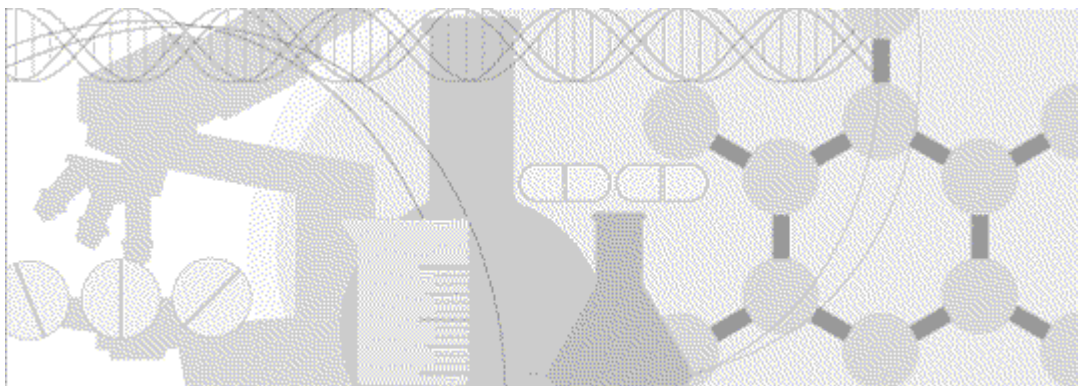


Clinical Trial Design and Resource Management Guide

Oracle[®] Health Sciences LabPas
Release 3.1



ORACLE[®]

Copyright © 2008 - 2013, Oracle and/or its affiliates. All rights reserved.

The Programs (which include both the software and documentation) contain proprietary information; they are provided under a license agreement containing restrictions on use and disclosure and are also protected by copyright, patent, and other intellectual and industrial property laws. Reverse engineering, disassembly, or decompilation of the Programs, except to the extent required to obtain interoperability with other independently created software or as specified by law, is prohibited.

The information contained in this document is subject to change without notice. If you find any problems in the documentation, please report them to us in writing. This document is not warranted to be error-free. Except as may be expressly permitted in your license agreement for these Programs, no part of these Programs may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose.

If the Programs are delivered to the United States Government or anyone licensing or using the Programs on behalf of the United States Government, the following notice is applicable:

U.S. GOVERNMENT RIGHTS Programs, software, databases, and related documentation and technical data delivered to U.S. Government customers are "commercial computer software" or "commercial technical data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, use, duplication, disclosure, modification, and adaptation of the Programs, including documentation and technical data, shall be subject to the licensing restrictions set forth in the applicable Oracle license agreement, and, to the extent applicable, the additional rights set forth in FAR 52.227-19, Commercial Computer Software -- Restricted Rights (June 1987). Oracle USA, Inc., 500 Oracle Parkway, Redwood City, CA 94065.

The Programs are not intended for use in any nuclear, aviation, mass transit, medical, or other inherently dangerous applications. It shall be the licensee's responsibility to take all appropriate fail-safe, backup, redundancy and other measures to ensure the safe use of such applications if the Programs are used for such purposes, and we disclaim liability for any damages caused by such use of the Programs.

The Programs may provide links to Web sites and access to content, products, and services from third parties. Oracle is not responsible for the availability of, or any content provided on, third-party Web sites. You bear all risks associated with the use of such content. If you choose to purchase any products or services from a third party, the relationship is directly between you and the third party. Oracle is not responsible for: (a) the quality of third-party products or services; or (b) fulfilling any of the terms of the agreement with the third party, including delivery of products or services and warranty obligations related to purchased products or services. Oracle is not responsible for any loss or damage of any sort that you may incur from dealing with any third party.

Oracle is a registered trademark of Oracle Corporation and/or its affiliates. Other names may be trademarks of their respective owners.

This documentation may include references to materials, offerings, or products that were previously offered by Phase Forward Inc. Certain materials, offerings, services, or products may no longer be offered or provided. Oracle and its affiliates cannot be held responsible for any such references should they appear in the text provided.

Contents

About this guide	xi
Overview of this guide.....	xii
Audience	xii
Documentation	xiii
If you need assistance.....	xv
Part 1: Introduction	1
Chapter 1 Getting started	1
The LabPas application.....	2
Users, permissions, and roles.....	3
Navigation.....	4
Main menu.....	4
Page heading.....	5
Data frame.....	5
Logging on.....	7
Logging off.....	8
Changing the contents of the data grid.....	9
Filtering grid data.....	10
Setting a home page.....	11
Creating a bookmark.....	12
Deleting a bookmark.....	13
Working with messages	14
Reading a message.....	14
Sending a message	14
Deleting a message.....	15
Adding a message group	15
Editing a message group	15
Deleting a message group.....	16
Part 2: Resource Management	17
Chapter 2 Resource management	19
Resource Management module.....	20
Clinics.....	21
Tasks: Clinics page	21
Creating a clinic.....	21
Editing the properties of a clinic	22
Deleting a clinic	22
Studies.....	23
Tasks: Studies page.....	23
Creating a study	23
Deleting a study	25
LabPas CT module study properties copied to a new study	25
LabPas Recruiting module study properties copied to a new study.....	26
Study properties	27
Tasks: Study - Properties page (Resource Management module).....	27
Editing the properties of a study	27
Granting external access to a study.....	29

Study setup (Resource Management)	30
Tasks: Study - Setup page.....	30
Configuring study approval comments	30
Creating and editing a study part	31
Assigning a facility and sample type to a lab	31
Deleting a study part	32
Deleting the association between a facility, sample type, and lab.....	33
Study groups	34
Tasks: Study - Groups page.....	34
Adding and editing a group	34
Adding group data.....	35
Removing a group from a study	36
Payments	37
Study - Payments page.....	37
Tasks: Study - Payments Setup page.....	38
Adding a payment.....	38
Editing a payment.....	39
Deleting a payment	39
Changing the review status of a payment.....	40
Tasks: Study - Payments Review page	41
Adding a volunteer payment	41
Editing a volunteer payment	42
Deleting a volunteer payment	43
Changing the review status of a volunteer payment	43
Clinic schedules.....	45
Clinic Schedule page	45
Tasks: Clinic Schedule page.....	46
Calculation of clinic days.....	46
Filtering the Clinic Schedule page	46
Assigning clinics to time periods	47
Clearing clinic assignments	48
Staff and shift assignment	49
Shift Assignment - Shifts page	49
Tasks: Shift Assignment page.....	50
Creating a shift	50
Clearing a shift assignment from an event.....	51
Adding an event to a shift.....	51
Assigning staff to a shift.....	51
Removing a staff assignment from a shift	52
Viewing staff assignment details.....	52
Viewing the status of staff assignments.....	53
Locking and unlocking a staff assignment.....	53
Assigning a clinic to and removing a clinic from an event	53

Part 3: Designing a clinical trial 55

Chapter 3 Event types in a study 57

Event Types page.....	58
Tasks: Event Types page.....	59
Adding and editing an event type	60
Deleting an event type	61

Chapter 4 Study properties in the LabPas CT module 63

CT Studies page.....	64
Tasks: CT Studies page.....	65

Selecting a study to work with.....	66
Tasks: Study - Properties page.....	67
Editing study properties	68
Locking and unlocking a study.....	71
Adding and editing a study team member.....	72
Deleting study team members	73
Allowing users to view the study	74

Chapter 5 Setting up elements of a study 75

Tasks: Study - Setup page.....	76
Test panels in a study.....	77
Tasks: Study - Setup - Panels page	77
Adding a test panel to a study.....	77
Removing a test panel from a study.....	80
Refreshing a test panel for a study	80
Clinical labs in a study.....	81
Study - Setup - Clin Lab page.....	81
Tasks: Study - Setup - Clin Lab page	81
Adding a sample type to a Clinical Lab	81
Removing a sample type from the Clin Lab settings	81
PK Lab setup in a study.....	82
Study - Setup - PK Lab page	82
Tasks: Study - Setup - PK Lab page.....	82
Adding a sample type to the PK Lab.....	82
Setting PK sample type parameters.....	82
Removing a sample type from the PK Lab	87
Forms setup in a study.....	88
Tasks: Study - Setup - Forms page.....	88
Specifying custom forms.....	88
Importing custom fields for AE forms	90
Removing a form with custom fields for AE forms	90
Form events logging	90
Events setup in a study.....	91
Study - Setup - Events page.....	91
Events and event plans.....	91
Prerequisites: Adding an event to a study	92
Tasks: Study - Setup - Events page	92
Adding a Dose event to a study.....	92
Adding a PK Testing event to a study.....	99
Adding a Clinical Testing event to a study.....	105
Adding a Testing event to a study.....	111
Adding an Other event to a study	117
Approving events in a study.....	122
Copying an event plan in a study.....	123
Editing an event in a study	123
Deleting an approved or unapproved event from a study	138
Treatments in a study.....	139
Tasks: Study - Setup - Treatments page	139
Adding a treatment to a study.....	139
Editing a treatment.....	140
Removing a treatment from a study.....	141
Adding a sequence to a study.....	141
Editing a sequence.....	142
Removing a sequence from a study.....	143
Labels setup in a study.....	144
Tasks: Study - Setup - Labels page	144
Label types and categories	144

Configuring study labels.....	145
Addresses in a study.....	147
Tasks: Study - Setup - Addresses page.....	147
Adding and editing a shipping address.....	147
Deleting a shipping address from a study.....	148
AE setup in a study.....	149
Tasks: Study - Setup - AEs page.....	149
Adding and removing a treatment related.....	149
Adding and removing an action taken.....	150
Adding and removing a severity.....	150
Adding and removing a significance.....	151
Adding and removing an outcome.....	151
Selecting the custom fields to appear on an AE form.....	152
Other elements in a study.....	153
Study - Setup - Other page.....	153
Tasks: Study - Setup - Other page.....	153
Adding and removing a visit.....	153
Adding and removing a qualifier.....	154

Chapter 6 Participants and candidates in the LabPas CT module 157

Study - Participants - Candidates page.....	158
Tasks: Study - Participants - Candidates page.....	158
Candidates in the CT module.....	158
Adding a candidate to a study.....	161
Viewing existing recruiting data for a candidate.....	164
Approving a candidate in a study.....	166
Dropping a candidate in a study.....	167
Editing a candidate in a study.....	167
Deleting a candidate from a study.....	172
Printing candidate labels in a study.....	172
Renumbering candidates in a study.....	173
Study - Participants - Subjects page.....	175
Tasks: Study - Participants - Subjects page.....	175
About subjects and scheduling.....	175
Adding a subject to a study.....	175
Approving and undoing approval of a subject.....	177
Editing a subject.....	177
Deleting a subject from a study.....	179
Printing subject labels in a study.....	179

Chapter 7 Scheduled events in a study 181

Tasks: Study - Events - Schedule page.....	182
About schedules and events.....	183
How a schedule of events is created.....	183
Example of time slots and expected time.....	183
Event status for different event types.....	184
Colors used in the Scheduled Events table.....	185
Rules for saving an event.....	185
About deleting events.....	186
About scheduling and rescheduling events.....	186
Creating a schedule in a study.....	187
Rescheduling events in a study.....	189
Changing the status of an event.....	192
Printing study labels.....	196

Chapter 8 Data events in a study	199
Tasks: Study - Events - Data page.....	200
Exported data.....	201
Viewing data for any event.....	202
Approving an event.....	203
Unapproving an event.....	205
Editing a scheduled Draw event.....	206
Editing an ad hoc Draw event.....	209
Editing a scheduled Testing event.....	211
Editing an ad hoc Testing event.....	215
Editing a scheduled Other event.....	219
Editing an ad hoc Other event.....	221
Editing an AE observation or non-AE observation.....	223
Editing a Dose event.....	226
Reclassifying an AE or non-AE observation.....	227
Exporting study event data.....	228
Batch approving event data.....	229
Chapter 9 Study samples	231
Sample data.....	232
Study - Samples - Samples page.....	232
Tasks: Study - Samples - Samples page.....	232
Permissions needed for sample status changes.....	233
Viewing sample data.....	233
Approving a sample.....	234
Unapproving a sample.....	235
Editing sample data for scheduled events.....	236
Editing sample data for ad hoc events.....	240
Changing the event status of a sample.....	244
Batch approving sample data.....	246
Aliquots.....	248
Tasks: Study - Samples - Aliquots page.....	248
Cancelling aliquots.....	248
Samples in boxes.....	249
Tasks: Study - Samples - Boxes page.....	249
Viewing details of samples in boxes.....	249
Shipments.....	250
Tasks: Study - Samples - Shipments page.....	250
Editing a shipment.....	250
Cancelling a shipment.....	251
Chapter 10 Study labs in the LabPas CT module	253
Study - Labs page.....	254
Prerequisites: Working with clinical event results from the Study - Labs page.....	255
Tasks: Study - Labs page.....	256
About updating test results for clinical events.....	257
Viewing results for a clinical event.....	259
Approving a lab result.....	260
Unapproving a lab result.....	262
Editing results for a clinical lab.....	263
Importing results for a clinical event.....	267
Exporting results for a clinical event.....	268
Batch approving lab results.....	269
Chapter 11 Queries in the LabPas CT module	271
Study - Queries page.....	272

Tasks: Studies - Queries page	273
Viewing a query	274
Answering a query	275

Chapter 12 Adverse events and AE forms 277

Study - AEs page.....	278
Prerequisites: Working with AE forms	279
Tasks: Study - AEs page	280
About AE forms	281
About approved AE forms.....	281
About editing AE forms on the Study - AEs page	281
Security permissions for working with AE forms	281
Viewing an AE form	282
Approving an AE form	287
Unapproving an AE Form.....	289
Batch approving AE forms.....	290
Adding an AE form.....	291
Editing an AE form.....	296
Associating an AE observation with an AE form	301
Resolving an AE form	302
Deleting an AE form.....	303

Chapter 13 Study metrics 305

Tasks: Study - Metrics page.....	306
Locking and unlocking a group/period.....	307
Releasing and undoing the release of a group/period.....	308

Chapter 14 Barcode identification 309

Barcode Identification page	310
Tasks: Barcode Identification page.....	311
Viewing vessel information associated with a barcode ID.....	312
Printing a CT label for a vessel associated with a barcode.....	313

Chapter 15 PK Lab Schedule 315

PK Lab Schedule page	316
About samples in the PK Lab schedule.....	317
Filter selections	317
Conditions for samples to appear.....	317
Samples that do not appear	317
Samples that are removed.....	317
Tasks: PK Lab Schedule page.....	318
Viewing PK Lab schedule information.....	319

Chapter 16 Study schedule 325

Tasks: Study Schedule page.....	326
Viewing the study schedule.....	327

Part 4: Designing recruitment for a clinical trial 329

Chapter 17 Designing recruitment for a clinical trial 331

Studies in the LabPas Recruiting module	332
SR Studies page.....	332
Tasks: SR Studies page	332
Selecting a study.....	332
Study properties in the LabPas Recruiting module	333

Tasks: Study - Properties page in the LabPas Recruiting module	333
Editing study properties (Recruiting).....	333
Locking and unlocking a study	334
Setting up recruiting elements of a study.....	335
Study - Setup page.....	335
Study description and parameters.....	335
Panels for screening in the study	337
Clinical Labs for screening in a study	343
Screening forms in a recruiting study.....	344
Events setup for screening in a study	348
Email templates	362
Labels in a recruiting study	366
Screening visits and email addresses in a recruiting study.....	367
Restrictions for recruiting.....	370
Study - Restrictions page.....	370
Tasks: Study - Restrictions page	370
Data collection options descriptions.....	370
Data collection options for specific criteria types	371
Range and Date options and qualifiers.....	373
Adding a restriction.....	374
Approving a restriction.....	376
Deleting a restriction.....	376
Questionnaire	377
Study - Questionnaire page.....	377
Tasks: Study - Questionnaire page	377
Adding a question.....	377
Approving a question	379
Editing a question.....	380
Deleting a question.....	382
Importing a master question	383
Volunteers.....	384
Study - Volunteers page	384
Tasks: Study - Volunteers - Volunteers page.....	384
Notifying a volunteer.....	384
Cancelling notification of a volunteer.....	385
Reviewing eligibility of volunteers.....	385
Adding a volunteer to a study	393
Editing a volunteer's screening results.....	394
Importing volunteers	396
General practitioner information.....	397
Tasks: Study - GP page	397
Editing a volunteer's GP letter information	397
Printing GP address label for all volunteers	397
Exporting GP information	398
Scheduled events for screening.....	399
Tasks: Study - Events - Events page (Recruiting).....	399
Scheduling a screening event.....	399
Changing the status of a screening event to Not Started or Cancelled	400
Printing labels for screening events.....	401
Tasks: Study - Events - Data page (Recruiting)	402
Viewing data from a screening event.....	402
Approving a screening event.....	403
Unapproving a screening event.....	404
Batch approving screening events.....	405
Editing the results of a screening event.....	406
Labs in a recruiting study.....	411
Tasks: Study - Labs page	411

Viewing lab results from a screening event	411
Approving a lab result (recruiting)	412
Unapproving a lab result (recruiting)	413
Batch approving lab results (recruiting).....	414
Editing lab results	415
Changing the event status of a sample	418
Importing clinical lab results	419
Exporting clinical lab results	420

Appendix A Reports 421

Tasks: View Reports page	422
Tasks: Report Groups page	423
Report layout	424
LabPas CT reports.....	425
LabPas Recruiting reports	427
LabPas Resource Management reports.....	429
Viewing the list of available reports	430
Viewing a report.....	431
Creating a new report.....	433
Deleting a report.....	436
Adding and editing a report group	437
Deleting a report group	438
Printing a report.....	439

Appendix B Labels 441

Tasks: Labels page	442
Printing an existing barcode.....	443
Printing an auto-generated barcode.....	444

Index 445

About this guide

In this preface

Overview of this guide.....	xii
Documentation	xiii
If you need assistance.....	xv

Overview of this guide

The LabPas *Clinical Trial Planning and Design 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.

Audience

This guide is for everyone who uses the Oracle® Health Sciences LabPas application to design clinical trials and do other planning. This audience includes study coordinators, study managers, and other study setup staff.

Documentation

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

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

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

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

If you need assistance

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

Part 1: Introduction

CHAPTER 1

Getting started

In this chapter

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

The LabPas application

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

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

Users, permissions, and roles

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

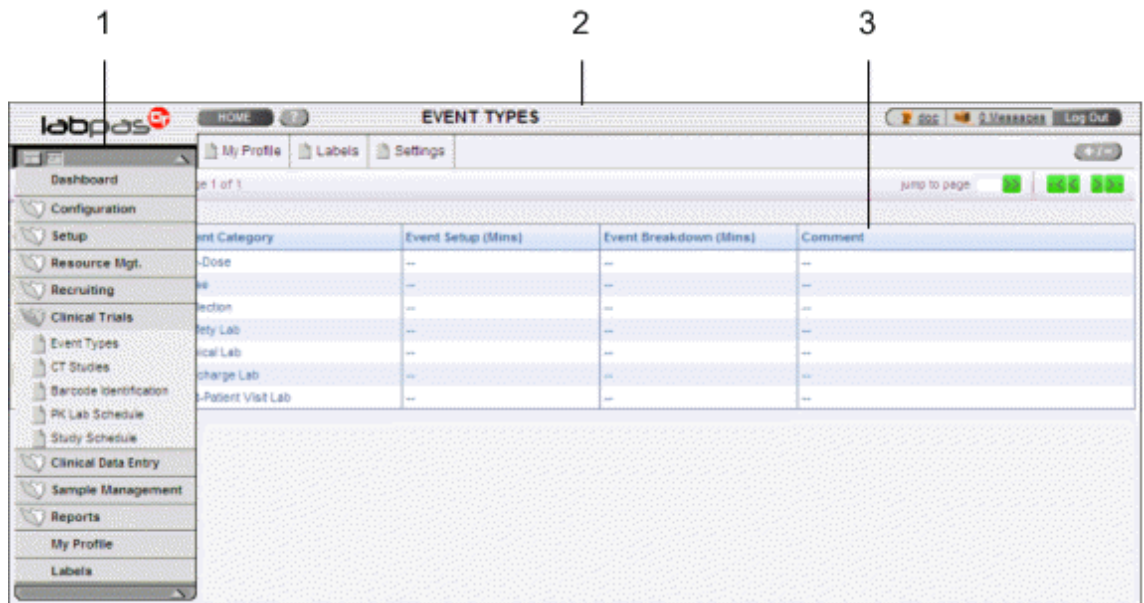
When a system administrator assigns you to a role, you are automatically assigned the permissions associated with that role.

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

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)



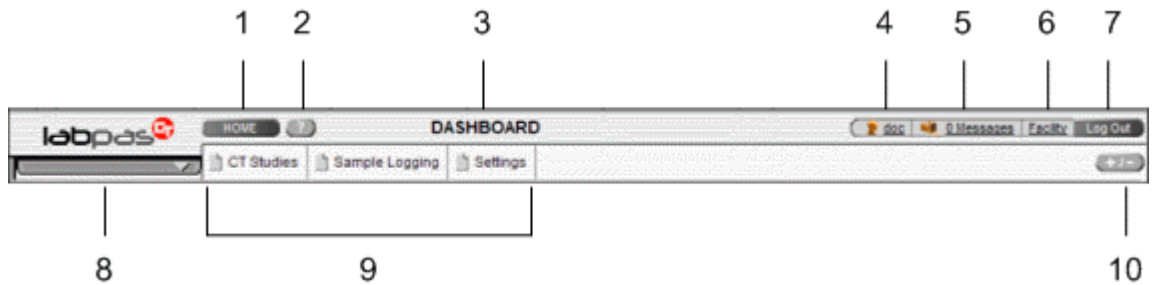
Main menu

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

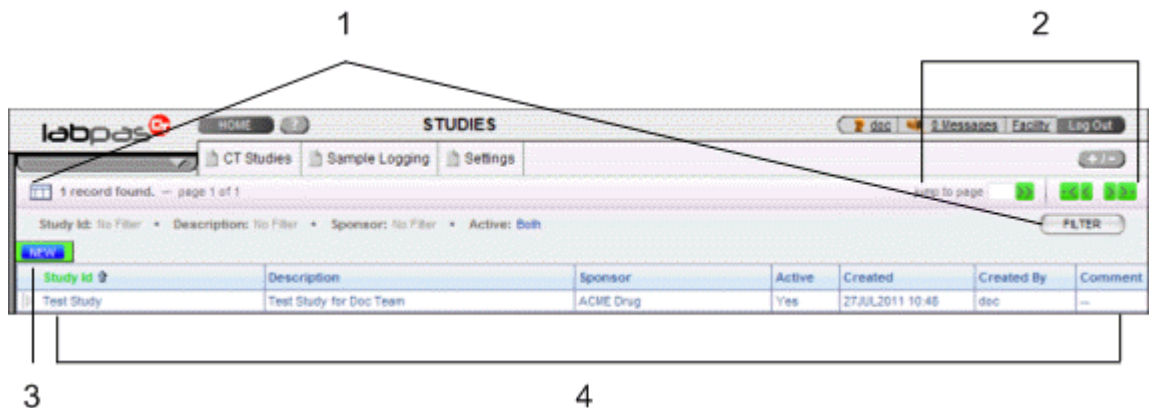
The page heading is similar on all LabPas pages.



- 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**.

Part 2: Resource Management

CHAPTER 2

Resource management

In this chapter

Resource Management module.....	20
Clinics.....	21
Studies.....	23
Study properties	27
Study setup (Resource Management).....	30
Study groups	34
Payments	37
Clinic schedules.....	45
Staff and shift assignment.....	49

Resource Management module

You use the Resource Management module to:

- Create studies for use in the LabPas CT module and LabPas Recruiting module.
- Manage global studies that are conducted across multiple facilities.
- Configure study groups and periods, as well as associated treatment dates.
- Define *clinics* (on page 21) or locations in your facility.
- Establish a high-level *clinic schedule* (on page 47) for long-term capacity planning.
- Generate a detailed *clinic schedule* (on page 47) for staff and clinic scheduling.
- Create *work shifts* (on page 50), assign staff, and view *status* (on page 52).

You create all studies in the Resource Management module. After you create a study, you perform configuration tasks in either the LabPas CT module or LabPas Recruiting module. Changes to clinics, studies, and staff assignment appear in the RM Change Log report.

Clinics

Tasks: Clinics page

On the Clinics page, you create clinics for a facility.

- *Creating a clinic* (on page 21).
- *Editing the properties of a clinic* (on page 22).
- *Deleting a clinic* (on page 22).

Creating a clinic

Prerequisite: You must configure settings.

- 1 From the main menu, select **Resource Management > Clinics**.

The Clinics page appears, listing the clinics in the facility.

- 2 Click **NEW**.

The New Clinic dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Clinics page

Field	Description	Notes
Clinic	Name of the clinic. The name must be unique to the facility.	REQUIRED.
Location	Location of the clinic in the facility.	REQUIRED. Maximum characters: 80.
Color	Color that represents the clinic.	REQUIRED. The color appears on the Clinic Schedule when you assign the clinic to a group of subjects for a specific study and period.
Comment	Comment about the clinic.	Maximum characters: 80.
Active	Whether the clinic is active when it is created.	

- 4 Click **SAVE**.

The clinic is saved with the properties you specified.

The New Clinic dialog box remains open so that you can create another clinic.

- 5 After you finish creating clinics, close the dialog box.

The new clinics appear in the table on the Clinics page.

Editing the properties of a clinic

Changes do not affect events that have already been assigned to a clinic.

- 1 From the main menu, select **Resource Management > Clinics**.

The Clinics page appears, listing the clinics in the facility.

You can filter the list by name, location, and active status.

- 2 Select one or more clinics, and click **EDIT**.

The Edit Clinic page appears.

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

Field descriptions for the Clinics page

Field	Description	Notes
Clinic	Name of the clinic. The name must be unique to the facility.	REQUIRED.
Location	Location of the clinic in the facility.	REQUIRED. Maximum characters: 80.
Color	Color that represents the clinic.	REQUIRED. The color appears on the Clinic Schedule when you assign the clinic to a group of subjects for a specific study and period.
Comment	Comment about the clinic.	Maximum characters: 80.
Active	Whether the clinic is active when it is created.	

If you selected more than one clinic, the Edit Clinic page shows the properties of the next clinic to edit.

After you save changes for the last clinic you selected to edit, the Clinics page appears.

Deleting a clinic

You cannot delete a clinic if it is assigned to an event with a status of Not Started in the LabPas CT module.

- 1 From the main menu, select **Resource Management > Clinics**.

The Clinics page appears, listing the clinics in the facility.

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

A confirmation dialog box appears.

- 3 Click **OK**.

Studies

Tasks: Studies page

On the Studies page, you create and view all studies. You can access studies created in the Resource Management module from either the LabPas CT module or the LabPas SR module.

- *Creating a study* (on page 23).
- *Editing the properties of a study* (on page 27).
- *Deleting a study* (on page 25).

Creating a study

You can base your new study on an existing study, or start from the beginning with a new study.

- 1 From the main menu, select **Resource Management > Studies**.

The Studies page appears.

- 2 Click **NEW**.

The New Study dialog box appears.

- 3 Fill in the fields.

Field descriptions for the New Study dialog box

Field	Description	Notes
Study Id	Name of the study. Each study must have a unique name.	REQUIRED. Maximum characters: 30.
Description	Description of the study.	Maximum characters: 80.
No. Periods	Number of periods in the study.	REQUIRED. Must be a number from 1 to 9.

- 4 Click **SAVE**.

The Properties page appears.

- 5 Fill in the fields and click **UPDATE**.

Field descriptions for the Properties page

Field	Description	Notes
Study Id	Name of the study.	
Active	Whether the study is active.	
Description	Description of the study.	

Field	Description	Notes
Comment	Comment about the study.	Required to lock or unlock a study.
Sponsor	Sponsor name.	To choose from a list of sponsors, click the magnifying glass button next to the field.
Contact	Contact name at the sponsor.	
Email	Email address of the contact.	Maximum characters: 80.
Telephone	Telephone number of the contact.	Maximum characters: 30.
Fax	Fax number of the contact.	Maximum characters: 30.
CT Settings: No of periods	Number of periods in the study.	<p>Must be a number from 1 to 99.</p> <p>If no treatments or visits in the CT study are associated with a period of higher value, you can change the value to a lower number.</p> <p>Note: If the study has been scheduled, this field is read-only.</p>
CT Settings: Based on Study	<p>To base the study on an existing study in the LabPas CT module, click the magnifying glass button next to the field, and select the study.</p> <p>Otherwise, leave this field blank.</p>	<p>For more information, see LabPas CT module study properties copied to a new study.</p> <p>Note: If the study has been scheduled, this field is read-only.</p>
SR Settings: Based on Study	<p>To base the study on an existing study in the LabPas Recruiting module, click the magnifying glass button next to the field, and select the study.</p> <p>Otherwise, leave this field blank.</p>	<p>For more information, see <i>LabPas Recruiting module study properties copied to a new study</i> (on page 26).</p> <p>Note: If the study has volunteers, this field is read-only.</p>
External Access	When selected, users from a second Active Directory or LDAP server can access the study in the LabPas DQ module.	<p>Click ADD and specify the User ID of the external user.</p> <p>For more information, see Granting external access.</p> <p>Note: If the study has volunteers, this field is read-only.</p>

Deleting a study

You cannot delete a study that has data associated with it.

- 1 From the main menu, select **Resource Management > Studies**.

The Studies page appears.

- 2 Select the study to delete.

The Properties tab appears.

- 3 Click **DELETE**.

A confirmation message appears.

- 4 Click **Yes**.

LabPas CT module study properties copied to a new study

When you create a new study from an existing study in the LabPas Clinical Trials module, the following study areas are copied to the new study:

Area	Properties copied
Setup data	<ul style="list-style-type: none"> • Setup (without approvals).
PK Lab setup page	<ul style="list-style-type: none"> • Pooling and Sample Information instructions for all sample types. • Pooling Sample Type. • Temperature. • Allow Temporary Storage. • Suppress from CT PK Sample Processing Log.
Study Properties	<ul style="list-style-type: none"> • Allow Multiple Time Points in a Box. • Centrifuge Speed.
Subjects	<ul style="list-style-type: none"> • Subjects. <p>Note: Groups to which the subjects are assigned must exist on the Study Groups page in the new study.</p>
Visits and treatments	<ul style="list-style-type: none"> • Visits and treatments. <p>Note: The visit or treatment must be associated with a period that is less than or equal to the value entered in the No. Periods field.</p>

LabPas Recruiting module study properties copied to a new study

When you create a new study from an existing study in the LabPas Recruiting module, the following fields are copied to the new study:

- Properties
- Setup (without approvals)
- Restrictions
- Questionnaire

Study properties

Tasks: Study - Properties page (Resource Management module)

On the Study page, you create groups, study parts, and payments.

- *Editing the properties of a study* (on page 27).
- *Granting external access to a study* (on page 28).
- *Working with study groups* (on page 34).
- *Working with study parts* (on page 30).
- *Working with study payments* (on page 38).

Editing the properties of a study

- 1 From the main menu, select **Resource Management > Studies**.

The Studies page appears, listing all studies.

- 2 In the table, select a study.

The Study page appears with the Properties tab selected.

- 3 Fill in the fields.

Field descriptions for the Properties page

Field	Description	Notes
Study Id	Name of the study.	
Active	Whether the study is active.	
Description	Description of the study.	
Comment	Comment about the study.	Required to lock or unlock a study.
Sponsor	Sponsor name.	To choose from a list of sponsors, click the magnifying glass button next to the field.
Contact	Contact name at the sponsor.	
Email	Email address of the contact.	Maximum characters: 80.
Telephone	Telephone number of the contact.	Maximum characters: 30.
Fax	Fax number of the contact.	Maximum characters: 30.

Field	Description	Notes
CT Settings: No of periods	Number of periods in the study.	If no treatments or visits in the CT study are associated with a period of higher value, you can change the value to a lower number. Note: If the study has been scheduled, this field is read-only.
CT Settings: Based on Study	To base the study on an existing study in the LabPas CT module, click the magnifying glass button next to the field, and select the study. Otherwise, leave this field blank.	For more information, see LabPas CT module study properties copied to a new study. Note: If the study has been scheduled, this field is read-only.
SR Settings: Based on Study	To base the study on an existing study in the LabPas Recruiting module, click the magnifying glass button next to the field, and select the study. Otherwise, leave this field blank.	For more information, see <i>LabPas Recruiting module study properties copied to a new study</i> (on page 26). Note: If the study has volunteers, this field is read-only.
External Access	When selected, users from a second Active Directory or LDAP server can access the study in the LabPas DQ module.	Click ADD and specify the User ID of the external user. For more information, see Granting external access. Note: If the study has volunteers, this field is read-only.

- 4 Click **UPDATE**.

Granting external access to a study

You can grant external access to allow users from a second Active Directory or LDAP server to access the study in the LabPas DQ module.

- 1 From the main menu, select **Resource Management > Studies**.

The Studies page appears.

- 2 In the table, select a study.

The Study page appears with the Properties tab selected.

- 3 In the External Access area, click **ADD**.

A dialog box appears.

- 4 Type the User ID of the user to be granted external access to the study in the LabPas DQ module. Select the Query Permission or Monitor Review Permission options to grant the user these permissions.

- 5 Click **SAVE**.

The user is saved, and the dialog box remains open.

- 6 If necessary, grant access to additional users.

- 7 After you finish adding users, close the dialog box.

Study setup (Resource Management)

Tasks: Study - Setup page

On the Study - Setup page, you perform the following tasks:

- In the Approval Comments section, configure approval comments.
- In the Study Parts section, configure study parts for the study.
- In the Lab Interfaces section, assign a facility and sample type to a lab.
- *Configuring study approval comments* (on page 30).
- *Creating and editing a study part* (on page 30).
- *Deleting a study part* (on page 32).
- *Assigning a facility and sample type to a lab* (on page 31).
- *Deleting the association between a facility, sample type, and lab* (on page 32).

Configuring study approval comments

To configure approval comments:

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.
The Study page appears with the Properties tab selected.
- 3 Select the **Setup** tab.
- 4 In the Approval Comments area, add or edit approval comments for:
 - a Study Data.
 - b Eligibility Review Form.
 - c Adverse Event Form.
 - d Sample Processing.
 - e Email Text.The fields accept up to 200 characters.
- 5 Click **UPDATE**.
An entry is recorded in the RM Change Log with a source of Study Setup.

Creating and editing a study part

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.
The Study page appears with the Properties tab selected.
- 3 Select the **Setup** tab.
- 4 To create a study part, in the Study Parts area, click **ADD**.
To edit a study part, click the ellipsis button (...) to the left of a study part in the Study Parts area.
The Study Part dialog box appears.
- 5 Fill in the fields and click **SAVE**.

Field descriptions for the New Study Part dialog box

Field	Description	Notes
Study Part	Name of the study part. Must be unique within the study.	REQUIRED.
Description	Description of the study part.	Maximum characters: 80.

Assigning a facility and sample type to a lab

Prerequisites:

- Add a facility, and associate one or more lab interfaces with it.
- Create a study part in a study.
- Add a group to a study.
- Add a sample type for either a *Clinical Lab* (on page 81) or a PK Lab in a study.

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.
The Study page appears with the Properties tab selected.
- 3 Select the **Setup** tab.
- 4 To assign sample types and facility to a specific lab, click **ADD** in the Lab Interfaces area.
or
To edit the assignments of samples types and facilities for a lab, click the ellipsis button (...) to the left of an interface in the Lab Interfaces area.
The Lab Interface dialog box appears.
- 5 Fill in the fields and click **SAVE**.

Field descriptions for the Lab Interface dialog box

Field	Description	Notes
Facility	Facility for which you are specifying a clinical lab interface.	REQUIRED. Lists all facilities associated with groups in the study.
Sample Type	Sample type for which you are specifying a clinical lab interface.	REQUIRED. Lists all sample types associated with the study on the following pages: <ul style="list-style-type: none"> • <i>Clinical Trials - CT Studies - Setup - Clin Lab</i> (on page 81). • Clinical Trials - CT Studies - Setup - PK Lab.
Lab	Lab to use for all samples of the specified sample type in the selected facility. The ellipsis button (...) allows you to choose from the lab interfaces that were configured for the selected facility.	REQUIRED. You must select an option from the Facility drop-down list before you can select an option from the Lab drop-down list.

Deleting a study part

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.
The Study page appears with the Properties tab selected.
- 3 Select the **Setup** tab.
- 4 In the Study Parts area, click the **X** to the left of a study part.
A confirmation dialog box appears.
- 5 Click **OK**.

Deleting the association between a facility, sample type, and lab

An entry is recorded in the RM Change Log with a source of Study Setup.

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.
The Study page appears with the Properties tab selected.
- 3 Select the **Setup** tab.
- 4 In the Lab Interfaces area, click the **X** to the left of a lab interface.
A confirmation dialog box appears.
- 5 Click **OK**.

Study groups

Tasks: Study - Groups page

On the Study - Groups page, you view the groups that are in a study. A study can contain one or more groups. Each group is associated with a facility and a specified number of subjects and alternates.

If a study is created based on a LabPas CT module study, approved subjects assigned to the group in the source study are copied to the current study.

- *Adding and editing a group* (on page 34).
- *Adding group data* (on page 35).
- *Removing a group from a study* (on page 36).

Adding and editing a group

- 1 From the main menu, select **Resource Management > Studies**.

The Studies page appears.

- 2 In the table, select a study.

The Study page appears with the Properties tab selected.

- 3 Select the **Groups** tab.

- 4 To add a group, click **ADD**.

To edit a group, in the group to edit, click **EDIT**.

The Group dialog box appears.

- 5 Fill in the fields.

Field descriptions for the Group dialog box

Field	Description	Notes
Group	Name of the group. The name must be unique in the study.	REQUIRED. Maximum characters: 25. If you modify the group after saving, the change appears in both the LabPas CT module and the LabPas Recruiting module.
Facility	Facility to which the group is associated. Options include blank and all facilities.	REQUIRED.

Field	Description	Notes
Study Part	Study part to which the group is associated. Options include blank and all study parts configured for the study on the Study - Setup page.	REQUIRED.
No. Subjects	Number of subjects in the group.	REQUIRED.
No. Alternates	Number of alternates in the group.	REQUIRED.
Note: When you edit a group, if a subject or candidate is associated with the group in the LabPas CT module, or if a volunteer is associated with the group in the LabPas Recruiting module, you cannot edit Group and Facility.		

- 6 Click **SAVE**.

The changes appear on the page. Each row in the table represents a period.

Adding group data

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.
The Study page appears with the Properties tab selected.
- 3 Select the **Groups** tab.
- 4 Fill in the fields for the group for which you want to provide data.

Field descriptions for the Study - Groups page

Field	Description	Notes
Arrival Date	Click the calendar button next to the field and specify an arrival date.	Required to determine the schedule and for the study, group, and period to appear in the schedule.
No. Clinic Days	Number of clinic days.	Required to determine the schedule, and for the study, group, and period to appear in the schedule.
Dose Day	Number of days from the arrival date when the dose is given. If the value is 1, the dose is given on the arrival day.	
Dose Time of day	Time period when the dose is given.	
Outpatient Days	Number of outpatient days.	Required to determine the schedule.

- 5 Click **UPDATE**.

Removing a group from a study

You cannot remove a group from a study if either of the following is true:

- A subject or candidate is associated with the group in the LabPas CT module.
- A volunteer is associated with the group in the LabPas Recruiting module.

1 From the main menu, select **Resource Management > Studies**.

The Studies page appears.

2 In the table, select a study.

The Study page appears with the Properties tab selected.

3 Select the **Groups** tab.

4 For the group to remove, click **REMOVE**.

A confirmation message appears.

5 Click **OK**.

Payments

Study - Payments page

The Study - Payments page has two options:

- On the Study - Payments Setup page, you configure clinical and screening events for payments to volunteers.

You can set up your study to include payments to volunteers for their participation in certain screening and clinical events. In addition, you can specify whether volunteers should also be reimbursed for their travel.

After payments are set up and approved, volunteers are paid automatically.

- On the Study - Payments Review page, you enter and manage individual volunteer payments for specific screening and clinical events.

On this page, you view and manage volunteer payments that were created automatically based on payment events that were created and approved on the Payments Setup page.

Requirements for setting up payments

To set up automatic payments to volunteers, the following fields are required.

- When specifying facility settings (in the *Administration Guide*):
 - Max. Stipend Payment.
 - Currency.
 - Max Travel Distance (if travel is to be reimbursed).
- When specifying identification information for a volunteer (in the *Recruiting User Guide*):
 - Travel Distance (if travel is to be reimbursed).

Calculation of travel reimbursement

Travel reimbursement is calculated as follows:

$(\text{Distance} * 2) * \text{Travel reimbursement rate on the Facility Settings page}$

where Distance is the lesser of:

- The value entered in **Travel Distance** on the Volunteers - Personal - Demographics page for the volunteer.
- The value entered in **Max. Travel Distance** on the Facility Settings page.

Tasks: Study - Payments Setup page

- *Adding a payment* (on page 38).
- *Editing a payment* (on page 39).
- *Deleting a payment* (on page 39).
- *Changing the review status of a payment* (on page 40).

Adding a payment

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.
The Study page appears with the Properties tab selected.
- 3 Select the **Payments** tab.
The Payments Setup page appears.
- 4 Click **NEW**.
The New Payment dialog box appears.
- 5 Fill in the fields.

Field descriptions for the New Payment dialog box

Field	Description	Notes
Facility	Drop-down list of facilities assigned to a group in the current study.	REQUIRED.
Event Class	<ul style="list-style-type: none"> • Clinical (default)—Select from the list of approved clinical events in the study. • Screening—Select from the list of approved screening events in the study. 	REQUIRED. Select an option, and then select a specific event of that type.
Amount	Amount of the payment.	REQUIRED. Value cannot exceed the maximum stipend payment for the facility.
Reimburse Travel	Select if travel is reimbursed.	

- 6 Click **SAVE**.
The payment is added to the table on the Payments Setup page, and a record is added to the RM Change Log report with Payments Setup as the source of the change.

Editing a payment

You must have the Study Setup function permission to edit payment records.

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.
The Study page appears with the Properties tab selected.
- 3 Select the **Payments** tab.
The Payments Setup page appears.
- 4 Select one or more payments and click **EDIT**.
The Edit Payment dialog box for the first selected payment appears.
- 5 Fill in the fields.

Field descriptions for the Edit Payment dialog box

Field	Description	Notes
Facility	Facility in the current study for which the payment applies.	READ-ONLY.
Event Class	Clinical or screening event to which the payment applies.	READ-ONLY.
Amount	Amount of the payment.	REQUIRED. Value cannot exceed the maximum stipend payment for the facility.
Reimburse Travel	Select if travel is to be reimbursed.	

- 6 In the Approval area, type your User ID, password, and a Comment, and click **Apply**.
- 7 Click **SAVE**.
The payment is updated in the table on the Payments Setup page, and a record is added to the RM Change Log report with Payments Setup as the source of the change.
If you selected more than one event, the next event appears. Fill in the fields.

Deleting a payment

You must have the Study Setup function permission to delete payment records.

You can delete a payment only if its review status is blank.

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.

The Study page appears with the Properties tab selected.

- 3 Select the **Payments** tab.

The Payments Setup page appears.

- 4 Select one or more payments, and click **DELETE**.

- If the Delete Payments dialog box appears, the review status for at least one of the selected payments is not blank.

- Enter the required approval information and click **APPLY**.

The review status changes to Revised, and the payments table on the Payments Setup page is updated.

- If a confirmation message appears, the review status for every selected payment is blank.

- Click **OK**.

The payments are deleted.

For each deletion, a record is added to the RM Change Log report with Payments Setup as the source of the change.

Changing the review status of a payment

Prerequisites:

- You must have the Approve Payments function permission to set the event review status to Approved.
- You must have either the Approve Payments or Review Payments function permission to set the event review status to Not Reviewed, Reviewed, or Revised.

- 1 From the main menu, select **Resource Management > Studies**.

The Studies page appears.

- 2 In the table, select a study.

The Study page appears with the Properties tab selected.

- 3 Select the **Payments** tab.

The Payments Setup page appears.

- 4 Select one or more payments and click **REVIEW**.

The Change Review Status dialog box appears.

- 5 Select a status, enter your approval information, and click **APPLY**.

The new status is applied to all selected payments. For each change, a record is added to the RM Change Log with **Payments Setup** as the source of the change.

Tasks: Study - Payments Review page

- *Adding a volunteer payment* (on page 41).
- *Editing a volunteer payment* (on page 42).
- *Deleting a volunteer payment* (on page 43).
- *Changing the review status of a volunteer payment* (on page 43).

Adding a volunteer payment

- 1 From the main menu, select **Resource Management > Studies**.
The Studies page appears.
- 2 In the table, select a study.
The Study page appears with the Properties tab selected.
- 3 Select the **Payments** tab > **Review** tab.
The Payments Review page appears.
- 4 Click **NEW**.
The New Volunteer Payment page appears.
- 5 Fill in the fields and click **SAVE**.

Field descriptions for the Payments Review page

Field	Description	Notes
Screening No.	Screening number for a subject associated with the study.	REQUIRED.
Event Class	<ul style="list-style-type: none"> • Clinical (default)—Select from the list of approved clinical events in the study. • Screening—Select from the list of approved screening events in the study. 	REQUIRED. Select an option, and then select a specific event of that type.
Event Date	Date and time of the event for which the volunteer is to be paid.	REQUIRED. Date must be in the past. Select the date from the calendar or enter it using the format specified on the Settings - Facility page.
Amount	Amount of the payment.	REQUIRED. Value cannot exceed the maximum stipend payment for the facility.
Reimburse Travel	Select if travel is reimbursed.	

The payment is added to the table on the Payments Review page, and a record is added to the RM Change Log with **Review Payments** as the source of the change.

Editing a volunteer payment

You must have the Study Setup function permission to edit volunteer payments.

- 1 From the main menu, select **Resource Management > Studies**.

The Studies page appears.

- 2 In the table, select a study.

The Study page appears with the Properties tab selected.

- 3 Select the **Payments** tab > **Review** tab.

The Payments Review page appears.

- 4 Select one or more payments, and click **EDIT**.

The Edit Volunteer Payment dialog box for the first selected volunteer payment appears.

- 5 Fill in the fields.

Field descriptions for the Edit Volunteer Payment dialog box

Field	Description	Notes
Screening No.	Screening number for the subject.	READ-ONLY.
Event Class	Clinical or screening event to which the payment applies.	READ-ONLY.
Event Date	Date and time of the event for which the volunteer is to be paid.	REQUIRED. Date must be in the past. Select the date from the calendar or enter it using the format specified on the Settings - Facility page.
Amount	Amount of the payment.	REQUIRED. Value cannot exceed the maximum stipend payment for the facility.
Reimburse Travel	Select if travel is to be reimbursed.	

- 6 In the Approval area, type your User ID, password, and a Comment, and click **Apply**.

- 7 Click **SAVE**.

The payment is updated in the table on the Payments Review page, and a record is added to the RM Change Log report with Review Payments as the source of the change.

If you selected more than one event, the next event appears. Fill in the fields.

Deleting a volunteer payment

You must have the Study Setup function permission to delete volunteer payments.

- 1 From the main menu, select **Resource Management > Studies**.

The Studies page appears.

- 2 In the table, select a study.

The Study page appears with the Properties tab selected.

- 3 Select the **Payments** tab > **Review** tab.

The Payments Review page appears.

- 4 Select one or more volunteer payments, and click **DELETE**.

- If the Delete Payments dialog box appears, the review status for at least one of the selected volunteer payments is not blank, or the payment was generated automatically for a screening or clinical event that was already processed.

- Enter the required approval information, and click **APPLY**.

The payments table on the Payments Review page is updated.

- If a confirmation message appears, all the selected records were created through the New Volunteer Payment dialog box and the review status for every selected volunteer payment is blank.

- Click **OK**.

The volunteer payments are deleted.

For each deletion, a record is added to the RM Change Log report with Review Payments as the source of the change.

Changing the review status of a volunteer payment

Prerequisites:

- You must have the Approve Payments function permission to set the event review status to Approved.
- You must have either the Approve Payments or Review Payments function permission to set the event review status to Not Reviewed, Reviewed, or Revised.

- 1 From the main menu, select **Resource Management > Studies**.

The Studies page appears.

- 2 In the table, select a study.

The Study page appears with the Properties tab selected.

- 3 Select the **Payments** tab > **Review** tab.

The Payments Review page appears.

- 4 Select one or more payments and click **REVIEW**.

The Change Review Status page appears.

- 5 Select a status, enter your approval information, and click **APPLY**.

The new status is applied to all selected payments. For each change, a record is added to the RM Change Log report with Review Payments as the source of the change.

Clinic schedules

Clinic Schedule page

On the Clinic Schedule page, you view active studies for the current facility. The page displays one row for each study, group, and period scheduled during the selected month.

The Clinic Schedule shows the number of subjects in each study, group, period, and facility on a given day. Each day has two parts, before noon and after noon. For capacity-planning purposes, you can assign a clinic to each part of each day.

The schedule is determined by information from the Study - Groups page for a study, group, and period:

- If the Arrival Date on the Study - Groups page is:
 - In the selected month—The study, group, and period combination appears for the study.
 - Not in the selected month—The study, group, and period combination appears for the study if any clinic days or outpatient visits fall in the selected month.
- If no study, group, and period combination exists for the selected month, an empty table appears.

Components on the page	
Component	Description
Rows	Rows are sorted by study, group, and period. Each row displays the Study ID, Group, Period, and a bar that represents the duration of the period for the group.
Bars in each row	<ul style="list-style-type: none"> • Each bar starts on the arrival date for the group and period. • The application calculates the length of the bar by adding the number of clinic days to the arrival date for the group and period. • For each day, the bar has sections for the number of subjects in the first half and second half of the day. • The numbers in each section represent the number of subjects and alternates expected for that period of the day.
Colors of sections in each bar	<p>The color associated with the clinic that is assigned to the AM and PM portion of each day determines the colors of each AM and PM section.</p> <ul style="list-style-type: none"> • If blank is selected, the section is blue. • If (No Selection) is selected, the section does not appear on the bar.

Tasks: Clinic Schedule page

- *Filtering the Clinic Schedule page* (on page 46).
- *Assigning clinics to time periods* (on page 47).
- *Clearing clinic assignments* (on page 47).

Calculation of clinic days

Calculation	How the value is calculated
Clinic days up to and including the dose day	The number of subjects and alternates for the group are added.
Clinic days after the dose day	The number of subjects for the group are added. An asterisk (*) after the value indicates an outpatient visit.

Note: If Before Noon is selected in the Dose Time of Day field on the Studies - Groups page for the group and period, the value for the second section of the dose day is the number of subjects in the group.

Filtering the Clinic Schedule page

- 1 From the main menu, select **Resource Management > Clinic Schedule**.
The Clinic Schedule page appears.
- 2 Click **FILTER**.
The Clinic Schedule Selection Criteria dialog box appears.
- 3 Select your filtering criteria, and click **Apply**.

Notes about specifying filtering criteria

Filter	Notes
Clinic	<ul style="list-style-type: none"> • A study, group and period appear only if the clinic has been assigned to at least one half-day period during the current month. • Bars appear only for half-day periods that are assigned to the clinic.

Filter	Notes
Assigned	<p>Yes:</p> <ul style="list-style-type: none"> • A study, group, and period appear only if at least one half-day period during the current month is assigned to a clinic. • Bars appear only for half-day periods that are assigned to a clinic. <p>No:</p> <ul style="list-style-type: none"> • A study, group, and period appear only if at least one half-day period during the current month is not assigned to a clinic. • Bars appear only for half-day periods that are not assigned.

Assigning clinics to time periods

Prerequisite: You must *create clinics for the facility* (on page 21).

You can assign a clinic to each half-day time period for a selected study, group, and period.

- 1 From the main menu, select **Resource Management > Clinic Schedule**.

The Clinic Schedule page appears, listing all study, group, and period combinations for the facility.

By default, the current month appears. Select another month using the calendar or the arrow buttons.

- 2 Select the checkboxes for one or more study, group, and period combinations, and click **ASSIGN**.

The Clinic Assignment dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Clinical Assignment dialog box

Field	Description
Day	Number of the outpatient visit day that is configured for the selected study, group, and period. Read only.
Before Noon	Clinic assigned to the time period.
After Noon	If you select (No Selection) , the Clinic Schedule page does not display any bar or data for the half-day time period.

- 4 Click **SAVE**.
- 5 If you selected more than one study, group, and period combination, use the Next and Previous arrow buttons to navigate to the next combination, and fill in the fields.

Clearing clinic assignments

- 1 From the main menu, select **Resource Management > Clinic Schedule**.
The Clinic Schedule page appears, listing all study, group, and period combinations for the facility.
- 2 Select the checkbox to the left of the study, group, and period combination for which clinic assignments are to be cleared.
- 3 Click **CLEAR**.
Days displayed in the current month are cleared.

Staff and shift assignment

Shift Assignment - Shifts page

On the Shift Assignment - Shifts page, you view the study events that have at least one collection with an event status of Not Started and that are scheduled to run in the current facility on the selected day. Each row represents an event for a particular study, group, and period combination.

A bar represents the duration of each event. Point to the bar to view the shifts and the clinic assigned to the event.

The Start Time and End Time for work shifts and events do not display seconds, even if an event associated with the work shift is configured with the Consider Seconds option selected on the CT Studies > Setup – Events page.

How times are calculated

Value	How it is calculated
Start time of a bar	Earliest scheduled time with a status of Not Started for the event minus the value in the Event Setup (Mins) field for the event category.
End time of a bar for post-dose events	Latest scheduled time with a status of Not Started for the event plus the value in the Event Breakdown (Mins) field for the event category.

Note: The start time and end time of a work shift are always calculated based on the entire duration of the assigned events, regardless of whether the shift is assigned to specific subjects or candidates.

Descriptions of the colors of bars

Bar color	Description
Blue	A shift is not assigned to all subjects and candidates associated with the event, and there is no conflicting event for any shift associated with the event.
Green	A shift is assigned to all subjects and candidates associated with the event, and there is no conflicting event for any shift associated with the event.
Red	The shift that is assigned to the event is also assigned to another event during the same time period.

Tasks: Shift Assignment page

- *Creating a shift* (on page 50).
- *Clearing a shift assignment from an event* (on page 51).
- *Adding an event to a shift* (on page 51).
- *Assign staff to shifts.* (on page 51)
- *Removing a staff assignment from a shift* (on page 52).
- *Viewing staff assignment details* (on page 52).
- *Viewing the status of staff assignments.* (on page 53)
- *Locking and unlocking a staff assignment* (on page 53).
- *Assigning a clinic to and removing a clinic from an event* (on page 53).

Creating a shift

You can create a shift from events that are associated with the same study and group. You can restrict a shift to include only specific subjects and candidates.

- 1 From the main menu, select **Resource Management > Staff Assignment**.

The Shift Assignment page appears with the Shifts tab selected, displaying information for today.

- 2 To select a different day, click the calendar button or the Next or Previous arrow buttons.
- 3 Select the checkboxes of the events to combine into a shift, and click **ASSIGN**.

The Staff Assignment page appears. The Select Shifts section lists all unlocked shifts that start on the selected day or the day before or after.

- 4 Click **ADD**.

The new shift appears in a row in the Select Shifts table. The Start Time and End Time default to midnight of the selected date and are updated after you save.

In the Shift Details area, the Select Subjects and Select Candidates areas list subjects and candidates that are associated with any of the events selected on the Shifts page that have a status of Not Started.

- 5 To restrict the shift to specific subjects or candidates:

- a In the Shift Details section, select **Assign: Events for Subject/Candidate**.

Checkboxes for subjects and candidates that are not already assigned to a shift are no longer read-only.

- b In the Select Subjects and Select Candidates lists, select the subjects and candidates to include in the shift. You must select at least one subject or candidate.

- 6 Click **SAVE**.

If the work shift results in a time period longer than eight hours after the events selected on the Shifts page are assigned, a warning appears.

- 7 If the warning appears, click **Continue** or **Cancel**.

The Shift Assignment page appears. The tooltip for each bar indicates the shift to which the time period is assigned.

- If you selected All Events, the shift is assigned to all subjects/candidates for all selected events on the Shifts page.
- If you selected Events for Subject/Candidate, the shift is assigned to all selected events for the specified subjects and candidates.
- If a shift is already assigned to an event, a second assignment is not created. Use the RM Staff Schedule report to view events assigned to users or the RM Administrative Staff Assignment report to view work shifts and staff assigned to events.

Clearing a shift assignment from an event

When you clear a shift assignment, you remove the event from the shift. The clinic assigned to the event is not affected.

- 1 From the main menu, select **Resource Management > Staff Assignment**.
- 2 Select the checkbox of the event from which you want to remove an event.
- 3 Click **CLEAR**.
A confirmation dialog box appears.
- 4 Click **OK**.

Adding an event to a shift

- 1 From the main menu, select **Resource Management > Staff Assignment**.
The Shift Assignment page appears.
- 2 Select the checkbox of the event to which to add to a shift.
- 3 Click **ASSIGN**.
The Staff Assignment page appears with a list of existing shifts.
- 4 Select the checkbox of the shift to which you want to add the event.
- 5 Click **SAVE**.

The Staff Assignment page closes. On the Shift Assignment page, the tooltip for the colored bar of the event shows the shift to which the event is assigned.

Assigning staff to a shift

Prerequisites:

- Configure facility, application, and global settings (in the *Administration Guide*).
- Set up the elements that are used in studies, such as users, instruments, storage devices, sample types, vessel types, and test panels (in the *Administration Guide*).
- **Create clinics** (on page 21).
- **Create a study**. (on page 23)

- Establish *event types* (on page 59), study properties, *study setup tasks* (on page 76), and an event plan.
 - Schedule the study.
- 1 From the main menu, select **Resource Management > Staff Assignment**.
The Shift Assignment page appears.
 - 2 Select the **Staff** tab.
The Staff page lists all work shifts that are for the current facility and that start today. User ID is blank if the shift has not been assigned.
 - 3 To view only staff that meet certain criteria, filter the list.
 - 4 Select the checkbox of a shift, and click **ASSIGN**.
The Staff Assignment page appears, listing users who meet the following criteria:
 - Are active in the current facility.
 - Have access to all studies associated with the selected work shifts or have the View All Studies permission.
 - Have permission to all clinic floor pages required to perform each event that is assigned to the selected work shift.
 - 5 Select the staff member to assign to the shift.
 - 6 Click **SAVE**.

Removing a staff assignment from a shift

- 1 From the main menu, select **Resource Management > Staff Assignment**.
The Shift Assignment page appears.
- 2 Select the **Staff** tab.
A list of all shifts appears.
User ID is blank if the shift is not assigned.
- 3 Select the shifts from which to remove a staff assignment.
- 4 Click **ASSIGN**.
The Staff Assignment page appears.
- 5 From the selection list, select the blank option.
- 6 Click **SAVE**.

Viewing staff assignment details

- 1 From the main menu, select **Resource Management > Staff Assignment**.
The Shift Assignment page appears.
- 2 In the table, select the checkboxes of one or more work shifts, and click **DETAILS**.

The Staff Assignment Details page appears, displaying details of all events assigned to each work shift record.

- 3 To return to the Staff page, click **CANCEL**.

Viewing the status of staff assignments

- 1 From the main menu, select **Resource Management > Staff Assignment**.

The Shift Assignment page appears.

- 2 Select the **Staff** tab.
- 3 Select the checkbox of a shift, and click **STATUS**.

The PK Time and Expected Time columns display seconds if the Consider Seconds option is selected for an event on the CT Studies > Setup – Events page.

Locking and unlocking a staff assignment

- 1 From the main menu, select **Resource Management > Staff Assignment**.

The Shift Assignment page appears.

- 2 Select the **Staff** tab.
- 3 Select the checkbox of a shift, and click **STATUS**.
- 4 Select or clear the **LOCKED** checkbox.

Assigning a clinic to and removing a clinic from an event

You can assign a clinic to one or more events.

- 1 From the main menu, select **Resource Management > Staff Assignment**.

The Shift Assignment page appears.

- 2 Select the checkboxes of one or more events, and click **CLINIC**.

The Clinic Assignment page appears.

- 3 Do one of the following:
 - To assign the clinic to the events, select a clinic name.
 - To remove the assigned clinic from the selected events, select **Blank**.
- 4 Click **SAVE**.

Part 3: Designing a clinical trial

CHAPTER 3

Event types in a study

In this chapter

Event Types page.....	58
Tasks: Event Types page	59
Adding and editing an event type.....	60
Deleting an event type.....	61

Event Types page

On the Event Types page, you view all event types set up in a facility. Event types and categories help to define study procedures and events.

Event categories help to group events and differentiate between them. You create event categories for event types. In addition, event type Other has default event categories (for example, Check-In, Check-Out, and Informed Consent) that you can use.

On the Event Types page, event types are sorted in the following order:

- Dose
- PK Testing
- Clinical Testing
- Testing
- Other
- Observation

Tasks: Event Types page

- *Adding and editing an event type* (on page 60).
- *Deleting an event type* (on page 61).

Adding and editing an event type

You cannot change the category or type of an event. Instead, you must delete the event type and create a new event with the new name.

Changes you make to Event Setup and Event Breakdown times do not affect events that are already scheduled.

- 1 From the main menu, select **Clinical Trial > Event Types**.

The Event Types page appears.

- 2 To add an event type, click **NEW**.

To edit an event type, select an event, and click **EDIT**.

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

Field descriptions for the Event Types page

Field	Description	Notes
Event Type	Event type that best describes your event.	REQUIRED. Default: Dose. After you create an event type, this field is read-only.
Event Category	Name for the event category. The Other event type has the default event categories of Check-In, Check-Out, Informed Consent, Volunteer Medical History, and Volunteer Demographics.	REQUIRED. Maximum characters: 30. Must be unique for the event type. After you create an event type, this field is read-only. The categories that you create for the Observation event type appear in the Category drop-down list when you record a non-AE observation.
Event Setup (Mins.)	Time in minutes required to set up the event.	Changes do not affect events that are already scheduled.
Event Breakdown (Mins)	Time in minutes to break down the event.	Changes do not affect events that are already scheduled.
Comment	Comment about the event type.	Maximum characters: 80.

Deleting an event type

You cannot delete a default event type or category. You cannot delete an event that is associated with a study.

- 1 From the main menu, select **Clinical Trial > Event Types**.
The Event Types page appears.
- 2 Select the checkboxes for one or more event types, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

CHAPTER 4

Study properties in the LabPas CT module

In this chapter

CT Studies page.....	64
Tasks: CT Studies page	65
Selecting a study to work with	66
Tasks: Study - Properties page.....	67
Editing study properties.....	68
Locking and unlocking a study	71
Adding and editing a study team member	72
Deleting study team members	73
Allowing users to view the study.....	74

CT Studies page

On the CT Studies page, you view all CT studies in which at least one group in the study is assigned to the current facility, as long as your role has the **View All Studies permission**. For more information, see **Users, roles, and access** (in the *Administration Guide*). The LabPas application can be configured to show all items in all facilities. For more information, see **Global Settings** (in the *Administration Guide*).

Recruiting studies in your facility appear if your license includes the LabPas Recruiting module.

You work with one study at a time. You create new studies in the **Resource Management** (on page 19) module.

Tasks: CT Studies page

Selecting a study to work with (on page 66).

Selecting a study to work with

Prerequisites:

- A study must be created in the Resource Management module.
- To view a study, you must have been granted access in the **User Access** section of the Properties page for the study, or have been granted the View all Studies security permission.

- 1 From the main menu, select **Clinical Trials > CT Studies**.

The CT Studies page appears.

- 2 Select a study.

The Study page appears with the Properties tab selected.

Tasks: Study - Properties page

On the Study - Properties page, you view descriptive information about the study, number of periods, packing settings, and centrifuge speed settings, as well as the study team members and users who can view the study.

- *Editing study properties* (on page 68).
- *Locking and unlocking a study* (on page 71).
- *Adding and editing a study team member* (on page 72).
- *Deleting study team members* (on page 73).
- *Allowing users to view the study* (on page 74).

Editing study properties

Prerequisites:

- A study must be created in the Resource Management module.
 - To view a study, you must have been granted access in the **User Access** section of the Properties page for the study, or have been granted the View all Studies security permission.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study.

The Study page appears with the Properties tab selected.

- 2 In the Properties section, fill in the fields.

Field descriptions for the Study - Properties page

Field	Description	Notes
Properties		
Study Id	Read-only fields that display the values entered for the study on the <i>Resource Management Study Properties page</i> (on page 27).	
Description		
No. Periods		
No. Parallel Subjects	Number of subjects that can receive treatment at the same time in the current study.	REQUIRED. Maximum: 9. Default: 1.
Vendor Labeled Transfer Tubes checkbox	<ul style="list-style-type: none"> • Selected—Transfer tubes used in the study are pre-labeled by the trial sponsor • Not selected—The application automatically generates barcodes in the Aliquoting task. 	
Allow Multiple Subjects in a Box	<ul style="list-style-type: none"> • Selected—Samples originating from more than one subject can be packaged together on the Sample Packing page. • Not selected—Samples from more than one subject in the study cannot be packaged together. 	For more information, see <i>Sample Packing</i> (in the <i>Sample Management Guide</i>).

Field	Description	Notes
Allow Multiple Aliquots in a Box	<ul style="list-style-type: none"> • Selected—Aliquots that originate from more than one sample can be packaged together on the Sample Packing page. • Not selected—Aliquots that originate from more than one sample cannot be packaged together. 	
Allow Multiple Time Points in a Box	<ul style="list-style-type: none"> • Selected—Samples that are taken during different time points can be packaged together on the Sample Packing page. • Not selected—Samples from more than one time point cannot be packaged together. 	
Study manager	Name of the study manager.	Maximum characters: 30, including comma, ampersand, and parentheses.
Comment	Comment about the study.	
Sponsor	Sponsor conducting the study.	
Contact	Contact person from the sponsor for this study protocol.	
E-mail	Sponsor's email address.	

- 3 To add one or more users to the study team:
 - a In the Study Team area, click **ADD**.
The New Study Team Member dialog box appears.
 - b Type the name and role of the user, and click **SAVE**.
 - c After you finish adding team members, close the dialog box.
- 4 To allow one or more users to view the study:
 - a In the User Access area, click **MODIFY**.
The User List dialog box appears, displaying users in the current facility.
 - b Select one or more users, and click **UPDATE**.

Note: Your changes do not affect users assigned to the study from other facilities. Users who have the View All Studies security permission can view the study without being listed in this section. Additionally, the user who created the study is selected by default.

- 5 In the **Properties** section, click **UPDATE**.

Locking and unlocking a study

Prerequisites:

- A study must be created in the Resource Management module.
- To view a study, you must have been granted access in the **User Access** section of the Properties page for the study, or have been granted the View all Studies security permission.
- You must have Manage Study Data function permission.

Locked studies display No in the Active column.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study.

The Study page appears, with the Properties tab selected.

- 2 To lock the study, click **LOCK**.

To unlock the study, click **UNLOCK**.

An approval dialog box appears.

- 3 In the Approval area, type your User ID, password, and a Comment, and click **Apply**.

Adding and editing a study team member

Prerequisites:

- A study must be created in the Resource Management module.
 - To view a study, you must have been granted access in the **User Access** section of the Properties page for the study, or have been granted the View all Studies security permission.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study.
The Study page appears with the Properties tab selected.
 - 2 To add a team member, in the Study Team section, click **ADD**.
To edit a team member, in the Study Team section, click the ellipsis button (...) for a team member.
The Study Team Member dialog box appears.
 - 3 Fill in the fields, and click **SAVE**.
If you edited a team member, the dialog box closes.
If you added a team member, the dialog box remains open for you to add additional members.
 - 4 After you finish adding members, close the dialog box.

Deleting study team members

Prerequisites:

- A study must be created in the Resource Management module.
 - To view a study, you must have been granted access in the **User Access** section of the Properties page for the study, or have been granted the View all Studies security permission.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study.
The CT Studies page appears.
 - 2 In the **Study Team** section, click the **X** to the left of a team member.
A confirmation dialog box appears.
 - 3 Click **OK**.

Allowing users to view the study

Prerequisites:

- A study must be created in the Resource Management module.
- To view a study, you must have been granted access in the **User Access** section of the Properties page for the study, or have been granted the View all Studies security permission.

Users who have the View All Studies permission can view the study. You do not need to list them in the User Access section.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study.
The study opens with the Properties tab selected.
- 2 In the **User Access** section, which lists the users who can view the study, click **MODIFY**.
The User List dialog box appears with a list of users from the current facility.
- 3 Select the checkboxes for users that you want to be able to view the study, and click **UPDATE**.
Names of selected users appear in the User Access section.
- 4 In the **Properties** section, click **UPDATE**.

CHAPTER 5

Setting up elements of a study

In this chapter

Tasks: Study - Setup page	76
Test panels in a study	77
Clinical labs in a study	81
PK Lab setup in a study.....	82
Forms setup in a study	88
Events setup in a study	91
Treatments in a study	139
Labels setup in a study	144
Addresses in a study	147
AE setup in a study.....	149
Other elements in a study.....	153

Tasks: Study - Setup page

Create the study in the Resource Management module, and define study properties.

Complete the tasks in the order listed.

- 1 *Setting up test panels* (on page 77).
- 2 *Setting up clinical labs* (on page 81).
- 3 *Setting up PK Labs* (on page 82).
- 4 *Setting up other elements* (on page 153).
- 5 *Setting up events* (on page 91).
- 6 *Setting up treatments* (on page 139).
- 7 *Setting up labels* (on page 144).
- 8 *Setting up addresses* (on page 147).

Test panels in a study

Tasks: Study - Setup - Panels page

On the Study - Setup - Panels page, you view the test panels assigned to a study. Individual tests are displayed, by panel, along with their reference ranges and demographic reference ranges for the current study.

- *Adding a test panel to a study* (on page 77).
- *Removing a test panel from a study* (on page 80).
- *Refreshing a test panel for a study* (on page 80).

Adding a test panel to a study

Prerequisites:

- Create the study in the Resource Management module, and define study properties.
 - Define *tests* and *test panels* (in the *Administration Guide*).
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Panels** category.

The Study - Setup - Panels page appears.

- 2 Click **ADD**.

A dialog box appears, listing the existing test panels of all event types that have not been assigned to the current study.

Note: Only active test panels appear in the list.

- 3 Select a test panel to add to the study.

The dialog box closes. The Panels page appears, with the name of the panel listed in the Panels section, and the tests for the panel in the Test Ranges section.

- 4 In the **Test Ranges** section, deselect the **Include** checkboxes for any tests that should not be included in the panel for this study.
- 5 Fill in the fields.

Field descriptions for the Study - Setup - Panels page

Component	Description	Notes
Panels section	All test panels that are assigned to the study.	You must assign a panel to the study if you want the panel to be available for ad hoc events.
Test Ranges section	Characteristics of the test panel that is selected in the Panels section.	Used to set study level reference ranges.

Component	Description	Notes
Include	<p>Selected—The test is included in the panel for this study.</p> <p>Not selected—The test is not included in the panel for this study. Reference Range and Demographic fields for the test are read-only.</p>	Default: Selected.
Optional	<p>Selected—Test is optional in this study.</p> <p>Not selected—Test is required in this study.</p>	<p>Default: Not selected.</p> <p>Tests that are marked optional in the test panel are not exported, but test results are imported if sent by the external lab.</p>
Editable	<p>Selected—Test is editable in this study. Imported test values can be manually edited on the Clinical Trials – CT Studies – Setup – Panels page.</p> <p>Not selected—Test is not editable in this study. Results are imported as-is and cannot be modified manually.</p>	The Editable checkbox is unchecked and disabled if the Include field is not checked.
Test	Value that was selected when the test was defined.	<p>READ-ONLY.</p> <p>For more information, see Tests (in the <i>Administration Guide</i>).</p>
Type	Value that was selected when the test was defined.	READ-ONLY.
Reference Range	<p>Reference range or reference value to use in the current study.</p> <p>This field is used for test types that support reference ranges.</p>	<p>Default: Values that were selected when the test was defined.</p> <p>You can edit these fields. New values you specify must fall within the Out of Range limits that were chosen when the test was defined.</p> <p>For more information, see Tests (in the <i>Administration Guide</i>).</p>
Demographic	Whether demographic reference ranges have been set up for this test.	Demographic reference ranges are not supported for Long Text, Text, List, Pos/Neg, and Pass/Fail type tests.

- 6 To edit or add a Demographic reference range for a test, click the ellipsis button (...) in the Demographic column.

The Edit Demographic Ranges dialog box appears.

- 7 Click **ADD**.

The Reference Range dialog box appears.

- 8 Fill in the fields.

Field descriptions for the Reference Range dialog box

Field	Description	Notes
Gender	Gender to which the result validation is applied.	If the range applies to both males and females, select Not Available .
Age-Min Age-Max	Minimum and maximum age to which the result validation is applied.	If the age range is unbounded, leave the Age-max field blank.
Result qualifier drop-down list	Restricts the value in the Result field by the qualifier you select: > greater than >= greater than or equal to	
Result text box	Minimum expected test value for this demographic reference range.	At least one of the Result AND text boxes must include a value.
AND qualifier drop-down list	Restricts the value in the AND field by the qualifier you select: > greater than >= greater than or equal to	
AND text box	Maximum expected value for this demographic reference range	At least one of the Result AND text boxes must include a value.

The Edit Demographic Ranges dialog box lists the new range.

- 9 Click **SAVE**.
- 10 To delete a demographic reference range, click the **X** for the range.
- 11 After you finish all changes to demographic reference ranges, click **SAVE**.
The Study - Setup - Panels page appears.
- 12 Add additional panels for the study if necessary.
- 13 Click **UPDATE**.

Removing a test panel from a study

Prerequisites: Create the study in the Resource Management module, and define study properties.

You cannot delete a panel that is associated with one or more scheduled events in the study. In addition, you cannot delete a panel that is referenced by a screening event.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Panels** category.
- 2 In the Panels section, select a panel, and click **REMOVE**.

Refreshing a test panel for a study

Prerequisites: Create the study in the Resource Management module, and define study properties.

After a study is designed, you can define additional tests and test panels, and edit existing tests and test panels for the LabPas application. This procedure adds these new or edited test panels to the panels for the study.

For more information, see *Test panels and edit checks* (in the *Administration Guide*).

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Panels** category.
- 2 In the Panels section, select a panel.

The tests that comprise that panel appear in the Test Ranges section.

- 3 Click **REFRESH**.

The test panel is refreshed and new tests are added to the panel from the Test Panels page.

Clinical labs in a study

Study - Setup - Clin Lab page

Note: If the study is locked, the **UPDATE, ADD, REMOVE** and all **Lab Instructions** fields are disabled. Changes cannot be saved.

Lab Instructions fields allow characters from all languages.

Tasks: Study - Setup - Clin Lab page

- *Adding a sample type to a clinical lab event* (on page 81).
- *Removing a sample type from the clinical lab settings* (on page 81).

Adding a sample type to a Clinical Lab

Prerequisites:

- Create the study in the Resource Management module, and define study properties.
- *Create a sample type* (in the *Administration Guide*).

- 1 From the main menu, select **Clinical Trials > CT Studies** and select a study. On the Study page, select the **Setup** tab > **Clin Lab** category.
- 2 Click **ADD**.

A dialog box appears, listing all sample types that do not already appear in the Clinical Lab Setup section.

- 3 Select a sample type.

The dialog box closes, and the sample type you selected appears in the Clinical Lab Setup section.

Removing a sample type from the Clin Lab settings

Prerequisites: Create the study in the Resource Management module, and define study properties.

You can delete a sample type only if it is not associated with any scheduled events in the study.

- 1 From the main menu, select **Clinical Trials > CT Studies** and select a study. On the Study page, select the **Setup** tab > **Clin Lab** category.
- 2 In the sample type table you want to delete, click **REMOVE**.
A confirmation dialog box appears.
- 3 Click **OK**.

PK Lab setup in a study

Study - Setup - PK Lab page

On the Study - Setup - PK Lab page, you define sample type settings for PK Lab events in this study.

Note: If the study is locked the **UPDATE**, **ADD**, and **REMOVE** buttons are disabled. Changes cannot be saved.

You can add sample types to the study, and define Aliquot, Centrifuge, and Storage settings for PK tasks by sample type.

Lab Instructions fields allow characters from all languages.

Tasks: Study - Setup - PK Lab page

- *Adding a sample type to the PK Lab* (on page 82).
- *Setting PK sample type parameters* (on page 82).
- *Removing a sample type from the PK Lab* (on page 87).

Adding a sample type to the PK Lab

Prerequisites: Create the study in the Resource Management module, and define study properties.

- 1 From the main menu, select **Clinical Trials > CT Studies** and select a study. On the Study page, select the **Setup** tab > **PK Lab** category.
- 2 Click **ADD**.
A list appears, showing all sample types that do not already appear on the PK Lab Setup page.
- 3 Select a sample type.
The sample type appears on the PK Lab Setup page.
- 4 Continue to Setting *PK sample type parameters* (on page 82).

Setting PK sample type parameters

Prerequisites:

- Create the study in the Resource Management module, and define study properties.
- *Add the sample type.* (on page 82)

Fill in the sections in the order listed.

- 1 Fill in the **Sample Information** section.

Field descriptions for the PK Lab Sample Information section

Field	Description	Notes
Additional Data	Test panel to associate with the sample type.	<p>The drop-down list includes test panels that were:</p> <ul style="list-style-type: none"> • Defined in the LabPas application (in the <i>Administration Guide</i>) and associated with the event type PK Testing. • Added to the study. <p>Tests on the panel you select are performed as part of the PK Testing event during clinical data entry (in the <i>Clinical Data Entry Guide</i>).</p> <p>After the samples are processed, results from the panel appear when you edit sample data.</p>

- 2 Fill in the **Aliquots** section.

Field descriptions for the PK Lab Aliquots section

PK Lab Aliquots Field	Description	Notes
Quantity	Number of aliquots that must be made for all PK samples of this sample type in the study.	Must be a number from 1 to 25.
Transfer Tube	Vessel type to use for transferring aliquots.	If the Quantity field is not blank, you must choose a value other than No Selection .
Tube Description	Records additional text that is printed on labels. Click the ellipsis button (...) and type a description for each tube. Click APPLY .	<p>The number of lines in the Tube Description dialog box is determined by the number of vessels you specify in the Quantity field.</p> <p>When setting up labels, you can select the Transfer Description field to print this text. For more information, see the <i>Study - Setup - Labels page</i> (on page 144).</p>

- 3 Fill in the **Centrifuge** section.

Field descriptions for the Centrifuge section

PK Lab Centrifuge Field	Description	Notes
Temp	Temperature for samples in the centrifuge	<p>Must be a number from -9999 to 9999.</p> <p>The value that you specify appears as a default value on the Sample Centrifuge page during sample management.</p> <p>Values appear in the following <i>reports</i> (on page 421):</p> <ul style="list-style-type: none"> CT KP Sample Processing Log.
Speed	Speed for samples in the centrifuge	<p>A number between 0 and 9999999999.</p> <p>The speed you specify appears as the default value on the Centrifuge page when the sample barcode is scanned during sample management.</p>
RPM or RCF	Speed measurement unit	<p>Select either the RPM or RCF radio button to define the speed measurement unit.</p> <p>No unit is selected by default. A unit is required if the Speed field is not blank.</p> <p>The unit is disabled if an option is selected and at least one sample associated with the sample type has a centrifuge date that is not blank.</p>
Duration (min)	Number of minutes to spin the sample in the centrifuge.	<p>Must be from 0 to 999 minutes.</p> <p>The value that you specify appears as a default value on the Sample Centrifuge page during sample management.</p> <p>Values appear in the following <i>reports</i> (on page 421):</p> <ul style="list-style-type: none"> CT PK Sample Processing Log.

PK Lab Centrifuge Field	Description	Notes
Alert	<p>Number of minutes before the Time To countdown reaches 0 before an alert appears for samples (of this type only) that are waiting to be centrifuged.</p> <p>The alert appears on the Dashboard and PK Lab Schedule pages.</p>	<p>Must be from 0 to 999 minutes.</p> <p>If specified—The value appears during sample management as a default value on the Centrifuge task and on the Sample Centrifuge page.</p> <p>If the sample is not loaded in the centrifuge by the Actual Sample Time plus (Time To minus Alert) an alert appears on the Metrics, Dashboard, and PK Schedule pages.</p> <p>The value appears in the following <i>reports</i> (on page 421):</p> <ul style="list-style-type: none"> CT PK Sample Processing Log CT Lab Summary <p>If the value is left blank or is 0—A centrifuge alert is not used for this sample.</p>
Time To:	<p>Maximum number of minutes that can elapse from the time a sample is drawn to when it must be centrifuged.</p>	<p>Must be from 0 to 999 minutes.</p> <p>The value appears in the following <i>reports</i> (on page 421):</p> <ul style="list-style-type: none"> CT PK Sample Processing Log CT Lab Summary <p>If the value is left blank or is 0—The centrifuge is not used for this sample.</p>

- 4 Fill in the **Storage** and **Temporary Storage** sections.

Field descriptions for the Storage and Temporary Storage sections

PK Lab Storage Field	Description	Notes
Alert	<p>Number of minutes before the Time To countdown reaches 0 before an alert appears on the Dashboard and PK Lab Schedule pages.</p>	<p>REQUIRED.</p> <p>Must be from 0 to 999 minutes.</p> <p>A value of 0 indicates that a storage alert is not used.</p> <p>The value you specify appears in both the Storage task page and the Sample Storage page during Sample Management.</p>

PK Lab Storage Field	Description	Notes
Time To	Maximum number of minutes that can elapse from the time a sample is drawn to when it must be stored.	<p>REQUIRED.</p> <p>Must be from 0 to 999 minutes.</p> <p>Values appear in the following <i>reports</i> (on page 421):</p> <ul style="list-style-type: none"> CT PK Sample Processing Log. CT Lab Summary.
Temperature Class	Temperature class that is used to store the sample.	The drop-down list includes all unique temperature classes and the option No Selection .
Temporary Storage checkbox	When selected, the Temporary Storage checkbox appears on the Sample Storage page during sample management.	

- 5 Fill in the **Pooling** section

Field descriptions for the Pooling section

Field	Description
Allow CDE Pooling	When selected, pool barcodes that are associated with the current sample type can be processed on the Clinical Data Entry - Pooling page.
Pool Sample Type	Choose from all PK sample types that are associated with the study.

- 1 To add instructions that appear when samples of this type are processed, click the **i** icon in the upper-left corner of the box.

The Lab Instructions dialog box appears.

- 2 Fill in the fields.

Field descriptions for the Lab Instructions dialog box

Field	Description	Notes
Logging	Text that appears in the Instructions field of the Sample Logging page.	For more information, see Sample Logging (in the <i>Sample Management Guide</i>).

Field	Description	Notes
Centrifuge	Text that appears in the following locations:	Maximum characters: 200 (in each area).
Aliquoting		
Pooling	<ul style="list-style-type: none"> The Instructions field of any task pages that were set up using the task templates of the same name. 	For more information, see Sample Management (in the <i>Sample Management Guide</i>).
Storage		
Packing		
Shipping		
Sample Information	<ul style="list-style-type: none"> Instructions on the corresponding sample processing pages. 	

- Click **Apply**.
The Lab Instructions dialog box closes.
- Click **UPDATE**.

Example—PK Lab Centrifuge Alerts

A blood sample is drawn at 3:00 P.M. (**Actual Sample Time**) and is assigned to the Centrifuge task.

The PK Sample Type settings for Blood in this study are:

Centrifuge - Time To: 45 min

Centrifuge - Alert: 15 min

(Time To minus Alert) = 30 min

If the sample has still not been loaded by 3:30 P.M. (**Actual Sample Time + (Time To minus Alert)**), an alert appears on the Dashboard and PK Lab Schedule pages, indicating that the sample is in danger of being too late.

Removing a sample type from the PK Lab

Prerequisites:

- Create the study in the Resource Management module, and define study properties.
- You can delete a sample only if the candidate's **VRN** field is blank.

You cannot delete a sample type that is associated with any events.

- From the main menu, select **Clinical Trials > CT Studies** and select a study. On the Study page, select the **Setup** tab > **PK Lab** category.
- In the sample type to delete, click **REMOVE**.
A confirmation dialog box appears.
- Click **OK**.

Forms setup in a study

Tasks: Study - Setup - Forms page

On the Study - Setup - Forms page, you specify custom fields for AE forms.

- *Specifying custom fields for AE forms* (on page 88).
- *Importing custom fields for AE forms* (on page 90).
- *Removing a form with custom fields for AE forms* (on page 90).

Specifying custom forms

You can specify custom configurable fields to appear on a specific form or on all AE forms in a study. For example, you can use the custom fields to capture additional analysis information about an adverse event. The form can then be associated with clinical events and adverse events in the study.

If a form is associated with a clinical event on the CT Studies > Setup – Events page, the form cannot be removed.

If the currently selected form is associated with an approved clinical event on the Clinical Trials – CT Studies – Setup – Events page, the ADD button is not visible, and all rows, edit and delete buttons for questions are disabled.

You create the custom fields on a form. You can create multiple forms, but you can select only one form to appear on all AE forms in a study.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Forms** category.
- 2 To add questions to an existing form, select the form from the list on the left.

Note: If the form is *selected for a study* (on page 152), you cannot modify the form.

or

To add questions to a new form:

- a Click **NEW**.
The New Form dialog box appears.
 - b Fill in the fields, and click **SAVE**.
- 3 To add a question to the form:
 - a On the gray header bar that contains the name of the form, click **ADD**.
The Add Question dialog box appears.
 - b Fill in the fields and click **SAVE**.

Field descriptions for the Add Question dialog box

Field	Description	Note
Question	Text of the custom field.	REQUIRED.
Gender	Gender of the subject to whom the question is asked, or NA if both males and females are asked the question.	
Order	Order in which the question appears on the form.	REQUIRED.
Response Type	Format of the response, such as a date or text field.	Some response types involve additional fields, described below.

Additional option for the List response type

List Values	<p>List of options from which to choose a response.</p> <p>To add a value, type the option, and click the plus sign (+).</p> <p>To remove a value, select the value, and click the minus sign (-).</p> <p>Use the up and down arrows to arrange the order of the list.</p>
-------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Additional options for the Number response type

Max. Length	Maximum characters allowed in the response field.	REQUIRED.
Min	Minimum value.	
Max	Maximum value.	

Additional option for the Text response type

Max. Length	Maximum characters allowed in the response field.
-------------	---------------------------------------------------

- c Add additional questions, or close the dialog box.
- 4 To edit a question, click the ellipsis button (...) to the right of the question.
- 5 To remove a question from the form, click the X to the left of the question.
- 6 To rename the form:
 - a Click **RENAME**.
The Rename Form dialog box appears.
 - b Fill in the fields, and click **SAVE**.
- 7 **Select the custom fields to appear on an AE form** (on page 152).

Importing custom fields for AE forms

You can import a form containing custom fields from the *Setup - Forms page* (in the *Administration Guide*).

Importing a form appears in the CT Change Log report with a source of Form Setup.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Forms** category.

- 2 Click **IMPORT**.

A dialog box appears.

Forms that share names with forms in the study do not appear. If Global Forms is not selected, only forms for the current facility appear.

- 3 Select a form.

The form and all its questions are imported.

Removing a form with custom fields for AE forms

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Forms** category.

- 2 In the list of forms on the left, select a form, and click **REMOVE**.

A confirmation dialog box appears.

- 3 Click **OK**.

Form events logging

When you perform one of the following form setup actions, a corresponding entry is recorded in the Recruiting Change Log, with a source of Form Setup:

- Create a new form.
- Import a form.
- Rename a form.
- Remove a form.
- Add a question to a form.
- Remove a question from a form.
- Edit a form question.

Events setup in a study

Study - Setup - Events page

An event is an action that occurs in the study, at a point in time relative to the Zero Date and Time, which is generally considered the date and time that the first dose is administered.

A series of events in a study are called an Event Plan. One event plan at a time is shown on the Events tab.

On the Study - Setup - Events page, you view one event plan at a time, in a table listing the events that are included in the event plan. You can create additional event plans.

For each event, you can:

- Set the time the event is to take place.
- Determine whether to build time into the schedule for staggering participants, and how to handle the schedule if the event is late.
- Specify whether to exclude the event from specific periods or treatments in the study.
- For events in which a sample is collected, specify the number of vessels and any optional text to print on the vessel labels.
- Add information to qualify the event data for data management purposes.

The events that you create on the Study - Setup - Events page are later assigned to each study participant, and the study schedule is created.

Events and event plans

Event Plan 1 is the default event plan on the Study - Setup - Events page. Events that you set up are added to the event plan and appear in the table. To change to a different event plan, use the filter.

When an event is created, it is assigned a version number.

Events must be approved.

- **Unapproved events**—If you edit an unapproved event, the event retains the same version number.
- **Approved events**—Each time an approved event is edited, it is assigned a new version number. You can edit only the most recent version of an event.

In the table of events, checkboxes for deleted or revised events are read-only.

You can create a new event plan by copying an existing event plan. Only approved events are copied to the new event plan.

Prerequisites: Adding an event to a study

Elements used in events must have been defined:

- Create the study in the Resource Management module, and define study properties.
- Define at least one sample type, vessel type, and test panel.

For more information, see (in the *Administration Guide*):

- *Sample types*
- *Vessel types*
- *Test Panels*
- Set up the following information for the study:
 - At least one event category per event type.
For more information, see *Event types in a study* (on page 57).
 - Panels, Clin Lab, and PK Lab categories.
For more information, see:
 - *Test panels in a study* (on page 77).
 - *Clinical labs in a study* (on page 81).
 - *PK Lab setup in a study* (on page 82).

Tasks: Study - Setup - Events page

- *Adding a Dose event to a study* (on page 92).
- *Adding a PK Testing event to a study* (on page 99).
- *Adding a Clinical Testing event to a study* (on page 105).
- *Adding a Testing event to a study* (on page 111).
- *Adding an Other event to a study* (on page 117).
- *Approving events in a study* (on page 122).
- *Copying an event plan in a study* (on page 123).
- *Editing an event in a study* (on page 123).
- *Deleting an approved or unapproved event from a study* (on page 137).

Adding a Dose event to a study

Prerequisite: Study elements used in events must have been defined. For more information, see *Prerequisites: Adding an event to a study* (on page 92).

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Events** category.

- 2 Click **NEW**.
The New Event dialog box appears with the Dose tab selected.
- 3 In the Properties and Event Properties sections, fill in the fields.
Fields in the Event Properties section pertain to Dose events.

Field descriptions for the New Event - Dose dialog box

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	REQUIRED. The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date. The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	For Dose events, this field is read-only. Dose events can take place only at or after the Zero Date and Time.

Properties Field	Description	Notes
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	<p>Days—A number from 0 to 999.</p> <p>Hours—A number from 0 to 23.</p> <p>Minutes—A number from 0 to 59.</p> <p>Seconds—A number from 0 to 59.</p> <p>For more information, see <i>About schedules and events</i> (on page 183).</p>

Event Properties - Dose events

Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	Allows characters from all languages.

- 4 Click **ADVANCED**.

The Advanced Properties appear in the lower part of the dialog box.

- 5 Fill in the fields.

Field descriptions for the New Event Advanced Properties

Advanced Field	Description	Notes
Exclude From Periods	<p>Time periods in which the event is excluded.</p> <p>For each time period checkbox:</p> <ul style="list-style-type: none"> • Selected—The period does not include this event. • Not selected—The period includes this event. 	<p>The schedule that is generated for the selected period does not include the event.</p> <p>If selected, the events table lists events that are not excluded from the specified period.</p>
Exclude from Treatments	<p>For each treatment checkbox:</p> <ul style="list-style-type: none"> • Selected—The treatment does not include this event. • Not selected—The treatment includes this event. 	<p>The schedule that is generated for a given period does not include the selected treatments.</p> <p>If selected, the events table lists events that are not excluded from the specified treatment.</p>
Deviation Settings section		
Negative Tolerance	<p>The negative tolerance for an event.</p> <p>Includes edit boxes for Minutes and Seconds.</p>	<p>The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank.</p> <p>The Minutes field for Negative Tolerance allows 5 digits.</p> <p>The Seconds field for Negative Tolerance allows 2 digits.</p>
Positive Tolerance	<p>The tolerance for an event.</p> <p>Includes edit boxes for Minutes and Seconds.</p>	<p>The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank.</p> <p>The Minutes field for Positive Tolerance allows 5 digits.</p> <p>The Seconds field for Positive Tolerance allows 2 digits.</p>

Advanced Field	Description	Notes
----------------	-------------	-------

Advanced Field	Description	Notes
Schedule Options section		
Tolerance	Number of minutes before or after the PK Time that the event can take place and still be considered on time.	Must be from 0 to 999 minutes.
Anchor	Selected —The event is an anchor event. This field is read-only if PK Time - Negative is selected.	For anchor events, the PK time created for the event is not changed if the schedule is adjusted for late events. Anchors reset the schedule at the specified event.
Ignore Offset	Selected —The event is not staggered by participant when the schedule is created. All participants are scheduled for the same time. Overrides the Offset Interval value that is set when the schedule is created on the Study - Events page.	The Offset Interval is specified when the schedule is created. It builds time into the schedule for staggering participants. Any offset intervals for other events in the schedule are not applied to this event.
Adjust Schedule	Whether the PK times for participant should be adjusted in the schedule when the sample collection is late. Selected —All events that are scheduled to take place after this event have their PK times adjusted accordingly, so that the appropriate time intervals are still met.	This field is used so that a late event does not affect any sample collections scheduled after the event. Events resume their originally scheduled PK Times at the next Anchor event. When selected, the Adjust column in the events table lists Yes. You can select either Adjust Schedule or Adjust Schedule (Restricted) but not both.

Advanced Field	Description	Notes
Adjust Schedule (Restricted)	<p>Whether the schedule is adjusted when the sample collection is late.</p> <p>Selected—Events with a status of Not Started that are scheduled to take place after this event are rescheduled if one of the following conditions is met:</p> <ul style="list-style-type: none"> • The Adjusted By setting for the event being rescheduled is set to Previous Event and the sample being logged is associated with the event that precedes the event being rescheduled. • The Adjusted By setting for the event being rescheduled is set to the event associated with the sample being logged. 	<p>If selected, the Adjust column in the events table lists Restricted.</p>
Use Tolerance for Adjust	<p>Selected—Uses event tolerance to adjust the event schedule.</p>	<p>Available if Adjust Schedule and Adjust Schedule (Restricted) are selected.</p>
Adjusted by	<p>Event that, when its sample is collected late, causes this event to be adjusted.</p>	<p>Available if Adjust Schedule (Restricted) is selected.</p> <p>The Drop-down list contains all events in the event plan that meet the following conditions:</p> <ul style="list-style-type: none"> • A status of Approved or blank. • The Adjust Schedule (restricted) checkbox is selected. <p>Note: The event you select must have a PK time earlier than the current event, or the same PK Time Negative setting as the current event.</p>

Advanced Field	Description	Notes
Qualifier section		
Qualifier	Qualifier code to mark event data for data management purposes.	Default: (No Selection) . The drop-down list contains qualifiers that were previously created for the study. For more information, see <i>Study - Setup - Other page</i> (on page 153).

- 6 Click **SAVE**.

The New Event dialog box remains open. If the repeat checkbox is selected, all fields retain their data.

- 7 Create additional events as needed. Click **SAVE** after each event.

- 8 After you finish creating events, close the dialog box.

New events appear on the Study - Setup - Events page.

Adding a PK Testing event to a study

Prerequisite: Study elements used in events must have been defined. For more information, see *Prerequisites: Adding an event to a study* (on page 92).

If more than one sample is collected from the same participant at a given time, but each sample needs to be tracked individually, create a separate event for each sample and give the events the same PK Time.

During sample collection, when a barcode is entered, the schedule searches for any other barcodes with the same PK time. If more than one is found, the Sample page prompts for multiple samples to be taken at one time.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Events** category.

- 2 Click **NEW**.

The New Event dialog box appears with the Dose tab selected.

- 3 Select the **PK Testing** tab.

- 4 In the Properties and Event Properties sections, fill in the fields.

Fields in the Event Properties section pertain to PK Testing events.

Field descriptions for the New Event - PK Testing dialog box

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	REQUIRED. The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date. The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	For Dose events, this field is read-only. Dose events can take place only at or after the Zero Date and Time.
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	Days —A number from 0 to 999. Hours —A number from 0 to 23. Minutes —A number from 0 to 59. Seconds —A number from 0 to 59. For more information, see <i>About schedules and events</i> (on page 183).

Event Properties section - PK Testing events

Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Sample Type	Sample type to be tested in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on PK Lab settings created for the study.</p>
Vessel Type	Vessel type to use to contain the sample in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on the <i>vessel types defined in the LabPas application</i> (in the <i>Administration Guide</i>).</p>
Quantity	Number of vessels that are used to collect the sample type	<p>REQUIRED.</p> <p>Must be a number from 1 to 9.</p> <p>Default: 1.</p>
Collection Description	<p>Description for each tube.</p> <p>Click the ellipsis button (...). The Tube Description dialog box appears.</p> <p>Type descriptions for the tubes and click APPLY.</p>	<p>The number of fields on the Tube Description dialog box is determined by the Quantity.</p> <p>Descriptions can be selected when labels are set up for the study. For more information, see <i>Study - Setup - Labels page</i> (on page 144).</p>

Field	Description	Notes
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	Allows characters from all languages.

- 5 Click **ADVANCED**.

The Advanced Properties appear in the lower part of the dialog box.

- 6 Fill in the fields.

Field descriptions for the New Event Advanced Properties

Advanced Field	Description	Notes
Exclude From Periods	Time periods in which the event is excluded. For each time period checkbox: <ul style="list-style-type: none"> • Selected—The period does not include this event. • Not selected—The period includes this event. 	The schedule that is generated for the selected period does not include the event. If selected, the events table lists events that are not excluded from the specified period.
Exclude from Treatments	For each treatment checkbox: <ul style="list-style-type: none"> • Selected—The treatment does not include this event. • Not selected—The treatment includes this event. 	The schedule that is generated for a given period does not include the selected treatments. If selected, the events table lists events that are not excluded from the specified treatment.

Deviation Settings section

Negative Tolerance	The negative tolerance for an event. Includes edit boxes for Minutes and Seconds.	The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank. The Minutes field for Negative Tolerance allows 5 digits. The Seconds field for Negative Tolerance allows 2 digits.
--------------------	------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Advanced Field	Description	Notes
Positive Tolerance	The tolerance for an event. Includes edit boxes for Minutes and Seconds.	The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank. The Minutes field for Positive Tolerance allows 5 digits. The Seconds field for Positive Tolerance allows 2 digits.
Schedule Options section		
Tolerance	Number of minutes before or after the PK Time that the event can take place and still be considered on time.	Must be from 0 to 999 minutes.
Anchor	Selected —The event is an anchor event. This field is read-only if PK Time - Negative is selected.	For anchor events, the PK time created for the event is not changed if the schedule is adjusted for late events. Anchors reset the schedule at the specified event.
Ignore Offset	Selected —The event is not staggered by participant when the schedule is created. All participants are scheduled for the same time. Overrides the Offset Interval value that is set when the schedule is created on the Study - Events page.	The Offset Interval is specified when the schedule is created. It builds time into the schedule for staggering participants. Any offset intervals for other events in the schedule are not applied to this event.
Adjust Schedule	Whether the PK times for participant should be adjusted in the schedule when the sample collection is late. Selected —All events that are scheduled to take place after this event have their PK times adjusted accordingly, so that the appropriate time intervals are still met.	This field is used so that a late event does not affect any sample collections scheduled after the event. Events resume their originally scheduled PK Times at the next Anchor event. When selected, the Adjust column in the events table lists Yes. You can select either Adjust Schedule or Adjust Schedule (Restricted) but not both.

Advanced Field	Description	Notes
Adjust Schedule (Restricted)	<p>Whether the schedule is adjusted when the sample collection is late.</p> <p>Selected—Events with a status of Not Started that are scheduled to take place after this event are rescheduled if one of the following conditions is met:</p> <ul style="list-style-type: none"> • The Adjusted By setting for the event being rescheduled is set to Previous Event and the sample being logged is associated with the event that precedes the event being rescheduled. • The Adjusted By setting for the event being rescheduled is set to the event associated with the sample being logged. 	<p>If selected, the Adjust column in the events table lists Restricted.</p>
Use Tolerance for Adjust	<p>Selected—Uses event tolerance to adjust the event schedule.</p>	<p>Available if Adjust Schedule and Adjust Schedule (Restricted) are selected.</p>
Adjusted by	<p>Event that, when its sample is collected late, causes this event to be adjusted.</p>	<p>Available if Adjust Schedule (Restricted) is selected.</p> <p>The Drop-down list contains all events in the event plan that meet the following conditions:</p> <ul style="list-style-type: none"> • A status of Approved or blank. • The Adjust Schedule (restricted) checkbox is selected. <p>Note: The event you select must have a PK time earlier than the current event, or the same PK Time Negative setting as the current event.</p>

Advanced Field	Description	Notes
Qualifier section		
Qualifier	Qualifier code to mark event data for data management purposes.	Default: (No Selection) . The drop-down list contains qualifiers that were previously created for the study. For more information, see <i>Study - Setup - Other page</i> (on page 153).

- 7 Click **SAVE**.

The New Event dialog box remains open. If the repeat checkbox is selected, all fields retain their data.

- 8 Create additional events as needed. Click **SAVE** after each event.
- 9 After you finish creating events, close the dialog box.

New events appear on the Study - Setup - Events page.

Adding a Clinical Testing event to a study

Prerequisite: Study elements used in events must have been defined. For more information, see *Prerequisites: Adding an event to a study* (on page 92).

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Events** category.
- 2 Click **NEW**.
The New Event dialog box appears with the Dose tab selected.
- 3 Select the **Clinical Testing** tab.
- 4 In the Properties and Event Properties sections, fill in the fields.

Fields in the Event Properties section pertain to clinical testing events.

Field descriptions for the New Event - Clinical Testing dialog box

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.

Properties Field	Description	Notes
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	<p>REQUIRED.</p> <p>The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date.</p> <p>The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.</p>
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	<p>For Dose events, this field is read-only.</p> <p>Dose events can take place only at or after the Zero Date and Time.</p>
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	<p>Days—A number from 0 to 999.</p> <p>Hours—A number from 0 to 23.</p> <p>Minutes—A number from 0 to 59.</p> <p>Seconds—A number from 0 to 59.</p> <p>For more information, see <i>About schedules and events</i> (on page 183).</p>

Event Properties section - Clinical Testing events

Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Sample Type	Sample type to be tested in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on PK Lab settings created for the study.</p>
Vessel Type	Vessel type to use to contain the sample in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on the <i>vessel types defined in the LabPas application</i> (in the <i>Administration Guide</i>).</p>
Quantity	Number of vessels that are used to collect the sample type	<p>REQUIRED.</p> <p>Must be a number from 1 to 9.</p> <p>Default: 1.</p>
Collection Description	Additional text that is printed on vessel labels.	<p>The number of fields on the Tube Description dialog box is determined by the Quantity.</p> <p>Descriptions can be selected when labels are set up for the study. For more information, see <i>Study - Setup - Labels page</i> (on page 144).</p>

Field	Description	Notes
Panels	<p>Test panels included in this event.</p> <p>Click the ellipsis button (...). A list of panels appears.</p> <p>Select the checkboxes for the panels to include in the event, and click UPDATE.</p>	<p>REQUIRED.</p> <p>The test panels were created on the Study - Setup - Panels page.</p>
Instructions	<p>Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.</p>	<p>Allows characters from all languages.</p>

5 Click **ADVANCED**.

The Advanced Properties appear in the lower part of the dialog box.

6 Fill in the fields.

Field descriptions for the New Event Advanced Properties

Advanced Field	Description	Notes
Exclude From Periods	<p>Time periods in which the event is excluded.</p> <p>For each time period checkbox:</p> <ul style="list-style-type: none"> • Selected—The period does not include this event. • Not selected—The period includes this event. 	<p>The schedule that is generated for the selected period does not include the event.</p> <p>If selected, the events table lists events that are not excluded from the specified period.</p>
Exclude from Treatments	<p>For each treatment checkbox:</p> <ul style="list-style-type: none"> • Selected—The treatment does not include this event. • Not selected—The treatment includes this event. 	<p>The schedule that is generated for a given period does not include the selected treatments.</p> <p>If selected, the events table lists events that are not excluded from the specified treatment.</p>

Advanced Field	Description	Notes
Deviation Settings section		
Negative Tolerance	<p>The negative tolerance for an event.</p> <p>Includes edit boxes for Minutes and Seconds.</p>	<p>The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank.</p> <p>The Minutes field for Negative Tolerance allows 5 digits.</p> <p>The Seconds field for Negative Tolerance allows 2 digits.</p>
Positive Tolerance	<p>The tolerance for an event.</p> <p>Includes edit boxes for Minutes and Seconds.</p>	<p>The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank.</p> <p>The Minutes field for Positive Tolerance allows 5 digits.</p> <p>The Seconds field for Positive Tolerance allows 2 digits.</p>
Schedule Options section		
Tolerance	<p>Number of minutes before or after the PK Time that the event can take place and still be considered on time.</p>	<p>Must be from 0 to 999 minutes.</p>
Anchor	<p>Selected—The event is an anchor event.</p> <p>This field is read-only if PK Time - Negative is selected.</p>	<p>For anchor events, the PK time created for the event is not changed if the schedule is adjusted for late events. Anchors reset the schedule at the specified event.</p>
Ignore Offset	<p>Selected—The event is not staggered by participant when the schedule is created. All participants are scheduled for the same time.</p> <p>Overrides the Offset Interval value that is set when the schedule is created on the Study - Events page.</p>	<p>The Offset Interval is specified when the schedule is created. It builds time into the schedule for staggering participants.</p> <p>Any offset intervals for other events in the schedule are not applied to this event.</p>

Advanced Field	Description	Notes
Adjust Schedule	<p>Whether the PK times for participant should be adjusted in the schedule when the sample collection is late.</p> <p>Selected—All events that are scheduled to take place after this event have their PK times adjusted accordingly, so that the appropriate time intervals are still met.</p>	<p>This field is used so that a late event does not affect any sample collections scheduled after the event.</p> <p>Events resume their originally scheduled PK Times at the next Anchor event.</p> <p>When selected, the Adjust column in the events table lists Yes.</p> <p>You can select either Adjust Schedule or Adjust Schedule (Restricted) but not both.</p>
Adjust Schedule (Restricted)	<p>Whether the schedule is adjusted when the sample collection is late.</p> <p>Selected—Events with a status of Not Started that are scheduled to take place after this event are rescheduled if one of the following conditions is met:</p> <ul style="list-style-type: none"> • The Adjusted By setting for the event being rescheduled is set to Previous Event and the sample being logged is associated with the event that precedes the event being rescheduled. • The Adjusted By setting for the event being rescheduled is set to the event associated with the sample being logged. 	<p>If selected, the Adjust column in the events table lists Restricted.</p>
Use Tolerance for Adjust	<p>Selected—Uses event tolerance to adjust the event schedule.</p>	<p>Available if Adjust Schedule and Adjust Schedule (Restricted) are selected.</p>

Advanced Field	Description	Notes
Adjusted by	Event that, when its sample is collected late, causes this event to be adjusted.	<p>Available if Adjust Schedule (Restricted) is selected.</p> <p>The Drop-down list contains all events in the event plan that meet the following conditions:</p> <ul style="list-style-type: none"> • A status of Approved or blank. • The Adjust Schedule (restricted) checkbox is selected. <p>Note: The event you select must have a PK time earlier than the current event, or the same PK Time Negative setting as the current event.</p>

Qualifier section		
Qualifier	Qualifier code to mark event data for data management purposes.	<p>Default: (No Selection).</p> <p>The drop-down list contains qualifiers that were previously created for the study. For more information, see <i>Study - Setup - Other page</i> (on page 153).</p>

- 7 Click **SAVE**.

The New Event dialog box remains open. If the repeat checkbox is selected, all fields retain their data.

- 8 Create additional events as needed. Click **SAVE** after each event.
- 9 After you finish creating events, close the dialog box.

New events appear on the Study - Setup - Events page.

Adding a Testing event to a study

Prerequisite: Study elements used in events must have been defined. For more information, see *Prerequisites: Adding an event to a study* (on page 92).

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Events** category.
- 2 Click **NEW**.
The New Event dialog box appears with the Dose tab selected.
- 3 Select the **Testing** tab.

- 4 In the Properties and Event Properties sections, fill in the fields. Fields in the Event Properties section pertain to Testing events.

Field descriptions for the New Event - Testing dialog box

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	REQUIRED. The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date. The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	For Dose events, this field is read-only. Dose events can take place only at or after the Zero Date and Time.

Properties Field	Description	Notes
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	<p>Days—A number from 0 to 999.</p> <p>Hours—A number from 0 to 23.</p> <p>Minutes—A number from 0 to 59.</p> <p>Seconds—A number from 0 to 59.</p> <p>For more information, see <i>About schedules and events</i> (on page 183).</p>

Event Properties - Testing events

Event Properties Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Panels	<p>Test panels included in this event.</p> <p>Click the ellipsis button (...). A list of panels appears.</p> <p>Select the checkboxes for the panels to include in the event, and click UPDATE.</p>	<p>REQUIRED.</p> <p>The test panels were created on the Study - Setup - Panels page.</p>
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	Allows characters from all languages.

- 5 Click **ADVANCED**.

The Advanced Properties appear in the lower part of the dialog box.

- 6 Fill in the fields.

Field descriptions for the New Event Advanced Properties

Advanced Field	Description	Notes
Exclude From Periods	<p>Time periods in which the event is excluded.</p> <p>For each time period checkbox:</p> <ul style="list-style-type: none"> • Selected—The period does not include this event. • Not selected—The period includes this event. 	<p>The schedule that is generated for the selected period does not include the event.</p> <p>If selected, the events table lists events that are not excluded from the specified period.</p>
Exclude from Treatments	<p>For each treatment checkbox:</p> <ul style="list-style-type: none"> • Selected—The treatment does not include this event. • Not selected—The treatment includes this event. 	<p>The schedule that is generated for a given period does not include the selected treatments.</p> <p>If selected, the events table lists events that are not excluded from the specified treatment.</p>
Deviation Settings section		
Negative Tolerance	<p>The negative tolerance for an event.</p> <p>Includes edit boxes for Minutes and Seconds.</p>	<p>The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank.</p> <p>The Minutes field for Negative Tolerance allows 5 digits.</p> <p>The Seconds field for Negative Tolerance allows 2 digits.</p>

Advanced Field	Description	Notes
Positive Tolerance	The tolerance for an event. Includes edit boxes for Minutes and Seconds.	The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank. The Minutes field for Positive Tolerance allows 5 digits. The Seconds field for Positive Tolerance allows 2 digits.
Schedule Options section		
Tolerance	Number of minutes before or after the PK Time that the event can take place and still be considered on time.	Must be from 0 to 999 minutes.
Anchor	Selected —The event is an anchor event. This field is read-only if PK Time - Negative is selected.	For anchor events, the PK time created for the event is not changed if the schedule is adjusted for late events. Anchors reset the schedule at the specified event.
Ignore Offset	Selected —The event is not staggered by participant when the schedule is created. All participants are scheduled for the same time. Overrides the Offset Interval value that is set when the schedule is created on the Study - Events page.	The Offset Interval is specified when the schedule is created. It builds time into the schedule for staggering participants. Any offset intervals for other events in the schedule are not applied to this event.
Adjust Schedule	Whether the PK times for participant should be adjusted in the schedule when the sample collection is late. Selected —All events that are scheduled to take place after this event have their PK times adjusted accordingly, so that the appropriate time intervals are still met.	This field is used so that a late event does not affect any sample collections scheduled after the event. Events resume their originally scheduled PK Times at the next Anchor event. When selected, the Adjust column in the events table lists Yes. You can select either Adjust Schedule or Adjust Schedule (Restricted) but not both.

Advanced Field	Description	Notes
Adjust Schedule (Restricted)	<p>Whether the schedule is adjusted when the sample collection is late.</p> <p>Selected—Events with a status of Not Started that are scheduled to take place after this event are rescheduled if one of the following conditions is met:</p> <ul style="list-style-type: none"> • The Adjusted By setting for the event being rescheduled is set to Previous Event and the sample being logged is associated with the event that precedes the event being rescheduled. • The Adjusted By setting for the event being rescheduled is set to the event associated with the sample being logged. 	<p>If selected, the Adjust column in the events table lists Restricted.</p>
Use Tolerance for Adjust	<p>Selected—Uses event tolerance to adjust the event schedule.</p>	<p>Available if Adjust Schedule and Adjust Schedule (Restricted) are selected.</p>
Adjusted by	<p>Event that, when its sample is collected late, causes this event to be adjusted.</p>	<p>Available if Adjust Schedule (Restricted) is selected.</p> <p>The Drop-down list contains all events in the event plan that meet the following conditions:</p> <ul style="list-style-type: none"> • A status of Approved or blank. • The Adjust Schedule (restricted) checkbox is selected. <p>Note: The event you select must have a PK time earlier than the current event, or the same PK Time Negative setting as the current event.</p>

Advanced Field	Description	Notes
Qualifier section		
Qualifier	Qualifier code to mark event data for data management purposes.	Default: (No Selection) . The drop-down list contains qualifiers that were previously created for the study. For more information, see <i>Study - Setup - Other page</i> (on page 153).

- 7 Click **SAVE**.

The New Event dialog box remains open. If the repeat checkbox is selected, all fields retain their data.

- 8 Create additional events as needed. Click **SAVE** after each event.
- 9 After you finish creating events, close the dialog box.

New events appear on the Study - Setup - Events page.

Adding an Other event to a study

Prerequisite: Study elements used in events must have been defined. For more information, see *Prerequisites: Adding an event to a study* (on page 92).

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Events** category.
- 2 Click **NEW**.
The New Event dialog box appears with the Dose tab selected.
- 3 Click the **Other** tab.
- 4 In the Properties and Event Properties sections, fill in the fields.

Fields in the Event Properties section pertain to Other events.

Field descriptions for the New Event - Other dialog box

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.

Properties Field	Description	Notes
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	<p>REQUIRED.</p> <p>The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date.</p> <p>The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.</p>
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	<p>For Dose events, this field is read-only.</p> <p>Dose events can take place only at or after the Zero Date and Time.</p>
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	<p>Days—A number from 0 to 999.</p> <p>Hours—A number from 0 to 23.</p> <p>Minutes—A number from 0 to 59.</p> <p>Seconds—A number from 0 to 59.</p> <p>For more information, see <i>About schedules and events</i> (on page 183).</p>

Event Properties - Other events

Field	Description	Notes
Event Category	Category for the event.	REQUIRED. Items in the drop-down list depend on the event type you selected. If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events. Categories are based on the <i>event types created for the study</i> (on page 57).
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	Allows characters from all languages.

- 5 Click **ADVANCED**.

The Advanced Properties appear in the lower part of the dialog box.

- 6 Fill in the fields.

Field descriptions for the New Event Advanced Properties

Advanced Field	Description	Notes
Exclude From Periods	Time periods in which the event is excluded. For each time period checkbox: <ul style="list-style-type: none"> Selected—The period does not include this event. Not selected—The period includes this event. 	The schedule that is generated for the selected period does not include the event. If selected, the events table lists events that are not excluded from the specified period.

Advanced Field	Description	Notes
Exclude from Treatments	<p>For each treatment checkbox:</p> <ul style="list-style-type: none"> • Selected—The treatment does not include this event. • Not selected—The treatment includes this event. 	<p>The schedule that is generated for a given period does not include the selected treatments.</p> <p>If selected, the events table lists events that are not excluded from the specified treatment.</p>
Deviation Settings section		
Negative Tolerance	<p>The negative tolerance for an event.</p> <p>Includes edit boxes for Minutes and Seconds.</p>	<p>The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank.</p> <p>The Minutes field for Negative Tolerance allows 5 digits.</p> <p>The Seconds field for Negative Tolerance allows 2 digits.</p>
Positive Tolerance	<p>The tolerance for an event.</p> <p>Includes edit boxes for Minutes and Seconds.</p>	<p>The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank.</p> <p>The Minutes field for Positive Tolerance allows 5 digits.</p> <p>The Seconds field for Positive Tolerance allows 2 digits.</p>
Schedule Options section		
Tolerance	<p>Number of minutes before or after the PK Time that the event can take place and still be considered on time.</p>	<p>Must be from 0 to 999 minutes.</p>
Anchor	<p>Selected—The event is an anchor event.</p> <p>This field is read-only if PK Time - Negative is selected.</p>	<p>For anchor events, the PK time created for the event is not changed if the schedule is adjusted for late events. Anchors reset the schedule at the specified event.</p>

Advanced Field	Description	Notes
Ignore Offset	<p>Selected—The event is not staggered by participant when the schedule is created. All participants are scheduled for the same time.</p> <p>Overrides the Offset Interval value that is set when the schedule is created on the Study - Events page.</p>	<p>The Offset Interval is specified when the schedule is created. It builds time into the schedule for staggering participants.</p> <p>Any offset intervals for other events in the schedule are not applied to this event.</p>
Adjust Schedule	<p>Whether the PK times for participant should be adjusted in the schedule when the sample collection is late.</p> <p>Selected—All events that are scheduled to take place after this event have their PK times adjusted accordingly, so that the appropriate time intervals are still met.</p>	<p>This field is used so that a late event does not affect any sample collections scheduled after the event.</p> <p>Events resume their originally scheduled PK Times at the next Anchor event.</p> <p>When selected, the Adjust column in the events table lists Yes.</p> <p>You can select either Adjust Schedule or Adjust Schedule (Restricted) but not both.</p>
Adjust Schedule (Restricted)	<p>Whether the schedule is adjusted when the sample collection is late.</p> <p>Selected—Events with a status of Not Started that are scheduled to take place after this event are rescheduled if one of the following conditions is met:</p> <ul style="list-style-type: none"> • The Adjusted By setting for the event being rescheduled is set to Previous Event and the sample being logged is associated with the event that precedes the event being rescheduled. • The Adjusted By setting for the event being rescheduled is set to the event associated with the sample being logged. 	<p>If selected, the Adjust column in the events table lists Restricted.</p>

Advanced Field	Description	Notes
Use Tolerance for Adjust	Selected —Uses event tolerance to adjust the event schedule.	Available if Adjust Schedule and Adjust Schedule (Restricted) are selected.
Adjusted by	Event that, when its sample is collected late, causes this event to be adjusted.	<p>Available if Adjust Schedule (Restricted) is selected.</p> <p>The Drop-down list contains all events in the event plan that meet the following conditions:</p> <ul style="list-style-type: none"> • A status of Approved or blank. • The Adjust Schedule (restricted) checkbox is selected. <p>Note: The event you select must have a PK time earlier than the current event, or the same PK Time Negative setting as the current event.</p>

Qualifier section

Qualifier	Qualifier code to mark event data for data management purposes.	<p>Default: (No Selection).</p> <p>The drop-down list contains qualifiers that were previously created for the study. For more information, see <i>Study - Setup - Other page</i> (on page 153).</p>
-----------	-----------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

- 7 Click **SAVE**.

The New Event dialog box remains open. If the repeat checkbox is selected, all fields retain their data.

- 8 Create additional events as needed. Click **SAVE** after each event.
- 9 After you finish creating events, close the dialog box.

New events appear on the Study - Setup - Events page.

Approving events in a study

Prerequisites:

- Create the study in the Resource Management module, and define study properties.
- You must have the Approve Study Setup function permission.

All events are approved each time you complete the Approve Events dialog box. You cannot approve one event at a time.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Events** category.
- 2 Click **APPROVAL**.
The Approve Events dialog box appears.
- 3 In the Approval area, type your password and click **Apply**.
If any events have a version number greater than 1, a comment is required.
- 4 Click **APPLY**.
Approval data appears on the Study - Setup - Events page.

Copying an event plan in a study

Prerequisites: Create the study in the Resource Management module, and define study properties.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Events** category.
- 2 Click **COPY**.
The Copy Event Plan dialog box appears. The Event Plan field displays the current event plan.
- 3 In the **Copy To** field, type a unique name for the new event plan.
- 4 Click **APPLY**.
The Study - Setup - Events page appears. All approved events from the current event plan are copied to the new event plan. All events in the new event plan are initially unapproved.
- 5 To access the new event plan, click **FILTER** and choose the new plan.

Editing an event in a study

Prerequisites: Create the study in the Resource Management module, and define study properties.

You can edit only the most recent version of an event:

- If an event is not approved, you can edit it as many times as necessary; a new version is not created.
 - If an event is approved, you cannot change its event type.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Events** category.
 - 2 Select one or more events, and click **EDIT**.
The Edit Event dialog box appears.
 - 3 Fill in the fields.

Fields depend on the type of event you are editing.

Field descriptions for a Dose event

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	REQUIRED. The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date. The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	For Dose events, this field is read-only. Dose events can take place only at or after the Zero Date and Time.
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	Days —A number from 0 to 999. Hours —A number from 0 to 23. Minutes —A number from 0 to 59. Seconds —A number from 0 to 59. For more information, see <i>About schedules and events</i> (on page 183).

Event Properties - Dose events

Field	Description	Notes
Event Category	Category for the event.	REQUIRED. Items in the drop-down list depend on the event type you selected. If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events. Categories are based on the <i>event types created for the study</i> (on page 57).
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	Allows characters from all languages.

Field descriptions for a PK Testing event

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.

Properties Field	Description	Notes
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	<p>REQUIRED.</p> <p>The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date.</p> <p>The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.</p>
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	<p>For Dose events, this field is read-only.</p> <p>Dose events can take place only at or after the Zero Date and Time.</p>
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	<p>Days—A number from 0 to 999.</p> <p>Hours—A number from 0 to 23.</p> <p>Minutes—A number from 0 to 59.</p> <p>Seconds—A number from 0 to 59.</p> <p>For more information, see <i>About schedules and events</i> (on page 183).</p>

Event Properties section - PK Testing events

Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Sample Type	Sample type to be tested in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on PK Lab settings created for the study.</p>
Vessel Type	Vessel type to use to contain the sample in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on the <i>vessel types defined in the LabPas application</i> (in the <i>Administration Guide</i>).</p>
Quantity	Number of vessels that are used to collect the sample type	<p>REQUIRED.</p> <p>Must be a number from 1 to 9.</p> <p>Default: 1.</p>
Collection Description	<p>Description for each tube.</p> <p>Click the ellipsis button (...). The Tube Description dialog box appears.</p> <p>Type descriptions for the tubes and click APPLY.</p>	<p>The number of fields on the Tube Description dialog box is determined by the Quantity.</p> <p>Descriptions can be selected when labels are set up for the study. For more information, see <i>Study - Setup - Labels page</i> (on page 144).</p>

Field	Description	Notes
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	Allows characters from all languages.

Field descriptions for a Clinical Testing event

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	REQUIRED. The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date. The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	For Dose events, this field is read-only. Dose events can take place only at or after the Zero Date and Time.

Properties Field	Description	Notes
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	<p>Days—A number from 0 to 999.</p> <p>Hours—A number from 0 to 23.</p> <p>Minutes—A number from 0 to 59.</p> <p>Seconds—A number from 0 to 59.</p> <p>For more information, see <i>About schedules and events</i> (on page 183).</p>

Event Properties section - Clinical Testing events

Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Sample Type	Sample type to be tested in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on PK Lab settings created for the study.</p>
Vessel Type	Vessel type to use to contain the sample in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on the <i>vessel types defined in the LabPas application</i> (in the <i>Administration Guide</i>).</p>

Field	Description	Notes
Quantity	Number of vessels that are used to collect the sample type	REQUIRED. Must be a number from 1 to 9. Default: 1.
Collection Description	Additional text that is printed on vessel labels.	The number of fields on the Tube Description dialog box is determined by the Quantity . Descriptions can be selected when labels are set up for the study. For more information, see <i>Study - Setup - Labels page</i> (on page 144).
Panels	Test panels included in this event. Click the ellipsis button (...). A list of panels appears. Select the checkboxes for the panels to include in the event, and click UPDATE .	REQUIRED. The test panels were created on the Study - Setup - Panels page.
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	Allows characters from all languages.

Field descriptions for a Testing event

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.

Properties Field	Description	Notes
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	<p>REQUIRED.</p> <p>The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date.</p> <p>The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.</p>
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	<p>For Dose events, this field is read-only.</p> <p>Dose events can take place only at or after the Zero Date and Time.</p>
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	<p>Days—A number from 0 to 999.</p> <p>Hours—A number from 0 to 23.</p> <p>Minutes—A number from 0 to 59.</p> <p>Seconds—A number from 0 to 59.</p> <p>For more information, see <i>About schedules and events</i> (on page 183).</p>

Event Properties - Testing events

Event Properties Field	Description	Notes
Event Category	Category for the event.	REQUIRED. Items in the drop-down list depend on the event type you selected. If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events. Categories are based on the <i>event types created for the study</i> (on page 57).
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Panels	Test panels included in this event. Click the ellipsis button (...). A list of panels appears. Select the checkboxes for the panels to include in the event, and click UPDATE .	REQUIRED. The test panels were created on the Study - Setup - Panels page.
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	Allows characters from all languages.

Field descriptions for an Other event

Properties Field	Description	Notes
Time Point	Description of when the event occurs.	REQUIRED. Maximum characters: 30. Used for your own reference.
Consider Seconds	Enables the capture of seconds when the event occurs.	Default value is not selected. Enables the Seconds field.

Properties Field	Description	Notes
PK Time	Time an event is scheduled to take place, relative to the Zero Date and Time.	<p>REQUIRED.</p> <p>The PK Time is specified in terms of days, hours, minutes, and seconds. The Days, Hours, Minutes, and Seconds fields default to 0. The combination of these fields represents the number of days, hours, minutes, and seconds to be added or subtracted (if negative) from the Zero Date and Time when calculating the expected event date.</p> <p>The Seconds field is disabled and set to 0 when the Consider Seconds option is not selected.</p>
PK Time Negative	When selected, the event takes place earlier than the Zero Date and Time. The Anchor field (in Advanced properties) is read-only.	<p>For Dose events, this field is read-only.</p> <p>Dose events can take place only at or after the Zero Date and Time.</p>
Days, Hours, Minutes, Seconds	The combined value of these fields is the amount of time to be added to (or subtracted from, if PK Time - Negative is selected) the Zero Date and Time when calculating the expected time for this event in the Study - Events page.	<p>Days—A number from 0 to 999.</p> <p>Hours—A number from 0 to 23.</p> <p>Minutes—A number from 0 to 59.</p> <p>Seconds—A number from 0 to 59.</p> <p>For more information, see <i>About schedules and events</i> (on page 183).</p>

Event Properties - Other events

Field	Description	Notes
Event Category	Category for the event.	REQUIRED. Items in the drop-down list depend on the event type you selected. If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events. Categories are based on the <i>event types created for the study</i> (on page 57).
Form	You can choose between No Selection and any form configured for the study on the Setup – Forms page.	Available for all event types.
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	Allows characters from all languages.

Field descriptions—Edit Advanced properties (for all events).

Advanced Field	Description	Notes
Exclude From Periods	Time periods in which the event is excluded. For each time period checkbox: <ul style="list-style-type: none"> • Selected—The period does not include this event. • Not selected—The period includes this event. 	The schedule that is generated for the selected period does not include the event. If selected, the events table lists events that are not excluded from the specified period.
Exclude from Treatments	For each treatment checkbox: <ul style="list-style-type: none"> • Selected—The treatment does not include this event. • Not selected—The treatment includes this event. 	The schedule that is generated for a given period does not include the selected treatments. If selected, the events table lists events that are not excluded from the specified treatment.

Advanced Field	Description	Notes
Deviation Settings section		
Negative Tolerance	<p>The negative tolerance for an event.</p> <p>Includes edit boxes for Minutes and Seconds.</p>	<p>The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank.</p> <p>The Minutes field for Negative Tolerance allows 5 digits.</p> <p>The Seconds field for Negative Tolerance allows 2 digits.</p>
Positive Tolerance	<p>The tolerance for an event.</p> <p>Includes edit boxes for Minutes and Seconds.</p>	<p>The Seconds field is enabled only when the Consider Seconds option is selected; otherwise the field is disabled and set to blank.</p> <p>The Minutes field for Positive Tolerance allows 5 digits.</p> <p>The Seconds field for Positive Tolerance allows 2 digits.</p>
Schedule Options section		
Tolerance	Number of minutes before or after the PK Time that the event can take place and still be considered on time.	Must be from 0 to 999 minutes.
Anchor	<p>Selected—The event is an anchor event.</p> <p>This field is read-only if PK Time - Negative is selected.</p>	<p>For anchor events, the PK time created for the event is not changed if the schedule is adjusted for late events. Anchors reset the schedule at the specified event.</p>
Ignore Offset	<p>Selected—The event is not staggered by participant when the schedule is created. All participants are scheduled for the same time.</p> <p>Overrides the Offset Interval value that is set when the schedule is created on the Study - Events page.</p>	<p>The Offset Interval is specified when the schedule is created. It builds time into the schedule for staggering participants.</p> <p>Any offset intervals for other events in the schedule are not applied to this event.</p>

Advanced Field	Description	Notes
Adjust Schedule	<p>Whether the PK times for participant should be adjusted in the schedule when the sample collection is late.</p> <p>Selected—All events that are scheduled to take place after this event have their PK times adjusted accordingly, so that the appropriate time intervals are still met.</p>	<p>This field is used so that a late event does not affect any sample collections scheduled after the event.</p> <p>Events resume their originally scheduled PK Times at the next Anchor event.</p> <p>When selected, the Adjust column in the events table lists Yes.</p> <p>You can select either Adjust Schedule or Adjust Schedule (Restricted) but not both.</p>
Adjust Schedule (Restricted)	<p>Whether the schedule is adjusted when the sample collection is late.</p> <p>Selected—Events with a status of Not Started that are scheduled to take place after this event are rescheduled if one of the following conditions is met:</p> <ul style="list-style-type: none"> • The Adjusted By setting for the event being rescheduled is set to Previous Event and the sample being logged is associated with the event that precedes the event being rescheduled. • The Adjusted By setting for the event being rescheduled is set to the event associated with the sample being logged. 	<p>If selected, the Adjust column in the events table lists Restricted.</p>
Use Tolerance for Adjust	<p>Selected—Uses event tolerance to adjust the event schedule.</p>	<p>Available if Adjust Schedule and Adjust Schedule (Restricted) are selected.</p>

Advanced Field	Description	Notes
Adjusted by	Event that, when its sample is collected late, causes this event to be adjusted.	<p>Available if Adjust Schedule (Restricted) is selected.</p> <p>The Drop-down list contains all events in the event plan that meet the following conditions:</p> <ul style="list-style-type: none"> • A status of Approved or blank. • The Adjust Schedule (restricted) checkbox is selected. <p>Note: The event you select must have a PK time earlier than the current event, or the same PK Time Negative setting as the current event.</p>
Qualifier section		
Qualifier	Qualifier code to mark event data for data management purposes.	<p>Default: (No Selection).</p> <p>The drop-down list contains qualifiers that were previously created for the study. For more information, see Study - Setup - Other page (on page 153).</p>

4 Click **SAVE**.

The Events page appears.

If the edited event was previously approved, a warning message appears. A new version of the event is created, and the old version is disabled. The new version of the event must be approved before you can add it to the schedule.

Deleting an approved or unapproved event from a study

Prerequisites:

- Create the study in the Resource Management module, and define study properties.
 - You must have the Approve Study Setup function permission.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Events** category.
 - 2 Select one or more events, and click **DELETE**.

A confirmation dialog box appears.

- 3 **If the event is approved**—In the Approval area, type your User ID, password, and a Comment, and click **Apply**.

If the event is unapproved—Click **OK**.

The Study - Setup - Events page appears.

Approved deleted events are disabled and their status is Deleted. Values appear in the Deleted Date, Deleted By, and Deleted Comment fields.

Unapproved events are removed from view.

Treatments in a study

Tasks: Study - Setup - Treatments page

On the Study - Setup - Treatments page, you view the treatments and sequences assigned to a study.

A treatment is the application of a medication (dose) or a procedure. A treatment can also be defined as a course of medication or a series of procedures. Treatments are identified in a study in order to define the event plan for a given subject.

- *Adding a treatment to a study* (on page 139).
- *Editing a treatment* (on page 140).
- *Removing a treatment from a study* (on page 141).
- *Adding a sequence to a study* (on page 141).
- *Editing a sequence* (on page 142).
- *Removing a sequence from a study* (on page 143).

Adding a treatment to a study

Prerequisites:

- At least one study and at least one event plan must exist. For more information, see *Study - Setup - Events page* (on page 91).
 - Create the study in the Resource Management module, and define study properties.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Treatments** category.
 - 2 In the Treatment area, click **ADD**.
The New Treatment dialog box appears.
 - 3 Fill in the fields.

Field descriptions for the New Treatment dialog box

Field	Description	Notes
Treatment	Unique name for the treatment.	REQUIRED. Maximum characters: 30.
Event Plan	Event plan in which the treatment is used.	When you create a treatment, this field is required. The drop-down list contains event plans that were created on the Study - Setup - Events page. When you edit a treatment, this field is read-only if the treatment been used in a sequence. Approval is required.
Comment	Comment about the treatment.	Maximum characters: 200.

- 4 Click **APPLY**.

Editing a treatment

Prerequisites: Create the study in the Resource Management module, and define study properties.

If a treatment has already been used in a sequence, the Event Plan field is read-only, and the edits must be approved.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Treatments** category.
- 2 In the **Treatments** section, click the ellipsis button (...) for a treatment.
The Edit Treatment dialog box appears.
- 3 Fill in the fields.

Field descriptions for the Edit Treatment dialog box

Field	Description	Notes
Treatment	Unique name for the treatment.	REQUIRED. Maximum characters: 30.
Event Plan	Event plan in which the treatment is used.	When you create a treatment, this field is required. The drop-down list contains event plans that were created on the Study - Setup - Events page. When you edit a treatment, this field is read-only if the treatment been used in a sequence. Approval is required.
Comment	Comment about the treatment.	Maximum characters: 200.

- 4 If approval is required, type your User ID, password, and a comment, and click **APPLY**.

Removing a treatment from a study

Prerequisites: Create the study in the Resource Management module, and define study properties.

You cannot remove a treatment that is used in a sequence.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Treatments** category.
- 2 In the **Treatments** area, click the **X** next to a treatment.
A confirmation dialog box appears.
- 3 Click **OK**.

Adding a sequence to a study

Prerequisites:

- At least one study and at least one event plan must exist. For more information, see *Study - Setup - Events page* (on page 91).
 - Create the study in the Resource Management module, and define study properties.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Treatments** category.
 - 2 In the Sequence area, click **ADD**.
The New Sequence dialog box appears.
 - 3 Fill in the fields and click **APPLY**.

Field descriptions for the New Sequence dialog box

Field	Description	Notes
Sequence ID	Unique name for the sequence.	REQUIRED. Maximum characters: 30.
Sequence	Period —Period in which the treatment is applied. Treatment —Treatment for each period.	The number of treatments in the drop-down list for each period depends on the treatments created in the Treatments area.
Comment	Comment about the sequence.	Maximum characters: 200.

Editing a sequence

Prerequisite: Create the study in the Resource Management module, and define study properties.

If any treatments in a sequence have been scheduled in an event plan, the Sequence ID field is read-only, and the Treatment field for the scheduled period is disabled. You can edit the unscheduled periods.

To add more periods (and therefore more treatments) to a sequence, you must first add periods to the study by editing the Study - Properties page. Then you can add treatments to a sequence at any time, even after all other treatments have been scheduled.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Treatments** category.
- 2 In the **Sequence** box, click the ellipsis button (...) for a sequence.

The Edit Sequence dialog box appears.

- 3 Fill in the fields and click **APPLY**.

Field descriptions for the Edit Sequence dialog box

Field	Description	Notes
Sequence ID	Unique name for the sequence.	REQUIRED. Maximum characters: 30. Read-only if the sequence contains a treatment that is scheduled in an event plan.
Sequence	Period —Period in which the treatment is applied. Treatment —Treatment for each period.	If any treatments are scheduled in an event plan, the treatment field for the scheduled period is disabled. You can edit the unscheduled periods.
Comment	Comment about the sequence.	Maximum characters: 200.

Removing a sequence from a study

Prerequisites: Create the study in the Resource Management module, and define study properties.

You cannot delete a sequence if any of the periods in the sequence have been scheduled in an event plan for any subjects.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Treatments** category.
- 2 In the Sequence box, click the **X** for a sequence.
A confirmation dialog box appears.
- 3 Click **OK**.

Labels setup in a study

Tasks: Study - Setup - Labels page

On the Study - Setup - Labels page, you define label formatting for Collection, Transfer, Dose, Candidate and Subject labels in a study. Labels are formatted to determine the label type to use, and the data to be printed on each label. You can use the date format that was defined when the LabPas application was configured (on the Setting - Facility page) or you can select a different date format to be used for printed date fields on labels.

Each label can contain up to five lines of text. On each line, you can select up to two data items and provide a description for each item.

When the label is printed, the data item is automatically populated with study data. Your description appears to the left of the data item.

Note: If the study is locked, all MODIFY buttons and the Date Format field are disabled.

The type of label to print is based on the schedule that is created for the study.

- *Configuring study labels* (on page 145).

Label types and categories

The type of label to print is based on the schedule created for the study.

The following label categories are available:

- **Pre-Dose** labels are printed for events that have a negative time point.
- **Post-Dose** labels are printed for events that have a positive time point.
- **Other** labels are used only for participant identification labels.

Label type	Description	Categories	Printed from
Collection	Used for sample draws. Can be either pre-dose or post dose labels.	Pre-dose Post dose	Study - Events page <i>Labels page</i> (on page 441)
Transfer	Used for sample aliquots.	Pre-dose Post dose	Study - Events page <i>Labels page</i> (on page 441) <i>Sample Aliquoting page</i> (in the <i>Sample Management Guide</i>)
Dose	Used for each dose event in the study.	Post dose	Study - Events page <i>Labels page</i> (on page 441)

Label type	Description	Categories	Printed from
Candidate	Printed for candidates.	Other	<i>Study - Participants - Subjects page</i> (on page 175)
Subject	Printed for subjects.	Other	<i>Study - Participants - Subjects page</i> (on page 175)
CDE Pooling	Used to determine the label type and the information to include when you print the CDE Pooling labels.	Other	Clinical Data Entry - Pooling page (in the <i>Clinical Data Entry Guide</i>)

Configuring study labels

Prerequisites:

- *Define labels on the Label Configuration page* (in the *Administration Guide*).
- Create the study in the Resource Management module, and define study properties.

Each label can contain up to 5 lines of text. Each line can contain 2 data items that are populated by the study, with a description you provide for each data item

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Labels** category.
- 2 In the **Date Format** field, select the date to use when dates are printed on Dose, Collection, and Transfer labels in this study.

(No Selection) uses the date format that was defined for the LabPas application on the Settings - Facility page.

- 3 For any label you want to configure, click **MODIFY**.

The Modify Label dialog box appears.

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

Field descriptions for the Modify Label dialog box

Field	Description	Notes
Label Type	<p>Available options depend on the type of label:</p> <ul style="list-style-type: none"> • Dose, Collection, Transfer, CDE Pooling—All CT function labels. • Candidate, Subject—All Wrist labels. 	<p>REQUIRED.</p> <p>Options are based on how CT function labels and Wrist function labels were defined on the Label Configuration page.</p>
Drop-down list	<p>Item of study data to include on the label in this location on the line.</p>	<p>Options are based on the category of label.</p> <p>When the label is printed, the field is automatically populated with the study data for the item you selected.</p>
Text field to the left of the drop-down list	<p>Text that describes the data you selected from the drop-down list.</p> <p>On the printed label, your text appears to the left of the study data item.</p>	<p>Maximum characters: 30.</p> <p>The text you provide is the only description of the data item that appears on this part of the line when the label is printed.</p>

Addresses in a study

Tasks: Study - Setup - Addresses page

- *Adding and editing a shipping address* (on page 147).
- *Deleting a shipping address from a study* (on page 148).

Adding and editing a shipping address

Prerequisites: Create the study in the Resource Management module, and define study properties.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Addresses** category.
- 2 Click **NEW**.
- 3 To add a shipping address to the study, click **NEW**.

To edit a shipping address, select an address, and click **EDIT**.

The Address dialog box appears.

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

Field descriptions for the Address dialog box

Field	Description	Notes
Customer	Customer name.	REQUIRED. Maximum characters: 80, including comma, ampersand, and parentheses.
Contact	Contact person name.	REQUIRED. Maximum characters: 80, including comma, ampersand, and parentheses.
Address 1	First line of address.	REQUIRED. Maximum characters: 80.
Address 2	Second line of address.	Maximum characters: 80.
City	City.	REQUIRED. Maximum characters: 30.
State	State.	1-30 characters.
Postal Code	Zip code.	REQUIRED. Maximum characters: 30.
Country	Country.	Maximum characters: 30.
Telephone	Telephone number.	Maximum characters: 30. Numerals and dashes (-) are allowed. Do not use parentheses.

Field	Description	Notes
Fax	Fax number.	Maximum characters: 30. Numerals and dashes (-) are allowed. Do not use parentheses.

Deleting a shipping address from a study

Prerequisites: Create the study in the Resource Management module, and define study properties.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Addresses** category.
- 2 Select one or more addresses, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

AE setup in a study

Tasks: Study - Setup - AEs page

On the Study - Setup - AEs page, you specify the options that appear in the drop-down lists when you add or edit an AE form.

Note: All buttons and fields are disabled if the study is locked.

- *Adding and removing a treatment related* (on page 149).
- *Adding and removing an action taken* (on page 149).
- *Adding and removing a severity* (on page 150).
- *Adding and removing significance* (on page 151).
- *Adding and removing an outcome* (on page 151).
- *Selecting the custom fields to appear on an AE form* (on page 152).

Adding and removing a treatment related

Prerequisites: Create the study in the Resource Management module, and define study properties.

The treatments that you create are available in the Related to Treatment drop-down list when you add or edit an AE form. You cannot remove a treatment that is associated with an AE form.

Changes appear in the CT Change Log report with a source of AE Setup.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **AEs** category.
- 2 To add a treatment related:
 - a In the **Treatment Related** section, click **ADD**.
The New Treatment dialog box appears.
 - b In the **Description** field, type a unique description for the treatment.
 - c Click **APPLY**.
The new treatment appears in the Treatment Related section.
- 3 To remove a treatment related:
 - a In the **Treatment Related** section, click the **X** for a treatment related, and click **DELETE**.
A confirmation dialog box appears.
 - b Click **OK**.

Adding and removing an action taken

Prerequisites: Create the study in the Resource Management module, and define study properties.

The actions that you create are available in the Action Taken drop-down list when you add or edit an AE form. You cannot remove an action taken that is associated with an AE form.

Changes appear in the CT Change Log report with a source of AE Setup.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **AEs** category.
- 2 To add an action taken:
 - a In the **Action Taken** section, click **ADD**.
The New Action Taken dialog box appears.
 - b In the **Description** field, type a unique description for the new action.
 - c Click **APPLY**.
- 3 To remove an action taken:
 - a In the **Action Taken** section, click the **X** for an action taken, and click **DELETE**.
A confirmation dialog box appears.
 - b Click **OK**.

Adding and removing a severity

Prerequisites: Create the study in the Resource Management module, and define study properties.

The severity options that you create are available in the Severity drop-down list when you add or edit an AE form. You cannot remove a severity that is associated with an AE form.

Changes appear in the CT Change Log report with a source of AE Setup.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **AEs** category.
- 2 To add a severity:
 - a In the **Severity** section, click **ADD**.
The New Severity dialog box appears.
 - b In the **Description** field, type a unique description for the new severity.
 - c Click **APPLY**.
- 3 To remove a severity:
 - a In the **Severity** section, click the **X** for a severity, and click **DELETE**.
A confirmation dialog box appears.
 - b Click **OK**.

Adding and removing a significance

Prerequisites: Create the study in the Resource Management module, and define study properties.

The significance options that you create are available in the Significance drop-down list when you add or edit an AE form. You cannot remove a significance that is associated with an AE form.

Changes appear in the CT Change Log report with a source of AE Setup.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **AEs** category.
- 2 To add a significance:
 - a In the **Significance** section, click **ADD**.
The New Significance dialog box appears.
 - b In the **Description** field, type a unique description for the new significance.
 - c Click **APPLY**.
- 3 To remove a significance:
 - a In the **Significance** section, click the **X** for a significance, and click **DELETE**.
A confirmation dialog box appears.
 - b Click **OK**.

Adding and removing an outcome

Prerequisites: Create the study in the Resource Management module, and define study properties.

The outcomes that you create are available in the Outcome drop-down list when you add or edit an AE form. You cannot remove an outcome that is associated with an AE form.

Changes appear in the CT Change Log report with a source of AE Setup.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **AEs** category.
- 2 To add an outcome:
 - a In the **Outcome** section, click **ADD**.
The New Outcome dialog box appears.
 - b In the **Description** field, type a unique description.
 - c Click **APPLY**.
- 3 To remove an outcome:
 - a In the **Outcome** section, click the **X** for an outcome, and click **DELETE**.
A confirmation dialog box appears.
 - b Click **OK**.

Selecting the custom fields to appear on an AE form

Prerequisite: Specify custom fields for AE forms.

Changes appear in the CT Change Log report with a source of AE Setup.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **AEs** category.
- 2 In the Additional Data section, from the **Form** drop-down list, select the form containing the custom fields.

When you leave the page, your selection is saved.

Other elements in a study

Study - Setup - Other page

On the Study - Setup - Other page, you view visit and qualifier codes that can be used in the study.

Visit and qualifier codes are optional and are used to mark event data for data management purposes. The qualifier code is used in the *Study - Setup - Events page* (on page 91) to further qualify certain events in a period. Visits and qualifiers help to sort data after it has been exported to a third party.

Note: All buttons and fields are disabled if the study is locked.

Tasks: Study - Setup - Other page

- *Adding and removing a visit* (on page 153).
- *Adding and removing a qualifier* (on page 154).

Adding and removing a visit

Prerequisites: Create the study in the Resource Management module, and define study properties.

You cannot remove a visit that is associated with any events.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Other** category.
- 2 To remove a visit:
 - a In the **Visit** section, click the **X** for a visit.
 - b Click **DELETE**.
A confirmation dialog box appears.
 - c Click **OK**.
- 3 To add a visit:
 - a In the **Visit** section, click **ADD**.
The New Visit dialog box appears.
 - b Fill in the fields.

Field descriptions for the New Visit dialog box

Field	Description	Notes
Period	Period for the visit	REQUIRED.
Code	Unique code for the visit	REQUIRED. Must be unique. Maximum characters: 8.
Description	Text to describe the visit.	REQUIRED.
PK Start	Time range to apply to the visit.	REQUIRED.
PK Finish		The PK Start date must be prior to the PK finish date. If the period has already been defined, the PK Time range cannot overlap the existing range.

- c Click **APPLY**.
The visit appears in the Visit section.

Adding and removing a qualifier

Prerequisites: Create the study in the Resource Management module, and define study properties.

You cannot remove a qualifier that is associated with any events.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Setup** tab > **Other** category.
- 2 To add a qualifier:
 - a In the **Qualifier** section, click **ADD**.
The New Qualifier dialog box appears.
 - b In the **Code** field, type a unique code of 1 to 8 characters for the qualifier.
 - c Click **APPLY**.
- 3 To remove a qualifier:
 - a In the **Qualifier** section, click the **X** for a qualifier, and click **DELETE**.
A confirmation dialog box appears.
 - b Click **OK**.

CHAPTER 6

Participants and candidates in the LabPas CT module

In this chapter

Study - Participants - Candidates page	158
Study - Participants - Subjects page	175

Study - Participants - Candidates page

On the Study - Participants - Candidates page, you manage study candidates, who are potential study subjects. Volunteer records become candidate records when they are assigned a screening number.

Tasks include adding, approving, un-approving, editing, renumbering, and deleting candidates, linking volunteers to screening numbers, and printing labels for use with a candidate's samples.

On the Candidates section, you assign screening numbers to candidates, and on the Subjects page, you link candidates to subject numbers. The CT Change Log reports all edits made to candidates, and all approval activity for candidate records.

The Study - Participants - Candidates page lists:

- All candidates that are associated with groups assigned to the current facility.
- Volunteers who have been accepted into the current study through the LabPas Recruiting module are listed if the application allows recruiting volunteers.

Tasks: Study - Participants - Candidates page

- *Adding a candidate to a study* (on page 161).
- *Viewing existing recruiting data for a candidate* (on page 164).
- *Approving a candidate in a study* (on page 166).
- *Dropping a candidate in a study* (on page 166).
- *Editing a candidate in a study* (on page 167).
- *Deleting a candidate from a study* (on page 172).
- *Printing candidate labels in a study* (on page 172).
- *Renumbering candidates in a study* (on page 173).

Candidates in the CT module

Candidate status

The Status column appears on the far right of the Candidates table. Fields are read-only if the VRN field is blank or the candidate is a Pending Volunteer.

Value in Status column	Candidate status
--	Created and not yet approved.
Accepted	Accepted.
Approved	Approved.
Completed	Records are complete.
Consent Withdrawn	Withdrawal of consent is logged.
Dropped	Dropped.

Value in Status column	Candidate status
Pending Candidate	Pending.
Screen Fail	Did not meet the screening requirements.

The Clinicals field indicates whether a candidate has failed any clinical tests. If you select Failed Clinicals when you edit a candidate, the Clinicals field states Fail.

Approved and unapproved candidates

Candidates must be approved to be scheduled on the Study - Events - Scheduled page. Candidate rows in the schedule turn red if candidates are unapproved after having been scheduled.

If a candidate is unapproved:

- The scheduled events for that candidate can be cancelled (if the events have a status of Not Started), and the candidate's ranking can be cleared.
- Any assigned time slots for the candidate are automatically cleared.
- You can renumber candidates by time slot and reassign rankings.
- Candidate approval activity is recorded in the CT Change Log report.

If a Volunteer's status is changed in the LabPas Recruiting module to any status other than Accepted or Alternate, before the volunteer has been assigned a screening number, the volunteer record is removed from the Study - Participants - Candidate page.

Candidates that originate from the LabPas Recruiting module

If a candidate originated as a volunteer in the Recruiting module, any data that was collected for the volunteer in the LabPas Recruiting module appears and can be updated on the Edit Candidate page. Whether candidate data is linked between the LabPas Recruiting module and the LabPas CT module depends on whether the candidate has been assigned a screening number.

Volunteer screening number	Information originating in the LabPas Recruiting module
Before candidate is assigned a screening number	Volunteer is not visible as a candidate in the LabPas CT module.
After volunteer is assigned a screening number	<ul style="list-style-type: none"> • The record is locked as a LabPas CT candidate record. • Future updates made to the corresponding record in the LabPas Recruiting module are not transferred to the CT candidate record. • Changes made to the record in the LabPas CT module do not affect the corresponding volunteer record in the LabPas Recruiting module.

In the Edit Candidate window, the Tobacco History, Additional Demographics, Medical, Other, Surgical, Medications, Screening Tests, Study Questions and Restrictions tabs can be updated and contain data only for candidates that originated as volunteers in the LabPas Recruiting module.

All edits made to candidate records are reported in the CT Change Log report.

Fields that are calculated

On the Demographics tab, the Age, BMI, %IBW, Serum Creatinine, and CrCl fields are read-only fields and are calculated based on data entered on the Edit Candidate page or in the Recruiting module.

If *facility settings* (in the *Administration Guide*) are configured for standard height and weight measurements, the LabPas application automatically converts to metric for the calculation.

Field	Calculation
Age	Calculated based on the candidate's birth date in relation to the current date.
BMI	Body Mass Index, calculated if the candidate's height and weight are provided. BMI is calculated to two decimal places using the following formula: $\text{BMI} = \text{Weight (kg)} / \text{Height}^2 \text{ (m)}$
% IBW	Percentage of ideal body weight. Automatically calculated if the candidate's height, weight, frame and gender are provided. % IBW is calculated to two decimal places using the standard Hammond calculation: <ul style="list-style-type: none"> Men (medium frame): $\text{IBW} = 48 \text{ kg} + (1.1 \text{ kg} * (\text{Height cm} - 150 \text{ cm}))$. Women (medium frame): $\text{IBW} = 45 \text{ kg} + (.9 \text{ kg} * (\text{Height cm} - 150 \text{ cm}))$. $\% \text{ IBW} = (\text{Weight kg} / \text{IBW}) * 100$ For both men and women, subtract 10% of IBW for a small frame, and add 10% of IBW for a large frame.
Serum Creatinine	Measured in mg/dL.
CrCl	(Creatinine Clearance) Calculated to three decimal places using the Cockcroft-Gault formula: <ul style="list-style-type: none"> Men: $\text{CrCl (mL/min)} = ((140 - \text{age}) * \text{Weight kg} / (72 * \text{serum creatinine mg/dL}))$. Women: $\text{CrCl (mL/min)} = .85 * ((140 - \text{age}) * \text{Weight kg} / (72 * \text{serum creatinine mg/dL}))$

Placeholder candidates

Placeholder candidates are used to schedule events for a candidate before the candidate is promoted by being brought from the LabPas Recruiting module to the LabPas CT module. This feature lets you create a study and schedule events before you know all the available candidates.

When you assign an actual candidate (by selecting the candidate from the Assign To list and saving the Edit Candidate page), the events that were associated with the placeholder candidate are transferred to the actual candidate, and the placeholder candidate is removed from the study. An entry is written to the CT Change Log.

The Placeholder checkbox on the New Candidate page is not selected by default. On the Edit Candidate page, the Placeholder checkbox is disabled if the candidate has a non-blank VRN.

The Assign To selection list options include blank and all candidates in the same group with a status of Approved and Placeholder set to Yes. Assign To is read-only if the candidate has a blank VRN.

Adding a candidate to a study

Prerequisite: You must define elements as appropriate for the study on the *Study - Setup page* (on page 76).

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab > **Candidates** category.

The Study - Participants - Candidates page appears.

- 2 Click **NEW**.

The New Candidate dialog box appears.

- 3 Fill in the fields and click **APPLY**.

Field descriptions for the New Candidate dialog box

Field	Description	Notes
VRN	Volunteer recruiting number.	<p>READ-ONLY.</p> <p>Appears for candidate records that originated as volunteers in the LabPas Recruiting module.</p> <p>If this field is not blank, the Screening No., Placeholder, Group, Initials, Alternate, Last Dose, and Last Exit fields are read-only.</p>

Field	Description	Notes
Screening No.	<p>Unique screening number for the candidate.</p> <p>The number can be either:</p> <ul style="list-style-type: none"> • An existing screening number that is not already associated with another VRN. • A new unique screening number. 	<p>REQUIRED.</p> <p>Maximum characters: 30.</p> <p>Cannot be the same as any existing Subject No. in the study.</p> <p>Screening numbers are assigned in this dialog box, or in the Edit Candidate dialog box for candidates that originate from the LabPas Recruiting module.</p>
Placeholder	<p>Selected—The candidate is a placeholder candidate.</p> <p>Used for scheduling events for candidates before they are brought to the LabPas CT module from the LabPas Recruiting module. For more information, see Placeholder candidates.</p>	<p>Default: Not selected.</p> <p>On the Edit Candidate dialog box, this field is disabled if the candidate has a blank VRN.</p>
Group	<p>Group to which the candidate belongs.</p> <p>A blank indicates no group.</p>	<p>REQUIRED.</p> <p>Default: Group number set in the filter, if filter was used.</p> <p>Groups in the drop-down list are defined in the Resource Management module.</p>
Cohort	<p>Custom text used to further categorize groups of candidates.</p>	<p>Maximum characters: 30.</p>
Initials	<p>Custom text.</p>	<p>Maximum characters: 10.</p> <p>The value can be the candidate's actual initials or any other text.</p>

Field	Description	Notes
Time Slot	<p>Number that specifies the subject's place in the scheduling order when an Offset Interval is defined during event scheduling or rescheduling in a study.</p> <p>Used for scheduling candidates for pre-dose events.</p> <p>The Expected Time for pre-dose events in Period 1 is calculated using the Time Slot in relation to the Offset Interval.</p> <p>If a candidate has events scheduled based on the current group, and the candidate's group number changes, the candidate appears in <i>both</i> the current and the new group.</p>	<p>The value:</p> <ul style="list-style-type: none"> • Must be a number from -999 to 9999, excluding zero. • Must be unique, unless the No. Parallel Subjects setting in study properties is greater than 1, in which case the Time Slot can be shared among the number of parallel subjects (or candidates). <p>The field is read-only for recruiting candidates that have not been assigned a screening number.</p>
Rank	Custom text to further identify the candidate	<p>Maximum characters: 30.</p> <p>When reassigning ranking, only uppercase letters are allowed.</p>
Comment	Comment text.	Maximum characters: 200.
Gender	Gender of the candidate.	Default: N/A .
Birth Date	<p>Birth date of the candidate.</p> <p>Enter a date, or click the calendar icon and select the date.</p>	
Age	Age of the candidate.	Read-only. Automatically populated after you enter the birth date.
Frame	Body frame of the candidate.	Default is No Selection .
BMI	Body mass index of the candidate.	<p>READ-ONLY.</p> <p>Calculated to two decimal places after you enter both height and weight.</p>
Height	Height of the candidate.	
Weight	Weight of the candidate.	

Field	Description	Notes
%IBW	Percentage of ideal body weight.	READ-ONLY Calculated after you enter height, weight, frame, and gender.
Race Race Category	Race information associated with the candidate.	
Ethnicity Ethnicity Category	Ethnicity information associated with the candidate.	
Last Study	If the candidate has previously participated in any studies, describe the latest study completed.	
Dose	Date the candidate received their final dose in the last study.	Complete this field only if you entered text in the Last Study field.
Exit	Date the last study was completed.	Complete this field only if you entered text in the Last Study field.
Alternate	When selected, the candidate is an alternate in the study.	

Viewing existing recruiting data for a candidate

Prerequisite: You must define elements as appropriate for the study on the *Study - Setup page* (on page 76).

Recruiting candidates include a VRN number in the VRN column.

Volunteers from the LabPas Recruiting module are listed only if Allow Recruiting Volunteers was enabled when the LabPas application was configured.

Note: The Group, Cohort, Initials, Time Slot, Rank, Failed Clinicals and Comment fields are read-only for Recruiting candidates that have not been assigned a screening number.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab > **Candidates** category.

The Study - Participants - Candidates page appears.

- 2 Select a Recruiting candidate, and click **EDIT**.

The Edit Candidate dialog box appears with the Demographics tab selected.

- 3 Click the other tabs to view corresponding data.

Tabs for Recruiting data on the Edit Candidate dialog box

Data is collected either during an incoming call, or on the page listed in the Notes column.

Tab	Description	Notes
Tobacco History	Candidate's history of tobacco use	Information collected on the <i>Volunteer - Personal Demographics - Add Tobacco page</i> (in the <i>Recruiting User Guide</i>).
Additional Demographics	Demographics information for the candidate.	Information collected on the <i>Volunteer - Personal - Other page</i> (in the <i>Recruiting User Guide</i>).
Medical	Medical conditions recorded for the candidate.	Information collected on the <i>Volunteer - Clinical History - Medical page</i> (in the <i>Recruiting User Guide</i>).
Other	Nonmedical conditions recorded for the candidate.	Information collected on the <i>Volunteer - Clinical History - Medical page</i> (in the <i>Recruiting User Guide</i>).
Surgical	Surgical procedures recorded for the candidate.	Information collected on the <i>Volunteer - Clinical History - Surgical page</i> (in the <i>Recruiting User Guide</i>).
Medications	Medication intake recorded for the candidate.	Information collected on the <i>Volunteer - Clinical History - Medical page</i> (in the <i>Recruiting User Guide</i>).
Screening Data	Screening information for the candidate.	
Screening Tests	Screening tests recorded during recruiting. Events with a status of Non Started, In Progress, or Completed appear. All fields are read-only.	Information collected on the <i>Volunteer - Studies page</i> (in the <i>Recruiting User Guide</i>).

Approving a candidate in a study

Prerequisites:

- You must define elements as appropriate for the study on the *Study - Setup page* (on page 76).
- You must have the Approve Study Data function permission.

Candidate approval activity is recorded in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab > **Candidates** category.

The Study - Participants - Candidates page appears.

- 2 Select one or more candidates, and click **APPROVAL**.

If the **VRN** is not blank for any of the candidates, an error message appears. Any candidate that originates in the Recruiting module must be approved using the Eligibility Review page.

Otherwise, the Candidate Approval dialog box appears.

- 3 Change the status to Approved, and fill in other fields.

Field descriptions for the Candidate Approval dialog box

Field	Description	Notes
Status	<p>Approved—Approve the candidate in the study.</p> <p>Dropped—Drop the candidate from the study.</p>	If you select Accepted or Approved, the Cancel Scheduled Events and Clear Rank checkboxes for the candidate are read-only.
Cancel Scheduled Events	<p>Selected—Any future events that have been scheduled for the candidate are cancelled.</p> <p>All events for this candidate with a status of Not Started are canceled on the Study - Events - Scheduled page.</p>	Read-only if the status is Accepted or Approved.
Clear Rank	Selected —The Rank field for the candidate is cleared. The candidate's ranking is removed.	Read-only if the status is Accepted or Approved.

- 4 In the Approval area, type your User ID, password, and a Comment, and click **Apply**.

Dropping a candidate in a study

Prerequisite: You must define elements as appropriate for the study on the *Study - Setup page* (on page 76).

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab > **Candidates** category.

The Study - Participants - Candidates page appears.

- 2 Select one or more candidates, and click **APPROVAL**.

The Candidate Approval dialog box appears.

- 3 Change the status to Dropped, and fill in other fields.

Field descriptions for the Candidate Approval dialog box

Field	Description	Notes
Status	<p>Approved—Approve the candidate in the study.</p> <p>Dropped—Drop the candidate from the study.</p>	If you select Accepted or Approved, the Cancel Scheduled Events and Clear Rank checkboxes for the candidate are read-only.
Cancel Scheduled Events	<p>Selected—Any future events that have been scheduled for the candidate are cancelled.</p> <p>All events for this candidate with a status of Not Started are canceled on the Study - Events - Scheduled page.</p>	Read-only if the status is Accepted or Approved.
Clear Rank	Selected —The Rank field for the candidate is cleared. The candidate's ranking is removed.	Read-only if the status is Accepted or Approved.

- 4 In the Approval area, type your User ID, password, and a Comment, and click **Apply**.

Editing a candidate in a study

Prerequisite: You must define elements as appropriate for the study on the *Study - Setup page* (on page 76).

If a candidate has events scheduled based on the current group, and you change the candidate's group number, the candidate appears in *both* the current and the new group.

If you edit a candidate, approval is required. All edits made to candidate records are reported in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab > **Candidates** category.

The Study - Participants - Candidates page appears.

- 2 Select one or more candidates, and click **EDIT**.

The Edit Candidate dialog box appears.

- If the candidate originated in the LabPas CT module, the dialog box contains only a Demographics tab.
- If the candidate originated in the LabPas Recruiting module, the dialog box contains additional tabs with editable data.

- 3 Fill in the fields.

When you edit these fields, the Eligibility Review status for the candidate changes to Pending.

Field descriptions for the Edit Candidate dialog box (Demographics tab)

Note: The Demographics tab contains the same fields as the New Candidate dialog box, and several additional fields.

Fields appearing in both New Candidate and Edit Candidate dialog boxes

Field	Description	Notes
VRN	Volunteer recruiting number.	<p>READ-ONLY.</p> <p>Appears for candidate records that originated as volunteers in the LabPas Recruiting module.</p> <p>If this field is not blank, the Screening No., Placeholder, Group, Initials, Alternate, Last Dose, and Last Exit fields are read-only.</p>
Screening No.	<p>Unique screening number for the candidate.</p> <p>The number can be either:</p> <ul style="list-style-type: none"> • An existing screening number that is not already associated with another VRN. • A new unique screening number. 	<p>REQUIRED.</p> <p>Maximum characters: 30.</p> <p>Cannot be the same as any existing Subject No. in the study.</p> <p>Screening numbers are assigned in this dialog box, or in the Edit Candidate dialog box for candidates that originate from the LabPas Recruiting module.</p>

Field	Description	Notes
Placeholder	<p>Selected—The candidate is a placeholder candidate.</p> <p>Used for scheduling events for candidates before they are brought to the LabPas CT module from the LabPas Recruiting module. For more information, see Placeholder candidates.</p>	<p>Default: Not selected.</p> <p>On the Edit Candidate dialog box, this field is disabled if the candidate has a blank VRN.</p>
Group	<p>Group to which the candidate belongs.</p> <p>A blank indicates no group.</p>	<p>REQUIRED.</p> <p>Default: Group number set in the filter, if filter was used.</p> <p>Groups in the drop-down list are defined in the Resource Management module.</p>
Cohort	<p>Custom text used to further categorize groups of candidates.</p>	<p>Maximum characters: 30.</p>
Initials	<p>Custom text.</p>	<p>Maximum characters: 10.</p> <p>The value can be the candidate's actual initials or any other text.</p>
Time Slot	<p>Number that specifies the subject's place in the scheduling order when an Offset Interval is defined during event scheduling or rescheduling in a study.</p> <p>Used for scheduling candidates for pre-dose events.</p> <p>The Expected Time for pre-dose events in Period 1 is calculated using the Time Slot in relation to the Offset Interval.</p> <p>If a candidate has events scheduled based on the current group, and the candidate's group number changes, the candidate appears in <i>both</i> the current and the new group.</p>	<p>The value:</p> <ul style="list-style-type: none"> • Must be a number from -999 to 9999, excluding zero. • Must be unique, unless the No. Parallel Subjects setting in study properties is greater than 1, in which case the Time Slot can be shared among the number of parallel subjects (or candidates). <p>The field is read-only for recruiting candidates that have not been assigned a screening number.</p>

Field	Description	Notes
Rank	Custom text to further identify the candidate	Maximum characters: 30. When reassigning ranking, only uppercase letters are allowed.
Comment	Comment text.	Maximum characters: 200.
Gender	Gender of the candidate.	Default: N/A .
Birth Date	Birth date of the candidate. Enter a date, or click the calendar icon and select the date.	
Age	Age of the candidate.	Read-only. Automatically populated after you enter the birth date.
Frame	Body frame of the candidate.	Default is No Selection .
BMI	Body mass index of the candidate.	READ-ONLY. Calculated to two decimal places after you enter both height and weight.
Height	Height of the candidate.	
Weight	Weight of the candidate.	
%IBW	Percentage of ideal body weight.	READ-ONLY Calculated after you enter height, weight, frame, and gender.
Race Race Category	Race information associated with the candidate.	
Ethnicity Ethnicity Category	Ethnicity information associated with the candidate.	
Last Study	If the candidate has previously participated in any studies, describe the latest study completed.	
Dose	Date the candidate received their final dose in the last study.	Complete this field only if you entered text in the Last Study field.
Exit	Date the last study was completed.	Complete this field only if you entered text in the Last Study field.

Field	Description	Notes
Alternate	When selected, the candidate is an alternate in the study.	

If you save a candidate when you have selected this candidate as a placeholder candidate, the Cohort, Rank, and Time Slot fields are copied from the placeholder candidate to the candidate that you are editing. An error occurs if the placeholder candidate is either associated with an adhoc event or a scheduled event that has a status other than Not Started or Cancelled.

Additional fields, Edit Candidate dialog box

Field	Description	Notes
Failed Clinicals checkbox	Selected —The candidate has failed one or more clinical tests.	The field is read-only for recruiting candidates that have not been assigned a screening number. When editing a candidate, this field is always disabled.
Serum Creatinine	Populated only if data was entered for the candidate in the LabPas Recruiting module.	
CrCl	Creatinine Clearance. Automatically calculated if a candidate's serum creatinine, gender, age, and weight are provided.	Cockcroft-Gault formula is used to calculate Creatinine Clearance.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

- 4 Click **SAVE**.

An warning message appears if:

- The **VRN** field for the candidate is a not blank.
- The data on any tab has changed.

The message includes a list of all tabs with changed data.

If the page contains a **Delete** field that has been selected, these fields are deleted when you save.

The Eligibility Review Status of the candidate is set to Pending if:

- The Completed field is selected for the participant on the Eligibility Review page, then the Completed field is updated to unselected and an audit record is written to the CT Change

Log with a source of Study Participant Approval. The comment associated with the audit record is set to Approved data was changed.

- The Monitor Review Status field for the candidate is set to Reviewed, then the Monitor Review Status is updated to Not Reviewed and an audit record is written to the CT Change Log with a source of Study Data Approval. The comment associated with the audit record is set to Reviewed data was changed.

Deleting a candidate from a study

You can delete a candidate if:

- The candidate is not associated with a subject or a scheduled event.
 - The candidate has a blank VRN field.
 - The candidate is a volunteer from the Recruiting module and has a screening number.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab > **Candidates** category.

The Study - Participants - Candidates page appears.

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

A confirmation dialog box appears.

- 3 Click **OK**.

Printing candidate labels in a study

Prerequisites:

- You must have already defined elements for the study on the *Study - Setup page* (on page 76), as appropriate for the study.
- Candidate Labels must have been set up on the *Study - Setup - Labels page* (on page 144).

Labels contain a barcode that is prefixed with a unique alphanumeric identifier for the study.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab > **Candidates** category.

The Study - Participants - Candidates page appears.

- 2 Click **LABELS**.

The Candidate Labels dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Candidate Labels dialog box

Field	Description	Notes
Group	Provide a group number that is associated with the current facility, or a blank to indicate no group.	REQUIRED. If the page is being filtered by group, this field is read-only and, by default, shows the group selected in the filter. Groups are associated with the current facility on the Resource Management - Study - Groups page.
Candidate No.	First candidate number in the range of labels you want to print.	Numbers you provide must match screening numbers in the study.
To	Last candidate number for the range of labels you want to print.	Default: The data that you enter in the Candidate No. field. Edit as needed.

- 4 Click **PRINT**.
Labels are formatted and the Print dialog appears.
- 5 Select printer options, and click **OK**.

Renumbering candidates in a study

Prerequisites:

- You must define elements as appropriate for the study on the *Study - Setup page* (on page 76).
- You must have the Approve Study Data function permission.

Approval is required to renumber candidates.

Unapproved candidates that were numbered or ranked display their previous time slot and ranking, but they are not included when you create a schedule for a study.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab > **Candidates** category.
The Study - Participants - Candidates page appears.
- 2 Click **RENUMBER**.
The Renumber Candidates dialog box appears.
- 3 Fill in the fields.

Field descriptions for the Renumber Candidates dialog box

Field	Description	Notes
Group	Group from which the candidates are renumbered.	REQUIRED. Default: The group selected in the filter.
Start Time Slot	Number of the time slot where the renumbering of candidates begins.	REQUIRED. All time slots including the Start Time Slot are renumbered in order, leaving out all unapproved candidates.
Direction	Ascending —Renumbering goes forward in increments of 1. Descending —Renumbering goes in reverse, in increments of -1.	Default: Ascending.
Adjust Rank	Yes —Start Rank field is enabled. No —Start Rank field is read-only.	Default: No.
Start Rank	Uppercase letter where the new ranking begins	Only uppercase letters are recognized in this field. Ranking is automatically reassigned in the same order as the new time slot order, beginning with the letter you specify.

- In the Approval area, type your user ID, password, and an optional comment, and click **Apply**.
When a candidate is linked to a subject, the Subject No. appears on the Study - Participants - Candidates page.

Study - Participants - Subjects page

On the Study - Participants - Subjects page, you view subjects that are required for a study. Subjects are associated with groups assigned to the current facility.

On this page, you can organize, edit, and approve subjects, and print labels that are used for the subject's samples.

Subjects can be linked to candidates by adding a screening number to a subject's record in the New Subject or Edit Subject dialog box. Subjects must then be approved in order to be scheduled on the Study - Events page.

After a subject is linked to a candidate, the candidate's demographic information appears on the *Study - Participants - Subjects page* (on page 175).

All approval activity is reported in the CT Change Log.

Tasks: Study - Participants - Subjects page

- *Adding a subject to a study* (on page 175).
- *Approving and undoing approval of a subject* (on page 177).
- *Editing a subject* (on page 177).
- *Deleting a subject from a study* (on page 179).
- *Printing subject labels in a study* (on page 179).

About subjects and scheduling

The time slot specifies the subject's place in the scheduling order and adjusts the expected time of an event by adding to or subtracting from the PK Time (the time the event is scheduled to take place in relation to Zero Time), using the Offset Interval as defined on the Study - Events page.

- **Scheduling pre-dose events**—If the subject and candidate have already been linked, and the candidate has also been assigned a time slot, the time slot of the subject is used for the pre-dose event.
- **Ignore Offset Interval**—If this field is selected for an event (Study - Setup - Events page), all time slots are ignored when the schedule is created for that event.

Adding a subject to a study

Prerequisites:

- Create at least one sequence on the *Study - Setup - Treatments page* (on page 139).
 - Complete the tasks on the *Study - Participants - Candidates page* (on page 158).
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab.
 - 2 Click **NEW**.

The New Subject dialog box appears.

- 3 Fill in the fields.

Field descriptions for the New Subject dialog box

Field	Description	Notes
Group	Group to which the subject belongs. For new subjects, a blank indicates no group.	REQUIRED. Must be a number from 1 to 99. Choices include all groups that are associated with the facility on the Resource Management Study - Groups page. Default is the group number currently selected in the filter, if any.
Subject No.	Identifier for the subject. Must be unique in the study. The Subject No. cannot be the same as any existing Screening No. in the study.	REQUIRED. Maximum characters: 30. Must be an alphanumeric value.
Sequence ID	You can edit the Sequence ID until the first dose of the last period has been recorded. The sequence for the subject must always match the previous sequence for the subject for the periods in which the subject has already been dosed.	REQUIRED. Options include the sequences previously configured on the <i>Study - Setup - Treatments page</i> (on page 139).
Time Slot	Number to specify the subject's place in the scheduling order.	REQUIRED. Must be a number from 1 to 9999. The number of subjects that can share the same time slot is defined in the Number Parallel Subjects field on the Study - Properties page. The Time Slot field determines if the number of subjects has been reached.

Field	Description	Notes
Screening No.	Screening number.	If you provide a screening number, values appear in the fields on the Study - Participants - Subjects page (on page 175).
Comment	A comment.	

- 4 Click **APPLY**.

Approving and undoing approval of a subject

Prerequisite: You must have the Approve Study Setup function permission

All approval activity is reported in the CT Change Log.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab.
- 2 Select one or more subject numbers, and click **APPROVAL**.
The Subject Approval dialog box appears.
- 3 To approve a subject, select **Yes**.
To undo approval of a subject, select **No**.
- 4 In the Approval area, type your User ID, password, and a Comment, and click **Apply**.

Editing a subject

Prerequisite: You must have the Study Setup function permission.

If a subject has been approved at least one time, even if the subject's Accepted status is currently No, your edits must be approved.

All approval activity is reported in the CT Change Log. Additionally, after a subject has an approval history, all edits made to the subject are reported to the CT Change Log.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab.
- 2 Select one or more subjects that have never been approved.
or
Select a subject that has been approved at least one time, even if the subject's Accepted status is currently No.
- 3 Click **EDIT**.
The Edit Subject dialog box appears.
- 4 Fill in the fields.

Field descriptions for the Edit Subject dialog box

Field	Description	Notes
Group	Group to which the subject belongs. For new subjects, a blank indicates no group.	REQUIRED. Must be a number from 1 to 99. Choices include all groups that are associated with the facility on the Resource Management Study - Groups page. Default is the group number currently selected in the filter, if any.
Subject No.	Identifier for the subject. Must be unique in the study. The Subject No. cannot be the same as any existing Screening No. in the study.	REQUIRED. Maximum characters: 30. Must be an alphanumeric value.
Sequence ID	You can edit the Sequence ID until the first dose of the last period has been recorded. The sequence for the subject must always match the previous sequence for the subject for the periods in which the subject has already been dosed.	REQUIRED. Options include the sequences previously configured on the Study - Setup - Treatments page (on page 139).
Time Slot	Number to specify the subject's place in the scheduling order.	REQUIRED. Must be a number from 1 to 9999. The number of subjects that can share the same time slot is defined in the Number Parallel Subjects field on the Study - Properties page. The Time Slot field determines if the number of subjects has been reached.
Screening No.	Screening number.	If you provide a screening number, values appear in the fields on the Study - Participants - Subjects page (on page 175).
Comment	A comment.	

- If the subject has an approval history, in the Approval area, type your User ID, password, and a Comment, and click **Apply**.

If the subject does not have an approval history, click **SAVE**.

Deleting a subject from a study

You cannot delete a subject that has an approval history.

- From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab.
- Select one or more subject numbers, and click **DELETE**.
A confirmation dialog box appears.
- Click **OK**.

Printing subject labels in a study

Before you can print labels, Subject Labels must have been set up on the *Study - Setup - Labels page* (on page 144).

Labels contain a barcode that is prefixed with a unique alphanumeric identifier for the study.

- From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Participants** tab.
- Click **LABELS**.
The Subject Labels dialog box appears.
- Fill in the fields.

Field descriptions in the Subject Labels dialog box

Field	Description	Notes
Group	Provide a group number that is associated with the current facility, or a blank to indicate no group.	REQUIRED. If the page is being filtered by group, this field is read-only and, by default, shows the group selected in the filter. Groups are associated with the current facility on the Resource Management - Study - Groups page.
Subject No.	First subject number in the range of labels to print.	
To	Last subject number for the range of labels to print.	Default: The data that you enter in the Subject No. field. Edit as needed.

- 4 Click **PRINT**.
The Print dialog appears.
- 5 Select printer options, and click **OK**.

CHAPTER 7

Scheduled events in a study

In this chapter

Tasks: Study - Events - Schedule page	182
About schedules and events	183
Creating a schedule in a study	187
Rescheduling events in a study	189
Changing the status of an event	192
Printing study labels.....	196

Tasks: Study - Events - Schedule page

On the Study - Events - Scheduled page, you schedule and reschedule events, change an event's Event Status, and print labels for a study.

You can use the filter to sort schedules and list the selected Group and Period along with any filter criteria specified. The Group filter lets you select from the groups assigned to the current facility.

- *Creating a schedule in a study* (on page 187).
- *Rescheduling events in a study* (on page 189).
- *Changing the status of an event in a study* (on page 192).
- *Printing study labels* (on page 196).

About schedules and events

How a schedule of events is created

When you create a schedule, all approved events that were created on the Study - Setup - Events page are applied to the approved candidates and approved subjects that were set up on the Study - Participants page. The schedule begins at the Zero Date and Zero Time you specify.

In the Create Schedule and Re-Schedule dialog boxes, the Arrival Date and Dose Day values were previously configured for the study and group in on the Resource Management - Study Groups page. The Zero Date defaults to the date generated from the following formula:

$$(\text{Arrival Date} + (\text{Dose Day} - 1))$$

When you schedule or reschedule events, if you override the date, a warning appears.

Participants are staggered in the schedule by their time slots, which specify the participant's place in the scheduling order. The Sub Time Slot is used for scheduling purposes (and overrides candidate time slot) in events where a subject and candidate are linked.

Time slots adjust the Expected Time of an event by adding to or subtracting from the PK Time (the time the event is scheduled to take place in relation to Zero Time), using the Offset Interval. The Offset Interval is set when the schedule is created, and indicates the number of minutes to stagger between each participant. If Ignore Offset Interval was selected for specific events on the Study - Setup - Events page, participants for those events are all scheduled for the same time.

Note: The Expected Time for events with the Consider Seconds options selected on the CT Studies - Setup - Events is calculated using the PK Time Seconds field.

Example of time slots and expected time

In this example:

- The PK time for an event is -3 hours.
- Zero time is noon.
- The Offset interval is 5.
- Subjects have assigned time slots.

Sub Time slot: Expected Time	Event
1	9:00am
2	9:05am
3	9:10am
4	9:15am

Event status for different event types

After the schedule has been created, and an event is edited and approved, any subsequent changes made to the event are not applied to the schedule unless a new schedule is created using the **RESCHEDULE** button.

Status is applied or changed by the following actions:			
Status	For PK Events	For Clinical Testing events	For Events other than PK or Clinical Testing
Not started	Creating the event.	Creating the event.	Creating the event.
Revised	After creating the schedule and then editing and approving the event on the <i>Study - Setup - Events page</i> (on page 91).	After creating the schedule and then editing and approving the event on the <i>Study - Setup - Events page</i> (on page 91).	After creating the schedule and then editing and approving the event on the <i>Study - Setup - Events page</i> (on page 91).
In Progress	From the time that a value is established for an Actual Sample date until the Storage Date has a value.	From the time that a value is established for the Actual Sample Data until the panel test result data is saved.	
Completed	Establishing a storage date for the event.	Saving panel test results.	Establishing a value for the Actual Sample Data.
Missed	Saving the event with the Missed Event field selected on the Clinical Data Entry page.	Saving the event with the Missed Event field selected on the Clinical Data Entry page.	
Failed	Saving the event with the Failed status selected on the Samples - Samples page.	Saving the event with the Failed status selected on the Samples - Samples page.	
Cancelled	Cancelling the event using the Event Status page.	Cancelling the event using the Event Status page.	

For more information, see:

- ***About scheduling and rescheduling events*** (on page 186).
- ***Creating a schedule in a study.*** (on page 187)
- ***Rescheduling events in a study.*** (on page 189)

Colors used in the Scheduled Events table

Color and location	Information
Red text in Expected time column	The event status is Not Started and the expected time has passed without action.
Red highlighting in a row	Any of the following conditions: <ul style="list-style-type: none"> • The candidate has been unaccepted. • The subject has been unaccepted. (Subject Accepted field is No). • The candidate has failed a clinical test. • The event has been unapproved. (Approval field is any value other than Approved.) • The time slot for a subject does not match. • Candidate Status is any value other than Approved.
Orange highlighting in a row	The Sub Time Slot was changed in the <i>Study - Participants - Subjects page</i> (on page 175) after the schedule was created. The Subject's new time slot appears in brackets to the right of the original time slot, but is not be applied to the schedule unless a new schedule is created with the Reschedule button. If the schedule is re-scheduled, the orange highlighting is removed.

The Adjust column in the Scheduled Events table contains one of the following values:

- **Yes** if the Adjust Schedule field is checked for the event.
- **Restricted** if the Adjust Schedule (Restricted) field is checked.
- **No** if neither is checked.

When you create a schedule, vessel barcodes are assigned and appear in the Vessel Barcode field of each Clinical, PK and Dose event. The prefixes and suffixes are assigned as determined on the *Settings - Facility page* (in the *Administration Guide*).

After you print labels from this page, the value in the corresponding column (Collection Printed or Transfer Printed) is Yes.

Rules for saving an event

When you save a new or edited event, an error message appears if a specific event is selected in the Adjusted By field and the event scheduled has either a PK time later than the current event or has a different PK Time Negative setting than the current event.

About deleting events

If you delete an approved event on the *Study - Setup - Events page* (on page 82) after the schedule has been created, the Approval changes to Deleted.

About scheduling and rescheduling events

- You can reschedule events that have an event status of Not Started or Revised.
- Existing user and clinic assignments for events in the Changed Events table are not removed when events in the table are rescheduled.
- If you delete an approved event on the *Study - Setup - Events page* (on page 91) after the schedule has been created, the Approval status changes to Deleted.
- You cannot schedule or reschedule approved events from an event plan if either of the following conditions are set in the properties of each event:

- The period being scheduled is selected in the Exclude From Periods field.
- The treatment being scheduled is selected in the Exclude From Treatments field.

For more information, see Editing an event in a study and the properties for the specific events.

- If the Study, Group, and Period is not configured on the Event Schedule page, an error appears on the corresponding Clinic Floor page.
- All status changes are logged in the CT Change Log. For more information, see *Reports* (on page 421).

Creating a schedule in a study

Prerequisites:

- At least one candidate and one subject must be approved.
- At least one event must be approved on the Study - Setup -Events page.
- The group and period you select must be unlocked.
- You must have the Create/Modify Events function permission.

For more information, see *About scheduling and rescheduling events* (on page 186).

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Scheduled** category.
- 2 Use the filter to select the group and period you want to schedule.
- 3 Click **SCHEDULE**.

The Create Schedule dialog box appears.

- 4 Fill in the fields.

Field descriptions for the Create Schedule dialog box

Field	Description	Notes
Group and Period	Fields that you accessed using the filter.	Read-only. To select a different Group and Period, click CANCEL and use the filter.
Zero Date	The date the study begins. Click the calendar icon and select a date.	Required. If you enter the date manually, you must use the format that was defined on the Settings - Facility page when the LabPas application was configured.
Zero Time	The time the study begins.	Required. Use the format that was defined on the Settings - Facility page when the LabPas application was configured.
Offset interval	The number of minutes needed between each participant	A number between 0 and 999.

- 5 In the Approval area, type your User ID, password, and a Comment, and click **Apply**.
The events table reappears with your changes.

Colors in the Events table

Color and location	Information
Red text in Expected time column	The event status is Not Started and the expected time has passed without action.
Red highlighting in a row	Any of the following conditions: <ul style="list-style-type: none">• The candidate has been unaccepted.• The subject has been unaccepted. (Subject Accepted field is No).• The candidate has failed a clinical test.• The event has been unapproved. (Approval field is any value other than Approved.)• The time slot for a subject does not match.• Candidate Status is any value other than Approved.
Orange highlighting in a row	The Sub Time Slot was changed in the <i>Study - Participants - Subjects page</i> (on page 175) after the schedule was created. The Subject's new time slot appears in brackets to the right of the original time slot, but is not be applied to the schedule unless a new schedule is created with the Reschedule button. If the schedule is re-scheduled, the orange highlighting is removed.

Rescheduling events in a study

Prerequisites:

- At least one candidate and one subject must be approved.
- At least one event must be approved on the Study - Setup -Events page.
- The group and period you select must be unlocked.
- You must have the Create/Modify Events function permission.

You can reschedule events if a schedule already exists for the group and period.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Scheduled** category.
- 2 Use the filter to select the Group and Period you want to schedule.
- 3 Click **SCHEDULE**.

The Re-Schedule dialog box appears.

- 4 Fill in the fields.

Field descriptions for the Re-Schedule dialog box

Fields on the Schedule Events and Re-Schedule Events dialog boxes

Field	Description	Notes
Group and Period	Fields that you accessed using the filter.	Read-only. To select a different Group and Period, click CANCEL and use the filter.
Zero Date	The date the study begins. Click the calendar icon and select a date.	Required. If you enter the date manually, you must use the format that was defined on the Settings - Facility page when the LabPas application was configured.
Zero Time	The time the study begins.	Required. Use the format that was defined on the Settings - Facility page when the LabPas application was configured.
Offset interval	The number of minutes needed between each participant	A number between 0 and 999.

Additional fields on the Re-Schedule dialog box

Field	Description	Notes
Remove Deleted Events	Selected —Events with an event status of Not Started are deleted.	Default: Not selected. Read-only if there are no deleted events in the schedule.
Remove Excluded Events	Selected —Excluded events are removed.	Default: Not selected. Read-only if there are no excluded events in the schedule. Excluded events have an event status of Not Started, an approval status of Revised, and meet one of the following conditions: <ul style="list-style-type: none"> The period being scheduled is selected in the Exclude From Periods field on the CT Studies - Setup - Events page for the approved version of the event. The treatment being scheduled is selected in the Exclude From Treatments field on the CT Studies - Setup - Events page for the approved version of the event.
Changed Events list	Events that require a new barcode. Note: When you save the edited schedule, events for which the checkbox is selected have the Collection Printed and Transfer Printed columns set to blank on the Study - Events - Schedule page. Label audit history for the original barcode is no longer available.	The list includes approved events that have already been scheduled and that have a higher version than they had the last time the current group and period was scheduled.

- In the Approval area, type your User ID, password, and a Comment, and click **Apply**.
The events table reappears with your changes.
Events that have not yet occurred are rescheduled.
 - If a Dose event has been completed, only events after the Dose are rescheduled.
 - The Zero date and Offset Interval fields show the updated information.

Colors in the Events table alert you to certain conditions

Color and location	Information
Red text in Expected time column	The event status is Not Started and the expected time has passed without action.
Red highlighting in a row	Any of the following conditions: <ul style="list-style-type: none"> • The candidate has been unaccepted. • The subject has been unaccepted. (Subject Accepted field is No). • The candidate has failed a clinical test. • The event has been unapproved. (Approval field is any value other than Approved.) • The time slot for a subject does not match. • Candidate Status is any value other than Approved.
Orange highlighting in a row	The Sub Time Slot was changed in the <i>Study - Participants - Subjects page</i> (on page 175) after the schedule was created. The Subject's new time slot appears in brackets to the right of the original time slot, but is not be applied to the schedule unless a new schedule is created with the Reschedule button. If the schedule is re-scheduled, the orange highlighting is removed.

Note: The Expected Time for events with the Consider Seconds options selected on the CT Studies - Setup - Events is calculated using the PK Time Seconds field.

Changing the status of an event

Prerequisites:

- You must have the Create/Modify Events function permission.
- To change the status of an event to Not Started, you must have the Restart Events permission.

Note: If the study is locked, the row selection checkboxes, and the **STATUS**, **SCHEDULE** and **LABELS** buttons, are not visible.

You can cancel an event (change the event status to Cancelled) using this procedure or from the Study - Participants - Candidates page.

To change the status of more than one event, select events of the same type; for example, Dose events.

Approval is required to change the status of an event.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Scheduled** category.
- 2 Select one or more events of the same type, and click **STATUS**.

The Event Status dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Event Status dialog box

Field	Description	Notes
Status buttons	<p>Not Started—Changes the status of all selected events to Not Started.</p> <p>Cancelled—Changes the status of all selected events to Cancelled</p>	
Generate new Dose Barcode	Selected —Generates new Vessel Barcode for each selected event.	The label audit history for the original Vessel Barcode is no longer available.

- 4 Click **APPLY**.

The Study - Events - Schedule page appears. Results depend on the type of events whose status you changed, and the new status of the events.

When you click **APPLY**, the following changes are made:

- The Approval Status of the event is changed to Not Approved if the Approval Status is currently set to Approved. An entry is recorded in the CT Change Log with a source of Study Data Approval. The comment for the audit record states that approved data was changed.

- The Monitor Review Status of the event is changed to Not Reviewed if the Monitor Review Status is currently Reviewed. An entry is recorded in the CT Change Log with a source of Study Data Approval. The comment for the audit record states that reviewed data was changed.

Results—Status change to Dose events

New status	Results
Cancelled	Event Status is set to Cancelled.
Not Started	<ul style="list-style-type: none"> • Actual Sample Date is reset to blank. • The Generate new Dose Barcode checkbox is enabled. • The Actual Sample Date is reset to blank. • The Expected Time for the event is not changed. You can reschedule the event from the Re-Schedule dialog box or by entering a preceding event with an Adjust Schedule setting.

If you selected New Barcode:

- A new Vessel Barcode is generated for each selected event. The label audit history for the original Vessel Barcode is no longer available.
- Any additional form data associated with the event is recorded in the CT Change Log report and reset to blank.
- The original Vessel Barcode is recorded in the CT Change Log and set to blank if both of the following conditions exist:
 - A candidate link exists
 - No post-dose events have been started for the subject.

Results—Status change to PK Testing events

New status	Results
Cancelled	<ul style="list-style-type: none"> • Event Status is set to Cancelled • The Collection Printed and Transfer Printed columns are set to blank.
Not Started	<ul style="list-style-type: none"> • Event Status is set to Not Started. • The Actual Sample Date is recorded in the CT Change Log report and is reset to blank. • A new Vessel Barcode is generated for each PK event. • The Collection Printed and Transfer Printed columns are reset to blank. • The Expected Time for the event is not changed. You can reschedule the event from the Re-Schedule dialog box or by entering a preceding event with an Adjust Schedule setting.

If new vessel barcodes are generated:

- The label audit history for the original Vessel Barcode is no longer available.
- Any test result data associated with the original Vessel Barcode is recorded in the CT Change Log report and reset to blank.
- Any additional form data associated with the event is recorded in the CT Change Log report and reset to blank.

Results—Status change to Clinical Testing events

New status	Results
Cancelled	<ul style="list-style-type: none"> • Event Status is set to Cancelled. • The Collection Printed column is set to blank.
Not Started	<ul style="list-style-type: none"> • Event Status is set to Not Started. • The Actual Sample Date is recorded in the CT Change Log report and is reset to blank. • A new Vessel Barcode is generated for each Clinical Testing event.

If new vessel barcodes are generated:

- The label audit history for the original Vessel Barcode is no longer available.
- Any test result data associated with the original Vessel Barcode is recorded in the CT Change Log report and reset to blank.
- Any additional form data associated with the event is recorded in the CT Change Log report and reset to blank.

Results—Status change to Testing events

New status	Results
Cancelled	Event Status is set to Cancelled.
Not Started	<ul style="list-style-type: none"> • Event Status is set to Not Started. • Any test result data associated with the event will be recorded in the CT Change Log report and reset to blank. • Any additional form data associated with the event is recorded in the CT Change Log report and reset to blank. • The Actual Sample Date is reset to blank. • The Expected Time for the event is not changed. You can reschedule the event from the Re-Schedule dialog box or by entering a preceding event with an Adjust Schedule setting.

Results—Status change to Other events

New status	Results
Cancelled	Event Status is set to Cancelled.
Not Started	<ul style="list-style-type: none">• Event Status is set to Not Started.• Any test result data associated with the event will be recorded in the CT Change Log report and reset to blank.• Any additional form data associated with the event is recorded in the CT Change Log report and reset to blank.• The Expected Time for the event is not changed. You can reschedule the event from the Re-Schedule dialog box or by entering a preceding event with an Adjust Schedule setting.

Printing study labels

Prerequisite: The label formatting must be defined and a printer specified on the *Study - Setup - Labels page* (on page 144).

If one event uses multiple tubes, the number specified on the *Study - Setup - Events page* (on page 144) determines the number of labels to print. Tube descriptions are included if descriptions were provided during study setup.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Scheduled** category.

- 2 Click **LABELS**.

The Print Labels dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Print Labels dialog box

Field	Description	Notes
Time Points	<p>Pre-Dose—Print labels only for events that have a negative time point.</p> <p>Post-Dose—Print labels only for events that have a positive time point.</p>	If you select Pre-Dose, the Dose Labels option is not available in the Label Type field.
Label Type	<p>Type of labels to print for events in the schedule.</p> <p>Collection Labels—Draw events.</p> <p>Transfer Labels—Aliquot events.</p> <p>Dose Labels—Dose events.</p> <p>CDE Pooling Labels—Pooling events.</p>	<p>Dose Labels option is available if the Time Points field selection is Post-Dose.</p> <p>Transfer Labels option is not available if the Vendor Labeled Transfer Tubes checkbox is selected on the Study - Properties page.</p>
Subject No. To	<p>Range of subjects to which to restrict labels.</p> <p>Subject No. First label to print.</p> <p>To—Last label to print.</p>	
Screening No. To	<p>Range of candidates, specified by screening number, to which to restrict labels.</p> <p>Screening No.—First label to print.</p> <p>To—Last label to print.</p>	

Field	Description	Notes
Vessel Barcodes To	Range of vessel barcodes to which to restrict labels. Vessel Barcodes —First label to print. To —Last label to print.	
Event Plan	Range of event plans to which to restrict labels. Event Plan —First label to print. To —Last label to print.	
Event No.	Restricts labels to a range of events Event No. —First label to print. To —Last label to print.	
Expected Time	Range of expected event times to which to restrict labels. Expected Time —First label to print. To —Last label to print.	Seconds appear in the Expected Time field on labels if the label is for an event configured with the Consider Seconds option selected on the CT Studies > Setup – Events page.
Sample Type	Print labels for a specific sample types.	
Not Yet Printed	Selected —Print only the labels that have not been printed previously, from your other selections in this dialog box.	For example, if you selected Time Points= Post Dose, Label Type = Transfer labels, and an Expected Time range, only Transfer labels within the time range that have not yet printed are printed.
Sort By drop-down list and Order	First criterion by which to sort. Order —Print in Ascending or Descending order.	Default: Subject No. Order default: Ascending
Then By	Second criteria by which to sort. Order —Print in Ascending or Descending order.	Default: PK Time. Order default: Ascending
Then By	Third criterion by which to sort.	Default: Screening No. Order default: Ascending

- 4 Click **PRINT**.

The Print dialog box appears.

An error occurs if the Label Type is set to CDE Pooling, and the CDE pooling label has not been configured on the Setup – Labels page for the selected option in the Time Points field.

- 5 Click **OK**.

CHAPTER 8

Data events in a study

In this chapter

Tasks: Study - Events - Data page	200
Exported data	201
Viewing data for any event.....	202
Approving an event.....	203
Unapproving an event.....	205
Editing a scheduled Draw event.....	206
Editing an ad hoc Draw event.....	209
Editing a scheduled Testing event.....	211
Editing an ad hoc Testing event.....	215
Editing a scheduled Other event.....	219
Editing an ad hoc Other event	221
Editing an AE observation or non-AE observation.....	223
Editing a Dose event.....	226
Reclassifying an AE or non-AE observation	227
Exporting study event data.....	228
Batch approving event data.....	229

Tasks: Study - Events - Data page

On the Study - Events - Data page, you edit details of scheduled events and export study data in XML format.

The page lists the details of all scheduled and ad hoc events that have a status other than Cancelled or Not Started, as well as AE observations that were recorded on Clinical Data Entry - AE Observations page and non-AE observations that were recorded on the Clinical Data Entry – Observations page. You can view and edit event details, and export all event details at one time as an XML file.

The Expected Time and Actual Sample Date fields display seconds for barcodes associated with CT study events when the Consider Seconds option is selected on the CT Studies > Setup – Events page.

- *Viewing data for any event* (on page 202).
- *Approving an event* (on page 203).
- *Unapproving an event* (on page 205).
- *Reclassifying an AE or non-AE observation* (on page 227).
- *Editing a scheduled Draw event* (on page 206).
- *Editing an ad hoc Draw event* (on page 209).
- *Editing a scheduled Testing event* (on page 211).
- *Editing an ad hoc Testing event* (on page 215).
- *Editing a scheduled Other event* (on page 219).
- *Editing an ad hoc Other event* (on page 221).
- *Editing an AE observation or non-AE observation* (on page 223).
- *Editing a Dose event* (on page 226).
- *Exporting study event data* (on page 228).

Exported data

Data is exported in XML format.

The data export file lists all data that is associated with the study, including data from other facilities. Exported data is not restricted to the events that appear on the page, which are set by the filter.

Data can be exported for events with an In Progress, Completed, Failed or Missed status.

Seconds appear in the Expected Time, Actual Sample Date, and Test Result Date fields associated with Testing events for Scheduled events with the Consider Seconds option selected on the CT Studies > Setup – Events page.

The exported data includes:

- Names and roles of each member of the study team.
- All scheduled and unscheduled (ad hoc) events with a status of Completed.
- All samples with a status of In Progress
- Centrifuge, aliquot, and storage information for ad hoc PK samples. Fields displayed match the fields displayed for scheduled PK samples.
- Clinical significance for testing and clinical test events.
- All sample results.
- Volunteer demographics, including tobacco history and creatinine clearance if available.
- All approved AE forms.
- The Medical Code for each adverse event.
- All available study information.

CT fields that are not required and have not been answered or have been set to a value of Not Applicable are not included in the exported data.

The Test Date, Performed By, Display Result and Result are not required for results associated with testing and clinical testing events and will be exported when no result has been entered.

Viewing data for any event

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
- 2 Select one or more events, and click **VIEW**.

The View Event page for the event appears. All fields are read-only. The page contains the same information as the Edit Event page, with the following differences:

- The SAVE button is not available. A DONE button is available instead.
- The Change Comment Information section is not available.
- All fields except the APPROVE/UNAPPROVE button are disabled.
- The APPROVE button is available when:
 - The Approval Status of the event is Not Approved
 - You have the Approve Study Data permission.
- The UNAPPROVE button is available when:
 - The Approval Status of the event is Approved
 - You have the Approve Study Data function permission.

Click the APPROVE button to display the Approve Study Data page. Click the UNAPPROVE button to display the Unapprove Study Data page.

- 3 After you finish viewing the event, click **DONE**.

Approving an event

Prerequisites:

- The Event Status for the event must be Completed, Failed, Missed, or Cancelled.
- The event must belong to an unlocked group or period.
- You must have the Approve Study Data function permission.

To approve an event:

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events tab > Data** category.
- 2 Select one or more events, and click **VIEW**.
- 3 The View Event page appears.

Click **APPROVE**.

The Approve Study Data dialog box appears.

- 4 In the Approval area, type your User ID, password and click **Apply**.

Field descriptions for the Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

If the Approval Status of the event is successfully changed to Approved:

- The APPROVE button no longer appears from View Event Data page.
- The UNAPPROVE button appears.
- The Approval Status read-only field is updated.

Unapproving an event

Prerequisite: The event must belong to an unlocked group or period.

To unapprove an event:

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events tab > Data** category.
- 2 Select one or more events, and click **VIEW**.
- 3 The View Event page appears.
Click **UNAPPROVE**.
- 4 The Unapprove Study Data dialog box appears.
- 5 In the Approval area, enter a Comment, and click **Apply**.

Field descriptions for the Unapprove Study Data dialog box

Field	Description	Notes
Comment		REQUIRED. Defaults to the text entered in the Study Data field on the Approval Comments section on the RM Studies > Setup page.

During save, the Approval Status of the event is changed to Not Approved and the Approved By and Approval Date fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval. The Comment saved with the audit record is set to the value entered in the Comment field.

If the Monitor Review Status of the event is Reviewed, it is changed to Not Reviewed. The change is recorded in the same audit trail entry as the Approval Status change.

If the Approval Status of the event is successfully changed to Not Approved:

- The UNAPPROVE button is hidden on the View Event Data page.
- The APPROVE button appears.
- The Approval Status read-only field is updated.
- The Monitor Review Status is updated to Not Reviewed.

Editing a scheduled Draw event

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

You can edit the Date/Time or Comment fields of a scheduled Draw event.

All edited events are identified in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
- 2 Select one or more Clinical or PK Testing events, and click **EDIT**.

The Edit Event dialog box opens for the type of event you selected.

Note: For scheduled events, the value in the Adhoc field is **No**.

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

Field descriptions for the Edit Event dialog box

Field	Description	Notes
Screening No.	Screening number of the subject.	READ-ONLY.
Subject No.	Subject number.	READ-ONLY.
Adhoc	<p>Yes—The event is an ad hoc event.</p> <p>No—The event is a scheduled event.</p> <p>Make sure you are editing the appropriate event.</p>	<p>READ-ONLY.</p> <p>If you chose the wrong event (for example, you intend to edit an ad hoc event but Adhoc=No, indicating a scheduled event), close the Edit Event dialog box without saving and select a different event.</p>
Consider Seconds	Displays whether the event considers seconds.	READ-ONLY.
Approval Status	<p>The event Approval Status:</p> <p>Approved—The event is an approved.</p> <p>Not Approved—The event is not approved.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>
Monitor Review Status	<p>The event Monitor Review Status:</p> <p>Reviewed—The event is reviewed.</p> <p>Not Reviewed—The event is not reviewed.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>

PK Draw or Clinical Draw Information

Field	Description	Notes
Data tab	The fields displayed in the Data tab depend on the selected event type.	
Date/Time	Date and time of the event. Click the calendar icon to enter a new date or make changes manually.	Read-only when the event has a status of Missed. Required for all other events.
Barcode	Barcode for sample collected in this event.	Read-only when you edit the following types of events: <ul style="list-style-type: none"> • A Clinical or PK event. • An event with a status of Missed.
Sample	Sample type.	Read-only when you edit the following types of events: <ul style="list-style-type: none"> • A scheduled Clinical or PK Draw event. • An event with a status of Missed.
Vessel	Vessel type.	Read-only when you edit the following types of events: <ul style="list-style-type: none"> • A Clinical or PK event. • An event with a status of Missed.
Comment	Comment about the event.	

History tab

Contains the audit trail records from the CT Change Log associated with the event.

Field	Description	Notes
Source	Source of the change.	READ-ONLY.
User ID	User that submitted the record.	READ-ONLY.
Date/Time	Date and time of the change.	READ-ONLY.
Comment	Change Comment.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

4 Click **SAVE**.

All fields except the Comment field are disabled if the Event Status of the event is Missed.

If the event is associated with a form, a section containing all form fields appears. Pressing SAVE button saves any changes to form fields and record changes in the CT Change Log.

When you save changes for an event with an Approval Status set to Approved, the Approval Status is changed to Not Approved, and the Approval Date and Approved By fields is set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval. A comment stating approved data has changed is also recorded.

When you save changes for an event with a Monitor Review Status set to Reviewed, the Monitor Review Status is changed to Not Reviewed. An entry is recorded in the CT Change Log with a source of Study Data Approval A comment stating reviewed data has changed is also recorded.

An error appears when you attempt to edit an event associated with a locked group/period if:

- The study is not locked.
- You have the Change Study Data Create/Change Study function permission.

Seconds appear and are required in the Date/Time field for Scheduled events with the Consider Seconds option selected on the CT Studies > Setup – Events page.

When you click SAVE, an error appears if:

- Seconds are not entered in the Date/Time field.
- The event is a Scheduled event with the Consider Seconds option selected on the CT Studies > Setup – Events page.

Editing an ad hoc Draw event

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

You can edit the Date/Time, Visit, Qualifier, Sample, and Comment fields of an ad hoc Draw event.

All edited events are identified in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.

- 2 Select one or more Adhoc Clinical or Adhoc PK Testing events, and click **EDIT**.

The Edit Event dialog box opens for the type of event you selected.

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

Field descriptions for the Edit Event dialog box

Field	Description	Notes
Screening No.	Screening number of the subject.	READ-ONLY.
Subject No.	Subject number.	READ-ONLY.
Adhoc	<p>Yes—The event is an ad hoc event.</p> <p>No—The event is a scheduled event.</p> <p>Make sure you are editing the appropriate event.</p>	<p>READ-ONLY.</p> <p>If you chose the wrong event (for example, you intend to edit an ad hoc event but Adhoc=No, indicating a scheduled event), close the Edit Event dialog box without saving and select a different event.</p>
Consider Seconds	Displays whether the event considers seconds.	READ-ONLY.
Approval Status	<p>The event Approval Status:</p> <p>Approved—The event is an approved.</p> <p>Not Approved—The event is not approved.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>
Monitor Review Status	<p>The event Monitor Review Status:</p> <p>Reviewed—The event is reviewed.</p> <p>Not Reviewed—The event is not reviewed.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>

PK Draw or Clinical Draw Information

Field	Description	Notes
Data tab	The fields displayed in the Data tab depend on the selected event type.	
Date/Time	Date and time of the event. Click the calendar icon to enter a new date or make changes manually.	This field is read-only when the event has a status of Missed and required for all other events.
Qualifier	Qualifier code to mark event data for data management purposes.	Only appears for Adhoc events.
Barcode	Barcode for the sample collected in this event.	This field is read-only when you edit a Clinical or PK event.
Sample	Sample type.	
Vessel	Vessel type.	This field is read-only when you edit a Clinical or PK event.
Comment	Comment about the event.	

History tab

Contains the audit trail records from the CT Change Log associated with the event.

Field	Description	Notes
Source	Source of the change.	READ-ONLY.
User ID	User that submitted the record.	READ-ONLY.
Date/Time	Date and time of the change.	READ-ONLY.
Comment	Change Comment.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

Editing a scheduled Testing event

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

All edited events are identified in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
- 2 Select one or more Testing events, and click **EDIT**.

The Edit Event dialog box opens for the type of event you selected.

The test name appears in red if any existing test results are in violation of an edit check with an action of **Alert** or **Warn and Alert**.

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

Field descriptions for the Edit Event dialog box

Field	Description	Notes
Screening No.	Screening number of the subject.	READ-ONLY.
Subject No.	Subject number.	READ-ONLY.
Adhoc	<p>Yes—The event is an ad hoc event.</p> <p>No—The event is a scheduled event.</p> <p>Make sure you are editing the appropriate event.</p>	<p>READ-ONLY.</p> <p>If you chose the wrong event (for example, you intend to edit an ad hoc event but Adhoc=No, indicating a scheduled event), close the Edit Event dialog box without saving and select a different event.</p>
Consider Seconds	Displays whether the event considers seconds.	READ-ONLY.
Approval Status	<p>The event Approval Status:</p> <p>Approved—The event is an approved.</p> <p>Not Approved—The event is not approved.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>
Monitor Review Status	<p>The event Monitor Review Status:</p> <p>Reviewed—The event is reviewed.</p> <p>Not Reviewed—The event is not reviewed.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>

Testing Information

Field	Description	Notes
Data lab	The fields displayed in the Data tab depend on the selected event type.	
Date/Time	Date and time of the event. Click the calendar icon to enter a new date, or make changes manually.	Read-only when the event has a status of Missed and required for all other events.
Comment	Comment about the event.	Comment was entered when the test was performed.
Clinical Significance	Whether any test results associated with the event are marked as clinically significant.	READ-ONLY
Instrument	Barcode and name of the instrument.	READ-ONLY

Test panel information

Displays the test panels associated with the event, with a row for each test in the panel.

Field	Description	Notes
Test	Name of the test. Tests with alerts are red.	
Optional	Yes —Test is optional in this study. No —Test is required in this study.	Results appear for optional tests that are performed/collected. Optional tests that are not performed/collected do not appear.
Result	Result of the test or tests.	Units depend on the type of test.
Alert	If a test has an alert, the alert code and description appear.	Test values must be within range. If you enter a value outside the reference range or reference value, an alert appears as defined for the LabPas application on the Tests page (in the <i>Administration Guide</i>)

Field	Description	Notes
Clin. Sig	Whether results of the test are marked as clinically significant.	
Source	Source of the test result data.	READ-ONLY If the source is a value other than blank or LabPas, all fields except Clin. Sig. are read-only.
Comment	Comment about the test.	Displays the comment made when test was performed. You can enter a new comment that pertains to the individual test in the panel. If a result is not entered and the Optional field for the test is set to No, a comment is required. The comment must be entered in the Comment field associated with the result.

History tab

Contains the audit trail records from the CT Change Log associated with the event.

Field	Description	Notes
Source	Source of the change.	READ-ONLY.
User ID	User that submitted the record.	READ-ONLY.
Date/Time	Date and time of the change.	READ-ONLY.
Comment	Change Comment.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

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

Any blank sources are changed to LabPas.

All test result fields in the Test Panel table, except Clin. Sig. and Comment, are read-only if:

- The test is associated with a Source other than blank or LabPas, and
- The Editable field for the test is not checked on the CT Studies – Setup – Panels page.

If a change is made to any result fields other than Clin. Sig. or Comment the Source value is updated to LabPas.

Editing an ad hoc Testing event

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

All edited events are identified in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
- 2 Select one or more Testing events, and click **EDIT**.

The Edit Event dialog box opens for the type of event you selected.

The test name appears in red if any existing test results are in violation of an edit check with an action of **Alert** or **Warn and Alert**.

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

Field descriptions for the Edit Event dialog box

Field	Description	Notes
Screening No.	Screening number of the subject.	READ-ONLY.
Subject No.	Subject number.	READ-ONLY.
Adhoc	<p>Yes—The event is an ad hoc event.</p> <p>No—The event is a scheduled event.</p> <p>Make sure you are editing the appropriate event.</p>	<p>READ-ONLY.</p> <p>If you chose the wrong event (for example, you intend to edit an ad hoc event but Adhoc=No, indicating a scheduled event), close the Edit Event dialog box without saving and select a different event.</p>
Consider Seconds	Displays whether the event considers seconds.	READ-ONLY.
Approval Status	<p>The event Approval Status:</p> <p>Approved—The event is an approved.</p> <p>Not Approved—The event is not approved.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>
Monitor Review Status	<p>The event Monitor Review Status:</p> <p>Reviewed—The event is reviewed.</p> <p>Not Reviewed—The event is not reviewed.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>

Testing Information

Field	Description	Notes
Date/Time	Date and time of the event. Click the calendar icon to enter a new date, or make changes manually.	Read-only when the event has a status of Missed and required for all other events.
Qualifier	Qualifier code to mark event data for data management purposes.	Only appears for Adhoc events.
Comment	Comment about the event.	Comment was entered when the test was performed.
Clinical Significance	Whether any test results associated with the event are marked as clinically significant.	READ-ONLY
Instrument	Barcode and name of the instrument.	READ-ONLY

Test panel information

Displays the test panels associated with the event, with a row for each test in the panel.

Field	Description	Notes
Test	Name of the test. Tests with alerts are red.	
Optional	Yes —Test is optional in this study. No —Test is required in this study.	Results appear for optional tests that are performed/collected. Optional tests that are not performed/collected do not appear.
Result	Result of the test or tests.	Units depend on the type of test.
Alert	If a test has an alert, the alert code and description appear.	Test values must be within range. If you enter a value outside the reference range or reference value, an alert appears as defined for the LabPas application on the Tests page (in the <i>Administration Guide</i>)

Field	Description	Notes
Clin. Sig	Whether results of the test are marked as clinically significant.	
Source	Source of the test result data.	READ-ONLY If the source is a value other than blank or LabPas, all fields except Clin. Sig. are read-only.
Comment	Comment about the test.	Displays the comment made when test was performed. You can enter a new comment that pertains to the individual test in the panel. If a result is not entered and the Optional field for the test is set to No, a comment is required. The comment must be entered in the Comment field associated with the result.

History tab

Contains the audit trail records from the CT Change Log associated with the event.

Field	Description	Notes
Source	Source of the change.	READ-ONLY.
User ID	User that submitted the record.	READ-ONLY.
Date/Time	Date and time of the change.	READ-ONLY.
Comment	Change Comment.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

Any edit checks created for the panels are applied.

Action of edit check	Result
Warn	A warning message appears
Warn and Alert	The test name appears in red.
Prevent	A warning message appears. You cannot save changes until you correct the results that are in violation.

Note: Edit checks are defined for test panels.

All test result fields in the Test Panel table, except Clin. Sig. and Comment, are read-only if:

- The test is associated with a Source other than blank or LabPas, and
- The Editable field for the test is not checked on the CT Studies – Setup – Panels page.

If a change is made to any result fields other than Clin. Sig. or Comment the Source value is updated to LabPas.

The edit checks for determining if the Comment field for a result is required do not apply if the result Source is not LabPas. If, however, the test is Editable and any value other than Clin. Sig. or Comment is changed, you must add a comment.

Editing a scheduled Other event

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

All edited events are identified in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
- 2 Select one or more scheduled Other events, and click **EDIT**.

The Edit Event dialog box opens for the type of event you selected.

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

Field descriptions for the Edit Event dialog box

Field	Description	Notes
Screening No.	Screening number of the subject.	READ-ONLY.
Subject No.	Subject number.	READ-ONLY.
Adhoc	<p>Yes—The event is an ad hoc event.</p> <p>No—The event is a scheduled event.</p> <p>Make sure you are editing the appropriate event.</p>	<p>READ-ONLY.</p> <p>If you chose the wrong event (for example, you intend to edit an ad hoc event but Adhoc=No, indicating a scheduled event), close the Edit Event dialog box without saving and select a different event.</p>
Consider Seconds	Displays whether the event considers seconds.	READ-ONLY.
Approval Status	<p>The event Approval Status:</p> <p>Approved—The event is an approved.</p> <p>Not Approved—The event is not approved.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>
Monitor Review Status	<p>The event Monitor Review Status:</p> <p>Reviewed—The event is reviewed.</p> <p>Not Reviewed—The event is not reviewed.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>

Other Information

Field	Description	Notes
Date/Time	Date and time of the event. Click the calendar icon to enter a new date, or make changes manually.	Read-only when the event has a status of Missed. Required for all other events.
Category	Category of the event.	READ-ONLY.
Outcome	Whether the event has been started.	Read-only when the event has a status of Missed.
Comment	Comment about the event.	

History tab

Contains the audit trail records from the CT Change Log associated with the event.

Field	Description	Notes
Source	Source of the change.	READ-ONLY.
User ID	User that submitted the record.	READ-ONLY.
Date/Time	Date and time of the change.	READ-ONLY.
Comment	Change Comment.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

Editing an ad hoc Other event

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

All edited events are identified in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
- 2 Select one or more scheduled Other events, and click **EDIT**.

The Edit Event dialog box opens for the type of event you selected.

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

Field descriptions for the Edit Event dialog box

Field	Description	Notes
Screening No.	Screening number of the subject.	READ-ONLY.
Subject No.	Subject number.	READ-ONLY.
Adhoc	<p>Yes—The event is an ad hoc event.</p> <p>No—The event is a scheduled event.</p> <p>Make sure you are editing the appropriate event.</p>	<p>READ-ONLY.</p> <p>If you chose the wrong event (for example, you intend to edit an ad hoc event but Adhoc=No, indicating a scheduled event), close the Edit Event dialog box without saving and select a different event.</p>
Consider Seconds	Displays whether the event considers seconds.	READ-ONLY.
Approval Status	<p>The event Approval Status:</p> <p>Approved—The event is an approved.</p> <p>Not Approved—The event is not approved.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>
Monitor Review Status	<p>The event Monitor Review Status:</p> <p>Reviewed—The event is reviewed.</p> <p>Not Reviewed—The event is not reviewed.</p>	<p>READ-ONLY.</p> <p>Default value is All.</p>

Other Information

Field	Description	Notes
Date/Time	Date and time of the event. Click the calendar icon to enter a new date, or make changes manually.	Read-only when the event has a status of Missed. Required for all other events.
Qualifier	Qualifier code to mark event data for data management purposes.	Only appears for Adhoc events.
Category	Category of the event.	READ-ONLY.
Outcome	Whether the event has been started.	Read-only when the event has a status of Missed.
Comment	Comment about the event.	

History tab

Contains the audit trail records from the CT Change Log associated with the event.

Field	Description	Notes
Source	Source of the change.	READ-ONLY.
User ID	User that submitted the record.	READ-ONLY.
Date/Time	Date and time of the change.	READ-ONLY.
Comment	Change Comment.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

Editing an AE observation or non-AE observation

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

All AE observations and non-AE observations appear on the Study - Events - Data page. You can edit and resolve existing data that is associated with an adverse event.

For information about recording additional observations, see the following information (in the *Clinical Data Entry Guide*):

- **Recording an AE observation.**
- **Recording a non-AE observation.**

All edited events are identified in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
- 2 Select one or more observations, and click **EDIT**.

The Edit Event - Observation dialog box appears.

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

Field descriptions for the Edit Event dialog box

Field	Description	Notes
Screening No.	Screening number of the subject.	READ-ONLY.
Subject No.	Subject number.	READ-ONLY.
Adhoc	Yes, indicating that the event is an ad hoc event.	READ-ONLY. If you chose the wrong event (for example, you intend to edit an ad hoc event but Adhoc is No, indicating a scheduled event), close the Edit Event dialog box without saving and select a different event.

Observation Information

Field	Description	Notes
Date/Time	Date and time of the event. Click the calendar button to enter a new date or make changes manually.	
Description	Description of the adverse event.	

Field	Description	Notes
Category	Category of the adverse event.	Options include all event categories that are associated with the Observation event type on the Clinical Trials - Event Types page. If you change a category for an AE form from Adverse Event to another category and an AE observation is associated with the AE form, the AE observation is detached from the AE form.
Onset	Date and time of onset.	Required for AE observations. Read-only for non-AE observations. For more information, see About updating the date and time for an event.
Resolution	Date and time that the adverse event was resolved.	Required for AE observations. Read-only for non-AE observations. Must be later than the onset date and time. For more information, see About updating the date and time for an event.
Severity	Severity of the adverse event.	Read-only for non-AE observations.
Comment	Text to further describe the adverse event.	
Medication Given		
Medication	A type-ahead list containing all active medications with one of the following term types from the Setup - Medical Terms page: <ul style="list-style-type: none"> Conmed, available for non-AE observations. AE Conmed, available for AE observations. 	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).

Field	Description	Notes
Indication	Reason the conmed was given. For AE observations, this field displays AE and is read-only.	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.	
Route	A drop-down list with all active routes with a term type of Conmed Route from the Setup - Medical Terms page.	

If the event is assigned to an AE form, and its category is changed from Adverse Event to a different category, then:

- If the AE Form has an Approval Status of Approved or Reviewed, an error appears. The save is cancelled.
- If the AE Form has an Approval Status of Not Approved, Not Reviewed, or Revised, a warning appears, prompting you to remove the event from the AE Form. If you save the changes, the event is removed from the AE form.

If you make changes to observation data associated with an AE Form that has an Approval Status of Approved or Reviewed, an error appears and the save is cancelled.

Editing a Dose event

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

All edited events are identified in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
- 2 Select one or more scheduled Dose events, and click **EDIT**.

The Edit Event dialog box opens for the type of event you selected.

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

Field descriptions for the Edit Event dialog box

Field	Description	Notes
Screening No.	Screening number of the subject.	READ-ONLY.
Subject No.	Subject number.	READ-ONLY.
Adhoc	<p>Yes—The event is an ad hoc event.</p> <p>No—The event is a scheduled event.</p> <p>Make sure you are editing the appropriate event.</p>	<p>READ-ONLY.</p> <p>If you chose the wrong event (for example, you intend to edit an ad hoc event but Adhoc=No, indicating a scheduled event), close the Edit Event dialog box without saving and select a different event.</p>

Dose Information

Field	Description	Notes
Date/Time	Date and time of the event.	<p>Changes to the date/time for this event do not affect the date/time of other scheduled events, regardless of whether this dose is an Adjust event.</p> <p>Read-only when the event has a status of Missed.</p> <p>Required for all other events.</p>
Barcode	Barcode for the dose.	READ-ONLY.
Comment	Comment.	

Reclassifying an AE or non-AE observation

You can reclassify an observation as either an AE observation or a non-AE observation. For example, you can reclassify:

- A non-AE observation that is later determined to be related to an adverse event.
 - An AE observation that is later determined to be unrelated to the study.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
 - 2 Select a record with an Event Type of Observation, and click **EDIT**.
The Edit Event dialog box appears.
 - 3 From the Category drop-down list, select one of the following options:
 - To reclassify an AE observation as a non-AE observation, select any category other than Adverse Event.
 - To reclassify a non-AE observation as an AE observation, select Adverse Event.
You must also select an onset date and time.
 - 4 Click **SAVE**.

If you reclassify an AE observation is associated with an AE form, a warning appears, informing you that the observation will be removed from the AE form. If you continue and the AE form has a Monitor Review Status of Approved or Reviewed, the status changes to Revised.

Exporting study event data

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

The data that is exported is not restricted to the events that appear based on filter criteria selections. For more information, see Exported data.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.

- 2 Click **EXPORT**.

The Data Export status message appears, followed by the File Download dialog box.

- 3 Click **SAVE**.

The Save As dialog box appears.

- 4 In the **File Name** field, type a new name, if desired.

- 5 Change the file extension from **-xml** to **.xml**

- 6 Click **SAVE**.

The Download Complete message appears. The data is exported in XML format to the filename you specified.

Batch approving event data

Prerequisites:

- Events must belong to an unlocked group, period or study.
- The study must be unlocked, or the BATCH APPROVE button does not appear.
- Only data with an event status of Completed, Failed, Missed, or Cancelled may be approved.
- You must have the Approve Study Data function permission.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Events** tab > **Data** category.
- 2 Select one or more events, and click **BATCH APPROVE**. An error appears if all selected samples have an Approval Status set to Approved.

The Batch Approve Study Data dialog box appears.

- 3 In the Approval area, type your User ID, password, and click **Apply**.

Field descriptions for the Batch Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

CHAPTER 9

Study samples

In this chapter

Sample data	232
Aliquots	248
Samples in boxes	249
Shipments	250

Sample data

Study - Samples - Samples page

On the Study - Samples - Samples page, you edit and review information about samples that were collected during Clinical and PK Testing events, and you can override sample process times. Samples collected from both scheduled and ad hoc sample events are listed by group and period, as specified in the filter. Information is displayed for both scheduled and ad hoc samples. You can also edit and review information about samples that were collected on test panels associated with the event.

Samples listed are restricted to samples associated with groups assigned to the current facility, were processed using one of the following methods:

- Samples were logged in using the Sample Logging page.
- Samples were processed using the Clinical Data Entry - Sample page.

This method is used if CT Sample Logging Required was not selected in the CT Settings area on the Settings - Facility page when the LabPas application was configured. For more information, see the *Administration Guide*.

Samples that are edited on this page are identified in the CT Change Log report.

Samples appear highlighted in orange if any of the following conditions exist:

- The event status field value is Cancelled or Failed.
A sample's event status can be changed only on the Study - Events - Scheduled page, or by cancelling an event.
- The sample has been edited on this page (Study - Samples - Samples).

Dialog boxes for editing sample data contain all values that have been obtained for the sample. Sections that are populated depend on the sample type.

The Expected Time and Actual Sample Date fields display seconds for barcodes associated with CT study events when the Consider Seconds option is selected on the CT Studies > Setup – Events page.

Tasks: Study - Samples - Samples page

- *Approving sample data* (on page 234).
- *Unapproving sample data* (on page 235).
- Editing sample data:
 - *For scheduled events* (on page 236).
 - *For ad hoc events* (on page 240).
- *Changing the event status of a sample* (on page 244).

Permissions needed for sample status changes

Task	Permission
Edit sample data	Change Study Data
Change sample status to In Progress, Failed, or Completed	Change Study Data
Approve data	Approve Sample Data
Change status	Order/Cancel Events
Change approval status of a sample to Approved	Approve Study Data

Viewing sample data

Prerequisite: At least one sample must have been processed through Sample Logging or through Clinical Data Entry.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Samples** category.
- 2 Select one or more samples, and click **VIEW**.

The View Sample Data Page for the sample appears. All fields are read-only.

View Sample Data page contains the same information as the Edit Sample Data page, with the following differences:

- The SAVE button is unavailable. A DONE button is available instead.
- The Change Comment section is not available.
- All fields except the APPROVE/UNAPPROVE buttons are disabled.
- The APPROVE button is available when:
 - The Approval Status of the sample is Not Approved
 - The sample is associated with a PK Testing event.
 - You have the Approve Study Data function permission.
- The UNAPPROVE button is available when:
 - The Approval Status of the sample is Approved.
 - The sample is associated with a PK Testing event.
 - You have the Approve Study Data function permission.

Click the APPROVE button to display the Approve Study Data page. Click the UNAPPROVE button to display the Unapprove Study Data page.

- 3 After you finish viewing the sample, click **DONE**.

Approving a sample

Prerequisites:

- The Event Status for the event must be Completed, Failed, or Cancelled.
- The event must belong to an unlocked group or period.
- You must have the Approve Sample Data function permission.

To approve a sample:

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Samples** category.
- 2 Select one or more samples, and click **VIEW**.
- 3 The View Sample page appears.

Click **APPROVE**.

- 4 The Approve Study Data dialog box appears.
- 5 In the Approval area, type your User ID and password and click **Apply**.

Field descriptions for the Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

If the Approval Status of the event is successfully changed to Approved:

- The APPROVE button no longer appears from View Event Data page.
- The UNAPPROVE button appears.
- The Approval Status read-only field is updated.

Unapproving a sample

Prerequisite: The event must belong to an unlocked group or period.

To unapprove a sample:

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Samples** category.
- 2 Select one or more events, and click **VIEW**.
- 3 The View Sample page appears.
Click **UNAPPROVE**.
- 4 The Unapprove Study Data dialog box appears.
- 5 In the Approval area, enter a Comment, and click **Apply**.

Field descriptions for the Unapprove Study Data dialog box

Field	Description	Notes
Comment		REQUIRED. Defaults to the text entered in the Study Data field on the Approval Comments section on the RM Studies > Setup page.

During save, the Approval Status of the event is changed to Not Approved and the Approved By and Approval Date fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval. The Comment saved with the audit record is set to the value entered in the Comment field.

If the Monitor Review Status of the event is Reviewed, it is changed to Not Reviewed. The change is recorded in the same audit trail entry as the Approval Status change.

If the Approval Status of the event is successfully changed to Not Approved:

- The UNAPPROVE button is hidden on the View Event Data page.
- The APPROVE button appears.
- The Approval Status read-only field is updated.
- The Monitor Review Status is updated to Not Reviewed.

Editing sample data for scheduled events

Prerequisites:

- At least one sample must have been logged on the Sample Logging page or gone through the Clinical Data Entry - Sample page.
- The Group and Period filters must be set to a group and period that is unlocked.

Group and Period of the sample are specified using the filter. If the Edit Sample dialog box displays a group and period you do not want, you must close the dialog box and use the filter to show samples in the desired group and period.

For samples associated with scheduled events, the value in the Adhoc column is **No**.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Samples** category.
- 2 Select one or more samples, and click **EDIT**.

The Edit Sample Data dialog box for scheduled events appears.

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

Field descriptions for the Edit Sample Data dialog box

Fields that appear depend on the type of sample you are editing. Not all fields appear on all Edit Sample dialog boxes.

Field	Description	Notes
Sample ID, Vessel Barcode, Sample Type, Screening No., Subject No., Actual Sample Date, Approval Status, Monitor Review Status	Read-only fields, populated from the sample whose checkbox you selected.	Seconds appear in the Actual Sample Date field if the sample is associated with an event with the Consider Seconds option selected on the CT Studies > Setup—Events page.
Lab Processing tab		
Sample Data		
Date Received	Date and time the sample was received. Click the calendar icon to specify a different date or enter the date manually.	
Specimen ID	Specimen ID associated with the sample.	Maximum characters: 30.
Centrifuge Information		

Field	Description	Notes
In Date/Time	Date and time the sample went into the centrifuge.	
Out Date/Time	Date and time the sample came out of the centrifuge.	
Instrument Barcode	Barcode of the centrifuge.	
Temperature	Temperature of the centrifuge.	
Centrifuge Comment	Comment text.	Maximum characters: 80.
Speed	Speed in RCF or RPM.	Based on centrifuge speed set in the study properties. Depending on the RPM or RCF speed selection made on the PK Lab Setup page for the sample type associated with the current sample, either the Speed (RPM) or Speed (RCF) field is displayed.
Aliquoting Information		
Aliquoting Date/Time	Date and time that the sample was aliquoted.	
Aliquoting Comment	Comment text.	Maximum characters: 80.
Storage Information		
Storage Date/Time	Date and time the sample was stored.	
Storage Comment	Comment text.	Maximum characters: 80.
Sample Information tab	Appears only for PK samples for which the sample type is associated with a panel on the CT Studies - Setup - PK Lab page - Sample Information section.	
Start Date/Time	Date and time you started processing the sample.	
End Date/Time	Date and time you finished processing the sample.	
Comment	Comment about the sample.	

Field	Description	Notes
Panel information	For PK Test panels: If a test panel is associated with the sample, a table lists a row for each test in the panel.	
Test	Name of test	
Optional	Yes —Test is optional in this study. No —Test is required in this study.	Results appear for optional tests that are performed/collected. Optional tests that are not performed/collected do not appear.
Result	Result value.	Units are based on the type of test.
Alert	Alert code and alert description associated with the result.	
Comment	Comment about the test.	If a result is not entered for the test, you must enter a comment.
Pooling tab	Appears only for PK samples for which either Allow CDE Pooling is selected, or for which a Pool Sample Type is selected for the sample type on the CT Studies - Setup - PK Lab page - Pooling section.	Each row in the table represents one pooling event involved in the current sample.
Date/Time	For a pooling event processed on: <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—Date and time the sample was added to the pool. • Clinical Data Entry - Pooling page—Date and time entered for the event. 	READ-ONLY
Vessel Barcode	For a pooling event processed on: <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—Barcode of the vessel added to the pool. • Clinical Data Entry - Pooling page—Vessel barcode entered for the event. 	READ-ONLY

Field	Description	Notes
Sample Id	<p>For a pooling event processed on:</p> <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—Sample ID of the ad hoc or scheduled sample added to the pool. • Clinical Data Entry - Pooling page—This field is blank. 	READ-ONLY
Sample Type	<p>For a pooling event processed on:</p> <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—Sample type associated with the sample added to the pool. • Clinical Data Entry - Pooling page—This field is blank. 	READ-ONLY
Comment	<p>For a pooling event processed on:</p> <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—This field is blank. • Clinical Data Entry - Pooling page—Comment entered for the event. 	READ-ONLY
History tab	<p>Displays the audit trail records from the CT Change Log associated with the sample.</p>	<p>Each row in the table represents an audit record from the CT Change Log associated with the current sample.</p> <p>The rows appear in descending order by Date/Time.</p>
Source	Change source.	READ-ONLY.
User ID	User that submitted the change.	READ-ONLY.
Date/Time	Change date and time	READ-ONLY.
Comment	Comment associated with the change.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

When you save changes for a sample with an Approval Status set to Approved, the Approval Status is changed to Not Approved, and the Approval Date and Approved By fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Approved data was changed..

When you save changes for a sample with a Monitor Review Status set to Reviewed, the Monitor Review Status is changed to Not Reviewed. An entry is recorded in the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Reviewed data was changed.

Editing sample data for ad hoc events

Prerequisites:

- At least one sample must have been logged on the Sample Logging page or gone through the Clinical Data Entry - Sample page.
- The Group and Period filters must be set to a group and period that is unlocked.

Group and Period of the sample are specified using the filter. If the Edit Sample dialog box displays a group and period you do not want, you must close the dialog box and use the filter to show samples in the desired group and period.

For samples associated with ad hoc events, the value in the Adhoc column is **Yes**.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Samples** category.
- 2 Select one or more samples, and click **EDIT**.

The Edit Sample Data dialog box for adhoc events appears.

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

Field descriptions for the Edit Sample Data dialog box

Fields that appear depend on the type of sample you are editing. Not all fields appear on all Edit Sample dialog boxes.

Field	Description	Notes
Sample ID, Vessel Barcode, Sample Type, Screening No., Subject No., Actual Sample Date, Approval Status, Monitor Review Status	Read-only fields, populated from the sample whose checkbox you selected.	Seconds appear in the Actual Sample Date field if the sample is associated with an event with the Consider Seconds option selected on the CT Studies > Setup – Events page.
Lab Processing tab		
Sample Data		
Date Received	Date and time the sample was received. Click the calendar icon to specify a different date or enter the date manually.	
Specimen ID	Specimen ID associated with the sample.	Maximum characters: 30.
Centrifuge Information		
In Date/Time	Date and time the sample went into the centrifuge.	
Out Date/Time	Date and time the sample came out of the centrifuge.	
Instrument Barcode	Barcode of the centrifuge.	
Temperature	Temperature of the centrifuge.	
Centrifuge Comment	Comment text.	Maximum characters: 80.
Speed	Speed in RCF or RPM.	Based on centrifuge speed set in the study properties. Depending on the RPM or RCF speed selection made on the PK Lab Setup page for the sample type associated with the current sample, either the Speed (RPM) or Speed (RCF) field is displayed.
Aliquoting Information		

Field	Description	Notes
Aliquoting Date/Time	Date and time that the sample was aliquoted.	
Aliquoting Comment	Comment text.	Maximum characters: 80.
Storage Information		
Storage Date/Time	Date and time the sample was stored.	
Storage Comment	Comment text.	Maximum characters: 80.
Sample Information tab	Appears only for PK samples for which the sample type is associated with a panel on the CT Studies - Setup - PK Lab page - Sample Information section.	
Start Date/Time	Date and time you started processing the sample.	
End Date/Time	Date and time you finished processing the sample.	
Comment	Comment about the sample.	
Panel information	For PK Test panels: If a test panel is associated with the sample, a table lists a row for each test in the panel.	
Test	Name of test	
Optional	Yes —Test is optional in this study. No —Test is required in this study.	Results appear for optional tests that are performed/collected. Optional tests that are not performed/collected do not appear.
Result	Result value.	Units are based on the type of test.
Alert	Alert code and alert description associated with the result.	
Comment	Comment about the test.	If a result is not entered for the test, you must enter a comment.

Field	Description	Notes
Pooling tab	Appears only for PK samples for which either Allow CDE Pooling is selected, or for which a Pool Sample Type is selected for the sample type on the CT Studies - Setup - PK Lab page - Pooling section.	Each row in the table represents one pooling event involved in the current sample.
Date/Time	For a pooling event processed on: <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—Date and time the sample was added to the pool. • Clinical Data Entry - Pooling page—Date and time entered for the event. 	READ-ONLY
Vessel Barcode	For a pooling event processed on: <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—Barcode of the vessel added to the pool. • Clinical Data Entry - Pooling page—Vessel barcode entered for the event. 	READ-ONLY
Sample Id	For a pooling event processed on: <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—Sample ID of the ad hoc or scheduled sample added to the pool. • Clinical Data Entry - Pooling page—This field is blank. 	READ-ONLY
Sample Type	For a pooling event processed on: <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—Sample type associated with the sample added to the pool. • Clinical Data Entry - Pooling page—This field is blank. 	READ-ONLY
Comment	For a pooling event processed on: <ul style="list-style-type: none"> • Sample Management - Sample Pooling page—This field is blank. • Clinical Data Entry - Pooling page—Comment entered for the event. 	READ-ONLY

Field	Description	Notes
History tab	Displays the audit trail records from the CT Change Log associated with the sample.	Each row in the table represents an audit record from the CT Change Log associated with the current sample. The rows appear in descending order by Date/Time.
Source	Change source.	READ-ONLY.
User ID	User that submitted the change.	READ-ONLY.
Date/Time	Change date and time.	READ-ONLY.
Comment	Comment associated with the change.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

On the Study - Samples - Samples page, the sample is highlighted, and the Data Changed field value (scroll to the last column) is **Yes**.

When you save changes for a sample with an Approval Status set to Approved, the Approval Status is changed to Not Approved and the Approval Date and Approved By fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval. The comment for the audit record states that approved data was changed.

When you save changes for a sample with a Monitor Review Status set to Reviewed, the Monitor Review Status is changed to Not Reviewed. An entry is recorded in the CT Change Log with a source of Study Data Approval. The comment for the audit record states that reviewed data was changed.

Changing the event status of a sample

Prerequisite: You must have the Change Study Setup function permission.

You cannot change the event status of samples packed in boxes that have already been shipped.

For each changed sample, an entry with a source of Event Status is added to the CT Change Log.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Samples** category.
- 2 Select one or more samples, and click **STATUS**.

The Change Status dialog box appears.

- 3 Select the status to apply, and click **SAVE**.

Status	Result after Save
Completed to In Progress	<ul style="list-style-type: none"> • The event status of samples is changed to In Progress. • The Approval Status is set to Not Approved for all samples with an Approval Status of Approved. A separate entry is written to the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Approved data was changed. • The Monitor Review Status is set to Not Reviewed for all samples with a Monitor Review Status of Reviewed. A separate entry is written to the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Reviewed data was changed. • If the Approval Status of the event associated with the sample is Approved, the Approval Status of the event is changed to Not Approved. If the sample was Not Approved, an entry is written to the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Approved data was changed. • PK samples are removed from storage, and the First Storage Date is set to blank.
Failed to In Progress	<ul style="list-style-type: none"> • The event status of samples is changed to In Progress. • The Approval Status is set to Not Approved for all samples with an Approval Status of Approved. A separate entry is written to the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Approved data was changed. • The Monitor Review Status is set to Not Reviewed for all samples with a Monitor Review Status of Reviewed. A separate entry is written to the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Reviewed data was changed. • If the Approval Status of the event associated with the sample is Approved, the Approval Status of the event is changed to Not Approved. If the sample was Not Approved, an entry is written to the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Approved data was changed.
In progress to Failed	<ul style="list-style-type: none"> • The event status of samples is changed Failed. • An entry is written to the CT Change Log. The source of the entry is Event Status.

Status	Result after Save
In Progress to Completed	<ul style="list-style-type: none"> The event status of samples is changed to Completed. An entry is written to the CT Change Log. The source of the entry is Event Status.

Batch approving sample data

Prerequisites:

- Data must belong to an unlocked group, period or study.
 - The study must be unlocked, or the BATCH APPROVE button does not appear.
 - Only data with an event status of Completed, Failed, or Cancelled may be approved.
 - You must have the Approve Sample Data function permission.
- From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Samples** category.
 - Select one or more samples, and click **BATCH APPROVE**.

The Batch Approve Study Data dialog box appears. An error appears if all selected samples have an Approval Status set to Approved or any of the samples is associated with a Clinical Testing event.

- In the Approval area, type your User ID, Password, and click **Apply**.

Field descriptions for the Batch Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

Aliquots

Tasks: Study - Samples - Aliquots page

On the Study - Samples - Aliquots page, you cancel aliquots that are associated with scheduled samples and ad hoc PK samples. This page displays the details of scheduled and ad hoc PK samples that have been separated into aliquots. Aliquots are displayed by group and period. Samples listed in the table are restricted to aliquots associated with groups assigned to the current facility. Values in the Adhoc field can be Yes, No, or Both.

When you cancel an aliquot, the aliquot is removed from any scheduled tasks that have not yet been started. If the aliquot is in an active task at the time of the cancellation, the aliquot is removed when it is scheduled for the next task. The aliquot row is highlighted in red if the value in the Cancelled field is Yes.

To appear on this page, samples must have already progressed through the Aliquoting task in the *Worklist* (in the *Sample Management Guide*), or been processed on the *Sample Aliquoting page* (in the *Sample Management Guide*).

- *Canceling aliquots* (on page 248).

Canceling aliquots

Prerequisites:

- The Group and Period filters must be set to an unlocked group or period.
- The Aliquoting task or the Sample Aliquoting page must have been completed as part of Sample Management.
- You must have the Change Study Data function permission.

1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Aliquots** category.

2 Select one or more aliquots, and click **CANCEL**.

The Cancel Aliquots dialog box appears.

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

The aliquot row in the table is highlighted in red. The Cancelled field value is **Yes**.

Samples in boxes

Tasks: Study - Samples - Boxes page

On the Study - Samples - Boxes page, you view the details of samples and aliquots that were packed into boxes using the packing task or the Sample Packing page. Samples listed in the table are restricted to boxes associated with groups assigned to the current facility.

If the box has progressed through the Sample Shipping page, the Shipment Date is listed. If a shipment is cancelled on the Study - Samples - Shipments page, the Shipment Date is removed, and the box is made available for shipping again.

- *Viewing details of samples that were packed in boxes* (on page 249).

Viewing details of samples in boxes

Prerequisite: The Packing task must be completed.

Samples are packed in boxes using either the Packing task in the Worklist or the Sample Packing page.

- From the main menu, select **Clinical Trials > CT Studies** and click the study to work with. On the Study page, click the **Setup** tab and then click the **Boxes** category.

All fields are read-only.

Shipments

Tasks: Study - Samples - Shipments page

On the Study - Samples - Shipments page, you edit or cancel shipments that are associated with scheduled samples and ad hoc PK samples.

This page shows the details of boxes that were packed and shipped, or packed and made ready to be shipped, using the Sample Shipping page. Shipments in the table are shown by group and period and are restricted to shipments associated with groups that are assigned to the current facility. Shipments associated with scheduled samples and ad hoc PK samples are listed.

You can *print a sample shipping report* (on page 439) in advance of the shipping event, and then update the report after the shipping event has occurred.

- *Editing shipments* (on page 250).
- *Cancelling shipments* (on page 251).

Editing a shipment

Prerequisites:

- At least one study must exist, and it must be unlocked.
- If you filter by group or period, the group/period you select must be unlocked.
- You must have the Change Study Data function permission.

You can edit a shipment that is associated with a scheduled sample or a PK sample. Approval is required.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Shipments** category.
- 2 Select a shipment, and click **EDIT**.

The Edit Shipments dialog box appears. All fields default to previously saved values.

Field Descriptions for the Edit Shipment dialog box

Field	Description	Notes
Customer	Customer.	READ-ONLY
Box Barcodes	Barcode of the box into which the samples will be packed.	READ-ONLY
Shipment Date	Shipment date and time.	REQUIRED. Date and time cannot be in the future.
Carrier	Name of the company that is shipping the shipment.	REQUIRED.

Field	Description	Notes
Tracking No.	Carrier's tracking number for the shipment.	REQUIRED.
Documents Enclosed	When selected, documents are included with the shipment.	This information is for reference only.

- 3 Make changes as needed.
- 4 Type your User ID, password, and an optional comment, and click **APPLY**.
Changes are listed in the CT Change Log report with a source of Sample Shipping.

Cancelling a shipment

Prerequisites:

- At least one study must exist, and it must be unlocked.
- If you filter by group or period, the group/period you select must be unlocked.
- You must have the Change Study Data function permission.

You can cancel a shipment that is associated with a scheduled sample or a PK sample. Approval is required.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Samples** tab > **Shipments** category.
- 2 Select one or more shipments, and click **CANCEL**.
The Cancel Shipments dialog box appears.
- 3 Type your User ID, password, and an optional comment, and click **APPLY**.
 - The cancelled shipment is highlighted on the Study - Samples - Shipments page. All boxes are removed from the shipment and made available for another shipment. The box barcode field is cleared.
 - On the Samples - Aliquots page for aliquots associated with scheduled samples and ad hoc PK samples, the **Shipment Date** field is cleared.
 - The cancelled shipment is listed in the CT Change Log report.

CHAPTER 10

Study labs in the LabPas CT module

In this chapter

Study - Labs page.....	254
Prerequisites: Working with clinical event results from the Study - Labs page	255
Tasks: Study - Labs page.....	256
About updating test results for clinical events	257
Viewing results for a clinical event.....	259
Approving a lab result.....	260
Unapproving a lab result.....	262
Editing results for a clinical lab.....	263
Importing results for a clinical event	267
Exporting results for a clinical event	268
Batch approving lab results	269

Study - Labs page

On the Study - Labs page, you view all Clinical Testing events that were either scheduled or drawn ad hoc. The Labs table shows only those samples associated with groups assigned to the current facility. All completed events in the study are listed, regardless of whether results have been recorded for the event. The row appears red if an alert exists for one or more tests in the event.

The Study - Labs page also lists clinical testing results that have been imported from external sources.

The Clin. Sig. column displays either Yes or No, for records with Clinical Significance set to either Yes or No. For all other cases, the Clin. Sig. column value is blank.

Seconds appear in the Actual Sample Date field for samples associated with an event that has the Consider Seconds option selected on the Resource Management > Studies – Setup – Events page.

For samples to be listed on the Study - Labs page, they must have been processed through either of the following methods:

- Using the Sample Logging page.
- Using the Clinical Data Entry - Sample page.

This method is used if CT Sample Logging Required was not selected for the CT Settings when the LabPas *facility settings were configured* (in the *Administration Guide*).

Prerequisites: Working with clinical event results from the Study - Labs page

- At least one study must exist.
- If you filter by group or period, the group/period you select must be unlocked.
- At least one Clinical Testing event must have been scheduled for the study. For more information, see *Scheduled events in a study* (on page 181).
- At least one Clinical Testing sample must have been logged in to the LabPas CT module, by using either or both of the following pages:
 - The *Sample Logging page* (in the *Clinical Data Entry Guide*).
 - The Clinical Data Entry - *Sample, Adhoc - PK*, or *Adhoc - Lab* pages (in the *Clinical Data Entry Guide*).

This method is used if CT Sample Logging Required was not selected for the CT Settings when the LabPas *facility settings were configured* (in the *Administration Guide*).

- Samples must have a status of In Progress.
- Files you want to import must conform to the XML import format, unless the Result Import Class was defined for the CT Settings when the LabPas *facility settings were configured*.
- To export results:
 - You must have the Study Setup function permission.
 - Configure directories for HL7 support. For more information, see the *Installation Guide*.
 - Specify support for the HL7 interface for a facility (in the *Administration Guide*).
 - Assign a facility and sample type to a lab.

Tasks: Study - Labs page

- *Viewing results for a clinical event* (on page 259).
- *Approving a clinical event* (on page 260).
- *Unapproving a clinical event* (on page 262).
- *Editing results for a clinical event* (on page 263).
- *Importing results for a clinical event* (on page 267).
- *Exporting results for a clinical event* (on page 268).
- *Batch approving clinical events* (on page 269).

About updating test results for clinical events

When tests and test panels were configured, ranges, limits, and edit checks were set up for the test panel. Edit checks define relationships between the tests in the panel that require an action to be taken when the test results that are recorded for a participant violate the conditions referenced in the edit.

For more information about edit checks, see the *Test Panels page* (in the *Administration Guide*).

Limit or check violated	Result	Notes/Details
Out of Range limit	An error message appears. The entry is not allowed.	
Demographic reference range	Results are compared to the reference range or value defined for the test. A warning appears, containing the appropriate expected result. Instructions for the test appear.	If a test has demographic reference ranges defined, and gender or age of participants is known. Reference ranges are defined for the test on the <i>Study - Setup - panels page</i> (on page 77). Instructions for tests are set up for the LabPas application on the <i>Tests page</i> (in the <i>Administration Guide</i>).
Reference range	A warning appears, containing the expected result and instructions that were set up on the Tests page.	
Edit checks on test panels	A warning appears, containing the edit check message.	To save, you must correct the results that violate the checks. You configure the checks on the Test Panels page.

When you update an event, edit checks that have been defined for the test panel are applied. If one or more tests are in violation of an edit check, the following actions occur.

Action defined for edit check	Result
Prevent	A warning displays the edit check message. You cannot save until you correct the erroneous result.
Warn	A message displays the edit check message.
Alert	The test that is in violation of the edit check includes the text Failed Edit Check in red. Point to the alert text to view the edit check message.
Warn and Alert	An edit check message appears. Tests in violation include the text Failed Edit Check in red. Point to the failed edit check to view the edit check message.

Viewing results for a clinical event

Prerequisites: See Prerequisites: Working with clinical event results from the Study - Labs page.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Labs** tab.
- 2 Select one or more clinical events, and click **VIEW**.

The View Lab Results page appears. All fields are read-only. If a result record exists for a test, the Ref. Range field displays the reference range stored with the result record. The page contains the same information as the Edit Lab Results page, with the following differences:

- The CANCEL and UPDATE buttons do not appear.
- The Change Comment section is not displayed.
- All fields except the Approve/Unapprove buttons are read-only.
- The APPROVE button is available when:
 - The Approval Status of the sample is Not Approved
 - You have the Approve Study Data permission.
- The UNAPPROVE button is available when:
 - The Approval Status of the sample is Approved.
 - You have the Approve Study Data function permission.

Click the APPROVE button to display the Approve Study Data page. Click the UNAPPROVE button to display the Unapprove Study Data page

If a panel includes a test that has an alert, the panel name appears in red. In each test, you can point to the Test and Alert test to view a tooltip about the failed edit check.

- 3 To view another panel that relates to the same event, use the **Panel** drop-down list to select the panel.

The first panel in the list is always the default selection, and its results appear when the dialog box appears.
- 4 After you finish viewing the results for the event, click **DONE**.

Approving a lab result

Prerequisites:

- The Event Status for the sample must be Completed or Cancelled.
- The sample must belong to an unlocked group or period.
- You must have the Approve Study Data function permission.

To approve a lab result:

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Labs** tab.
- 2 Select one or more samples, and click **VIEW**.
- 3 The View Lab Results dialog box appears.
Click **APPROVE**.
- 4 The Approve Study Data dialog box appears.
- 5 In the Approval area, type your User ID, password and click **Apply**.

Field descriptions for the Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

If the Approval Status of the event is successfully changed to Approved:

- The APPROVE button no longer appears from View Event Data page.
- The UNAPPROVE button appears.
- The Approval Status read-only field is updated.

Unapproving a lab result

Prerequisite: The event must belong to an unlocked group or period.

To unapprove a lab result:

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Labs tab**.
- 2 Select one or more lab results, and click **VIEW**.
- 3 The View Lab Result page appears.
Click **UNAPPROVE**.
- 4 The Unapprove Study Data dialog box appears.
- 5 In the Approval area, enter a Comment, and click **Apply**.

Field descriptions for the Unapprove Study Data dialog box

Field	Description	Notes
Comment		REQUIRED. Defaults to the text entered in the Study Data field on the Approval Comments section on the RM Studies > Setup page.

During save, the Approval Status of the event is changed to Not Approved and the Approved By and Approval Date fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval. The Comment saved with the audit record is set to the value entered in the Comment field.

During save, if the Monitor Review Status of the event is Reviewed, it is changed to Not Reviewed. The change is recorded in the same audit trail entry as the Approval Status change.

If the Approval Status of the event is successfully changed to Not Approved:

- The UNAPPROVE button is hidden on the View Event Data page.
- The APPROVE button appears.
- The Approval Status read-only field is updated.
- The Monitor Review Status is updated to Not Reviewed.

Editing results for a clinical lab

Prerequisites: See Prerequisites: Working with clinical event results from the Study - Labs page.

If you select more than one event, the events appear one at a time.

You cannot edit test results that are imported from an external source. If you edit a result for which the Export field is Yes, your edits will be overwritten when results are imported from the lab.

Edits are recorded in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Labs** tab.
- 2 Select one or more clinical events, and click **EDIT**.

The Edit Results dialog box appears.

If a panel includes a test that has an alert, the panel name appears in red. In each test, you can point to the Test and Alert test to view a tooltip about the failed edit check.

- 3 Fill in the fields.

Field descriptions for the Edit Results dialog box

You are not required to enter all tests in a panel. If you do not enter a result, you must enter a comment.

Field	Description	Notes
Adhoc, Sample Id, Barcode, Actual Sample Data, Sample Type, Screening No., Subject No., Event Category, Approval Status, Monitor Review Status	Read-only fields populated based on the clinical event you selected.	If this is an event that you do not want to edit, you must close the Edit Results dialog without saving (click the X) and select a different event. Seconds appear in the Actual Sample Date field if the sample is associated with an event with the Consider Seconds option selected on the CT Studies > Setup – Events page.

Data tab

Results

Test	Name of the test. Tests with alerts are red.	
Optional	<p>Yes—Test is optional in this study.</p> <p>No—Test is required in this study.</p>	<p>Results appear for optional tests that are performed/collected.</p> <p>Optional tests that are not performed/collected do not appear.</p>

Field	Description	Notes
Result	Result of the test or tests.	<p>If a test value is:</p> <p>Out of range—An error message appears. Entry is not allowed.</p> <p>Outside reference range or reference value—An alert appears with instructions that were <i>defined for tests in the LabPas application</i> (in the <i>Administration Guide</i>).</p>
Ref. Range		<p>If a result record exists for a test, the Ref. Range field displays the reference range stored with the result record.</p> <p>If a result record does not exist for a test, the Ref. Range field displays the reference range defined for the test on the CT Studies – Setup – Panels page.</p> <p>Any edit to a result is compared to the reference range that is defined for the test on the CT Studies – Setup – Panels page.</p>
Performed by	Person who obtained the results.	
Date / Time	Date and time the results were obtained.	
Alert	If a test has an alert, the alert code and description appear.	
Clin. Sig.	Whether results of the test are marked as clinically significant.	
Source	Source of the test result data.	If the source is a value other than blank or LabPas, all fields except Clin. Sig. are read-only.
Comment	Comment about the test.	If a result is not entered for the test, you must enter a comment.

History tab

Contains the audit trail records from the CT Change Log associated with the event.

Field	Description	Notes
Source	Source of the change.	READ-ONLY.
User ID	User that submitted the record.	READ-ONLY.
Date/Time	Date and time of the change.	READ-ONLY.
Comment	Change Comment.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

4 Click **UPDATE**.

Any blank sources are changed to LabPas.

Edit checks that were created for the test panels are applied.

Action defined for edit check	Result
Prevent	A warning displays the edit check message. You cannot save until you correct the erroneous result.
Warn	A message displays the edit check message.
Alert	The test that is in violation of the edit check includes the text Failed Edit Check in red. Point to the alert text to view the edit check message.
Warn and Alert	An edit check message appears. Tests in violation include the text Failed Edit Check in red. Point to the failed edit check to view the edit check message.

If multiple panels exist for the event, and you want to change another panel, from the **Panel** drop-down list, select a panel, and edit it.

Panel name appears in red if the panel includes tests with existing alerts.

5 After you finish editing panels, click **DONE**.

- On the Study - Labs page, the event row appears in red if any of the test results entered included an alert. In the Alert column, the text Edit Check Failed appears in red.

- After you finish editing all the panels, the Event Status for the sample is changed to Completed in the following locations:
 - *Study - Events - Scheduled page* (on page 181).
 - *Study - Events - Data page* (on page 199).
 - *Study - Labs page* (on page 253).
 - *Study - Samples - Samples page* (on page 232).
- On the Study - Events - Scheduled page, the Event Status for the sample changes to Completed.

When you save changes for a record with an Approval Status set to Approved, the Approval Status is changed to Not Approved, and the Approval Date and Approved By fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Approved data was changed.

When you save changes for a record with a Monitor Review Status set to Reviewed, the Monitor Review Status is changed to Not Reviewed. An entry is recorded in the CT Change Log with a source of Study Data Approval. The comment for the audit record defaults to Reviewed data was changed.

Importing results for a clinical event

Prerequisites: See Prerequisites: Working with clinical event results from the Study - Labs page.

The lab that you select determines the format of the import file. You specify the format to use when you **add a facility** (in the *Administration Guide*).

If you import results for an event that is already listed, the newly imported data replaces the previous data for the event.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Labs** tab.

- 2 Click **IMPORT**.

The Import Results dialog box appears.

- 3 Click **BROWSE**.

The Choose File dialog box appears.

- 4 From the **Lab** drop-down list, select a lab interface. Only the lab interfaces configured for the study and facility appear.

- 5 Locate and select the file to import, and click **OPEN**.

The file you selected appears in the File Name field of the Import Results dialog box.

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

Results are imported. For information about the format of the file, see the *Specification for the HL7 Lab Interface* document.

- 7 To return to the Study - Labs page, close the Import Results dialog box.

Exporting results for a clinical event

You can export only clinical lab samples. For each exported sample, an entry is created in the CT Change Log report with a source of Export Samples.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Labs** tab.

- 2 Select one or more clinical lab samples, and click **EXPORT**.

The Export Samples dialog box appears.

- 3 In the Approval area, type your user ID, password, and an optional comment, and click **Apply**.

The dialog box remains open, and the Export Log field indicates whether the export succeeded or failed.

For information about the format of the file, see the *Specification for the HL7 Lab Interface* document.

Batch approving lab results

Prerequisites:

- Data must belong to an unlocked group, period or study.
 - The study must be unlocked, or the BATCH APPROVE button does not appear.
 - Only data with an event status of Completed or Cancelled may be approved.
 - You must have the Approve Study Data function permission.
- 1 From the main menu, select **Clinical Trials > CT Studies** and select a study. On the Study page, select the **Labs** tab.
 - 2 Select one or more lab results, and click **BATCH APPROVE**.

The Batch Approve Study Data dialog box appears. An error appears if all selected records have an Approval Status set to Approved.

- 3 In the Approval area, type your User ID and Password, and click **Apply**.

Field descriptions for the Batch Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

CHAPTER 11

Queries in the LabPas CT module

In this chapter

Study - Queries page.....	272
Tasks: Studies - Queries page.....	273
Viewing a query	274
Answering a query	275

Study - Queries page

On the Study - Queries page, you view queries for subjects that are associated with groups assigned to the current facility. You can also view details related to specific queries and respond to queries that are Open or Re-Issued. Queries that are not associated with a subject are shown for all facilities.

You create queries in the LabPas DQ module.

Field	Description
Status	Status of the query: Open, Answered, Reissued, or Closed. The status is updated automatically by the LabPas CT module as queries are opened, edited, closed, or reissued in the LabPas DQ module, or answered on the Study - Queries page.
Data Item	Item of data that the query was opened against. Represents an event type or a test.
Item Detail	Piece of data within the data item that is being questioned in the LabPas DQ module.
Entry Date/Time	Date and time that the most recent thread of the query was created.
Name	User who issued the most recent thread of the query.
Data Status	Status of the data being questioned in the query: <ul style="list-style-type: none"> • Blank—Query status is Open, Re-Issued, or Closed. • Changed or Unchanged—Whether the data in question was changed in response to the query.
Query	Text of most recent thread in the query.

Tasks: Studies - Queries page

- *Viewing a query* (on page 274).
- *Answering a query.* (on page 275)

Viewing a query

Prerequisite: At least one query must have been raised in the *LabPas DQ module* (in the *Data Qualification Guide*).

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Queries** tab.

- 2 Select a query, and click **VIEW**.

The View Query dialog box appears. All fields are read-only.

The details of the query are displayed at the top of the window, and all threads associated with the query appear in the **Query History** table.

- 3 After you finish viewing the query, close the dialog box.

Answering a query

Prerequisites:

- At least one query must have been raised in the *LabPas DQ module* (in the *Data Qualification Guide*).
- The study must be unlocked, and the query must have a status of open and be associated with an unlocked Group/Period.

You cannot answer a query:

- That is associated with a locked group or period.
- That has a status of Closed.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Queries** tab.
- 2 Select a query, and click **ANSWER**.

The Answer Query dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Answer Query dialog box

Field	Description	Notes
Data Item, Item detail, Value, Query	Read-only fields that identify the item and the query.	Fields are populated based on the query you selected. To select a different query, you must first close the Answer Query dialog box by clicking the X .
Data Item	Item of data that the query was opened against. Represents either an event type or a test.	
Item Detail, Value	Part of the data within the data item that is being questioned (in the LabPas DQ module).	
Data Status	Status of the data in response to the query. <ul style="list-style-type: none"> • Changed—Data has been changed in response to the query. • Unchanged—Data has not been changed. 	REQUIRED.
Answer	Custom text in response to the query you are answering.	REQUIRED.
Query History table	All threads associated with the query.	

- 4 Click **SAVE**.

On the Studies - Queries page, updates appear in the following fields:

- **Status**—Answered.
- **Name**—Your user name.
- **Data Status** and **Query**—Entries you made in the Answer Query dialog box.

The query is also updated in the LabPas DQ module.

CHAPTER 12

Adverse events and AE forms

In this chapter

Study - AEs page.....	278
Prerequisites: Working with AE forms	279
Tasks: Study - AEs page	280
About AE forms	281
Viewing an AE form	282
Approving an AE form.....	287
Unapproving an AE Form	289
Batch approving AE forms	290
Adding an AE form.....	291
Editing an AE form.....	296
Associating an AE observation with an AE form.....	301
Resolving an AE form	302
Deleting an AE form.....	303

Study - AEs page

On the Study - AEs page, you edit and create AE forms, including associating AE observations with the AE forms. This page displays all AE forms for the current facility.

You record AE observations on the ***AE Observations page*** (in the *Clinical Data Entry Guide*) and associate them with AE forms on this page.

AE forms are always associated with a candidate. If the Candidate/Subject link is altered, the data remains with the candidate.

Prerequisites: Working with AE forms

- At least one study must exist, with at least one candidate or subject who is approved in the study.
- At least one group or candidate must be scheduled for an approved candidate or subject.
- The study must be unlocked.
- For an AE form to be edited, the group and period must be unlocked.
- The following permissions are required:
 - To create, edit, or delete an AE form—Create/Change Study.
 - To change the review status of an AE form—Review Clinical Data and Approve Clinical Data.
 - To save a review status of Approved or change the status of an approved AE form—Approve Clinical Data.
 - To change values in the Authorization Required section—Approve Adverse Events.

Note: If the study is locked the NEW, EDIT, BATCH APPROVE, and DELETE buttons do not appear.

Tasks: Study - AEs page

- *Viewing an AE form* (on page 282).
- *Approving an AE form* (on page 287).
- *Unapproving an AE form* (on page 289).
- *Adding an AE form* (on page 291).
- *Editing an AE form* (on page 296).
- *Deleting an AE form* (on page 303).
- *Batch approving AE forms* (on page 290).

About AE forms

About approved AE forms

- You must approve AE forms before you can export them from the Study - Events - Data page.
- After an AE form is approved, changes to it are reported in the CT Change Log report.

About editing AE forms on the Study - AEs page

You can make the following changes on the Study - AEs page:

- Record the result of the event on the participant (for example, hospitalization).
- Determine the final resolution of the AE form, if any.
- Assign status of Ongoing or Resolved to the event (requires Approve Adverse Events permission).
- Make final analysis about the event, such as determining the event's severity and significance.

Editing an approved AE form changes the review status of the event to Revised.

For more information, see [Editing an AE form](#).

Security permissions for working with AE forms

Permission	Allowed behavior
Change Study Data	<ul style="list-style-type: none"> • Review an AE form. • Edit an AE form. • Create an AE form. • Delete an AE form.
Approve Study Data	<ul style="list-style-type: none"> • Make final analysis for an AE form, such as determining the event's severity and significance. • Approve an AE form. • Edit the following fields for an AE form: Final Description, Severity, Related to Treatment, and Significance.

Viewing an AE form

Prerequisites: See Prerequisites: Working with AE forms.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **AEs** tab.
- 2 Select one or more AE forms, and click **VIEW**.

The View AE Form page appears. It contains the same information as the Edit AE Form page, with the following differences:

- The SAVE button is unavailable. A DONE button is available instead.
- The Approve and Unapprove buttons are available.
- The Change Comment section is not displayed.
- All check boxes and the DETACH button on the Attached AE Obs. Tab are not visible.
- All check boxes and the ATTACH button on the Other AE Obs. tab are not visible.
- All fields except the DONE button and Approve/Unapprove buttons are read-only.
- The APPROVE button is available when:
 - The Approval Status of the AE form is Not Approved
 - You have the Approve Study Data function permission.
- The UNAPPROVE button is available when:
 - The Approval Status of the AE form is Approved.
 - You have the Approve Study Data function permission.

Click the APPROVE button to display the Approve Study Data page. Click the UNAPPROVE button to display the Unapprove Study Data page.

Field descriptions for the View AE Form dialog box

If you are viewing an AE form, all fields are read-only.

Field	Description	Notes
Screening No.	Read-only fields.	To view or edit a different AE form, close this dialog box and select a different AE form from the AEs tab.
Subject No.		
Initials		
Group and Time Period		
AE Data		
Description	Description of the adverse event.	REQUIRED.

Field	Description	Notes
Onset	Date and time that the participant first began to experience the adverse event.	REQUIRED. A warning appears if the value is later than the Onset date of the earliest AE observation. For more information, see About updating the date and time for an event.
Action Taken	Select one: <ul style="list-style-type: none"> • Action Taken—Select the action from the drop-down list. • Other—Type a description. 	
Outcome	Select one: <ul style="list-style-type: none"> • Outcome—Select the outcome from the drop-down list. • Other—Type a description. 	
Notes	Custom text.	
Authorization Required		
Final Description	Medical term whose associated medical code is associated with this adverse event. If you enter an invalid medical term, it is removed from this field when you tab to a different field. An error message appears when you save.	A type-ahead lookup displays all active terms from the Setup - Medical Terms page (in the <i>Administration Guide</i>) with a term type of AE Final Description.
Severity	Severity of the adverse event.	You must have Approve Adverse Event permissions to edit this field.
Related to Treatment	Treatment related to the adverse event.	You must have Approve Adverse Event permissions to edit this field.
Significance	Significance of the adverse event.	You must have Approve Adverse Event permissions to edit this field.

Field	Description	Notes
AE Number	Serious adverse event (SAE) number that is reported to the FDA.	
[Custom fields]		
If custom fields are selected for AE forms, the fields appear in the Authorization Required section.		
AE Status		
Status	Status for the event: <ul style="list-style-type: none"> Resolved Ongoing 	If you select Resolved, you must provide a Resolution date.
Resolution	If the adverse event is over and a resolution has been reached, enter the date and time that a final resolution was determined for the adverse event, including all observations and analysis.	Must be later than the Onset date. A warning appears if the value is earlier than the latest Resolution date of an associated AE observation. For more information, see About updating the date and time for an event.
Review Status		
Review Status	Review status of the AE form.	You must have either the Approve Clinical Data or the Review Clinical Data security permission to see the fields. If you select Reviewed or Approved, approval is required.

Summary tables

Note: The following tabs are read-only when you are viewing an AE form.

Tab	Description
Attached AE Obs.	<p>AE observations that are associated with the AE form. You add AE observations on the <i>AE Observation page</i> (in the <i>Clinical Data Entry Guide</i>).</p> <p>To detach an AE observation from the AE form:</p> <ul style="list-style-type: none"> Select an observation, and click Detach. <p>If the review status of the AE form is Approved, a warning appears.</p> <p>If the review status of the AE form is Reviewed or Approved, you must approve the change. Afterwards, the review status changes to Revised.</p> <p>Detached observations move to the Other AE Obs. tab.</p> <p>You must have the Create/Change Study security permission to detach an AE observation.</p>
Other AE Obs.	<p>AE observations that are not associated with an AE form.</p> <p>To associate an AE observation with the AE form:</p> <ul style="list-style-type: none"> Select an observation, and click ATTACH. <p>If the review status of the AE form is Reviewed or Approved, you must approve the change. Afterwards, the review status changes to Revised.</p> <p>Associated observations move to the Attached AE Obs. tab.</p> <p>You must have the Create/Change Study security permission to associate an AE observation.</p>
Other Obs.	All non-AE observations associated with the subject in the study.
Additional AEs	<p>All AE forms that are associated with the subject in the study.</p> <p>Includes a description, onset date, resolution date (if any), and the number of observations associated with the form. Read-only.</p>
Conmeds	All concomitant medications (conmeds) given to a subject during all AE and non-AE observations in the study. You record the conmeds in the Medications Given section for each observation.
Doses	(Read-only) All completed Dose events for the subject in the study, including the time of each event.
Testing	<p>(Read-only) All test results that are for the subject in the study and that are associated with completed Testing events.</p> <p>If a result record exists for a test, the Ref. Range field displays the reference range stored with the result record.</p>

Tab	Description
Draws	(Read-only) All completed, failed, and in progress PK and Clinical Testing events for the subject in the study. If a result record exists for a test, the Ref. Range field displays the reference range stored with the result record.
Labs	(Read-only) All test results that are for the subject in the study and that are associated with completed or in progress Clinical Testing events.

- 3 After you finish viewing the adverse event, click **DONE**.

If the Description or Onset fields are modified and another AE Form exists with the same Study, Screening No., Description, and Onset Date and Time values, an error appears.

Approving an AE form

Prerequisites:

- The AE form must belong to an unlocked study.
- You must have the Approve Study Data function permission.

To approve an AE form:

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **AEs** tab.
- 2 Select one or more AE forms, and click **VIEW**.
- 3 The View AE Form page appears.

Click **APPROVE**.

- 4 The Approve Study Data dialog box appears.
- 5 In the Approval area, type your User ID, password and click **Apply**.

Field descriptions for the Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

When you click APPLY, an error appears if

- Any of the AE Form is associated with an unresolved AE observation group.
- The Status field is set to Ongoing.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.

- The Comment saved with each audit record is set to the value in the Comment field.

If the Approval Status of the event is successfully changed to Approved:

- The APPROVE button no longer appears from View Event Data page.
- The UNAPPROVE button appears.
- The Approval Status read-only field is updated.

Unapproving an AE Form

Prerequisite: The AE form must belong to an unlocked study, group or period.

To unapprove an AE form:

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **AEs** tab.
- 2 Select one or more AE forms, and click **VIEW**.
- 3 The View AE Form page appears.
Click **UNAPPROVE**.
- 4 The Unapprove Study Data dialog box appears.
- 5 In the Approval area, enter a Comment, and click **Apply**.

Field descriptions for the Unapprove Study Data dialog box

Field	Description	Notes
Comment		REQUIRED. Defaults to the text entered in the Study Data field on the Approval Comments section on the RM Studies > Setup page.

During save, the Approval Status of the event is changed to Not Approved and the Approved By and Approval Date fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval. The Comment saved with the audit record is set to the value entered in the Comment field.

If the Monitor Review Status of the event is Reviewed, it is changed to Not Reviewed. The change is recorded in the same audit trail entry as the Approval Status change.

If the Approval Status of the event is successfully changed to Not Approved:

- The UNAPPROVE button is hidden on the View Event Data page.
- The APPROVE button appears.
- The Approval Status read-only field is updated.
- The Monitor Review Status is updated to Not Reviewed.

Batch approving AE forms

Prerequisites:

- The study must be unlocked, or the BATCH APPROVE is unavailable.
 - You must have the Approve Study Data function permission.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **AEs** tab.
 - 2 Select one or more AE forms, and click **BATCH APPROVE**. An error appears if all selected forms have an Approval Status set to Approved.

The Batch Approve Study Data dialog box appears.

- 3 In the Approval area, type your User ID, password, and click **Apply**.

Field descriptions for the Batch Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

When you click APPLY, a warning message appears if:

- The Status field for any of the selected AE Forms is set to Ongoing.
- Any of the AE Forms selected are associated with an unresolved AE observation group.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

Adding an AE form

Prerequisites: See Prerequisites: Working with AE forms.

When you create an AE form, you can associate one or more AE observations or observation groups with it.

You cannot add an AE form that:

- Is associated with a locked group or period.
- Has the same study, screening number, description, and onset date as an existing AE form.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **AEs** tab.
- 2 Click **NEW**.

The New AE Form dialog box appears.

- 3 Fill in the fields.

Field descriptions for the New AE Form dialog box

Field	Description	Notes
Observation	Group of AE observations with which to associate the AE form. To associate an AE observation group with the AE form, click the ellipsis button (...) to the right of the field.	If you select an AE observation group, values appear in the Description, Id, and Onset fields.
Id	Subject number or candidate number of the participant who experienced the adverse event.	REQUIRED.
Description	Description of the event.	REQUIRED.
Onset Date and Time	Date and time that the participant first began to experience the adverse event. Click the calendar button, and select the date.	REQUIRED.
Period	Study period in which the adverse event occurred.	The study period must not be locked.

- 4 Click **SAVE**.

The AE form is created. The Approval Status for the new AE Form is set to Not Approved. The Monitor Review Status for the new AE Form is set to Not Reviewed.

If you selected an observation group with a resolution date and time, the AE form is created with a status of Resolved, and its resolution date is the resolution of the adverse event.

After the AE form is created, the Edit AE Form dialog box opens.

If the Description or Onset fields are modified and another AE Form exists with the same Study, Screening No., Description, Onset Date and Time values, an error appears.

- 5 Fill in the fields.

Field descriptions for the Edit AE Form dialog box

If you are viewing an AE form, all fields are read-only.

Field	Description	Notes
Screening No.	Read-only fields.	To view or edit a different AE form, close this dialog box and select a different AE form from the AEs tab.
Subject No.		
Initials		
Group and Time Period		
AE Data		
Description	Description of the adverse event.	REQUIRED.
Onset	Date and time that the participant first began to experience the adverse event.	REQUIRED. A warning appears if the value is later than the Onset date of the earliest AE observation. For more information, see About updating the date and time for an event.
Action Taken	Select one: <ul style="list-style-type: none"> • Action Taken—Select the action from the drop-down list. • Other—Type a description. 	
Outcome	Select one: <ul style="list-style-type: none"> • Outcome—Select the outcome from the drop-down list. • Other—Type a description. 	
Notes	Custom text.	

Field	Description	Notes
Authorization Required		
Final Description	<p>Medical term whose associated medical code is associated with this adverse event.</p> <p>If you enter an invalid medical term, it is removed from this field when you tab to a different field. An error message appears when you save.</p>	<p>A type-ahead lookup displays all active terms from the Setup - Medical Terms page (in the <i>Administration Guide</i>) with a term type of AE Final Description.</p>
Severity	Severity of the adverse event.	You must have Approve Adverse Event permissions to edit this field.
Related to Treatment	Treatment related to the adverse event.	You must have Approve Adverse Event permissions to edit this field.
Significance	Significance of the adverse event.	You must have Approve Adverse Event permissions to edit this field.
AE Number	Serious adverse event (SAE) number that is reported to the FDA.	
[Custom fields]		
If custom fields are selected for AE forms, the fields appear in the Authorization Required section.		
AE Status		
Status	<p>Status for the event:</p> <ul style="list-style-type: none"> Resolved Ongoing 	If you select Resolved, you must provide a Resolution date.
Resolution	If the adverse event is over and a resolution has been reached, enter the date and time that a final resolution was determined for the adverse event, including all observations and analysis.	<p>Must be later than the Onset date.</p> <p>A warning appears if the value is earlier than the latest Resolution date of an associated AE observation.</p> <p>For more information, see About updating the date and time for an event.</p>

Field	Description	Notes
Review Status		
Review Status	Review status of the AE form.	You must have either the Approve Clinical Data or the Review Clinical Data security permission to see the fields. If you select Reviewed or Approved, approval is required.

Summary tables

Note: The following tabs are read-only when you are viewing an AE form.

Tab	Description
Attached AE Obs.	<p>AE observations that are associated with the AE form. You add AE observations on the <i>AE Observation page</i> (in the <i>Clinical Data Entry Guide</i>).</p> <p>To detach an AE observation from the AE form:</p> <ul style="list-style-type: none"> Select an observation, and click Detach. <p>If the review status of the AE form is Approved, a warning appears.</p> <p>If the review status of the AE form is Reviewed or Approved, you must approve the change. Afterwards, the review status changes to Revised.</p> <p>Detached observations move to the Other AE Obs. tab.</p> <p>You must have the Create/Change Study security permission to detach an AE observation.</p>
Other AE Obs.	<p>AE observations that are not associated with an AE form.</p> <p>To associate an AE observation with the AE form:</p> <ul style="list-style-type: none"> Select an observation, and click ATTACH. <p>If the review status of the AE form is Reviewed or Approved, you must approve the change. Afterwards, the review status changes to Revised.</p> <p>Associated observations move to the Attached AE Obs. tab.</p> <p>You must have the Create/Change Study security permission to associate an AE observation.</p>
Other Obs.	All non-AE observations associated with the subject in the study.

Tab	Description
Additional AEs	All AE forms that are associated with the subject in the study. Includes a description, onset date, resolution date (if any), and the number of observations associated with the form. Read-only.
Conmeds	All concomitant medications (conmeds) given to a subject during all AE and non-AE observations in the study. You record the conmeds in the Medications Given section for each observation.
Doses	(Read-only) All completed Dose events for the subject in the study, including the time of each event.
Testing	(Read-only) All test results that are for the subject in the study and that are associated with completed Testing events.
Draws	(Read-only) All completed and in progress PK and Clinical Testing events for the subject in the study.
Labs	(Read-only) All test results that are for the subject in the study and that are associated with completed or in progress Clinical Testing events.

- 6 Click **SAVE**.

Editing an AE form

Prerequisites: See Prerequisites: Working with AE forms.

You can edit an AE form that has been approved. For more information, see *About editing AE forms on the Study - AEs page* (on page 281).

Changes to AE forms are logged in the CT Change Log report.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **AEs** tab.
- 2 Select an AE form, and click **EDIT**.

The Edit AE Form dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Edit AE Form dialog box

If you are viewing an AE form, all fields are read-only.

Field	Description	Notes
Screening No.	Read-only fields.	To view or edit a different AE form, close this dialog box and select a different AE form from the AEs tab.
Subject No.		
Initials		
Group and Time Period		
Approval Status		
Monitor Review Status		
AE Data		
Description	Description of the adverse event.	REQUIRED.
Onset	Date and time that the participant first began to experience the adverse event.	REQUIRED. A warning appears if the value is later than the Onset date of the earliest AE observation. For more information, see About updating the date and time for an event.
Action Taken	Select one: <ul style="list-style-type: none"> • Action Taken—Select the action from the drop-down list. • Other—Type a description. 	

Field	Description	Notes
Outcome	Select one: <ul style="list-style-type: none"> • Outcome—Select the outcome from the drop-down list. • Other—Type a description. 	
Notes	Custom text.	
Authorization Required		
Final Description	Medical term whose associated medical code is associated with this adverse event. If you enter an invalid medical term, it is removed from this field when you tab to a different field. An error message appears when you save.	A type-ahead lookup displays all active terms from the Setup - Medical Terms page (in the <i>Administration Guide</i>) with a term type of AE Final Description. You must have Approve Study Data function permission to edit this field.
Severity	Severity of the adverse event.	You must have Approve Study Data function permission to edit this field.
Related to Treatment	Treatment related to the adverse event.	You must have Approve Study Data function permission to edit this field.
Significance	Significance of the adverse event.	You must have Approve Study Data function permission to edit this field.
AE Number	Serious adverse event (SAE) number that is reported to the FDA.	
[Custom fields]		
If custom fields are selected for AE forms, the fields appear in the Authorization Required section.		
AE Status		
Status	Status for the event: <ul style="list-style-type: none"> • Resolved • Ongoing 	If you select Resolved, you must provide a Resolution date.

Field	Description	Notes
Resolution	If the adverse event is over and a resolution has been reached, enter the date and time that a final resolution was determined for the adverse event, including all observations and analysis.	<p>Must be later than the Onset date.</p> <p>A warning appears if the value is earlier than the latest Resolution date of an associated AE observation.</p> <p>For more information, see About updating the date and time for an event.</p>

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

Summary tables

Note: The following tabs are read-only when you are viewing an AE form.

Tab	Description
Attached AE Obs.	<p>AE observations that are associated with the AE form. You add AE observations on the <i>AE Observation page</i> (in the <i>Clinical Data Entry Guide</i>).</p> <p>To detach an AE observation from the AE form:</p> <ul style="list-style-type: none"> Select an observation, and click Detach. <p>If the review status of the AE form is Approved, a warning appears.</p> <p>If the Approval Status of the AE form is Approved, it is changed to Not Approved, and the Approval Date and Approved By fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval.</p> <p>If the Monitor Review Status of the AE form is Reviewed it is changed to Not. An entry is recorded in the CT Change Log with a source of Study Data Approval.</p> <p>Detached observations move to the Other AE Obs. tab.</p> <p>You must have the Change Study Data security permission to detach an AE observation.</p>

Tab	Description
Other AE Obs.	<p>AE observations that are not associated with an AE form.</p> <p>To associate an AE observation with the AE form:</p> <ul style="list-style-type: none"> Select an observation, and click ATTACH. <p>If the review status of the AE form is Reviewed or Approved, you must approve the change. Afterwards, the review status changes to Revised.</p> <p>If the AE Form column of the selected observation is not blank, an error appears if the Approval Status of that AE Form is Approved. Otherwise, the observation is removed from that AE Form and an entry is recorded in the CT Change Log with a source of Adverse Event.</p> <p>If the Approval Status of the AE form is Approved, it is changed to Not Approved, and the Approval Date and Approved By fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval.</p> <p>If the Monitor Review Status of the AE form is Reviewed it is changed to Not. An entry is recorded in the CT Change Log with a source of Study Data Approval.</p> <p>Associated observations move to the Attached AE Obs. tab.</p> <p>You must have the Change Study Data security permission to associate an AE observation.</p>
Other Obs.	All non-AE observations associated with the subject in the study.
Additional AEs	<p>All AE forms that are associated with the subject in the study.</p> <p>Includes a description, onset date, resolution date (if any), and the number of observations associated with the form. Read-only.</p>
Conmeds	All concomitant medications (conmeds) given to a subject during all AE and non-AE observations in the study. You record the conmeds in the Medications Given section for each observation.
Doses	<p>(Read-only) All completed Dose events for the subject in the study, including the time of each event.</p> <p>Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page.</p>
Testing	<p>(Read-only) All test results that are for the subject in the study and that are associated with completed Testing events.</p> <p>If a result record exists for a test, the Ref. Range field displays the reference range stored with the result record.</p> <p>Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page.</p>

Tab	Description
Draws	<p>(Read-only) All completed, failed, and in progress PK and Clinical Testing events for the subject in the study.</p> <p>If a result record exists for a test, the Ref. Range field displays the reference range stored with the result record.</p> <p>Seconds appear in the Date/Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page.</p>
Labs	<p>(Read-only) All test results that are for the subject in the study and that are associated with completed or in progress Clinical Testing events.</p>
History	<p>All audit trail entries from the CT Change Log associated with the AE Form. The entries list is sorted by Date/Time, in descending order.</p>

4 Click **SAVE**.

If an event in an observation group has a non-blank Resolution Date, the group it is part of is considered resolved.

An error message appears if:

- The Resolution Date of the AE Form is not blank and an observation group attached to the form has not been resolved.
- The Resolution Date of the AE Form is not blank, an observation group is attached to the form that is resolved, and the Resolution Date of the AE Form is earlier than the Resolution Date for the observation group.

A warning message appears if the AE Form is attached to an observation group, but not all events associated with the observation group are attached to the form.

A warning appears if the Approval Status is set to Approved and the Status field is set to Ongoing.

If the AE Form has an Approval Status set to Approved, it is changed to Not Approved, and the Approval Date and Approved By fields are set to blank. An entry is recorded in the CT Change Log with a source of Study Data Approval. A comment for the audit record is also saved, stating approved data was changed.

If an AE Form has a Monitor Review Status set to Reviewed, it is changed to Not Reviewed. An entry is recorded in the CT Change Log with a source of Study Data Approval. A comment for the audit record is also saved, stating reviewed data was changed.

Associating an AE observation with an AE form

You can associate an AE observation with an AE form when you add the AE form or after the form exists.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **AEs** tab.
- 2 Select an AE form, and click **EDIT**.
- 3 Select the **Other AE Obs.** tab.
- 4 Select an AE observation, and click **ATTACH**.

An Approval dialog box appears.

- 5 In the Approval area, type your User ID, password, and a Comment, and click **Apply**.

The observation is associated with the AE form and moves to the Attached AE Obs. tab.

If the AE observation already belongs to an AE form, when you click **ATTACH**, the AE Observation is linked to the current AE form and detached from the old AE form.

You cannot add an AE observation to an AE form with a status of **Approved**.

Resolving an AE form

You can perform final resolution of AE forms only in the Edit AE Form dialog box.

When you resolve an AE form, any observations that are associated with it are not resolved.

You can resolve individual observations that are associated with an AE form on either the Clinical Data Entry - AE Observations - Enter AE Observation Follow Up Details page or on the Study - Events - Data page, but these resolutions are not considered a final resolution.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **AEs** tab.
- 2 Select an AE form, and click **EDIT**.
- 3 In the AE Status section, select **Resolved**, and in the Resolution fields, enter a date and time.
- 4 In the Approval area, type your User ID, password, and a Comment, and click **SAVE**.

Deleting an AE form

Prerequisites: See Prerequisites: Working with AE forms.

You can delete AE forms that do not have any AE observations.

AE form deletions are recorded in the CT Change Log report with a source of Adverse Event.

You cannot delete an AE form if any of the following conditions apply:

- The AE form has an Approval Status of Approved.
 - The AE form includes one or more observations.
 - The AE form is associated with a locked group and period.
- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **AEs** tab.
 - 2 Select one or more AE forms, and click **DELETE**.
A confirmation dialog box appears.
 - 3 Click **OK**.

CHAPTER 13

Study metrics

In this chapter

Tasks: Study - Metrics page.....	306
Locking and unlocking a group/period	307
Releasing and undoing the release of a group/period	308

Tasks: Study - Metrics page

On the Study - Metrics page, you view each group and period that are assigned to the current facility. You can change the status of each group/period record to locked or unlocked. Locking prevents further changes to the data of the locked group/period.

The % Completed field displays the total percentage of events that have a status of Completed, Cancelled, Failed, or Missed.

You can release records for external viewing in the LabPas DQ module.

- *Locking and unlocking a group/period* (on page 307).
- *Releasing and undoing the release of a group/period* (on page 308).

Locking and unlocking a group/period

Prerequisite: You must have Manage Study Data function permission.

A study must have scheduled events for the group/period to appear on the Study - Metrics page.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Metrics** tab.
- 2 Select one or more group/periods, and click **STATUS**.
The Lock Status dialog box appears.
- 3 To lock the group/periods, select the **Locked** checkbox.
To unlock the group/periods, deselect the **Locked** checkbox.
- 4 Type your User ID, password, and an optional comment, and click **APPLY**.

Releasing and undoing the release of a group/period

Prerequisite: You must have Manage Study Data function permission.

A study must have scheduled events for the group/period to appear on the Study - Metrics page.

Releasing a group/period makes the record available for external viewing in the LabPas DQ module.

- 1 From the main menu, select **Clinical Trials > CT Studies**, and select a study. On the Study page, select the **Metrics** tab.

- 2 Select one or more group/periods, and click **RELEASE**.

The Release Status dialog box appears.

- 3 To release a group/period, select the **Released** checkbox.

To undo the release of a group/period, deselect the **Released** checkbox.

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

CHAPTER 14

Barcode identification

In this chapter

Barcode Identification page.....	310
Tasks: Barcode Identification page	311
Viewing vessel information associated with a barcode ID	312
Printing a CT label for a vessel associated with a barcode.....	313

Barcode Identification page

On the Barcode Identification page, you view vessels and study data for vessels associated with the selected barcode and with the current facility. From this page you can reprint bar-coded vessel labels for sample collection and transfer tubes.

The Barcode Id field is a search field that validates a barcode and then displays information associated with the barcode. Data is included for:

- Scheduled PK samples.
- Ad hoc PK samples.
- Aliquots.
- LabPas Recruiting module screening lab samples.

For box barcodes, the page lists the centrifuge, aliquot, and storage date for scheduled and ad hoc PK samples and aliquots that are packed in the box.

The Expected Time and Actual Sample Date fields display seconds for barcodes associated with CT study events when the Consider Seconds option is selected on the CT Studies > Setup – Events page.

For each barcode, you can:

- Display centrifuge, aliquot, and storage data for scheduled and ad hoc PK samples and aliquots associated with the barcode.
- Print individual LabPas Recruiting module screening lab samples. The type and format of the label is set up on the SR Studies - Setup - Labels page in LabPas Recruiting module.
- Print CT labels for vessels associated with a barcode, for both scheduled and ad hoc PK samples and aliquots.

The type of CT label is determined by the selections made on the *Study - Setup - Labels page* (on page 144) when the study was set up.

Tasks: Barcode Identification page

- *Viewing vessel information associated with a barcode ID* (on page 312).
- *Printing a CT label for a vessel associated with a barcode ID* (on page 313).

Viewing vessel information associated with a barcode ID

The Barcode Id must be associated with a valid vessel.

- 1 From the main menu, select **Clinical Trials > Barcode Identification**.
The Barcode Identification page appears.
- 2 In the **Barcode Id** field, type or scan a valid barcode ID.
- 3 Press **TAB** or **ENTER**.

Printing a CT label for a vessel associated with a barcode

You cannot print labels if the Study - Properties page specifies Vendor Labeled Transfer Tubes.

- 1 From the main menu, select **Clinical Trials > Barcode Identification**.

The Barcode Identification page appears.

- 2 In the **Barcode Id** field, type a valid barcode ID.

Note: Type up to 30 characters. The field is case-sensitive.

- 3 Press **TAB** or **ENTER**.

Details for the vessel associated with the barcode appear in the table. All fields are read-only.

- 4 Click **PRINT**.

The Print dialog box appears.

- 5 Select printer options and click **OK**.

Labels are printed to the printer that was specified for the study on the *Study - Setup - Labels page* (on page 144).

Seconds appear in the Expected Time field on labels when the event associated with the barcode is a CT study event configured with the Consider Seconds option selected on the CT Studies > Setup – Events page.

CHAPTER 15

PK Lab Schedule

In this chapter

PK Lab Schedule page	316
About samples in the PK Lab schedule	317
Tasks: PK Lab Schedule page	318
Viewing PK Lab schedule information	319

PK Lab Schedule page

On the PK Lab Schedule page, you view scheduled and ad hoc PK samples that are associated with the current facility and that have not been stored. The page is read-only.

This page shows the status of upcoming or missed samples for a given period of time, according to the settings defined for the LabPas application for the PK Lab Schedule job on the Job Administration page and the filter settings applied in this page.

On the header of the page, you view overall statistics, according to the parameters set by the PK Lab Statistics job that was defined for the LabPas application on the Job Administration page. For more information, see *Preformatted jobs* (in the *Administration Guide*).

- If Parameter 1 of the PK Lab Statistics job is set to 0, statistics do not appear.
- The value of Parameter 2 determines the number of days the application looks back from the current server date when calculating sample storage deviations.
- The value of Parameter 3 determines the number of minutes to be added to the Expected Date/Time plus tolerance to establish a delay for alerts to appear.

You can use the filter to select up to four study IDs, from all studies that have an active group and period associated with the current facility.

If the Consider Seconds option for the event is selected on the CT Studies > Setup – Events page:

- Values set for Negative Tolerance Seconds and Positive Tolerance Seconds fields are displayed.
- Seconds are displayed in the Expected Time and Draw Date fields for samples associated with the event.

When sorting by Tolerance, records are sorted first by Negative Tolerance, then by Positive Tolerance.

About samples in the PK Lab schedule

Filter selections

On the PK Lab Schedule page:

- The default Statistics filter selection is Yes.
- The Sample Type filter selection is restricted to the types of samples that appear in the selected studies.

Conditions for samples to appear

Samples appear on the PK Lab Schedule page when their Expected Time is before or equal to the current system time plus the Parameter 2 minutes defined in the PK Lab Schedule job. For more information, see *Preformatted jobs* (in the *Administration Guide*).

Samples must also meet the following criteria to appear:

- Samples must be PK samples that have not already been stored or cancelled.
- Samples must have a Storage - Time To value of 1 or more, as set up for the referenced study and sample type on the *Study - Setup - PK Lab page* (on page 82).

Samples are considered to have a storage deviation when the Date/Time that they were first stored is later than the Draw Date plus the Storage - Time To value for the referenced study and sample type on the *Study - Setup - PK Lab page* (on page 82).

Samples that do not appear

- Samples that have been cancelled.
- Samples that have already been stored.
- Samples that belong to a study and sample type that have a Storage - Time To value of less than 1 on the Study - Setup - PK Lab page.
- Samples that have a Store Mins value less than the Parameter 1 minutes defined in the PK Lab Schedule job.
- Samples that have an Expected Time after the current system time plus the Parameter 2 minutes defined in the PK Lab Schedule job.

Samples that are removed

Samples are removed from the PK Lab Schedule page when the Store Mins field is less than the Parameter 1 minutes defined in the PK Lab Schedule job. The first recorded storage date for an aliquot establishes when stored samples should be removed from the grid. The first recorded storage date for samples must be established by aliquot storage, not box storage.

Note: If you store packed aliquots that do not have a First Stored Date, the samples are not removed from the grid.

Tasks: PK Lab Schedule page

- *Viewing PKLab schedule information* (on page 319).

Viewing PK Lab schedule information

Prerequisites:

- The PK Lab Schedule job that was defined on the Job Administration page must be active and include time parameters.
- The PK Lab Statistics job that was defined on the Job Administration page must be active and include time parameters, in order for the statistics displayed in the page heading to be updated.
- At least one schedule with PK Testing events must have been created on the Study - Events page.

If you have Disable Status Screen Timeouts security permissions, the Inactivity Time-out and Application Timeout timers are read-only.

All information is read-only. For more information, see *About samples in the PK Lab Schedule* (on page 317).

- From the main menu, select **Clinical Trials > PK Lab Schedule**.

The PK Lab Schedule appears.

Field	Description
Updated	Last time the page was refreshed. This field shows the current server date and time, even if the Statistics filter selection is No.
Samples Today	Number of PK samples logged into the lab on the current server date.
Days Since Dev	Number of days since the last storage deviation for a PK sample in the current facility.
90 Day Dev %	Percentage of PK sample storage deviations within the current facility in the past 90 days.

In the table	
Cent Mins	Number of minutes left until the sample should be centrifuged, based on the current server date and time displayed in the Updated field in the header. A negative number in this field indicates the number of minutes that the sample is late being centrifuged. Cent Mins is calculated by subtracting the Updated date and time from the Cent By date and time.
Store Mins	Number of minutes left until the sample should be stored, based on the current server date and time displayed in the Updated field in the header. A negative number indicates the number of minutes that the sample is late being stored. Store Mins is calculated by subtracting the Updated date and time from the Store By date and time.

Field	Description
Draw Date	<p>Either:</p> <ul style="list-style-type: none"> Actual Sample Date recorded on the Sample Logging page during sample management. Date/Time the sample was drawn using the Sample page during clinical data entry. <p>If the Draw Date field has no value, then Cent. By = Expected Time + Positive Tolerance + Cent. Mins.</p> <p>If the Draw Date field has no value, then Store By = Expected Time + Positive Tolerance + Store Mins.</p>
ID	<p>Subject No. associated with the sample, if assigned.</p> <p>If no Subject No. is assigned, the Screening No. is used.</p>
Date Received	Date and time recorded for the sample in the Date Received field of the Sample Logging page during sample management.
Last process	<p>Last processing function that the sample has gone through:</p> <p>Draw—On the Sample page during clinical data entry.</p> <p>Sample Logging—On the Sample Logging page during sample management.</p> <p>Centrifuge—Sample Centrifuge page.</p> <p>Aliquoting—Sample Aliquoting page.</p> <p>The LabPas application assumes that all samples are processed in this order, although one or more of the specified processes can be skipped.</p>
Last Update	Date and time that was recorded for the process shown in the Last Process field. This value appears in the CT PK Sample Processing Log report.
Last User	User ID of the person who last processed the sample.
Cent By	<p>The time by which the sample should be centrifuged.</p> <p>This field is calculated in the following way:</p> <ul style="list-style-type: none"> If Draw Date is recorded—Cent Mins value plus the Draw Date time. If Draw Date is not recorded—Expected Time plus Tolerance (both recorded on the Study - Events page) is added to the Centrifuge - Time To value for the referenced study and sample type (on the <i>Study - Setup - PK Lab page</i> (on page 82)).

Field	Description
Store By	<p>The time by which the sample should be stored.</p> <p>How Store By is calculated:</p> <ul style="list-style-type: none"> • If Draw Date is recorded—Store Mins value is added to Draw Date time. • If Draw Date is not recorded—Expected Time plus Tolerance (both recorded on the Study - Events page) is added to the Storage - Time To value for the referenced study and sample type (on the <i>Study - Setup - PK Lab page</i> (on page 82)).

Status information

Status	Description and Conditions
Not Started	The event has not been drawn and the system time is before the Expected Time plus Positive Tolerance plus parameter 3.
In Progress	The sample has a value for Draw Date and does not have a status of either Alert or Missed.
Alert	<p>The sample row turns yellow if the status is Alert.</p> <p>An alert is associated with the sample, either for event data, centrifuge data, or storage data.</p>
Alert: Event Data	<p>Both conditions exist:</p> <ul style="list-style-type: none"> • The Lab Status in the Study - Scheduled - Events page is Not Started. • The current server date and time is within the Expected Time plus or minus the Tolerance. <p>The event has not been drawn and the system time is after the Expected Time plus Positive Tolerance plus parameter 3. If parameter 3 is not specified, it is considered as having a 0 value.</p>
Alert: Centrifuge Data	<p>Any of the following conditions exist:</p> <ul style="list-style-type: none"> • Lab Status is any value other than Cancelled or Not Started on the Study - Scheduled - Events page and the sample has not yet been centrifuged. • The current server date and time is after Actual Sample Date plus Centrifuge - Time to minutes less Centrifuge - Alert minutes, as set up for the referenced study and sample type on the Study - Setup - PK lab page. • The current server date and time is before the Actual Sample Date plus Centrifuge - Time to minutes.

Status	Description and Conditions
Alert: Storage Data	<p>Any of the following conditions exist:</p> <ul style="list-style-type: none"> • The Lab Status is any value other than Cancelled or Not Started on the Study - Scheduled - Events page, and the sample has not yet been stored. • The current server date and time is after Actual Sample Date plus Storage Time To minutes less Storage - Alert minutes, as set up for the referenced study and sample type on the Study - Setup - PK Lab page. • The current server date and time is before the Actual Sample Date plus Storage - Time To minutes.
Missed	<p>The sample row turns red when the status is Missed.</p> <p>A sample has been missed, either for event data, centrifuge data, or storage data.</p> <p>Alerts can exist for the reasons described below.</p>
Missed for Events	<p>The Lab Status on the Study - Events page is Not Started and the current date/time is after the Expected Date plus the event Tolerance minutes defined for the event.</p>
Missed for Centrifuge	<p>Any of the following conditions exist:</p> <ul style="list-style-type: none"> • The Lab Status is any value other than Cancelled or Not Started on the Study - Events page, and the sample has not yet been centrifuged. • The current server date and time is after the Actual Sample Date plus Centrifuge - Time To minutes, as set up for the referenced study and sample type on the Study - Setup - PK Lab page.
Missed for Storage	<p>Any of the following conditions exist:</p> <ul style="list-style-type: none"> • The Lab Status is any value other than Cancelled or Not Started on the Study - Events page, and the sample has not yet been stored. • The current server date and time is after the Actual Sample Date plus Storage - Time To minutes, as set up for the referenced study and sample type in the Study - Setup - PK Lab page.

CHAPTER 16

Study schedule

In this chapter

Tasks: Study Schedule page.....	326
Viewing the study schedule.....	327

Tasks: Study Schedule page

On the Study Schedule page, you view events that are associated with the current facility, with a row for each event that has a status of Not Started.

You can filter for samples from specific studies, selecting up to four Study IDs. The filter includes Study ID, Event Type, Subject No., Screening No., and User ID. The filters list studies with an active group and period that is associated with the current facility.

If User ID field is not blank, the Study Schedule page displays all events assigned to the specified user.

- *Viewing the study schedule* (on page 327).

Viewing the study schedule

Prerequisites:

- At least one schedule with events must have been created on the Study - Events page.
 - If you do not have View all Studies security permissions, you must be listed in the User Access List of the Study - Properties page for each study whose study schedule you want to view. For more information, see *Allowing users to view a study* (on page 74).

If you have the Disable Status Screen Timeouts security permissions, the Inactivity Time-out and Application Timeout timers are read-only.

The Study Schedule page contains a row for each event that has a status of Not Started.

- Events that are late (current date/time is greater than the expected date/time plus positive tolerance) are displayed in red.
- Events that are in alert (current date/time is within expected date/time plus positive tolerance) are displayed in yellow.

To view the study schedule:

- From the main menu, select **Clinical Trials > Study Schedule**.

The following information is shown for each event. The page refreshes automatically every minute.

Field	Description
Study Id	Study ID associated with the event
Time Point	Time point label specified on the Study - Setup - Events page.
Expected Time	Date and time scheduled for the event. Seconds appear in the Expected Time field for events with the Consider Seconds option selected on the CT Studies > Setup – Events page.
Mins	Number of minutes to the expected time. If the number is negative, the number of minutes after the expected time.
ID	ID of the person associated with the event: <ul style="list-style-type: none"> • Pre-dose event—Screening number. • Post-dose event—Subject number.
Initials	Initials of the candidate associated with the event.
Event Type	Event type associated with the event.
Assignment	List of user IDs assigned to the event, delimited by a comma. You cannot sort by the Assignment column.
Event Category	Category associated with the event.
Sample Type	Sample type associated with the event.

Field	Description
Group	Group associated with the Subject.
Period	Period associated with the event.
Tolerance	<p>Number of minutes of tolerance associated with the event.</p> <p>When you sort by the Tolerance column, records are sorted first by Negative Tolerance, then by Positive Tolerance.</p> <p>If the Consider Seconds option for the event is selected on the CT Studies > Setup – Event page, the values configured in the Negative Tolerance Seconds and Positive Tolerance Seconds fields also appear in the Tolerance field.</p>
Vessel Type	Vessel type associated with the event.
Barcode	Barcode of the vessel associated with the event.
No. Tubes	Number of tubes for a multi-tube drawn.
Panels	Panels associated with the event.

Part 4: Designing recruitment for a clinical trial

CHAPTER 17

Designing recruitment for a clinical trial

In this chapter

Studies in the LabPas Recruiting module.....	332
Study properties in the LabPas Recruiting module.....	333
Setting up recruiting elements of a study.....	335
Restrictions for recruiting.....	370
Questionnaire.....	377
Volunteers.....	384
General practitioner information.....	397
Scheduled events for screening.....	399
Labs in a recruiting study.....	411

Studies in the LabPas Recruiting module

SR Studies page

On the SR Studies page, you select a study to work with. The SR studies page lists all studies set up in either the LabPas CT module or the LabPas Recruiting module.

The LabPas application can be configured to show all items in all facilities. For more information, see *Global Settings* (in the *Administration Guide*).

To restrict the data that appears on the page, use the FILTER button.

You can work with only one study at a time, setting up the following areas for the study:

- *Study Properties in the LabPas Recruiting module* (on page 333).
- *Recruiting elements of a study* (on page 335).
- *Restrictions for recruiting* (on page 370).
- *Questionnaire* (on page 377).
- *Volunteers* (on page 384).
- *General Practitioner Information* (on page 397).

Tasks: SR Studies page

- *Selecting a study* (on page 332).

Selecting a study

- 1 From the main menu, select **Recruiting > SR Studies**.
The SR Studies page appears.
- 2 From the list, click a study.
The Study - Properties page appears.

Study properties in the LabPas Recruiting module

Tasks: Study - Properties page in the LabPas Recruiting module

On the Study - Properties page, you view general information about each study.

- *Editing study properties* (on page 333).
- *Locking and unlocking a study* (on page 334).

Editing study properties (Recruiting)

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. The Study - Properties page appears.
- 2 Edit the fields and click **UPDATE**.

Field descriptions for the Study - Properties page

Field	Description	Notes
Study Id	Study ID.	Editable if volunteers have not been accepted in the CT study.
Description	Description of the study.	
Study Type	Type of study (for example, Allergies). Select from a drop-down menu of all study types that were set up on the Settings - Study - Study Type page.	REQUIRED.
Study Rank	Study rank.	For reference only.
Recruiting Start Date	Date that you can begin assigning volunteers to the study. Either type a date, or click the calendar icon and select a date.	Must be in the same format that was configured on the Configuration - Settings - Facility page.
Phone Screening	<ul style="list-style-type: none"> • Active—The study can have volunteers assigned to it from incoming calls. • Inactive—The study does not appear for selection during incoming calls. 	Default is blank.
Sponsor	Study sponsor. Provide a name, or click the Lookup button (a magnifying glass) and select the sponsor name in the Customer Lookup dialog box.	If you select a sponsor from the Customer Lookup dialog box, customer information appears in the Sponsor, Contact, Email, Telephone, and Fax fields.

Field	Description	Notes
Contact	Name of the person to contact.	
Email	Email address of the contact.	
Telephone	Telephone number of the contact.	
Fax	Fax number of the contact.	

Locking and unlocking a study

Prerequisite: You must have the Approve Study Setup function permission to lock or unlock a study.

You cannot edit or delete a locked study, and you cannot assign volunteers to the study.

Studies locked in the LabPas Recruiting module are also locked in the LabPas CT module.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study.
The Study - Properties page appears.
- 2 To lock the study, click **LOCK**.
- 3 To unlock the study, click **UNLOCK**.
An approval dialog box appears.
- 4 Type your User ID, password, and an optional comment, and click **APPLY**.

Setting up recruiting elements of a study

Study - Setup page

On the Study - Setup page you set up recruiting elements for a study.

Study description and parameters

Tasks: Study - Setup - General page

On the Study - Setup - General page, you view descriptive and administrative information about a study.

- *Entering a study description* (on page 335).
- *Setting study parameters* (on page 335).
- *Editing a study group* (on page 336).

Entering a study description

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **General** category.

The Study - Setup - General page appears.

- 2 In the Study Description table, fill in the fields. You must click **SAVE** after entering text for each field.

Field descriptions for the Study Description table

Field	Description	Notes
Synopsis	Synopsis of the study.	This information appears on the Study Details dialog box, accessed from the Incoming Calls pages.
Screening Appt. Instr.	Instructions for the screening appointment.	This information appears when an appointment is scheduled, rescheduled, or cancelled; or when a reminder call is made to a volunteer regarding an appointment.
Outline	Outline of the study.	This information appears on the Study Details dialog box, accessed from the Incoming Calls pages.

Setting study parameters

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **General** category.

The Study - Setup - General page appears.

- 2 In the Parameters table, fill in the fields.

Field descriptions for the Study Parameters table

Field	Description	Notes
No. Subjects	Number of subjects that were specified in the Resource Management module.	READ-ONLY.
No. Alternates	Number of alternates that were specified in the Resource Management module.	READ-ONLY.
Screening Reminder Call	Number of days that an outgoing reminder call is automatically scheduled, prior to the scheduled appointment on the Outgoing Calls page.	
Allow Hormonal Medications	<ul style="list-style-type: none"> • Selected—Patients taking hormonal medications can participate in the study. • Not selected—Patients who indicate on the Incoming Calls - Concomitant Medications page that they are taking a hormonal medication are disqualified from the study. 	You can view the hormonal status of a medication on the Settings - Medical - Medications page.

- 3 Click **SAVE**.

Editing a study group

Study groups are created in the Resource Management module

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **General** category.

The Study - Setup - General page appears.

- 2 In the Groups table, fill in the fields.

Field descriptions for the Groups table

Field	Description	Notes
Group	Group name.	Numeric or alphanumeric entry of up to 3 characters. Volunteers are assigned to specific study groups on the Study - Volunteers page and the Incoming Calls - Study Questions page.
Location	Facility name. To select a different facility, click the ellipsis button (...).	If the LabPas application is configured for Global Recruiting, a list of all facilities appears. Recruiting studies apply for all CT studies in all facilities. If Global Recruiting is not configured, you cannot select a different facility.
Start	Start date.	Default: Arrival Date of the first period for the group.
End	End date of study.	Default: (Arrival Date + (No. Clinic Day - 1)) or (Arrival Date + Last Outpatient Visit Day - 1)) of the last period for the group, whichever is latest.

- 3 Click **SAVE**.

Panels for screening in the study

Tasks: Study - Setup - Panels page

On the Study - Setup - Panels page, you select the set of screening panels for screening volunteers in a study. The page lists all of the screening panels assigned to a study, the individual tests that comprise the panel, and the reference ranges and demographic reference ranges for the panel in the current study.

- *Adding a screening panel* (on page 337).
- *Adding demographic ranges* (on page 339).
- *Updating a screening panel.* (on page 340)
- *Refreshing a screening panel with new tests* (on page 342).
- *Removing a screening panel* (on page 342).

Adding a screening panel

Prerequisite: Define tests and test panels. For more information, see the Test Panels page (in the *Administration Guide*).

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Panels** category.

The Study - Setup - Panels page appears.

- 2 Click **ADD**.

A dialog box appears listing test panels that have not already been assigned to the current study as screening panels.

- 3 Click a panel.

The panel appears in the Screening Panels column. Each test in that panel appears in the Test Ranges box.

Field descriptions for the Study - Setup - Panels page for screening panels

Field	Description	Notes
Screening Panels column	List of screening panels assigned to the study.	
Test Ranges	A table with one row for each test in the panel that is selected in the Screening Panels column.	

For each test listed in the Test Ranges table

Field	Description	Notes
Include	<p>Selected—The test is included in the panel.</p> <p>Not selected—For this study only, the test is not included in the panel.</p>	<p>Default: Selected.</p> <p>If not selected:</p> <ul style="list-style-type: none"> • Reference Range and Demographic are read-only. • Optional is read-only and not selected.
Optional	<p>Selected—Test is optional in this study.</p> <p>Not selected—Test is required in this study.</p>	<p>Default: Not selected.</p> <p>Available only if Include is selected.</p>
Test	Name of the test.	Default: The value defined on the Tests page of the LabPas CT module.

Field	Description	Notes
Type	Type of the test.	Default: The value defined on the Tests page of the LabPas CT module.
Reference Range	Reference ranges or reference values, depending on the test type.	Default: The value defined on the Tests page of the LabPas CT module.
Demographic	Whether demographic reference ranges are set up for the test.	Read-only if the test does not support demographic reference ranges.

- Optionally, *add or edit demographic ranges* (on page 339) for the test for the current study only.
- Click **UPDATE**.

Adding demographic ranges

The fields are disabled for tests that do not support demographic reference ranges.

- From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Panels** category.

The Study - Setup - Panels page appears.

- In the list of panels, click a panel.

The tests that comprise the panel appear in the Test Ranges table, with a row for each test.

- For the test to which you want to add a demographic range, click the ellipsis button (...) located in the Demographic column.

The Edit Demographic Ranges dialog box appears.

- Click **ADD**.

The Reference Range dialog box appears.

- Fill in the fields.

Field descriptions for the Reference Range dialog box

Field	Description	Notes
Gender	Gender to which the result validation is applied.	Not Available —The range applies to both genders.
Age Min	Minimum age to which the result validation is applied.	
Age Max	Maximum age to which the result validation is applied.	For an unbounded age range, leave blank.

Field	Description	Notes
Result [qualifier]	<p>Minimum result qualifier.</p> <p>Restricts the range of the value that you specify in the Result field by the qualifier you select from the drop-down list.</p> <ul style="list-style-type: none"> • > greater than. • >= greater than or equal to. 	
Result	The minimum expected test value for this demographic range, as compared to the Age Min field.	Either or both of the Result / And fields must contain a value.
AND Result [qualifier]	<p>Maximum result qualifier.</p> <p>Restricts the range of the value you specify in the Result field by the qualifier you select from the drop-down list.</p> <ul style="list-style-type: none"> • < less than. • <= less than or equal to. 	
Result	Maximum expected test value for this demographic field, as compared to the Age Max field.	

- 6 Click **SAVE**.

The range appears in the Edit Demographic Ranges dialog box.

- 7 Click **SAVE**.

Updating a screening panel

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Panels** category.

The Study - Setup - Panels page appears.

- 2 In the **Screening Panels** section, click a panel.

The tests that comprise the panel appear in the Test Ranges table.

- 3 Fill in the fields.

Field descriptions for the Study - Setup - Panels page

Field	Description	Notes
Screening Panels column	List of screening panels assigned to the study.	
Test Ranges	A table with one row for each test in the panel that is selected in the Screening Panels column.	

For each test listed in the Test Ranges table

Field	Description	Notes
Include	<p>Selected—The test is included in the panel.</p> <p>Not selected—For this study only, the test is not included in the panel.</p>	<p>Default: Selected.</p> <p>If not selected:</p> <ul style="list-style-type: none"> Reference Range and Demographic are read-only. Optional is read-only and not selected.
Optional	<p>Selected—Test is optional in this study.</p> <p>Not selected—Test is required in this study.</p>	<p>Default: Not selected.</p> <p>Available only if Include is selected.</p>
Test	Name of the test.	Default: The value defined on the Tests page of the LabPas CT module.
Type	Type of the test.	Default: The value defined on the Tests page of the LabPas CT module.
Reference Range	Reference ranges or reference values, depending on the test type.	Default: The value defined on the Tests page of the LabPas CT module.
Demographic	Whether demographic reference ranges are set up for the test.	Read-only if the test does not support demographic reference ranges.

- 4 Optionally, add or edit demographic reference ranges for the test in this study only.

Field	Description	Notes
Gender	<p>Gender to which the result validation is applied.</p> <p>Not Available—The range applies to both genders.</p>	
Age Min	Minimum age to which the result validation is applied.	
Age Max	<p>Maximum age to which the result validation is applied.</p> <p>For an unbounded age range, leave blank.</p>	

Field	Description	Notes
Result [qualifier]	<p>Minimum result qualifier.</p> <p>Restricts the range of the value that you specify in the Result field by the qualifier you select from the drop-down list.</p> <ul style="list-style-type: none"> • > greater than. • >= greater than or equal to. 	
Result	The minimum expected test value for this demographic range, as compared to the Age Min field.	Either or both of the Result / And fields must contain a value.
AND Result [qualifier]	<p>Maximum result qualifier.</p> <p>Restricts the range of the value you specify in the Result field by the qualifier you select from the drop-down list.</p> <ul style="list-style-type: none"> • < less than. • <= less than or equal to. 	
Result	Maximum expected test value for this demographic field, as compared to the Age Max field.	

- 5 Click **UPDATE**.

Refreshing a screening panel with new tests

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Panels** category.
The Study - Setup - Panels page appears.
- 2 In the Screening Panels section, click a panel.
The tests that comprise the panel appear in the Test Ranges table.
- 3 Click **REFRESH**.
The panel is updated with tests that were added since the panel was added to the study.
Changes appear in the Recruiting Change Log report.

Removing a screening panel

A panel cannot be removed if either of the following conditions apply:

- The panel is associated with any scheduled events in the study.
 - The panel has been associated with the Clinical Testing or Onsite Testing list on the Study - Setup - Screening page
- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Panels** category.

- The Study - Setup - Panels page appears.
- 2 In the Screening Panels section, select a panel.
 - 3 Click **REMOVE**.
- A confirmation dialog box appears.
- 4 Click **OK**.

Clinical Labs for screening in a study

Tasks: Study - Setup - Clin Lab (Recruiting)

On the Study - Setup - Clin Lab page, you configure sample types for clinical lab samples in the study.

Note: The **ADD** button, the **UPDATE** button, all **REMOVE** buttons and all **Lab Instructions** fields are disabled if the study is locked.

- *Adding a sample type to a Clinical Lab event for recruiting* (on page 343).
- *Removing a sample type from a Clin Lab for recruiting* (on page 344).

Adding a sample type to a Clinical Lab event for recruiting

Prerequisites:

- *Create a sample type* (in the *Administration Guide*).
 - You must have Create/Change Study permissions.
- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Clin Lab** category.

The Clinical Lab Setup page appears.

- 2 Click **ADD**.

A dialog box appears listing all sample types configured in the LabPas application that do not already appear in the Clinical Lab Setup section.

- 3 Select a sample type.

The dialog box closes, and the sample type you selected appears in the Clinical Lab Setup section.

- 4 To add instructions that appear when samples of this type are processed, click the **i** icon in the upper-left corner of the box.

The Lab Instructions dialog box appears. Allows characters from all languages.

- 5 Enter instructions in any of the boxes, and click **APPLY**.

The Lab Instructions dialog box closes.

- 6 Click **UPDATE**.

An entry is written to the Recruiting Change Log with a source of Clinical Lab Setup.

Removing a sample type from a Clin Lab for recruiting

Prerequisite: You must have Create/Change Study permissions.

You can remove a sample type only if it is not associated with an event.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Clin Lab** category.

The Clinical Lab Setup page appears.

- 2 In the sample type table you want to remove, click **REMOVE**.

The sample type is removed from the list.

- 3 Click **UPDATE**.

An entry is written to the Recruiting Change Log with a source of Clinical Lab Setup.

Screening forms in a recruiting study

Tasks: Study - Setup - Forms for screening

On the Study - Setup - Forms page, you define the set of forms that can be assigned to screening events in the study.

This page lists the all forms that exist in the study and the contents of the selected form.

- *Adding a screening form* (on page 344).
- *Importing a screening form* (on page 345).
- *Renaming a screening form* (on page 345).
- *Adding a question to a form* (on page 345).
- *Editing a question on a form.* (on page 346)
- *Removing a question from a form* (on page 347).
- *Removing a screening form* (on page 348).

Adding a new screening form to a study

To add an existing *form that was defined* (in the *Administration Guide*) when the LabPas application was set up, you must *import the form* (on page 345).

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Forms** category.

The Forms page appears. The page contains a list of forms that currently exist in the study, along with the contents of the form that is selected in the list.

- 2 Click **NEW**.

The New Form dialog box appears.

- 3 Type a unique form name and an optional comment, and click **SAVE**.

Importing a screening form to a study

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Forms** category.
The Forms page appears.
- 2 Click **IMPORT**.
A dialog box appears with a list of forms that were *configured when the LabPas application was set up* (in the *Administration Guide*).
Forms that have the same name as a form that is already associated with the current study do not appear.
Only the forms associated with the current facility are listed, unless Global Forms were selected when *global settings were configured* (in the *Administration Guide*).
- 3 Select one or more forms, and click **UPDATE**.
The forms are added to the study along with all questions that are associated with the forms.

Renaming a screening form

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Forms** category.
The Forms page appears.
- 2 In the Forms list, select a form.
- 3 Click **RENAME**.
The Rename Form dialog box appears.
- 4 Type a unique form name and an optional comment, and click **SAVE**.

Adding a question to a form in a study

To obtain the form to which you want to add questions for the current study, you can use either of the following methods:

- Add a new form in the current study and add questions to it for the current study.
- Import a form that was *created when the LabPas application was set up* (in the *Administration Guide*), and add questions to it for the current study.

You cannot add questions to a form that is associated with an approved screening event.

- 1 Access the form by either of the following methods:
 - *Add a new form in the current study* (on page 344).
 - *Import a form to the current study* (on page 345).
 The form appears on the Study - Setup - Forms page.
- 2 In the Forms list, select a form.
- 3 In the Questions section, click **ADD**.
The Add Question dialog box appears.
- 4 Fill in the fields.

Field descriptions for the Add Question dialog box

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

- 5 Click **SAVE**.

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

- 6 Add additional questions as needed.
- 7 After you finish adding questions, close the dialog box.

Editing a question on a form in a study

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Forms** category.

The Forms page appears.

- 2 In the Forms list, select a form.

- 3 In the Questions section, click the ellipsis button (...) for a question.
The Edit Question dialog box appears.
- 4 Fill in the fields.

Field descriptions for the Edit Question dialog box

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

- 5 Click **SAVE**.

Removing a question from a form in a study

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Forms** category.
The Forms page appears.
- 2 In the Forms list, select a form.

The questions that comprise the form appear.

- 3 Click the **X** button for a question.
A confirmation dialog box appears.
- 4 Click **OK**.

Removing a screening form from a study

You cannot remove a form that is associated with a screening event.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Forms** category.

The Forms page appears.

- 2 Select a form.
The form content appears.
- 3 Click **REMOVE**.
A confirmation dialog box appears.
- 4 Click **OK**.

Events setup for screening in a study

Tasks: Study - Setup - Events page (Screening)

On the Study - Setup - Events page, you create events that are performed during screening visits.

To restrict the information that is shown on the page, use the filter.

- *Adding a Clinical Testing event for screening* (on page 349).
- *Adding a Testing event for screening* (on page 351).
- *Adding an Other event for screening* (on page 353).
- *Approving a screening event* (on page 355).
- *Editing a screening event* (on page 356).
- *Deleting an unapproved screening event* (on page 362).
- *Deleting an approved screening event* (on page 362).

Prerequisites: Adding screening events

Elements used in events must have been defined in the LabPas application:

- At least one sample type, vessel type, test panel, and form must have been defined for the LabPas application

For more information, see (in the *Administration Guide*):

- *Sample types*.
- *Vessel types*.

- *Test panels.*
- *Forms.*
- A study must exist, and the following must have been set up for the study:
For more information, see:
 - *Panels for screening in a study* (on page 337).
 - *Clinical labs for screening in a study* (on page 343).

Adding a Clinical testing event for screening

Prerequisites: Study elements used in screening events must have been defined in the LabPas application. For more information, see *Prerequisites: Adding screening events* (on page 348).

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Events** category.

The Study - Setup - Events page for screening events appears.

- 2 Click **NEW**.

The New Event dialog box appears with the Clinical Testing tab selected.

Fields in the Event Properties section pertain to clinical testing events.

- 3 In the Properties and Event Properties sections, fill in the fields.

Field descriptions for the New Event - Clinical Testing dialog box

Properties Field	Description	Notes
Event No.	Number of the event.	REQUIRED. Must be a number from 1 to 999. Duplicates are allowed..
Event	Event description.	REQUIRED.
Visit	Visit in which the event takes place. Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event. Select a value other than No Selection if either of the following conditions apply: <ul style="list-style-type: none"> • The event type is Testing or Clinical Testing. • The event category is not set to the Check-In or Check-Out event. 	Items on the drop-down list include No Selection and all <i>visits configured for the study</i> (on page 153).

Properties Field	Description	Notes
Required Event	<p>Event that must be completed before the current event is performed.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p>	<p>Items on the drop-down list include No Selection and all approved and unapproved events.</p> <p>Each option includes the event description and visit associated with the event.</p>
Exclude from Study Parts section	Selected —Exclude the event from any groups that are assigned to the study part.	Checkboxes for all study parts in the study.

Event Properties section - Clinical Testing events

Event Properties Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Form	Form associated with the event.	Items in the drop-down list are based on the <i>forms created for the LabPas application</i> (in the <i>Administration Guide</i>).
Sample Type	Sample type to be tested in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on PK Lab settings created for the study.</p>
Vessel Type	Vessel type to use to contain the sample in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on the <i>vessel types defined in the LabPas application</i> (in the <i>Administration Guide</i>).</p>

Event Properties Field	Description	Notes
Quantity	Number of vessels that are used to collect the sample type	REQUIRED. Must be a number from 1 to 9. Default: 1.
Collection Description	Additional text that is printed on labels.	The number of fields on the Tube Description dialog box is determined by the Quantity . Descriptions can be selected when labels are set up for the study. For more information, see <i>Study - Setup - Labels page</i> (on page 144).
Panels	Test panels included in this event. Click the ellipsis button (...). A list of panels appears. Select the checkboxes for the panels to include in the event, and click UPDATE .	REQUIRED. The test panels were created on the Study - Setup - Panels page.
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	

- 4 Click **SAVE**.

Adding a Testing event for screening

Prerequisites: Study elements used in screening events must have been defined in the LabPas application. For more information, see *Prerequisites: Adding screening events* (on page 348).

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Events** category.

The Study - Setup - Events page for screening events appears.

- 2 Click **NEW**.

The New Event dialog box appears with the Clinical Testing tab selected.

- 3 Click the **Testing** tab.
- 4 In the Properties and Event Properties sections, fill in the fields.

Field descriptions for the New Event - Testing dialog box

Properties Field	Description	Notes
Event No.	Number of the event.	REQUIRED. Must be a number from 1 to 999. Duplicates are allowed..
Event	Event description.	REQUIRED.
Visit	<p>Visit in which the event takes place.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p> <p>Select a value other than No Selection if either of the following conditions apply:</p> <ul style="list-style-type: none"> • The event type is Testing or Clinical Testing. • The event category is not set to the Check-In or Check-Out event. 	Items on the drop-down list include No Selection and all <i>visits configured for the study</i> (on page 153).
Required Event	<p>Event that must be completed before the current event is performed.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p>	<p>Items on the drop-down list include No Selection and all approved and unapproved events.</p> <p>Each option includes the event description and visit associated with the event.</p>
Exclude from Study Parts section	Selected —Exclude the event from any groups that are assigned to the study part.	Checkboxes for all study parts in the study.

Event Properties section - Testing events

Event Properties Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Panels	<p>Test panels included in this event.</p> <p>Click the ellipsis button (...). A list of panels appears.</p> <p>Select the checkboxes for the panels to include in the event, and click UPDATE.</p>	<p>REQUIRED.</p> <p>The test panels were created on the Study - Setup - Panels page.</p>
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	

- 5 Click **SAVE**.

Adding an Other event for screening

Prerequisites: Study elements used in screening events must have been defined in the LabPas application. For more information, see *Prerequisites: Adding screening events* (on page 348).

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Events** category.
The Study - Setup - Events page for screening events appears.
The New Event dialog box appears with the Clinical Testing tab selected.
- 2 Click the **Other** tab.
- 3 In the Properties and Event Properties sections, fill in the fields.

Field Descriptions for the New Event - Other dialog box

Properties Field	Description	Notes
Event No.	Number of the event.	REQUIRED. Must be a number from 1 to 999. Duplicates are allowed..
Event	Event description.	REQUIRED.
Visit	<p>Visit in which the event takes place.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p> <p>Select a value other than No Selection if either of the following conditions apply:</p> <ul style="list-style-type: none"> • The event type is Testing or Clinical Testing. • The event category is not set to the Check-In or Check-Out event. 	Items on the drop-down list include No Selection and all <i>visits configured for the study</i> (on page 153).
Required Event	<p>Event that must be completed before the current event is performed.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p>	<p>Items on the drop-down list include No Selection and all approved and unapproved events.</p> <p>Each option includes the event description and visit associated with the event.</p>
Exclude from Study Parts section	Selected —Exclude the event from any groups that are assigned to the study part.	Checkboxes for all study parts in the study.

Event Properties section - Other events

Event Properties Field	Description	Notes
Event Category	Event category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	

- 4 Click **SAVE**.

Approving screening events

Prerequisite: You must have the Approve Study Setup function permission to approve screening events.

All events are approved each time you complete the Approve Events dialog box. You cannot approve one event at a time.

The events must include a Check-In and a Check-Out event, each with a status of blank or Approved.

Approving events that have a version greater than 1 requires a comment. The comment appears for all events that are approved.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Events** category.

The Study - Setup - Events page for screening events appears.

- 2 Click **APPROVAL**.

The Approve Events dialog box appears.

- 3 Fill in the fields, and click **APPLY**.

Editing a screening event

You can edit only the most recent version of an event.

If an event is not approved, you can edit it as many times as necessary; a new version is not created.

If an event is approved, you cannot change its event type.

If you edit a Clinical Testing event that has been previously approved, the event barcodes will be invalid when the events are rescheduled, and new barcode labels are required.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Events** category.

The Study - Setup - Events page for screening events appears.

- 2 Select one or more events, and click **EDIT**.
- 3 Fill in the fields.

Fields depend on the type of event you are editing.

Field descriptions for Clinical Testing events for screening

Properties Field	Description	Notes
Event No.	Number of the event.	REQUIRED. Must be a number from 1 to 999. Duplicates are allowed..
Event	Event description.	REQUIRED.
Visit	<p>Visit in which the event takes place.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p> <p>Select a value other than No Selection if either of the following conditions apply:</p> <ul style="list-style-type: none"> • The event type is Testing or Clinical Testing. • The event category is not set to the Check-In or Check-Out event. 	Items on the drop-down list include No Selection and all <i>visits configured for the study</i> (on page 153).

Properties Field	Description	Notes
Required Event	<p>Event that must be completed before the current event is performed.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p>	<p>Items on the drop-down list include No Selection and all approved and unapproved events.</p> <p>Each option includes the event description and visit associated with the event.</p>
Exclude from Study Parts section	Selected —Exclude the event from any groups that are assigned to the study part.	Checkboxes for all study parts in the study.

Event Properties section - Clinical Testing events

Event Properties Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>
Form	Form associated with the event.	Items in the drop-down list are based on the <i>forms created for the LabPas application</i> (in the <i>Administration Guide</i>).
Sample Type	Sample type to be tested in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on PK Lab settings created for the study.</p>
Vessel Type	Vessel type to use to contain the sample in this event.	<p>REQUIRED.</p> <p>Items in the drop-down list are based on the <i>vessel types defined in the LabPas application</i> (in the <i>Administration Guide</i>).</p>

Event Properties Field	Description	Notes
Quantity	Number of vessels that are used to collect the sample type	REQUIRED. Must be a number from 1 to 9. Default: 1.
Collection Description	Additional text that is printed on labels.	The number of fields on the Tube Description dialog box is determined by the Quantity . Descriptions can be selected when labels are set up for the study. For more information, see <i>Study - Setup - Labels page</i> (on page 144).
Panels	Test panels included in this event. Click the ellipsis button (...). A list of panels appears. Select the checkboxes for the panels to include in the event, and click UPDATE .	REQUIRED. The test panels were created on the Study - Setup - Panels page.
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	

Field descriptions for Testing events for screening

Properties Field	Description	Notes
Event No.	Number of the event.	REQUIRED. Must be a number from 1 to 999. Duplicates are allowed..
Event	Event description.	REQUIRED.

Properties Field	Description	Notes
Visit	<p>Visit in which the event takes place.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p> <p>Select a value other than No Selection if either of the following conditions apply:</p> <ul style="list-style-type: none"> • The event type is Testing or Clinical Testing. • The event category is not set to the Check-In or Check-Out event. 	<p>Items on the drop-down list include No Selection and all <i>visits configured for the study</i> (on page 153).</p>
Required Event	<p>Event that must be completed before the current event is performed.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p>	<p>Items on the drop-down list include No Selection and all approved and unapproved events.</p> <p>Each option includes the event description and visit associated with the event.</p>
Exclude from Study Parts section	<p>Selected—Exclude the event from any groups that are assigned to the study part.</p>	<p>Checkboxes for all study parts in the study.</p>

Event Properties section - Testing events

Event Properties Field	Description	Notes
Event Category	Category for the event.	<p>REQUIRED.</p> <p>Items in the drop-down list depend on the event type you selected.</p> <p>If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events.</p> <p>Categories are based on the <i>event types created for the study</i> (on page 57).</p>

Event Properties Field	Description	Notes
Panels	<p>Test panels included in this event.</p> <p>Click the ellipsis button (...). A list of panels appears.</p> <p>Select the checkboxes for the panels to include in the event, and click UPDATE.</p>	<p>REQUIRED.</p> <p>The test panels were created on the Study - Setup - Panels page.</p>
Instructions	<p>Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.</p>	

Field descriptions for Other events for screening

Properties Field	Description	Notes
Event No.	Number of the event.	<p>REQUIRED.</p> <p>Must be a number from 1 to 999.</p> <p>Duplicates are allowed..</p>
Event	Event description.	REQUIRED.
Visit	<p>Visit in which the event takes place.</p> <p>Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.</p> <p>Select a value other than No Selection if either of the following conditions apply:</p> <ul style="list-style-type: none"> • The event type is Testing or Clinical Testing. • The event category is not set to the Check-In or Check-Out event. 	<p>Items on the drop-down list include No Selection and all <i>visits configured for the study</i> (on page 153).</p>

Properties Field	Description	Notes
Required Event	Event that must be completed before the current event is performed. Select No Selection if the event type is Other and the event category is set to either the Check-In or Check-Out event.	Items on the drop-down list include No Selection and all approved and unapproved events. Each option includes the event description and visit associated with the event.
Exclude from Study Parts section	Selected —Exclude the event from any groups that are assigned to the study part.	Checkboxes for all study parts in the study.

Event Properties section - Other events

Event Properties Field	Description	Notes
Event Category	Event category for the event.	REQUIRED. Items in the drop-down list depend on the event type you selected. If a Check-In event with a status of blank or Approved exists, you cannot create a new Check-In event. The same rule exists for Check-Out events. Categories are based on the <i>event types created for the study</i> (on page 57).
Instructions	Instructions for the event that appear on the clinical data entry page when this event is carried out on the clinic floor.	

4 Click **SAVE**.

Results depend on the status of the event before it was edited:

- If the event had a status of Approved:
 - A new event is created with a status of blank. The version number for the new event record is increased by 1.
 - For Clinical Testing events, a warning message appears. When the event is rescheduled, new event barcodes and barcode labels are required.
- If the event had a status of blank, the current event record is updated, and the version number remains the same.

Deleting an unapproved screening event

Prerequisite: You must have the Study Setup function permission to delete an event.

Deleting events with a status of blank removes the events.

You cannot delete an event if it has a status of Deleted or Revised.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Events** category.

The Study - Setup - Events page for screening events appears.

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

A confirmation dialog box appears.

- 3 Click **OK**.

The events you selected no longer appear.

Deleting an approved screening event

You must have Create/Change Study and Approve/Delete Events permissions.

You cannot delete an event that has a status of Deleted or Revised.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Events** category.

The Study - Setup - Events page for screening events appears.

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

An approval dialog box appears.

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

The status of the events is set to Deleted. The Deleted Date, Deleted By, and Delete Comment fields are updated.

Any events that have been generated for a screening appointment are highlighted on the SR Studies - Study - Events page.

Email templates

Tasks: Study - Setup – Email Templates page (Recruiting)

On the Study - Setup – Email Templates page, you configure email templates that are used in the volunteer lookup page.

You can create email templates for each study. Before the templates can be used, they must be approved and signed by a user with the Approve Study Data function permission.

Note: When creating templates read and consider the legal text embedded in the template creation and edit pages. You must ensure that no templates contain Personally Identifiable Information (PII) or Patient Health Information (PHI) in the template if applicable laws or regulation require the PII or PHI to be encrypted during transmission.

- *Adding an email template* (on page 363).
- *Editing an email template* (on page 363).
- *Batch approving email templates* (on page 364).
- *Deleting email templates* (on page 365).

Adding an email template

To create an email template:

- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Setup** tab > **Email Templates** category.
- 2 Click **NEW**.

The New Email Template page appears.

Note: The page contains the following warning text: Emails sent from LabPas as part of Volunteer Lookup are not encrypted. The creator of any email template must ensure that any emails sent do not include any Personally Identifiable Information (PII) or Patient Health Information (PHI) in the template if applicable laws or regulations require the PII or PHI to be encrypted during transmission.

- 3 Enter the Template Name, Subject and Email Text.
- 4 Click **SAVE**

Field descriptions for the New Email Template dialog box

Field	Description	Notes
Template Name	Template name.	REQUIRED. Must be unique in the study.
Subject	Template subject.	REQUIRED. Must be unique in the study.
Email Text	Template text.	REQUIRED.

Editing an email template

To edit an email template:

- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Setup** tab > **Email Templates** category.
- 2 Select an email template and click **Edit**.

The Edit Email Template page appears.

Note: The page contains the following warning text: Emails sent from LabPas as part of Volunteer Lookup are not encrypted. The creator of any email template must ensure that any emails sent do not include any Personally Identifiable Information (PII) or Patient Health Information (PHI) in the template if applicable laws or regulations require the PII or PHI to be encrypted during transmission.

- 3 Edit the Template Name, Subject, or Email Text.
- 4 Click **SAVE**

Field descriptions for the Edit Email Template dialog box

Field	Description	Notes
Template Name	Template name.	REQUIRED. Must be unique in the study.
Subject	Template subject.	REQUIRED. Must be unique in the study.
Email Text	Template text.	REQUIRED.

If the template status was Approved, editing and saving the template changes its status to Not Approved.

Batch approving email templates

Prerequisites:

- The study must be unlocked, or the BATCH APPROVE is unavailable.
 - You must have the Approve Study Data function permission.
- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Setup** tab > **Email Templates** category.
 - 2 Select one or more email templates and click **BATCH APPROVE**.

The Batch Approve Study Data dialog box appears. An error appears if all selected templates have an Approval Status set to Approved.

- 3 In the Approval area, type your User ID, password, and click **Apply**.

Field descriptions for the Batch Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

Deleting an email template

Prerequisite: You must have the Study Setup function permission .

- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Setup** tab > **Email Templates** category.
- 2 Select one or more email templates, and click **DELETE**.

The Delete Email Template dialog box appears.

- 3 In the Approval area, type your User ID, password, and click **APPLY**.
- 4 **Field descriptions for the Delete Email Template dialog box**

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.

Field	Description	Notes
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Labels in a recruiting study

Tasks: Study - Setup - Labels page (Recruiting)

On the Study - Setup - Labels page, you configure screening labels and clinical lab collection labels.

Note: All MODIFY buttons and the Date Format fields are disabled if the study is locked.

- *Configuring screening and collection labels* (on page 366).

Configuring screening and collection labels

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Labels** category.

The STUDY - Setup - Labels page for screening and clinical lab collection labels appears.

- 2 Make selections in the Label Configuration dialog box.
- 3 From the **Date Format** drop-down list, select the format for displaying dates on labels in the study.

(No Selection) uses the date format configured in Facility Settings.

- 4 To specify the label type and data to print on clinical lab sample collection labels:
 - a In the Collection Label area, click **MODIFY**.
The Modify Collection Label dialog box appears.
Each label can support two columns of five lines of text, with the vessel barcode of the sample printed as the barcode at the bottom of the label. You can add text to each line.
 - b From the **Label Type** drop-down list, select a label.
 - c Select an option from each drop-down list, and provide values in the text fields if necessary.
 - d Click **APPLY**.

- 5 To specify the label type and data to print on volunteer screening labels:

- a In the Screening Label area, click **MODIFY**.
The Modify Collection Label dialog box appears.

Label configuration can support two columns of five lines of data, with the VRN of the volunteer printed as the barcode at the bottom of the label. You can add text to each line.

- b From the **Label Type** drop-down list, select a label.
- c Select an option from each drop-down list, and provide values in the text fields if necessary.
- d Click **APPLY**.

Changes are written to the Recruiting Change Log with a source of Label Setup.

Screening visits and email addresses in a recruiting study

Tasks: Study - Setup - Other page (Recruiting)

On the Study - Setup - Other page, you configure email settings and screening visits for a study.

- *Adding a screening visit* (on page 367).
- *Removing a screening visit* (on page 367).
- *Setting study-specific email settings* (on page 368).
- *Testing study-specific email settings* (on page 368).

Adding a screening visit

You must have Create/Change Study permission.

- 1 From the main menu select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Other** category.

The Study - Setup - Other page for recruiting appears.

- 2 In the **Visits** section, click **ADD**.

The New Visit dialog box appears.

- 3 Fill in the fields.

Field descriptions for the New Visit dialog box for screening visits

Field	Description	Notes
Visit No.	Number of the visit.	REQUIRED. Must be unique in the study.
Code	Code used for data tracking purposes.	REQUIRED. Must be unique in the study.
Description	Description of the visit.	REQUIRED.

- 4 Click **APPLY**.

The new visit appears in the Visits section.

Removing a screening visit

You must have Create/Change Study permission.

You cannot remove a visit if it is associated with a screening session.

- 1 From the main menu select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Other** category.

The Study - Setup - Other page for recruiting appears.

- 2 In the **Visits** section, click the **X** for a visit.

A confirmation dialog box appears.

- 3 Click **OK**.
- 4 Click **SAVE**.

Setting study-specific email settings

Prerequisite: You must have Recruiting Setup permission.

The following characteristics apply to the email addresses you set on this page:

- These email addresses override the default mail settings specified when *email settings were set up for the LabPas Recruiting module* (in the *Administration Guide*).
- These email addresses are used when study-specific emails are sent from the *Volunteer Lookup page* (in the *Recruiting User Guide*).

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

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Other** category.

The Study - Setup - Other page appears.

- 2 In the Mail Settings area, provide the following information:

- **Sender**—Sender's email address.
- **Cc**—Email addresses to receive copies.
- **Bcc**—Email addresses to receive copies; other recipients do not see these email addresses.

Default values for all fields are the mail settings specified when email settings were set up for the LabPas Recruiting module.

- 3 Click **SAVE**.

Changes are written to the Recruiting Change Log.

Testing study-specific email settings

To send emails through the LabPas application, you must configure the email settings on the Configuration - Settings - Global page.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Setup** tab > **Other** category.

The Study - Setup - Other page appears.

- 2 Click **TEST**.

The Mail dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Mail dialog box

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

- 4 Click **SAVE**.

The test email is sent.

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

Restrictions for recruiting

Study - Restrictions page

On the Study - Restrictions page, you set the volunteer inclusion/exclusion criteria for the study so that you can qualify or disqualify volunteers for a trial based on demographics from the Volunteers - Personal - Demographics page and answers to screening question taken in the Incoming Calls page.

You must approve restrictions before they are applied to a study.

To restrict data that appears on the page, use the FILTER button.

The LabPas Recruiting module does not provide restrictions; you must create them.

Tasks: Study - Restrictions page

- *Adding a restriction* (on page 374).
- *Approving a restriction* (on page 375).
- *Deleting a restriction* (on page 376).

Data collection options descriptions

The following options are available for collecting data.

For information about the types of data that can be collected with each option, see *Data collection options for specific criteria types* (on page 371).

Option	Description and usage
User-created list	<p>Appears as the ellipsis button (...) below the criteria drop-down list.</p> <p>When you click the ellipsis button, a dialog box appears, containing the entire user-created list values for the criterion. When you select a row in the dialog box, the dialog box closes, and the selected row appears in the text area.</p> <p>A row with a label and read-only text area appears below the list. The label is set to the same value as the selected criterion, and the text area starts as empty.</p>
Code list	<p>Appears as a label and selection list below the criteria selection list and any user-created list.</p> <p>The label is either of the following:</p> <ul style="list-style-type: none"> • The value of the criterion if there is no user list for the criterion • The value When. <p>The selection list contains values based on the selected criterion.</p>
Secondary list	<p>Appears as a label and a selection list below the criteria selection list and a user-created list or a code list is present.</p> <p>The label is set and the list contains values based on the selected criterion.</p>

Option	Description and usage
Free entry field	Appears as a label and an entry field, below the selection criteria list and any lists. The label is the value specified in the criteria options. By default, the entry field is blank.
Range option	Appears as a label and two sets of entry fields. For more information, see <i>Range and Date options and qualifiers</i> (on page 373).

Data collection options for specific criteria types

The following options are available for collecting data for criteria.

Criteria	Option for collecting data	Notes
Age	Range	
Additional demographics	User-created list	Additional Demographic [AD] fields where type is not Display.
	Secondary list	If AD type is Checkbox— (Checked, Unchecked) If AD type is Radio or Selection— (List values for that AD) Labels— Set to the value selected in the user-created list.
	Free entry field	If AD type is Entry— Label set to AD name.
Availability	Immutable code list	(Anytime, Week Days Only, Weekends Only)
BMI	Range	n/a
CrCl	Range	n/a
Washout - Dose (Days)	Range	n/a
Washout - Exit (Days)	Range	
Frame	Immutable code list	(Small, Medium, Large)
Gender	Immutable code list	(Male, Female)
GFR	Range	n/a

Criteria	Option for collecting data	Notes
Height	Range	<p>If Height settings are Ft and In</p> <ul style="list-style-type: none"> 1st label (Feet), 2nd Entry enabled, 2nd label: (In) <p>If Height settings are Meters</p> <ul style="list-style-type: none"> 1st label: (Meters) <p>For more information, see <i>Adding and editing a facility</i> (in the <i>Administration Guide</i>).</p>
Ideal body weight	Range	n/a
Location preference	User-created list	(Facilities)
Medical question	User-created list	(Approved Medical Questions)
	Immutable code list	(Yes, No)
Medical condition	User-created list	(Approved Medical Conditions)
Medication	User-created list	(Medications)
Washout - OTC Meds (Days)	Range	n/a
Washout - Prescription Meds (Days)	Range	n/a
Scheduled for Study	Immutable code list	(Yes, No)
Study type exclusions	User-created list	(Study Types)
Surgical procedure	User-created list	(Approved Surgeries)
Washout - Tobacco (Days)	Immutable code list	(Any, Not Specified, Cigarettes, Smokeless Tobacco, other Tobacco)
	Range	For more information, see <i>Range and date options and qualifiers</i> (on page 373).
Tobacco history	Immutable code list	(Never, Quit, Ongoing)
	Secondary list	(Any, Not Specified, Cigarettes, Smokeless Tobacco, Other Tobacco)
Tobacco usage (Daily)	Immutable code list	(Any, Not Specified, Cigarettes, Smokeless Tobacco, Other Tobacco)
	Range	For more information, see <i>Range and date options and qualifiers</i> (on page 373).

Criteria	Option for collecting data	Notes
VRN	Free entry fields	Label set to VRN
Status	Immutable code list	(Active, In-Active, No Contact, Probation, Warning)
Weight	Range	<p>If Weight settings are Lbs—1st label (lbs)</p> <p>If weight settings are Kgs—1st label (kgs)</p> <p>For more information, see <i>Adding and editing a facility</i> (in the <i>Administration Guide</i>).</p>

Range and Date options and qualifiers

Range Option field	Description	Notes
Range options	<p>Appears on the form as a label and two sets of entry fields.</p> <p>Label and fields are located in a row below the criteria selection list and the rows for other options.</p> <p>Label is set to Value.</p>	
Value qualifier drop-down list	<p>Qualifier for the value.</p> <p>>= (Minimum) Greater than or equal to the value specified in the Value field for minimum value</p> <p>> (Minimum) Greater than the value specified in the Value field for minimum value</p> <p>= (Minimum) Equal to the value specified in the Value field for minimum value.</p> <p><= (Maximum) Less than or equal to the value specified in the Value field for maximum value.</p> <p>< (Maximum) Less than the value specified in the Value field for maximum value.</p> <p>= (Maximum) Equal to the value specified in the Value field for maximum value.</p>	

Range Option field	Description	Notes
First value field for entry	Value, with qualifier applied, that is acceptable in the entry field when data is collected.	Required. Two entry fields are available, for example, for Feet and Inches
First value field label	Label that appears to the right of the first value field.	
Second value field for entry	Value, with qualifier applied, that is acceptable in the entry field when data is collected.	
Second value field label	Label that appears to the right of the second value field.	

Date Option Field	Description	Notes
Start Date option	Appears as entry field and calendar selection button.	Date format is controlled by the facility setting (in the <i>Administration Guide</i>). Entry that does not match the setting returns an error.
End Date option	Entry field and calendar selection button	Date format is controlled by the facility setting (in the <i>Administration Guide</i>). Entry that does not match the setting returns an error.
Ongoing option	Appears as a label and checkbox in the same row as the date option, to their right if present. Label is set to Ongoing. Checkbox is unchecked by default.	

Adding a restriction

- From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Restrictions** tab.
The Study - Restrictions page appears.
- Click **NEW**.
The New Study Restriction dialog box appears.
- Fill in the fields.

Note: Options that appear are determined by your selection in the Criteria field.

Field descriptions for the New Study Restrictions dialog box

Field	Description	Notes
Qualifier	Whether a restriction pertains only to one gender.	Default: None.
Type	<ul style="list-style-type: none"> • Inclusion—Include volunteers whose data matches the restriction criteria. • Exclusion—Disqualify volunteers whose data matches the restriction criteria. 	
Criteria	<p>Preconfigured restriction criteria.</p> <p>Your selection determines the type of data that is collected in the value fields and the options available for collecting that type of data.</p>	<p>Default is Gender.</p> <p>If you select Male or Female in the Qualifier field, the Gender option is not available in the Criteria field, and the default selection is Age.</p>
Gender	Restrict the study to include or exclude the volunteer based on gender.	
Exclude from study parts	The inclusion/exclusion criteria is excluded from a study part.	

For more information, see:

- *Data collection option descriptions* (on page 370).
- *Data collection options available for specific criteria types* (on page 371).
- *Range and Date options and qualifiers* (on page 373).

- 4 Click **SAVE**.
- 5 You must approve restrictions before they can be applied to a study.

Approving a restriction

Prerequisite: You must have the Study Setup function permission to approve a restriction.

All restrictions on the Study - Restrictions page are approved at one time.

If you add new restrictions after the initial approval, you must repeat the approval process to apply the new restrictions to the study.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Restrictions** tab.

The Study - Restrictions page appears.

- 2 Click **APPROVAL**.

The Approve Restriction dialog box appears.

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

Deleting a restriction

Prerequisite: You must have the Study Setup function permission to delete a restriction.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Restrictions** tab.

The Study - Restrictions page appears.

- 2 Select a checkbox for a restriction, and click **DELETE**.

The Delete Restriction dialog box appears.

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

One of the following results occurs:

- If a restriction was previously approved, it remains in the list, but it is disabled and shows a status of Deleted.
- If the restriction has not yet been approved, it is removed.

Questionnaire

Study - Questionnaire page

On the Study - Questionnaire page, you create study-specific questions that are used when screening volunteers for studies.

Questions you create appear on the following pages in the LabPas Recruiting module:

- The Volunteers - Study History page.
- If **Phone Screening** is Yes, questions appear during phone screening when the study is selected from the Incoming Calls - Study Questions page.

The LabPas Recruiting module does not provide study-specific questions; you must create them on this page.

To restrict data that appears on the page, use the filter. If a value other than All is selected in the filter or Question Selection Criteria dialog box, the table is restricted to questions that are not excluded from the selected study part.

You can also import master questions that were created on the ***STUDY - Setup - Master Questions page*** (in the *Administration Guide*) when the LabPas Recruiting module was set up.

Tasks: Study - Questionnaire page

- *Adding a question* (on page 377).
- *Approving a question.* (on page 379)
- *Editing a question* (on page 380).
- *Deleting a question.* (on page 382)
- *Importing a master question* (on page 382).

Adding a question

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Questionnaire** tab.
The Study - Questionnaire page appears.
- 2 Click **NEW**.
The New Question dialog box appears.
- 3 Fill in the fields.

Field descriptions for the New Question dialog box

Field	Description	Notes
Question Id	Identifies the question.	<p>REQUIRED.</p> <p>Must be unique.</p> <p>Value can be alphanumeric.</p> <p>If a question with this ID has a status of Deleted, you can use the same ID for the new question, which is created and its version number is incremented by 1.</p>
Number	Number that is assigned to each question to determines the order in which the question appears during phone screening.	<p>REQUIRED.</p> <p>Must be unique.</p> <p>All questions in this page and the Settings - Study - Master Questions page appear in order of their assigned Number.</p> <p>It is recommended that you assign non-consecutive numbers, such as 10, 20, 30, so that if you subsequently add more questions, each new question can be assigned a number (for example, 15) that allows the new question to appear between the original numbers.</p> <p>If a question with this Number has a status of Deleted, you can use the number again for a new question, which is created and its version number is incremented by 1.</p>
Qualifier	Gender to whom the question applies.	Default: None.
Question	Question that is read to the caller or volunteer.	REQUIRED.
Question Type:	<p>Phone Screening (default)—The question appears during phone screening for this study, on the Incoming Calls - Study Questions page, and on the Volunteers - Study History page.</p> <p>Eligibility Review—The question appears during eligibility review.</p>	

Field	Description	Notes
Required	Selected —The question must be asked before a volunteer can qualify for the specific study.	Read-only and not selected if Question Type is set to Eligibility Review.
Disqualify When	<p>Yes or No—If the volunteer's answer to the question matches the value you select, the volunteer does not qualify for the study.</p> <p>NA—The volunteer's answer has no effect on whether the volunteer qualifies for the study.</p>	<p>If Question Type is set to Phone Screening, you must provide a value other than blank.</p> <p>Read-only and blank if Question Type is set to Eligibility Review.</p>
Exclude From Study Parts	<p>For each study part listed:</p> <p>Selected—The question is excluded from any group assigned to the study part.</p>	

4 Click **SAVE**

The new question is created and assigned a version number of 1. The question is initially unapproved.

5 You must approve the question for it to be used on other pages.

Approving a question

Prerequisite: You must have the Study Setup function permission to approve a question.

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

All questions on the Study - Questionnaire page are approved at one time.

1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Questionnaire** tab.

The Study - Questionnaire page appears.

2 Click **APPROVAL**.

The Approval dialog box appears.

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

- Previously unapproved questions have their status set to Approved. If any volunteers associated with the study have their Eligibility Review set to Completed, it will be changed to Pending.
- Earlier approved versions of edited questions have their status changed to Revised.

If questions with Question Type set to Eligibility Review were previously unapproved, all volunteers associated with the study and study part associated with the questions that have:

- The Eligibility Review set to Completed will be set to Pending and an entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The comment for the audit record states that approved data has changed.
- The Monitor Review Status set to Reviewed are set to Not Reviewed and an entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that reviewed data has changed.

Editing a question

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

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

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Questionnaire** tab.

The Study - Questionnaire page appears.

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

The Edit Question dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Edit Question dialog box

Field	Description	Notes
Question Id	Identifies the question.	<p>REQUIRED.</p> <p>Must be unique.</p> <p>Value can be alphanumeric.</p> <p>If a question with this ID has a status of Deleted, you can use the same ID for the new question, which is created and its version number is incremented by 1.</p>

Field	Description	Notes
Number	Number that is assigned to each question to determines the order in which the question appears during phone screening.	<p>REQUIRED.</p> <p>Must be unique.</p> <p>All questions in this page and the Settings - Study - Master Questions page appear in order of their assigned Number.</p> <p>It is recommended that you assign non-consecutive numbers, such as 10, 20, 30, so that if you subsequently add more questions, each new question can be assigned a number (for example, 15) that allows the new question to appear between the original numbers.</p> <p>If a question with this Number has a status of Deleted, you can use the number again for a new question, which is created and its version number is incremented by 1.</p>
Qualifier	Gender to whom the question applies.	Default: None.
Question	Question that is read to the caller or volunteer.	REQUIRED.
Question Type:	<p>Phone Screening (default)—The question appears during phone screening for this study, on the Incoming Calls - Study Questions page, and on the Volunteers - Study History page.</p> <p>Eligibility Review—The question appears during eligibility review.</p>	
Required	Selected —The question must be asked before a volunteer can qualify for the specific study.	Read-only and not selected if Question Type is set to Eligibility Review.
Disqualify When	<p>Yes or No—If the volunteer's answer to the question matches the value you select, the volunteer does not qualify for the study.</p> <p>NA—The volunteer's answer has no effect on whether the volunteer qualifies for the study.</p>	<p>If Question Type is set to Phone Screening, you must provide a value other than blank.</p> <p>Read-only and blank if Question Type is set to Eligibility Review.</p>

Field	Description	Notes
Exclude From Study Parts	For each study part listed: Selected —The question is excluded from any group assigned to the study part.	

- 4 Click **SAVE**.
You must approve the question for it to be available on other pages in the LabPas application.
- 5 Click **APPROVAL**.
- 6 Type your User ID, password, and an optional comment, and click **APPLY**.

Deleting a question

Prerequisite: You must have the Study Setup function permission to delete a question.

After a question is deleted, it is no longer generated during screening calls on the Incoming Calls - Study Questions page.

If the deleted question has already been answered by a volunteer, the question continues to appear on the Volunteers - Study History page and reported for those volunteers.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Questionnaire** tab.
The Study - Questionnaire page appears.
- 2 Select a question, and click **DELETE**.
The Deletion dialog box appears.
- 3 Type your User ID, password, and an optional comment, and click **APPLY**.
One of the following results occurs:
 - If a question is deleted after it has been approved, the question remains in the list, but it is disabled and shows a status of Deleted.
 - If the question has not yet been approved, it is removed.

Importing a master question

If a Question Id or Number is already in use on the Study - Questionnaire page, the question's selection box is read-only, and you cannot import the question.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Questionnaire** tab.

The Study - Questionnaire page appears.

- 2 Click **IMPORT**.

The Master Questions Import dialog box appears, listing approved questions from the *Settings - Study - Master Questions page* (in the *Administration Guide*).

- 3 Select a question, and click **DONE**.

The master question appears on the Study - Questionnaire page.

- 4 You must approve the question for it to be available on other pages in the LabPas application.

Volunteers

Study - Volunteers page

On the Study - Volunteers page, you view all volunteers who have qualified for the study through the phone screening process.

You can add existing volunteers to a study, edit volunteer study status information and screening test results, review a volunteer's eligibility for inclusion in a study, and set a notification call to the volunteer.

To restrict data that appears on the page, use the filter.

Only existing volunteers can be added to studies from this page. To add new volunteers to the LabPas Recruiting module, use the *Volunteers page* (in the *Recruiting User Guide*).

Tasks: Study - Volunteers - Volunteers page

- *Notifying a volunteer.* (on page 384)
- *Cancelling notification of a volunteer* (on page 385).
- *Reviewing eligibility of a volunteer.* (on page 385)
- *Adding a volunteer to a study.* (on page 393)
- *Editing a volunteer's screening results* (on page 394).
- *Importing volunteers* (on page 396).

Notifying a volunteer

Prerequisite: You must have the Recruiting Volunteer Administration permission.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Volunteers** tab.

The Study - Volunteers page appears.

- 2 Select one or more volunteers, and click **NOTIFY**.

The Notify Volunteers dialog box appears for the first volunteer you selected. The Message field contains:

- Blank if there is no unresolved Notification call for the volunteer.
 - The message associated with any unresolved Notification call for the volunteer.
- 3 Provide a new message, or edit the existing message if desired. The field cannot be blank.
 - 4 Enter a comment in the Comment field of the Change Comment section.
 - 5 Click **SAVE**.
 - If the volunteer has no existing unresolved Notification calls, an outgoing Notification call is scheduled.
 - If an unresolved outgoing Notification call is already scheduled for the volunteer, the

message is overwritten with the new message. On the Volunteers page, the Notified field is set to No and the Notification field is set to blank.

- If you changed the message field, an entry is created in the Recruiting Change Log with a source of Study Volunteers.

Canceling notification of a volunteer

Prerequisite: You must have the Recruiting Volunteer Administration permission.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Volunteers** tab.

The Study - Volunteers page appears.

- 2 Select a volunteer, and click **NOTIFY**.

The Notify Volunteers dialog box appears.

- 3 In the Notification Call area, select **Delete Notification Call**.
- 4 In the Approval area, provide your user ID, password, and an optional comment.
- 5 Click **SAVE**.

- The unresolved outgoing Notification call that is scheduled for the volunteer is deleted.
- On the Volunteers page, the Notified and Notification Data fields for the volunteer are set to blank.
- An entry is created in the Recruiting Change Log with a source of Study Volunteers.

Reviewing eligibility of volunteers

If a volunteer status is Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending, you cannot change the status to Unscheduled, Scheduled, Pending Volunteer, or Consent Refused.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Volunteers** tab.

The Study - Volunteers page appears.

- 2 Select one or more volunteers, and click **REVIEW**.

The Eligibility Review dialog box appears.

- 3 Fill in the fields.

Field descriptions for the Eligibility Review dialog box

Field	Description	Notes
Volunteer section		
VRN	Volunteer recruiting number.	If this field contains a value, and you update one of the following fields, the Status changes to Pending: Gender, Birth Date, Rate, Height, Weight
Name	Name of the volunteer.	If you do not have View Volunteer Ids permission, the name appears as **.
Screening No	Screening number of the volunteer.	Must be unique within the study. Can be blank only if Status is Unscheduled, Scheduled, or Consent Refused.
Initials	Initials of the volunteer.	REQUIRED. Must be unique within the study.

Field	Description	Notes
Status	<p>Current eligibility review status of the volunteer.</p> <p>Options: Accepted, Approved, Completed, Consent Refuse, Consent Withdrawn, Dropped, Pending Candidate, Pending Volunteer, Scheduled, Screen Fail, Unscheduled.</p>	<p>Field includes options for CRO Dropped, DNQ, Pending, Promoted, Revised, or Vol Dropped only if the status is set to one of those options.</p> <p>Only the option that is associated with the current status appears.</p> <p>If the status is set to any of the following:</p> <ul style="list-style-type: none"> Accepted, Approved, or Completed Approve Clinical Data permission is required. You must select the Completed checkbox before you save. <p>If the current status is any of the following:</p> <ul style="list-style-type: none"> Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending Candidate You cannot change the status to Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. <p>If status is changed from any of the following:</p> <ul style="list-style-type: none"> Unscheduled, Scheduled, Pending Volunteer, or Consent Refused <p>To: Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending Candidate</p> <p>The following fields are copied to the CT study when you save:</p> <ul style="list-style-type: none"> Current Volunteer Demographics, Tobacco History, Additional Demographics, Medical History, Other History, Surgical History, Medications.
Alternate	<p>Selected—Volunteer is an alternate.</p>	
Reason	<p>Reason for the Status of the volunteer.</p>	<p>Required or optional, depending on how the study was configured.</p> <p>Choices include No Selection and all reasons selected when general settings were set up for the LabPas Recruiting module (in the <i>Administration Guide</i>).</p>

Field	Description	Notes
Group	Study group.	Either all groups, or groups associated with the current facility, depending on whether Global Recruiting was selected when <i>global settings were specified</i> (in the <i>Administration Guide</i>).
Exit	Exit date.	Read-only if the Status is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. Default for other Status values: The date configured for the group associated with the volunteer.
Last Dose	Date of last dose.	Read-only if the Status is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. Default for other Status values: The date configured for the group associated with the volunteer.
Informed Consent	Date that informed consent was signed. You cannot specify a date in the future.	Can be blank only if the Status is Unscheduled, Scheduled, or Consent Refused. If this field is filled in, you cannot change the Status field from Pending Volunteer to either Scheduled or Unscheduled.
Eligibility Review		
Completed	Selected —The eligibility review is complete.	If selected, all of the following must be true before you save. <ul style="list-style-type: none"> • All percentage fields in the Eligibility Review area must be at 100 percent. • All eligibility review questions must be answered. • The answer to one or more questions in the Eligibility Review area must match the Disqualify When setting. • The status cannot be Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. The field is disabled for users that do not have the Approve Study Participants function permission.
% Screening - Completed	Percentage of events that do not have an approval status of Not Started or In Progress.	Percent rows appear in red if not 100 percent approved.

Field	Description	Notes
% Screening Data Approved	Percentage of events with an approval status of Approved.	
% Screening Labs Approved	Percentage of labs with an approval status of Approved.	

Eligibility Review Questions

	<p>For each question, select Yes, No, or NA.</p> <p>You must answer all the questions.</p>	<p>Questions from the Questionnaire page that meet all of the following conditions:</p> <ul style="list-style-type: none"> • The status is Approved. • The Question Type is Eligibility Review. • The Qualifier is None or matches the gender of the volunteer being reviewed • The Question is not excluded from the study part associated with the group to which the volunteer is assigned. <p>You must provide a comment for a question that is required if the answer matches the Disqualify When setting.</p>
--	-----------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Eligibility Review Data

History tab	<p>Audit trail of all eligibility review changes for the volunteer being reviewed.</p> <p>Read-only fields: Source, User ID, Date/Time, Comment, Change.</p>	
Demographics tab	<p>Read-only fields: Gender, Birth Date, Age, Frame, Race, Race Category, Ethnicity, Ethnicity Category, Height (Ft), Height (In), Height (M), Weight (Lbs), Weight (Kgs), BMI, %IBW, Serum Creatinine, CrCl, Last Study.</p>	<p>The Demographics tab displays data from:</p> <ul style="list-style-type: none"> • The Volunteer record when the Status field is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. • The CT Study when the Status field is Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending Candidate. This information matches the information that appears on the Clinical Trials > CT Studies > Participants – Candidates > Edit Candidate page.

Field	Description	Notes
Tobacco tab	Tobacco usage history. Read-only fields: Quantity, Type, Frequency, Start Date, End Date, Ongoing, Comment.	The Tobacco tab displays data from: <ul style="list-style-type: none"> • The Volunteer record when the Status field is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. • The CT Study when the Status field is Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending Candidate. This information matches the information that appears on the CT Studies > Participants – Candidates > Edit Candidate page. <p>If the Month and Day values are left blank, xx or xxx appear instead.</p>
Addl. Demog. (Additional Demographics) tab	Read-only fields: Field, Value.	The Addl. Demog. tab displays data from: <ul style="list-style-type: none"> • The Volunteer record when the Status field is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. • The CT Study when the Status field is Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending Candidate. This information matches the information that appears on the CT Studies > Participants – Candidates > Edit Candidate page.
Medical tab	Medical history. Read-only fields: Health area, Condition, Start Date, End Date, Ongoing, Comment.	The Medical tab displays data from: <ul style="list-style-type: none"> • The Volunteer record when the Status field is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. • The CT Study when the Status field is Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending Candidate. This information matches the information that appears on the CT Studies > Participants – Candidates > Edit Candidate page. <p>If the Month and Day values are left blank, xx or xxx appear instead.</p>

Field	Description	Notes
Other tab	Read-only fields: Question, Date, Comment.	<p>The Other tab displays data from:</p> <ul style="list-style-type: none"> • The Volunteer record when the Status field is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. • The CT Study when the Status field is Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending Candidate. This information matches the information that appears on the CT Studies > Participants – Candidates > Edit Candidate page. <p>If the Month and Day values are left blank, xx or xxx appear instead.</p>
Surgical tab	<p>Surgical procedures history.</p> <p>Read-only fields: Procedure, Date, Comment.</p>	<p>The Surgical tab displays data from:</p> <ul style="list-style-type: none"> • The Volunteer record when the Status field is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. • The CT Study when the Status field is Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending Candidate. This information matches the information that appears on the CT Studies > Participants – Candidates > Edit Candidate page. <p>If the Month and Day values are left blank, xx or xxx appear instead.</p>
Medications tab	<p>Medication usage history.</p> <p>Read-only fields: Medication, Condition, Dose, Units, Frequency, Method, Start Date, End Date, Ongoing, Comment.</p>	<p>The Medications tab displays data from:</p> <ul style="list-style-type: none"> • The Volunteer record when the Status field is Unscheduled, Scheduled, Pending Volunteer, or Consent Refused. • The CT Study when the Status field is Accepted, Screen Fail, Consent Withdrawn, Approved, Completed, Dropped, or Pending Candidate. This information matches the information that appears on the CT Studies > Participants – Candidates > Edit Candidate page. <p>If the Month and Day values are left blank, xx or xxx appear instead.</p>

Field	Description	Notes
Screening Data tab	Read-only fields: Event, Event Type, Category, Actual Sample Date, Event Status, Approval Status, Monitor Review Status, Completed, Signed, Copy Given To Volunteer, Comment, Repeat Event.	The Screening Data tab displays one row for each screening event that the volunteer is associated with in the current study. Events with an event status of Not Started, In Progress, Completed, or Repeat appear. . Events are sorted in descending order by Actual Sample Date.
Screening Tests tab	Read-only fields: Event, Event Type, Category, Panel, Test, Result, Ref. Range, Date/Time, Alert, Comment, Repeat.	

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

4 Click **SAVE**.

Changes are written to the Recruiting Change Log with a source of Eligibility Review.

An error appears when you click **SAVE** if all of the following are true:

- The Status is set to Accepted, Approved, or Completed.
- Multiple participants with the same VRN are participating in the study.
- The status of another participant with the same VRN is Accepted, Approved, or Completed.

When you click SAVE, the Approve Eligibility Review dialog box appears if:

- The Status field is set to Approved.
- The Completed field is checked.
- You have the Approve Study Participants function permission.

When you click SAVE:

- If the Completed field is checked and the user is not granted the Approve Study Participants function permission, the Completed option is deselected. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The comment for the audit record states that approved data has changed.
- If the Completed field is checked, and if the Status field is changed from Approved to any other status, the Completed option is deselected. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The comment for the audit record states that approved data has changed.
- If the edits are successfully saved to the eligibility review form for a candidate with a Monitor Review Status set to Reviewed, the Monitor Review Status is changed to Not Reviewed. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that reviewed data has changed.

Adding a volunteer to a study

You can add existing volunteers to a study. A volunteer must have a status of Active to be added to a study. To add a new volunteer to the LabPas Recruiting module, use the *Volunteers page* (in the *Recruiting User Guide*).

You must add volunteers to a study before you can schedule them for an appointment on the Appointments page.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Volunteers** tab.

The Study - Volunteers page appears.

- 2 The Study - Volunteers page appears. All volunteers that are already participating in the study are listed.

- 3 Click **NEW**.

The Select Volunteer dialog box appears, listing all volunteers who have not been assigned to a study.

- 4 In the **Select Group** box, select a group from the **Group** field.
- 5 Optionally, to restrict the list of volunteers, type the names in the **First Name** and **Last Name** fields, and click **FILTER**.
- 6 In the list, select a volunteer.

The volunteer is added to the study.

If the selected volunteer is participating in the study, a warning message appears. If you choose to continue, the volunteer is added to the study as a new participant.

Editing a volunteer's screening results

You cannot edit volunteer screening results if the status of the volunteer in the LabPas CT module is Accepted, Approved, or Dropped.

Prerequisites:

- You must have the Recruiting Volunteer Administration permission.
 - The study must be active.
 - Panels must be *configured for the study* (on page 337).
 - The volunteer whose results you want to edit must have an Informed Consent date.
- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Volunteers** tab.

The Study - Volunteers page appears.

- 2 Select one or more volunteers, and click **RESULTS**.

The Edit Results dialog box appears for the first volunteer you selected.

- 3 Fill in the fields.

Field descriptions for the Edit Results dialog box

Field	Description	Notes
Volunteer	Volunteer's name.	READ-ONLY.
Panel	<p>Panels that exist for the volunteer in this study.</p> <p>In the drop-down list, select the panel you want to edit.</p>	The panel name appears in red if the panel includes tests with existing alerts.
Results table	<p>Results for the tests in the Panel you select.</p> <p>Each test in the panel appears on a separate line.</p>	
Test	Name of the test.	READ-ONLY.

Results for each test in the panel

Field	Description	Notes
Test	Name of the test.	READ-ONLY.
Result	Test results. Fields that appear depend on the type of test.	<p>If you enter data that violates Out of Range limits for the test, an error message appears.</p> <p>Out of Range limits are defined for tests on the following pages:</p> <ul style="list-style-type: none"> • Test page in the LabPas CT module. • Study - Setup - Panels page of the LabPas Recruiting module.
Performed By	Name of the person who performed the test.	If you enter a value in this field for one test, the corresponding field for the next test is populated by the same value when you click within the field.
Date	<p>Date and time of the test.</p> <p>Type the date or click the calendar icon and select the date.</p> <p>Type the time.</p>	<p>If you enter values in this field for one test, the corresponding field for the next test is populated by the same values when you click in the field.</p> <p>Date cannot be in the future.</p>
Alert	Alert information.	<p>READ-ONLY.</p> <p>If an alert is issued, this field is populated after the results have been saved.</p>
Comment	Custom text.	<p>Required if either of the following apply:</p> <ul style="list-style-type: none"> • The result is outside of the reference range. • You do not enter a result.

- 4 In the Approval area, type your user ID, password, and a comment, and click **UPDATE**.

Changes are written to the Recruiting Change Log for the study.

If reference ranges are defined for the test, and are violated, alerts are issued and saved as alerts against the related results records.

If any entries violate edit checks, the following actions occur:

- **Warn** or **Warn and Alert** action—A warning message appears.
- **Alert** or **Warn and Alert** action—The test in violation is flagged with an alert on the Study - Labs page.
- **Prevent** action—A warning message appears, and you cannot save until you correct the results that violated the edit check.

Importing volunteers

Importing a volunteer reassigns the volunteer to the current study and copies any data associated with test panels and study questions that are assigned to both studies.

Note: If any panels, tests, or study questions exist in the study in which the volunteer is currently assigned, but not in the selected study, data will be lost when the volunteer is imported to the selected study. If this condition exists, a warning appears so that you can cancel the import.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Volunteers** tab.
The Study - Volunteers page appears.
- 2 Click **IMPORT**.
The Select Volunteer dialog box appears, listing all existing volunteers with a study status of Completed or Pending, and the name of the study to which they are currently assigned.
- 3 Select one or more volunteers, and click **APPLY**.
The volunteers are imported to the study.

General practitioner information

Tasks: Study - GP page

On the Study - GP page, you view general practitioner (GP) information for all volunteers who have been added to the study, either through the Incoming Call or Study - Volunteers page. The GP information includes the volunteer's VRN (volunteer record number), name, and social security number, as well as the date that the GP Letter was sent.

- *Editing a volunteer's GP letter information* (on page 397).
- *Printing GP address labels for all volunteers* (on page 397).
- *Exporting GP information* (on page 397).

Editing a volunteer's GP letter information

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Volunteers** tab > **GP** category.
The Study - Volunteers - GP page appears.
- 2 Select one or more volunteers, and click **EDIT**.
The GP Edit dialog box appears.
If you select multiple volunteers, the GP Edit dialog box appears for each record, one at a time.
- 3 In the **GP Letter** field, provide the date that the GP letter was received. Type the date or click the calendar icon and select the date.
The date cannot be prior to the volunteer's birth date, or a date in the future.
- 4 Click **SAVE**.

Printing GP address label for all volunteers

Labels are formatted according to the Mailing 1x2 label defined in the Configuration - Label Configuration page of the LabPas CT module.

Each label includes the name and address of the volunteer's general practitioner, and the volunteer's VRN number that corresponds with their GP.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Volunteers** tab > **GP** category.
The Study - Volunteers - GP page appears.
- 2 Click **LABELS**.
The Print dialog box appears.
- 3 Select the printer options, and click **OK**.

Exporting GP information

Data included in the CSV export file is the information that is collected on the Volunteers - Clinical History - Physician page, and includes the title, name, address, telephone, cell phone, additional phone and email address for each volunteer's GP. Each line also includes the volunteer's VRN that corresponds with their GP's data.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Volunteers** tab > **GP** category.

The Study - Volunteers - GP page appears.

- 2 Click **EXPORT**.

The Study GP Export message appears, followed by the File Download dialog box.

- 3 Click **SAVE**.

The Save As dialog box appears.

- 4 In the **File name** field, type a file name and change the file extension to **.csv**.

- 5 Click **SAVE**.

Scheduled events for screening

Tasks: Study - Events - Events page (Recruiting)

On the Study - Events - Events page, you schedule events for screening. Data on the page is restricted to events associated with the current facility.

To restrict the data that appears, use the filter.

- *Scheduling screening events* (on page 399).
- *Changing the status of a screening event to Not Started or Cancelled* (on page 400).
- *Printing labels for screening events* (on page 401).
- *Viewing a screening event* (on page 402).
- *Approving a screening event* (on page 403).
- *Unapproving a screening event* (on page 404).
- *Batch approving screening events* (on page 405).
- *Editing the results of a screening event* (on page 406).

Scheduling a screening event

Prerequisite: You must have the Create/Modify Events permission.

Events on the Study - Events - Events page are screening events in the study that have been associated with volunteers and visits.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Events** tab > **Events** category.

The Study - Events - Events page appears.

The page lists events for one group at a time.

- 2 If necessary, use the filter to view events in a different group.
- 3 Click **SCHEDULE**.

The Schedule Events dialog box appears.

- 4 Fill in the fields.

Field descriptions for the Schedule Events dialog box

Field	Description	Notes
Group	Group that was selected with the filter. Only events for the selected group can be scheduled.	READ-ONLY. Note: To schedule events for a different group, click CANCEL and use the filter to choose another group.

Field	Description	Notes
Remove Deleted Events	Selected —All existing events with an Approval status of Deleted and an Event Status of Not Started are deleted.	Enabled only when an event exists in the schedule with an approval status of Deleted.
Remove Excluded Events	Selected —Events that meet all of the following conditions are deleted: <ul style="list-style-type: none"> • Approval status is Revised. • Event status is Not Started. • A new version of the event exists with an approval status of Approved and is configured to exclude the study part that is associated with the current group. 	Enabled only when excluded events exist in the schedule.

- 5 In the Approval area, type your User ID, password, and a Comment, and click **Apply**.

Screening events are scheduled for all volunteers associated with the current group. An event is scheduled for each approved event.

Existing events with an event status of Not Started and an approval status of Revised are updated.

When a new schedule event is created, any volunteers associated with the events whose Eligibility Review is currently Completed is changed to Pending. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The comment for the audit record states that approved data was changed.

Changing the status of a screening event to Not Started or Cancelled

Prerequisite: You must have the Create/Modify Events permission.

If you select multiple events, the status of all the selected events is changed.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Events** tab > **Events** category.

The Study - Events - Events page appears.

- 2 Select one or more events, and click **STATUS**.

The Event Status dialog box appears.

- 3 Select a status to apply to the events. There is no default. Options are:

- Not Started
- Cancelled

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

Changes in status are written to the Recruiting Change Log.

Results depend on the status you selected.

Status changed to	Results
Not Started	<ul style="list-style-type: none"> • The event status of each selected event is changed to Not Started. • For Clinical Testing events: <ul style="list-style-type: none"> ▪ A new vessel barcode is generated, and the label audit history is no longer available for the original vessel barcode. ▪ Any test result data associated with the original vessel barcode is reset to blank. • For Testing events, any test result data associated with the event is reset to blank. • For Other events, data associated with the event is reset to blank. • The Collection Printed and Actual Sample Date columns are set to blank.
Cancelled	Event status of each selected event changes to Cancelled.

When you click APPLY:

- The Approval Status of the event is changed to Not Approved if the Approval Status is currently set to Approved. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that approved data was changed.
- The Monitor Review Status of the event is changed to Not Reviewed if the Monitor Review Status is currently set to Reviewed. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that approved data was changed.
- The Eligibility Review of the volunteer associated with the event is changed to Pending if that the volunteer Eligibility Review is currently set to Completed. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The comment for the audit record states that approved data was changed.

Printing labels for screening events

Dates are printed on labels using the format that was configured when *labels were set up for the LabPas Recruiting module* (on page 366).

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Events** tab > **Events** category.

The Study - Events - Events page for screening events appears.

- 2 Use the filter to specify the group for which to list the events. Events are listed for one group at a time, and you print labels from that group.

3 Click **LABELS**.

The Print labels dialog box appears, listing the selected group.

4 Specify the labels or range of labels to print. You can specify the labels by any of the following criteria. If you provide no criteria, all screening labels are printed.

- VRN range—Field is case-sensitive.
- Screening No. range.
- Event No. range.
- Sample Type.
- Not Yet Printed checkbox—Select to print only the labels that have not yet been printed.
- Sort By and Then By fields—Determines the order in which labels are printed. Specify sort criteria and whether the order is ascending or descending.

5 Click **PRINT**.

The number of labels printed is determined by the quantity configured for each event. The same barcode is printed.

If Collection Description was specified for the event, the value that is printed is determined based on the number of tubes being printed and the value that was entered corresponding to that value from the event setup.

The value in the Collection Printed column in the grid is set to Yes.

Tasks: Study - Events - Data page (Recruiting)

On the Study - Events - Data page, you view data for screening events that have an event status other than Not Started.

This page shows data that has been collected for Other events, such as Check-In, Check-Out, Informed Consent, questionnaires, and medical and surgical history.

To restrict the data shown on the page, use the filter.

- *Viewing data from a screening event.* (on page 402)
- *Approving a screening event.* (on page 403)
- *Unapproving a screening event.* (on page 404)
- *Editing the results of a screening event.* (on page 406)
- *Changing review status of data in a screening event.* (on page 400)
- *Batch approving screening events.* (on page 405)

Viewing data from a screening event

You can view data from Other events, such as Check-In, Informed Consent and Questionnaire. To view data from Clinical Testing or Testing events, see *Labs in a recruiting study* (on page 411),

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Events** tab > **Data** category.

The Study - Events - Data page appears.

The page lists all events from the current facility that have an event status other than Not Started.

- 2 Select one or more events, and click **VIEW**.

The View Event dialog box appears, showing event data. All fields are read-only. The page contains the same information as the Edit Event page, with the following differences:

- The SAVE button is not available. A DONE button is available instead.
- The Change Comment section is not available.
- All fields except the APPROVE/UNAPPROVE button are disabled.
- The APPROVE button is available when:
 - The Approval Status of the event is Not Approved
 - You have the Approve Study Data function permission.
- The UNAPPROVE button is available when:
 - The Approval Status of the event is Approved
 - You have the Approve Study Data function permission.

Click the APPROVE button to display the Approve Study Data page. Click the UNAPPROVE button to display the Unapprove Study Data page.

- 3 After you are finished, click **DONE**.

Approving a screening event

Prerequisites:

- The Event Status for the event must be Completed or Cancelled.
- The event must belong to an unlocked group or period.
- You must have the Approve Study Data function permission.

To approve an event:

- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Events tab > Data** category.
- 2 Select one or more events, and click **VIEW**.
- 3 The View Event page appears.
Click **APPROVE**.
The Approve Study Data dialog box appears.
- 4 In the Approval area, type your User ID, password and click **Apply**.

Field descriptions for the Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

If the Approval Status of the event is successfully changed to Approved:

- The APPROVE button no longer appears from View Event Data page.
- The UNAPPROVE button appears.
- The Approval Status read-only field is updated.

Unapproving a screening event

Prerequisite: The event must belong to an unlocked group or period.

To unapprove an event:

- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Events tab > Data** category.
- 2 Select one or more events, and click **VIEW**.
- 3 The View Event page appears.
Click **UNAPPROVE**.
- 4 The Unapprove Study Data dialog box appears.
- 5 In the Approval area, enter a Comment, and click **Apply**.

Field descriptions for the Unapprove Study Data dialog box

Field	Description	Notes
Comment		REQUIRED. Defaults to the text entered in the Study Data field on the Approval Comments section on the RM Studies > Setup page.

When you click SAVE:

- The event Approval Status of the event is changed to Not Approved and the Approved By and Approval Date fields are set to blank. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The Comment saved with the audit record is set to the value entered in the Comment field.
- If the event Monitor Review Status of the event is Reviewed, it is changed to Not Reviewed. The change is recorded in the same audit trail entry as the Approval Status change.
- If the Completed option is selected for the participant on the Eligibility Review page, the Completed option is updated to unselected. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The Comment saved with the audit record is set to the value entered in the Comment field.

If the Approval Status of the event is successfully changed to Not Approved:

- The UNAPPROVE button is hidden on the View Event Data page.
- The APPROVE button appears.
- The Approval Status read-only field is updated.
- The Monitor Review Status is updated to Not Reviewed.

Batch approving screening events

Prerequisites:

- Events must belong to an unlocked group, period or study.
 - The study must be unlocked, or the BATCH APPROVE button does not appear.
 - Only data with an event status of Completed or Cancelled may be approved.
 - You must have the Approve Study Data function permission.
- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Events tab > Data** category.
 - 2 Select one or more events, and click **BATCH APPROVE**. An error appears if all selected samples have an Approval Status set to Approved.

The Batch Approve Study Data dialog box appears.

- 3 In the Approval area, type your User ID, password, and click **Apply**.

Field descriptions for the Batch Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

Editing the results of a screening event

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Events** tab > **Data** category.

The Study - Events - Data page appears.

- 2 Select one or more events, and click **EDIT**.

The Edit Event dialog box appears. Fields depend on the event type and form that is associated with the event. Fields default to previously saved values.

Field descriptions for the Edit Event dialog box

Field	Description	Notes
VRN	Volunteer recruiting number.	READ-ONLY
Screening No.	Candidate screening number.	READ-ONLY
Approval Status	Candidate Approval Status.	READ-ONLY
Monitor Review Status	Candidate Monitor Review Status.	READ-ONLY

Field	Description	Notes
Event Information		
Data tab		
Date/time	Date and time of the event.	REQUIRED. Appears for all event types.
Comment	Comment about the event.	REQUIRED. Appears for all event types.
Complete	Whether the event is complete.	Appears for events associated with event type Other and not associated with event category Informed Consent.
Category		READ-ONLY Appears for event type Other.
Signed	Whether the event is signed.	Appears for events associated with event type Other and event category Informed Consent.
Copy Given To Volunteer	Selected —Copy of Informed Consent was given to the volunteer.	Appears for events associated with event type Other and event category Informed Consent.
Late	Selected —Volunteer was late for the appointment.	Appears for events that are associated with event type Other and event category Check-In.
Clinical Significance	Whether any test results associated with the event are marked as clinically significant.	READ-ONLY Appears for events associated with event type Testing. Always blank for Other events.
Instrument	Barcode and name of instrument.	READ-ONLY Appears for events associated with event type Testing.
Barcode		Appears for event type Clinical Testing. Always disabled.
Sample		Appears for event type Clinical Testing. Always disabled.
Vessel		Appears for event type Clinical Testing. Always disabled.

Field	Description	Notes
Repeat event	<p>Selected—Event is rescheduled. The existing event is not overwritten. Status of new event defaults to Repeat.</p> <p>Panels associated with the event are scheduled, but only tests with the Repeat checkbox selected are enabled when the results are entered</p>	Appears for all event types. Disabled for events associated with event type Other and event categories Check-In and Check-Out.
Form fields	Section with all form fields.	Appears if the event is configured with a form.
Results		
For testing events. Includes a row for each test associated with the event that has a non-blank result value or is required.		
Repeat		
Tests	Name of the test. Tests with alerts are red.	READ-ONLY
Optional	<p>Yes—Test is optional in this study.</p> <p>No—Test is required in this study.</p>	<p>READ-ONLY</p> <p>Results appear for optional tests that are performed/collected.</p> <p>Optional tests that are not performed/collected do not appear.</p>
Result	Result of the test.	
Alert	If a test has an alert, the alert code and description appear.	
Clin. Sig.	Whether results of the test are marked as clinically significant.	
Source	Source of the test result data.	<p>READ-ONLY</p> <p>Appears for events associated with event type Testing.</p> <p>If the source is a value other than blank or LabPas, all fields except Clin. Sig. are read-only.</p>
Comment	Comment about the test.	

Field	Description	Notes
History tab	For all event types, the History tab displays the audit trail records from the CT Change Log associated with the event.	
Source	Source of the change.	READ-ONLY.
User ID	User that submitted the record.	READ-ONLY.
Date/Time	Date and time of the change.	READ-ONLY.
Comment	Change comment.	READ-ONLY.
Change	Change information.	READ-ONLY.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

3 Click **SAVE**.

If *reference ranges and edit checks* (on page 339) have been configured for event fields, the allowed ranges and values are compared as you enter data.

- A result that violates an Out of Range value is not allowed, and a warning appears.
- If a test result is outside the reference range, you must provide a comment.

Edit checks that have been defined are applied. If data is in violation of an edit check, the following actions occur.

Action defined for edit check	Result
Prevent	The test name and associated message for each edit check appears. Saving is cancelled. No further edit checks are processed.
Either of the following: <ul style="list-style-type: none"> • Warn • Warn and Alert 	The test name and associated message for each edit check appears. A new line is started for each message.
Either of the following: <ul style="list-style-type: none"> • Alert • Warn and Alert 	The message for each relevant edit check is saved as an alert against the result that generated the alert.

For volunteers who are associated with the event and who have an Eligibility Review that is Completed, the Eligibility Review changes to Pending. Changes are written to the Recruiting Change Log. Any blank sources are changed to LabPas.

When you save an event with the Approval Status set to Approved, the Approval Status is changed to Not Approved, and the Approval Date and Approved By fields are set to blank. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that approved data was changed.

When you save an event associated with a study participant with the Completed option selected on the Eligibility Review page, the Completed field is updated to unselected. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The comment for the audit record states that approved data was changed.

When you save an event with a Monitor Review Status set to Reviewed, the Monitor Review Status is changed to Not Reviewed. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that reviewed data was changed.

Labs in a recruiting study

Tasks: Study - Labs page

On the Study - Labs page for screening, you view data for clinical lab samples that are associated with the current facility and that have an event status other than Not Started.

- *Viewing lab results from a screening event* (on page 411).
- *Approving lab results from a screening event* (on page 412).
- *Unapproving lab results from a screening event* (on page 413).
- *Batch approving lab results for screening events* (on page 414).
- *Editing lab results* (on page 415).
- *Changing the review status of a sample in a screening event* (on page 418).
- *Importing clinical lab results* (on page 419).
- *Exporting clinical lab results* (on page 420).

Viewing lab results from a screening event

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Labs** tab.

The Study - Labs page appears.

- 2 Select one or more samples, and click **VIEW**.

The View Lab Results page appears. All fields are read-only. The page contains the same information as the Edit Lab Results page, with the following differences:

- The SAVE button is not available. A DONE button is available instead.
- The Change Comment section is not available.
- All fields except the APPROVE/UNAPPROVE button are disabled.
- The APPROVE button is available when:
 - The Approval Status of the event is Not Approved
 - You have the Approve Study Data function permission.
- The UNAPPROVE button is available when:
 - The Approval Status of the event is Approved
 - You have the Approve Study Data function permission.

Click the APPROVE button to display the Approve Study Data page. Click the UNAPPROVE button to display the Unapprove Study Data page.

- 3 After you finish, click **DONE**.

Approving a lab result (recruiting)

Prerequisites:

- The Event Status for the event must be Completed or Cancelled.
- The event must belong to an unlocked group or period.
- You must have the Approve Study Data function permission.

To approve a result:

- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Labs** tab.
- 2 Select one or more results, and click **VIEW**.
- 3 The View Event page appears.

Click **APPROVE**.

- 4 The Approve Study Data dialog box appears.
- 5 In the Approval area, type your User ID, password and click **Apply**.

Field descriptions for the Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

If the Approval Status of the event is successfully changed to Approved:

- The APPROVE button no longer appears from View Event Data page.
- The UNAPPROVE button appears.
- The Approval Status read-only field is updated.

Unapproving a lab result (recruiting)

Prerequisite: The event must belong to an unlocked group or period.

To unapprove a result:

- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Labs** tab.
- 2 Select one or more results, and click **VIEW**.
- 3 The View Event page appears.
Click **UNAPPROVE**.
- 4 The Unapprove Study Data dialog box appears.
- 5 In the Approval area, enter a Comment, and click **Apply**.

Field descriptions for the Unapprove Study Data dialog box

Field	Description	Notes
Comment		REQUIRED. Defaults to the text entered in the Study Data field on the Approval Comments section on the RM Studies > Setup page.

When you click SAVE:

- The event Approval Status of the event is changed to Not Approved and the Approved By and Approval Date fields are set to blank. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The Comment saved with the audit record is set to the value entered in the Comment field.
- If the event Monitor Review Status of the event is Reviewed, it is changed to Not Reviewed. The change is recorded in the same audit trail entry as the Approval Status change.
- If the Completed option is selected for the participant on the Eligibility Review page, the Completed option is updated to unselected. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The Comment saved with the audit record is set to the value entered in the Comment field.

If the Approval Status of the event is successfully changed to Not Approved:

- The UNAPPROVE button is hidden on the View Event Data page.
- The APPROVE button appears.

- The Approval Status read-only field is updated.
- The Monitor Review Status is updated to Not Reviewed.

Batch approving lab results (recruiting)

Prerequisites:

- Data must belong to an unlocked group, period or study.
 - The study must be unlocked, or the BATCH APPROVE button does not appear.
 - Only data with an event status of Completed or Cancelled may be approved.
 - You must have the Approve Study Data function permission.
- 1 From the main menu, select **Recruiting > SR Studies**, and select a study. On the Study page, select the **Labs** tab.
 - 2 Select one or more results and click **BATCH APPROVE**. An error appears if all selected samples have an Approval Status set to Approved.

The Batch Approve Study Data dialog box appears.

- 3 In the Approval area, type your User ID, password, and click **Apply**.

Field descriptions for the Batch Approve Study Data dialog box

Field	Description	Notes
User ID		REQUIRED. The User ID is associated with the user displayed in the User Name field and defaults to the name of the logged on user.
Password		REQUIRED.
Comment		REQUIRED. READ-ONLY Defaults to the text entered in the Study Data field in the Approval Comments section on the Resource Management > Studies – Setup page.

Failed attempts due to an invalid signature are recorded in the CT Change Log with a source of Study Data Approval. The current logged on user is associated with the audit record.

After you enter a valid signature:

- The Approval Status of all selected records is changed to Approved.
- An entry is recorded in the CT Change Log for all selected records with a source of Study Data Approval.
- The Comment saved with each audit record is set to the value in the Comment field.

Editing lab results

You cannot edit test results that are imported from an external source. If you edit a result for which the Export field is Yes, your edits will be overwritten when results are imported from the lab.

From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Labs** tab.

The Study - Labs page appears.

- 1 Select one or more samples to edit, and click **EDIT**.

The Edit Results dialog box appears.

- 2 Fill in the fields.

Field descriptions for the Edit Results dialog box

Field	Description	Notes
Sample ID, Barcode, Actual Sample Date, Approval Status, Sample Type, VRN, Screening No., Monitor Review Status	Fields associated with the sample.	READ-ONLY.
Panel:	Name of the panel that appears. Click the down arrow to select another panel associated with the sample. Panel names that appear in red text contain tests with an alert.	
Performed By	User name of the person editing the results.	The value applies to each test result in the panel.
Date/Time	Date of the edits.	The value applies to each test result in the panel. Do not specify a date in the future.
Data tab		

Field	Description	Notes
Repeat	<p>Selected—All of the following occur after you make an update:</p> <ul style="list-style-type: none"> The event is rescheduled with a new barcode. <p>The existing event is not overwritten.</p> <ul style="list-style-type: none"> The status of the new event is Repeat. All panels associated with the event are scheduled, but only tests with the Repeat field selected are enabled when the results are entered. 	
Test	Name of the test. Tests with alerts are red.	
Optional	<p>Yes—Test is optional in this study.</p> <p>No—Test is required in this study.</p>	If Optional is selected and the test was not performed, the test is listed in the table with a blank result field.
Result	Result of the test or tests.	
Performed By	Person who obtained the results.	
Date / Time	Date and time the results were obtained.	<p>REQUIRED.</p> <p>You must provide both a date and a time.</p>
Alert	If a test has an alert, the alert code and description appear.	
Clin. Sig.	Whether results of the test are marked as clinically significant.	
Source	Source of the lab result data.	<p>READ-ONLY</p> <p>Appears for events associated with event type Clinical Labs.</p> <p>If the source is a value other than blank or LabPas, all fields except Clin. Sig. are read-only.</p>
Comment	Comment about the test.	If a result is not entered for the test, you must enter a comment.

Field	Description	Notes
History tab	For all event types, the History tab displays the audit trail records from the Recruiting Change Log associated with the event.	
Source	Source of the change.	
User ID	User that submitted the record.	
Date/Time	Date and time of the change.	
Comment	Change comment.	
Change	Change information.	

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

If **reference ranges and edit checks** (on page 339) have been configured for event fields, the allowed ranges and values are compared as you enter data.

- A result that violates an Out of Range value is not allowed, and a warning appears.
- If a test result is outside the reference range, you must provide a comment.

Edit checks that have been defined are applied. If data is in violation of an edit check, the following actions occur.

Action defined for edit check	Result
Prevent	The test name and associated message for each edit check appears. Saving is cancelled. No further edit checks are processed.
Either of the following: <ul style="list-style-type: none"> • Warn • Warn and Alert 	The test name and associated message for each edit check appears. A new line is started for each message.
Either of the following: <ul style="list-style-type: none"> • Alert • Warn and Alert 	The message for each relevant edit check is saved as an alert against the result that generated the alert.

For volunteers who are associated with the event and who have an Eligibility Review that is Completed, the Eligibility Review changes to Pending.

Changes are written to the Recruiting Change Log.

If the source is a value other than blank or LabPas, all fields except Clin. Sig. are read-only.

When you save an event with the Approval Status set to Approved, the Approval Status is changed to Not Approved, and the Approval Date and Approved By fields are set to blank. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that approved data was changed.

When you save an event associated with a study participant with the Completed option selected on the Eligibility Review page, the Completed field is updated to unselected. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The comment for the audit record states that approved data was changed.

When you save an event with a Monitor Review Status set to Reviewed, the Monitor Review Status is changed to Not Reviewed. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that reviewed data was changed.

Changing the event status of a sample

Prerequisite: You must have the Change Study Setup function permission.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Labs** tab.

The Study - Labs page appears.

- 2 Select one or more samples, and click **STATUS**.

The Change Status dialog box appears.

- 3 Select the event status. Options are:

- In Progress
- Completed

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

The event status is applied to the selected samples.

For volunteers associated with selected samples, the Eligibility Review is changed to pending if both of the following conditions are true:

- Before the status change, the Eligibility Review of the volunteer was Completed.
- The sample had a different status before the status change.

All changes are recorded in the Recruiting Change Log.

When you click APPLY:

- The Approval Status of the sample is changed to Not Approved provided that the Approval Status is currently Approved. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that approved data was changed.
- If the Approval Status of the event associated with the sample is Approved, then the Approval Status of the event is changed to Not Approved. If the sample was Not Approved, then an entry is written to the Recruiting Change Log with a source of Study Data Approval.

The comment for the audit record states that approved data was changed.

- The Monitor Review Status of the sample is changed to Not Reviewed provided that the Monitor Review Status is currently Reviewed. An entry is recorded in the Recruiting Change Log with a source of Study Data Approval. The comment for the audit record states that reviewed data was changed.
- The Eligibility Review of the volunteer associated with the sample is changed to Pending provided that the volunteer Eligibility Review is currently Completed. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The comment for the audit record states that approved data was changed.

Importing clinical lab results

Prerequisite: You must have the Study Setup function permission .

The lab that you select determines the format of the import file. You specify the format to use when you **add a facility** (in the *Administration Guide*).

Only clinical lab results for samples associated with groups assigned to the current facility are imported.

The import file can be imported more than once. A new value is recorded only if a result is changed. Changes to result values are recorded in the Recruiting Change Log.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Labs** tab.

The Study - Labs page appears.

- 2 Click **IMPORT**.

The Import Results dialog box appears.

- 3 Click **BROWSE**.

The Choose File dialog box appears.

- 4 From the **Lab** drop-down list, select a lab interface. Only the lab interfaces configured for the study and facility appear.

- 5 Locate and select the file to import, and click **OPEN**.

The file you selected appears in the **File Name** field of the Import Results dialog box.

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

Results are imported. For information about the format of the file, see the *Specification for the HL7 Lab Interface* document.

Any volunteers with a Completed Eligibility Review who are associated with each result have their Eligibility Review set to Pending. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. The comment for the audit record states that approved data was changed.

- 7 To return to the Study - Labs page, close the Import Results.

Exporting clinical lab results

Prerequisites:

- Prerequisite: You must have the Study Setup function permission .
- Samples must be associated with unlocked groups and screening visits.
- Configure directories for HL7 support. For more information, see the *Installation Guide*.
- Specify support for the HL7 interface for a facility.
- Assign a facility and sample type to a lab.

You can export only clinical lab samples. For each exported sample, an entry is created in the Recruiting Change Log report with a source of Export Samples.

- 1 From the main menu, select **Recruiting > SR Studies**. On the SR Studies page, select a study. On the Study page, select the **Labs** tab.
- 2 Select one or more clinical lab samples, and click **EXPORT**.

The Export Samples dialog box appears.

- 3 Click **APPLY**.

The dialog box remains open, and the Export Log field indicates whether the export succeeded or failed.

For information about the format of the file, see the *Specification for the HL7 Lab Interface* document.

APPENDIX A

Reports

In this appendix

Tasks: View Reports page.....	422
Tasks: Report Groups page.....	423
Report layout	424
LabPas CT reports	425
LabPas Recruiting reports	427
LabPas Resource Management reports	429
Viewing the list of available reports	430
Viewing a report.....	431
Creating a new report.....	433
Deleting a report	436
Adding and editing a report group.....	437
Deleting a report group.....	438
Printing a report	439

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 430)
- *Viewing a report* (on page 431)
- *Creating a new report* (on page 433)
- *Deleting a report* (on page 436)

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 437).
- *Deleting a report group* (on page 438).

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 431).

- 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 431). The footer for each report includes the following information:
 - Date the report was printed.
 - Page number/total.

LabPas CT reports

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

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

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

LabPas Recruiting reports

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

Report	Description
Recruiter Metrics	<p>Includes metrics for each user authorized to use the Incoming Calls and Outgoing Calls pages in the selected study.</p> <p>If the Global Recruiting application setting is not selected, the lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility.</p>
Recruiting Change Log	<p>Includes modifications made to previously recorded data (for example, volunteers, study setup, and study properties) on the Volunteer pages.</p> <p>If the Global Recruiting application setting is not selected, the lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility.</p>
Recruiting Media Campaigns	Tracks volunteer response, scheduling, and study participation based on an ad campaign and displays descriptive information about the campaign.
Recruiting Screening Appointment	<p>Includes appointment information for the selected volunteer, including demographic, medical, and testing data.</p> <p>If the Global Recruiting application setting is not selected:</p> <ul style="list-style-type: none"> • The lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility. • The data in the report is restricted to appointments associated with the current facility.
Recruiting Screening Schedule	<p>Includes the schedule of all approved appointments for volunteers, in order of date and time, including available openings and filled appointments for each time slot.</p> <p>If the Global Recruiting application setting is not selected, the lookup window for the Study filter is restricted to studies in which at least one group in the study is associated with the current facility.</p>
Recruiting Volunteer Data	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: <ul style="list-style-type: none"><li data-bbox="667 260 1414 327">• Number of subjects goal, percent of subjects goal, number of subjects needed to reach subjects goal.<li data-bbox="667 348 1425 449">• Number of backup (alternate) subjects goal, current percent of backup (alternate) subjects goal, current number of backup (alternate subjects needed to reach backup goal).<li data-bbox="667 470 1471 606">• Numbers of volunteers with the following statuses: Promoted that are not an alternate, Promoted that are an alternate, Completed, Scheduled, Revised, Pending, DNQ, CRO, Dropped, and Volunteer Dropped.
SR Label Audit	Provides details of collection labels that have been printed or reprinted in the current facility.

LabPas Resource Management reports

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

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

Viewing the list of available reports

- 1 From the main menu, select **Reports > View**.
The View Reports page appears, displaying a list of all available reports.
- 2 Review the list of reports.

Viewing a report

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

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

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

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

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

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

The report appears in an Adobe Reader window.

Field descriptions for the View Reports - Edit page

Field	Description	Notes
Study	Study ID. Either type the Study ID in the field, or click the Lookup icon and select the study from the list in the Study Lookup dialog box.	REQUIRED. The Study Lookup dialog box displays only studies to which you have been granted access (on the Study - Properties page.) If you have been granted permission to view all studies on the Security page, the dialog box displays all studies.
Report-specific criteria	Displays different criteria fields depending on the report type. Fields that might appear: <ul style="list-style-type: none"> • Storage Device • Vessel Barcode • Rack • Box 	Most of the report-specific fields appear under the Study field and above the Date Interval and Range fields.
Date Interval	Time interval (for example, Month to Date or Year to Date) used to filter the report.	The selected date choice is the date criteria by which the report is filtered. If you select Date Interval , a drop-down field is enabled. If you select Date Range , two calendar fields are enabled. You must select either Storage Date Interval or Date Range.

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

Creating a new report

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

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

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

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

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

- 3 Fill in the fields.

Field descriptions for the View Reports - Edit page

Field	Description	Notes
Study	Study ID. Either type the Study ID in the field, or click the Lookup icon and select the study from the list in the Study Lookup dialog box.	REQUIRED. The Study Lookup dialog box displays only studies to which you have been granted access (on the Study - Properties page.) If you have been granted permission to view all studies on the Security page, the dialog box displays all studies.
Report-specific criteria	Displays different criteria fields depending on the report type. Fields that might appear: <ul style="list-style-type: none"> • Storage Device • Vessel Barcode • Rack • Box 	Most of the report-specific fields appear under the Study field and above the Date Interval and Range fields.
Date Interval	Time interval (for example, Month to Date or Year to Date) used to filter the report.	The selected date choice is the date criteria by which the report is filtered. If you select Date Interval , a drop-down field is enabled. If you select Date Range , two calendar fields are enabled. You must select either Storage Date Interval or Date Range.

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

- 4 Click **SAVE**.

The Save Report As dialog box appears.

- 5 In the **Report Name** field, type a name for the new report.
- 6 In the **Group Name** field, make a selection:
 - **Existing** to add the report to an existing group.

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

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

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

Deleting a report

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

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

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

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

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

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

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

- 3 Click **DELETE**.

A confirmation message appears.

- 4 Click **OK**.

Adding and editing a report group

- 1 From the main menu, select **Reports > Groups**.
The Report Groups page appears.
- 2 To add a report group, click **NEW**.
To edit a report group, select a report group, and click **EDIT**.
The Report Groups page appears.
- 3 In the **Report Group** field, type a unique name with a maximum of 30 characters.
- 4 Optionally, in the **Comment** field, type a comment with a maximum of 80 characters.
- 5 Click **SAVE**.

Deleting a report group

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

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

- 1 From the main menu, select **Reports > Groups**.
The Report Groups page appears.
- 2 Select the checkboxes for the report groups, and click **DELETE**.
A confirmation dialog box appears.
- 3 Click **OK**.

Printing a report

- 1 *Create a report* (on page 433), or *view an existing report* (on page 431).
The report appears in an Adobe Reader window.
- 2 In the Adobe Reader window, click the printer icon, or select **File > Print**.
The report prints to the default printer.

APPENDIX B

Labels

In this appendix

Tasks: Labels page	442
Printing an existing barcode.....	443
Printing an auto-generated barcode	444

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 443).
- *Printing an auto-generated barcode* (on page 444).

Printing an existing barcode

Prerequisite: At least one default label must exist.

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

The Labels page appears.

- 2 From the **Label** drop-down list, select a default label.
- 3 In the **Barcode Mode** field, select **Use Existing**.
- 4 Fill in the fields.

Field descriptions for the Labels page

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

- 5 Click **PRINT**.
The Print dialog box appears.
- 6 Select the printer options, and click **OK**.

Printing an auto-generated barcode

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

- 1 From the main menu, select **Labels**.
The Labels page appears.
- 2 In the **Label** drop-down list, click a default label.
- 3 In the **Barcode Mode** field, select **Auto-Generate**.
- 4 Fill in the fields.

Field descriptions for the Labels page

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

- 5 Click **PRINT**.
The Print dialog box appears.
- 6 Select the printer options, and click **OK**.
The labels are generated based on the value in the No. of Barcodes field, starting with the last Barcode Id that was generated.

Note: You can save unused labels for other studies.

Index

A

- action taken
 - adding • 150
 - removing • 150
- adverse event • 277, 278, 281
 - approving • 281
 - editing • 281
- AE form
 - resolving • 302
- aliquot • 248

B

- barcode • 309
 - printing an auto-generated • 444
 - printing an existing • 443
 - viewing vessel information • 312
- bookmark
 - creating • 12
 - deleting • 13
- box • 249

C

- candidate • 157, 158
 - approving • 159
 - calculated fields • 160
 - deleting • 172
- candidate label
 - printing • 172
- clinic
 - assigning to time periods • 47
 - assigning to an event • 53
 - clearing an assignment • 48
 - creating • 21
 - deleting • 22
 - removing from an event • 53
- clinical event
 - exporting results • 268
 - updating test results • 257
- clinical lab • 81, 343
 - adding a sample type • 81
 - removing sample type • 81
- clinical schedule • 45, 46
 - filtering • 46
- collection label
 - modifying • 366
- custom field
 - importing • 90
 - selecting to appear on an AE form • 152

D

- data
 - collecting • 370
- data event • 199
- data frame • 5
 - configuring • 9
 - filtering • 10
- demographic range
 - adding • 339

E

- email address
 - testing • 369
- event • 91, 181
 - adding • 92
 - deleting • 186
 - setting up • 91
- event plan • 91
 - copying • 123
- event type • 57, 58
 - deleting • 61

F

- facility
 - deleting an association • 33
- form
 - removing • 90

G

- general practitioner • 397
 - editing volunteer letter information • 397
 - exporting information • 398
 - printing address label • 397
- group
 - adding data • 35
 - removing • 36

H

- home page
 - setting • 11

L

- lab • 411
 - deleting an association • 33
- label • 442
 - recruiting • 366
 - setting up • 144
- LabPas application • 2
 - getting started • 1

LabPas CT module
 study properties • 63, 64
LabPas Recruiting module
 candidate • 159
logon
 logging off • 8
 logging on • 7

M

main menu • 4
message
 deleting • 15
 reading • 14
 working with • 14
message group
 adding • 15
 deleting • 16

N

navigation • 4

P

page heading • 5
panel • 337
 adding • 338
 removing • 342
 updating • 342
participant • 157, 175
payment • 37
 setting up • 37
permission • 3
PK Lab
 setting PK sample type parameters • 87
 setting up • 82
PK Lab schedule • 315
 filtering • 317
 samples • 317

Q

qualifier
 adding • 154
 removing • 154
query • 271, 272, 273
 answering • 275
 viewing • 274
question
 adding • 345, 377
 deleting • 347
 editing • 346, 380
 importing a master question • 383
questionnaire • 377

R

range limit • 373
recruitment
 designing • 331
 removing • 344
 viewing data for a candidate • 164
recruitment event • 348

recruitment restrictions • 370
 adding • 374
reimbursement
 calculating • 37
report • 421, 429
 creating • 433
 layout aaa • 424
 printing • 439
 viewing • 422, 430, 431
report group • 423
 adding • 437
 editing • 437
resource management • 19, 20
result
 adding • 151
 importing • 267
 removing • 151
role • 3

S

sample data • 232
sample type
 deleting an association • 33
schedule • 183
 colors • 185
 creating • 183
 saving • 185
screening event • 399
 adding • 348
 printing label • 401
screening form • 344
 adding • 344
 importing • 345
 removing • 348
 renaming • 345
screening panel
 removing • 342
screening visit • 367
 adding • 367
 removing • 368
 setting up email • 368
severity
 adding • 150
 removing • 150
shift • 49
 adding an event • 51
 clearing an assignment from an event • 51
 creating • 50
 removing staff • 52
shipment • 250
shipping address • 147
 deleting • 148
significance
 adding • 151
 removing • 151
staff • 49
 locking an assignment • 53
 removing from a shift • 52
 unlocking an assignment • 53
 viewing assignment details • 52

- study • 23, 332
 - accessing • 74, 332
 - deleting • 25
 - properties copied to a new study • 26
 - selecting • 332
 - setting up • 335
- study description • 335
 - entering • 335
- study element • 153
 - setting up • 75, 76
- study group • 34
 - adding data • 35
 - editing • 336
 - removing • 36
- study lab • 253
- study metric • 305
- study parameter • 335
 - setting • 336
- study part
 - deleting • 32
- study properties • 333
 - editing • 27, 333
 - working with • 66
- study sample • 231
- study schedule • 325
- study team
 - adding members • 72
 - deleting a member • 73
 - editing members • 72
- subject • 175
 - adding • 175
 - deleting • 179
 - printing label • 179
 - scheduling • 175

T

- test panel
 - refreshing • 80
- treatment • 139
 - editing • 140
 - removing • 141, 149
 - removing a sequence • 143
 - setting up • 139

U

- user • 3

V

- visit
 - adding • 153
 - removing • 153
- volunteer • 384
 - editing screening results • 394
 - importing • 396
 - notifying • 385