page appears.

2   Click **NEW EVENT**.

If the Sub/Screen No. entered is associated with a candidate that is not linked to a subject, the candidate must have a study status of Accepted, Approved, Completed, Dropped, Screen Fail, Consent Withdrawn, or Pending Candidate.

3   Fill in the fields.

Field descriptions for the Observations page

Field	Description	Notes
Sub/Screening No.	Subject and screening number for the subject being observed.	REQUIRED. Maximum characters: 30. For more information, see **Rules for entering Sub/Screening numbers** (on page 45).
Description	Free-form description of the observation.	REQUIRED.
Date/Time	Date and time the observation occurred.	The Date/Time time field does not display seconds. For more information, see **About updating the date and time for an event.** (on page 41)
Category	Categorization for the observation.	REQUIRED.
Comment	Subject's description of the event.	Maximum characters: 800.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.
Medication Given		
Medication	A type-ahead list containing all active medications with a term type of Conmed from the Setup - Medical Terms page.	If you provide a Dose, Unit, or Route, you must provide a Medication. The conmeds that you add to an observation appear on the Conmeds tab when you view an AE form (Clinical Trials - CT Studies - AEs tab).
Indication	Reason why you are administering the concomitant medication.	

Field	Description	Notes
Dose	Amount of the medication that was dispensed.	
Route	A drop-down list with all active routes with a term type of Conmed Route from the Setup - Medical Terms page.	

4   Click **SAVE**.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

C H A P T E R 1 4
Pooling a sample

In this chapter

Tasks: Clinical Data Entry - Pooling page

Typically used for urine or feces samples, the Pooling page uses a simplified process that does not require you to separately draw and log a sample. In addition to the standard information that you provide on the Clinical Data Entry pages, you enter a pool barcode to ensure that you associate the pool with the correct subject. If you use a transfer container, you can optionally enter a Transfer Barcode.

- *Pooling a sample.* (on page 113)

Pooling a sample

1   From the main menu, select **Clinical Data Entry > Pooling**.

    The Pooling page appears.

2   Scan or type the barcode of the vessel that contains the sample in the **Pool Barcode** field.

3   Click the Clock icon to enter the date and time.

    For more information, see *About updating the date and time for an event.* (on page 41)

4   In the first **Sub/Screen No.** field, scan the barcode or enter the ID number of the subject or candidate from whom the sample was collected.

    For more information, see Rules for entering Sub/Screen numbers.

5   Fill in the remaining fields, and click **SAVE**.

Field descriptions for the Pooling page

Field	Description	Notes
Pool Barcode	Barcode of the sample to be pooled. The barcode must fulfill the following requirements: • It is associated with a scheduled PK event. • It has an event status of In Progress. • If it is associated with a sample that has been logged, the sample has not been aliquoted.	REQUIRED. After you enter a value, the read-only Transfer BC field in the header displays one of the following values: • If the barcode is associated with pooling events, the barcode from the most recent pooling event with a non-blank vessel barcode appears. • If the Pool Barcode is not associated with any pooling events, or if a Transfer BC was not entered for any of those events, then the CDE Pooling Barcode printed from the CT Studies > Events - Scheduled screen is displayed • Otherwise, a default value is generated. An error appears if Allow CDE Pooling is not selected (on page 47) for the sample type associated with the barcode on the CT Studies - Setup - PK Lab page - Pooling section. A warning appears if another in-progress scheduled PK event has not been aliquoted and is associated with the same study, group, period, subject/candidate, and sample type as the current pool barcode.
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	REQUIRED. Maximum characters: 30. For more information, see Rules for entering Sub/Screening numbers.

Field	Description	Notes
Transfer BC	Barcode of the vessel into which samples are pooled. The barcode must be one of the following values: • The value from the read-only Vessel BC in the header. • An ad hoc barcode that does not already exist. • A barcode that has been used in a pooling event for the current pool barcode.	Maximum characters: 30. If you scan the barcode, this field is filled in. Otherwise, you must type the barcode. If the Vessel Barcode is associated with a locked study, group, and period, an error occurs, and all buttons and entry fields are read-only.
Date Time	Date and time of the event.	REQUIRED. Click the clock to update the time and date after you have taken the dose. For more information, see *About updating the date and time for an event.* (on page 41)
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

An entry is recorded in the CT Change Log with a source of Create EDC Event.

When you click **SAVE**, the event is considered to use the correct pooling interval if:

• The Date and Time entered is later than or equal to the Expected Time of the Pool Barcode, and

• Either the Date and Time entered is earlier than the Expected Time of the next scheduled event associated with the same sample type as the Pool Barcode, or the Pool Barcode is the last scheduled event for the sample type

If the correct pooling interval is not used, a warning message appears.

Generating and printing a barcode for pooling a sample

Prerequisite: Configure a CDE pooling label on the CT Studies - Setup - Labels page.

1   From the main menu, select **Clinical Data Entry > Pooling**.

    The Pooling page appears.

2   In the Pool Barcode field, scan or type a value.

    Requirements for the Pool Barcode field

Field	Description	Note
Pool Barcode	Barcode of the sample to be pooled. The barcode must fulfill the following requirements: • It is associated with a scheduled PK event. • It has an event status of In Progress. • If it is associated with a sample that has been logged, the sample has not been aliquoted.	REQUIRED. After you enter a value, the read-only Vessel BC field in the header displays one of the following values: • If the barcode is associated with pooling events, the barcode from the most recent pooling event with a non-blank vessel barcode appears. • Otherwise, a default value is generated. An error appears if Allow CDE Pooling is not selected for the sample type associated with the barcode on the CT Studies - Setup - PK Lab page - Pooling section. A warning appears if another in-progress scheduled PK event has not been aliquoted and is associated with the same study, group, period, subject/candidate, and sample type as the current pool barcode.
Sub/Screen No.	Subject and screening number for the subject whose information you have entered.	REQUIRED. Maximum characters: 30. For more information, see *Rules for entering Sub/Screening numbers* (on page 45).

Field	Description	Note
Vessel BC	Barcode of the vessel into which samples are pooled. The barcode must be one of the following values: • The value from the read-only Vessel BC in the header. • An ad hoc barcode that does not already exist. • A barcode that has been used in a pooling event for the current pool barcode.	Maximum characters: 30. If you scan the barcode, this field is filled in. Otherwise, you must type the barcode. If the Vessel Barcode is associated with a locked study, group, and period, an error occurs, and all buttons and entry fields are read-only.
Date Time	Date and time of the event.	REQUIRED. Click the clock to update the time and date after you have taken the dose. For more information, see About updating the date and time for an event.
Countdown timer	Clock that counts down the time that is displayed on the Dose Clinic floor page after a valid Vessel Barcode and both Sub/Screen fields are entered.	For more information, see About updating the date and time for an event.
Comment	Preconfigured or freeform comment about the entry.	For more information, see About adding comments.
EVENTS button	Opens the Event History dialog box after you type a valid Sub/Screen No.	For more information, see Viewing nearby and historical events.

3   Click **LABELS**.

The barcode is associated with the sample in the Pool Barcode field.

After printing the barcode, you can scan it into the Vessel BC field while pooling a sample on the Clinical Data Entry - Pooling page.

Reports

In this appendix

Tasks: View Reports page

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

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

- **LabPas Report**—For use with all modules.

- **Change Log**—Describes security and user additions and modifications.

- *Viewing the list of available reports* (on page 128)

- *Viewing a report* (on page 129)

- *Creating a new report* (on page 131)

- *Deleting a report* (on page 134)

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 135).

- *Deleting a report group* (on page 136).

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 129).

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

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

Creating a new report

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

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

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

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

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

3   Fill in the fields.

Field descriptions for the View Reports - Edit page

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

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

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 131), or *view an existing report* (on page 129).

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.

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 141).

- *Printing an auto-generated barcode* (on page 142).

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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