# Siebel Clinical Trial Management System Guide

Siebel Innovation Pack 2014

November 2014

ORACLE

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# 1 What's New in This Release

## What's New in Siebel Clinical Trial Management System Guide, Siebel Innovation Pack 2014

Table 1 lists the changes in this revision of the documentation to support Siebel Innovation Pack 2014.

**NOTE:** Siebel Innovation Pack 2014 is a continuation of the Siebel 8.1/8.2 release.

Table 1. What's New in Siebel Clinical Trial Management System Guide, Siebel Innovation Pack 2014

| Topic | Description |
|---|---|
| "Features of Siebel Clinical Trial Management System" on page 21 | Modified topic. The following features have been added:<br>■ Siebel Clinical Trial Management System Cloud Service for Software as a Service (SaaS) deployments<br>■ Clinical operations integration for budget planning and tracking |
| Chapter 7, "Managing Partial Source Data Verification" | New chapter. It describes how to manage partial source data verification. |
| "Tracking Completion Status for Clinical Trip Reports" on page 149 | Modified topic. The Not Started status has been removed from the SmartScript Questions Answered field. |
| Chapter 11, "Setting Up and Configuring Clinical Operations Integration" | New chapter. It describes how to integrate Siebel Clinical Trial Management tracking and budgeting functionality with an external clinical operations application, such as Oracle ClearTrial. |
| "Workflows for Mobile Integration of Clinical Trip Reports" on page 190 | New topic. It describes the actions that the mobile integration workflows perform. |
| "Activating Workflows for Mobile Integration" on page 193 | Modified topic. The LS Clinical Get Site Snapshot Service workflow has been added for mobile integration. |
| "Configuring Web Services for Mobile Integration" on page 193 | Modified topic. The following Web services have been added for mobile integration:<br>■ SWILSClinicalTripReportTemplates<br>■ SWILSClinicalGetSiteSnapshot<br>■ SWILSClinicalGetSmartScriptDetails |

Table 1. What's New in Siebel Clinical Trial Management System Guide, Siebel Innovation Pack 2014

| Topic | Description |
|---|---|
| "About Exporting Snapshot Data for Site Enrollments" on page 199 | New topic. It describes exporting site enrollment data from Siebel Clinical Trial Management System to a mobile application. |
| "About Exporting Template Data for Clinical Trip Reports" on page 199 | New topic. It describes exporting template data for clinical trip reports from Siebel Clinical Trial Management System to a mobile application. |
| "About Exporting SmartScript Metadata for Clinical Trip Reports" on page 200 | New topic. It describes exporting SmartScript metadata for clinical trip reports from Siebel Clinical Trial Management System to a mobile application. |
| Chapter 14, "Setting Up and Configuring Clinical Data Capture and Query Management System Integration" | New chapter. It describes how to integrate Siebel Clinical Trial Management System with a clinical data capture application, such as Oracle InForm. |
| "User Properties for Business Components in Siebel Clinical" on page 246 | Modified topic. The description for the Named Method 2 business component user property has been updated to include information about the CL – Verify TripReportApprover system preference. |
| "System Preferences in Siebel Clinical" on page 263 | New topic. It describes the system preferences that have been added to configure Siebel Clinical Trial Management System core functionality, and integration with third-party applications. The following system preferences have been added:<br>■ **CL - BudgetingApp CustomerCode.** This system preference is used for clinical operations integration.<br>■ **CL - BudgetingApp RequestURL.** This system preference is used for clinical operations integration.<br>■ **CL – Verify TripReportApprover.** This system preference has been added to turn on or off approver verification for clinical trip reports. |

Table 1. What's New in Siebel Clinical Trial Management System Guide, Siebel Innovation Pack 2014

| Topic | Description |
|---|---|
| "Web Services in Siebel Clinical" on page 266 | Modified topic. The following Web services have been added or modified:<br>■ LS Clinical CRF Tracking Interface<br>■ LS Clinical Protocol Site Interface Service<br>■ LS Clinical Subject Information Interface Service<br>■ SWILSClinicalGetSiteSnapshot<br>■ SWILSClinicalGetSmartScriptDetails<br>■ SWILSClinicalTripReportTemplates |
| Appendix A, "ClearTrial Clinical Trial Management System Connector" | New appendix. It contains information about the ClearTrial Clinical Trial Management System Connector. |

## What's New in Siebel Clinical Trial Management System Guide, Version 8.1/8.2

Table 2 describes the changes in this version of the documentation to support Siebel CRM version 8.1.1.11 and Siebel CRM version 8.2.2.4.

Table 2. What's New in Siebel Clinical Trial Management System Guide, Version 8.1/8.2

| Topic | Description |
|---|---|
| "Creating Records for Clinical Subjects" on page 66 | Modified topic. It has been updated to include the following fields:<br>■ Subject ID<br>■ Encounter Date<br>Subject ID has replaced the Subject Initials field. Encounter Date has replaced the Subject DOB field. These changes have been made to remove personally identifiable information from Oracle's Siebel Clinical Trial Management System.<br>The application labels for these fields have been changed, but the application logic remains the same. Upgrading to Siebel Innovation Pack 2013 from a previous version does not delete existing values for these fields.<br>The screening number is now automatically generated from the Subject ID field and the Encounter Date field. |
| "Associating Accounts with Contracts" on page 93 | New topic. It describes how to associate an account with a contract for a clinical site. Multiple accounts can be associated with a contract for clinical site. |
| "Splitting Payment Activities Between Multiple Payees" on page 126 | New topic. It describes how to split a payment activity between multiple contracts and payees. |
| "Copying Details for Payment Splits" on page 127 | New topic. It describes how to copy the details of a split payment to multiple payment activities. Payment activity splits are copied at the payment exceptions level. |
| "Reversing Splits for Payment Activities" on page 128 | New topic. It describes how to reverse a payment activity split. |

Table 2. What's New in Siebel Clinical Trial Management System Guide, Version 8.1/8.2

| Topic | Description |
|---|---|
| "Creating Payment Activities for Sites" on page 129 | Modified topic. It has been updated to include contract, account, and payee details for a payment record of a clinical site. The following fields have been added to the Payment Activities view:<br>■ Account<br>■ Contract<br>■ Payee First Name<br>■ Payee Last Name |
| "Generating Final Payments for Sites" on page 133 | Modified topic. It has been updated to include the following fields:<br>■ Account<br>■ VAT Amount |
| "Reverting Payment Records" on page 134 | New topic. It describes how to revert a payment record to modify the payment details. The Revert button is enabled when a single payment record with one of the following statuses is selected:<br>■ In Progress<br>■ To Be Processed |
| "Creating Questions for Clinical Trip Reports Using Siebel SmartScript" on page 139 | New topic. It describes how to create questionnaires for clinical trip reports using Siebel SmartScript. |
| "Creating Clinical Trip Report Templates" on page 140 | New topic. It describes how to create a trip report template in the new Trip Report Templates view of the Administration - Clinical screen. |
| "Applying Clinical Trip Report Templates" on page 141 | Modified topic. It has been updated to describe support for SmartScript questionnaires. |
| "Completing Questionnaires for Clinical Trip Reports" on page 143 | New topic. It describes how to complete a questionnaire for a clinical trip report. The questionnaire is launched in the SmartScript player from the Questions view of the trip report. |
| "Deleting Unanswered Questions from Questionnaires of Clinical Trip Reports" on page 144 | New topic. It describes how to delete unanswered questions from a questionnaire of a clinical trip report. |

Table 2. What's New in Siebel Clinical Trial Management System Guide, Version 8.1/8.2

| Topic | Description |
|---|---|
| "Tracking Case Report Forms" on page 144 | Modified topic. The following fields have been added to the CRF Tracking applet:<br>■ Charts Reviewed Date<br>■ Forms Signed Date<br>■ Page Numbers Verified |
| "Tracking Completion Status for Clinical Trip Reports" on page 149 | New topic. It describes how to track the real-time status details for a clinical trip report in the Summary view. The status is tracked for the following fields for clinical trip reports:<br>■ Checklists Completed<br>■ Questions Answered<br>■ Current Follow-Ups Completed<br>■ All Follow-Ups Completed<br>■ CRF Tracking Completed<br>■ Total Attendees |
| "Tracking Status Accruals for Clinical Subjects of Sites" on page 151 | New topic. It describes how to track the progress of a clinical site by creating a real-time system snapshot of the current status accruals for the subjects of a site. |
| "Reviewing Clinical Trip Reports" on page 153<br>"Approving Clinical Trip Reports" on page 153 | Modified topics. Access control has been added for the following fields:<br>■ Reviewer Comments<br>■ Approver Comments |
| "Setting Up the LS Clinical Integration Workflow Monitor Agent for Clinical Data Management System Integration" on page 210 | New topic. It describes how to set up the LS Clinical Integration workflow monitor agent for a clinical data management system integration. The workflow policies for a clinical data management system integration were moved to a new policy group for improved performance. |

Table 2. What's New in Siebel Clinical Trial Management System Guide, Version 8.1/8.2

| Topic | Description |
|---|---|
| "Activating Synchronization of Data for Sites" on page 222 | Modified topic. The following integration fields have been added:<br>■ Locale<br>■ Maximum Enrollment Number<br>■ Time Zone |
| "User Properties for Business Components in Siebel Clinical" on page 246 | Modified topic. The following business component user properties have been added:<br>■ LS Amount Rollup Field 3<br>■ LS Amount Rollup On Status 1<br>■ LS Clinical Enable Revert On Status<br>■ Named Method 1 |

# 2 Overview of Siebel Clinical Trial Management System

This chapter provides an overview of Oracle's Siebel Clinical Trial Management System. It includes the following topics:



## About Siebel Clinical Trial Management System

Siebel Clinical Trial Managements System allows biotechnology companies, pharmaceutical companies, and CROs (clinical research organizations) to better manage the clinical trial process, maintain quality of clinical trials, and manage investigator relationships. It provides a comprehensive set of tools for CRAs (clinical research associates), clinical investigators, and site coordinators, and includes a personalized Internet portal to conduct study activities more efficiently.

The following products are supported:

- Siebel Clinical Trial Management System
- Siebel Clinical Trial Management System Cloud Service

## Features of Siebel Clinical Trial Management System

Siebel Clinical supports the following functionality:

- Support for full clinical trial hierarchies of Subject-Site-Region-Protocol-Program
- Support for global trials running in multiple countries, multiple languages, and multiple currencies
- Support for randomized trials
- Support for multi-arm, epoch, and adaptive trials
- Site management tools for CRAs (clinical research associates), including a site calendar, trip reports, document tracking, and payment generation
- Personalized Internet portal to help site coordinators, clinical investigators, and CRAs better manage clinical trials over the Web
- Project and resource management

- A flexible audit trail engine
- Investigator and site profiling
- Activity and calendar management for CRAs and clinical sites
- Clinical trial status and management reports for study manager and CRAs
- Integrated payment tracking for sites and investigators
- Support for multiple accounts associated with a clinical protocol
- Support for multiple contracts associated with a clinical site
- Subject visit templates for study staff to better plan subject visits and promote protocol adherence
- Automatic tracking of subject status on completion of relevant visits, eliminating manual errors.
- Clinical trip report templates for CRAs to facilitate compliance with good clinical practice (GCP)
- Automated notification emails sent to the owner, reviewer, and approver of the trip reports
- Audit trail for reviews and approvals of trip reports
- Approver verification of clinical trip reports
- Mobile support for remote updates of clinical trip reports
- Support for the Siebel high-interactivity framework and Siebel Open UI framework
- Siebel Clinical Trial Management System Cloud Service for Software as a Service (SaaS) deployments
- Clinical operations integration for budget planning and tracking

Siebel Clinical was designed to allow CROs (clinical research organizations), pharmaceutical and biotech companies, and other clinical trial sponsors to:

- Deploy a Web-based clinical trial management system to internal and external users.
- Make better decisions throughout the clinical trials process, leading to more efficient use of resources and faster time to market.
- Increase productivity of CRAs and their managers by automating repetitive tasks and allowing real-time information sharing.
- Create sustainable competitive advantage by allowing customers to provide breakthrough service to sites and investigators.
- Provide a solution integrated with Siebel Pharma Sales and Siebel Pharma Service to allow customers to deploy one customer management system across the entire enterprise.

Siebel Clinical supports the 21 CFR Part 11 industry standard.

# Product Modules and Options for Siebel Clinical Trial System

You can purchase many Siebel Business Applications modules and use them with Siebel Clinical Trial Management System and Siebel Life Sciences. In addition, you can purchase the optional modules that are specific to Siebel Life Sciences to provide enhanced functionality for various business processes. For information about the optional modules to use with Siebel Life Sciences and Siebel Clinical Trial Management System, contact your Oracle sales representative.

This guide documents Siebel Life Sciences with the optional modules installed. In addition, the Sample database includes data for optional modules. If your installation does not include some of these modules, then your software interface differs from that described in some sections of this guide.

The exact configuration of Siebel Life Sciences screens and views depends on your company's configuration of Siebel Life Sciences. For more information about Siebel Life Sciences, see *Siebel Life Sciences Guide*. For introductory information about using the Siebel Life Sciences interface, see *Siebel Fundamentals*.

**NOTE:** The *Siebel Bookshelf* is available on Oracle Technology Network (http://www.oracle.com/technetwork/indexes/documentation/index.html) and Oracle Software Delivery Cloud. It might also be installed locally on your intranet or on a network location.

# 3 Setting Up Siebel Clinical

This chapter covers setting up Siebel Clinical. It includes the following topics:



## About Setting Up Siebel Clinical

This chapter lists the administrative tasks that are specific to Siebel Clinical. Use this chapter in combination with the main guide for performing administrative tasks, *Siebel Applications Administration Guide*.

*Siebel Applications Administration Guide* covers the setup tasks that are common to all Siebel Business Applications, such as using license keys, defining employees, and defining your company's structure. It also provides the information that you need to implement, configure, and monitor the Sales, Service, and Marketing products and to perform Data Administration and Document Administration tasks.

Some tasks listed in this chapter might replace tasks in *Siebel Applications Administration Guide*. Other tasks might be additional tasks. Make sure you review Table 3 on page 30 before following the procedures in *Siebel Applications Administration Guide*.

This guide assumes that you have already installed Siebel Clinical or completed an upgrade from another Siebel Business Application. If you have not, then refer to the Installation/Upgrade section of the *Siebel Bookshelf*, and click the links to the guides that are relevant to your company's implementation.

The Siebel database server installation script creates a Siebel administrator account that can be used to perform the tasks described in this guide. For information about this process, see the *Siebel Installation Guide* for the operating system you are using and *Siebel System Administration Guide*.

**CAUTION:** Do not perform system administration functions on your local database, as it can cause data conflicts, an overly large local database, or a large number of additional transactions to route.

# Configuring Properties for Siebel Clinical in Siebel Tools

User properties are object definitions that are added to an applet, business component, control, field, or list column to enable and configure specialized behavior. Some Siebel Clinical features are driven by user properties. You can customize these features through their respective user properties. With user properties, you can control UI behavior, change default settings or leave them as they are, and enable or disable features. For information about enabling and configuring the Siebel Tools object definitions required for Siebel Clinical, see Appendix B, "Developer's Reference for Siebel Clinical."

# Enabling or Disabling Siebel Open UI for Siebel Clinical

To enable or disable Siebel Open UI for Siebel Clinical, you must configure the EnableOpenUI parameter for the eClinicalObjMgr_enu Object Manager. Siebel Open UI is disabled by default. For information about configuring the Object Manager to enable Siebel Open UI, see the *Siebel Installation Guide* for the operating system you are using.

# Enabling Siebel Server Component Groups for Siebel Clinical

This system administration task describes how to activate the component groups that are required for Siebel Clinical.

### *To enable Siebel Server component groups for Siebel Clinical*

1. Navigate to the Administration - Server Configuration screen, then the Component Groups view.
2. Query for the Workflow Management Component Group.
3. On the Component Groups applet, click Enable.
4. Query for the EAI Component Group.
5. On the Component Groups applet, click Enable.
6. Navigate to the Administration – Server Management screen, then the Servers and Component Groups view.

7 Verify that the State value for the Workflow Management and EAI Component Groups is set to Online.

8 Navigate to Administration – Server Configuration screen, then the Enterprises and Synchronize view.

9 Click Synchronize.

10 Restart the Siebel Server.

# Activating Workflow Policies for Siebel Clinical

This system administration task describes how to activate the workflows and workflow policies required for Siebel Clinical. For a full list of workflows provided for Siebel Clinical, see Table 26 on page 264.

### *To activate the workflow policies for Siebel Clinical*

1 Navigate to the Administration - Business Process screen, then the Workflow Deployment view.

2 Query for all the workflows using the following criteria, and activate the workflows:

- Clinical*
- LS Clinical*

3 Verify that each activated workflow is added to the Active Workflow Processes list view at the bottom of the screen.

4 Navigate to the Administration - Runtime Events screen, click the cogwheel icon, and select Reload Runtime Events.

5 Navigate to the Administration - Business Process screen, then the Workflow Policies view, and perform the following steps:

a Query workflow policies for LS Clinical*

b Set the activation date to one day before today's date for all policies.

c Check that expiration date is NULL for all policies.

6 Navigate to the Administration - Server Management screen, then the Jobs view, and generate triggers for the workflow policies returned from your query as follows:

a Define a job for Generate Triggers component with the following parameters:

EXEC: True

Mode: ALL

Privileged User: <%SADMIN%>

Privileged User Password: <%PASSWORD%>

b Start the job and query until the status is Success.

7 From the srvrmgr command utility, create a component definition for the policy group LS Clinical Rollup as follows:

Component definition: LSCLIN

Component type: WorkMon

Component group: Workflow

Run mode: Background

Full name: LS Clinical

Description: Monitors LS Clinical Workflow Manager events

Parameter DfltTasks=1, GroupName=LS Clinical Rollup, SleepTime=30

**NOTE:** When working with component definition commands, launch and run the srvrmgr program for the enterprise; that is, do not start srvrmgr with the back slashes (/s) (or -s for UNIX).

The component alias must be unique across the enterprise, and must not be more than 30 characters in length. Also be careful not to use keywords in the component description, such as *for* or *component*, unless they are enclosed in quotes.

The component definition command starts a task to perform actions on LS Clinical Rollup group policy as a result of updates on the corresponding tables monitored by the database triggers.

The SleepTime parameter represents the time in seconds for processing requests.

The default value is 20 seconds. Setting the SleepTime user property to a low value or zero can have serious negative performance consequences.

8 Enter the following in the srvrmgr command utility to enable the LS Clinical Rollup component:

```
enable component definition LSCLIN
```

9 From the srvrmgr command utility, create a component definition for the LS Clinical Trip Report policy group as follows:

Component definition: LSCLIN_TRIP

Component type: WorkMon

Component group: Workflow

Run mode: Background

Full name: LS ClinicalTrip Report

Description: Monitors LS Clinical Trip Report Workflow Manager events

Parameter DfltTasks=1, GroupName=LS Clinical Trip Report, SleepTime=30

The component definition command starts a task to perform actions on LS Clinical Trip Report group policy as a result of updates on the corresponding tables monitored by the database triggers.

10 Enter the following in the srvrmgr command utility to enable the LS Clinical Trip Report component:

```
enable component definition LSCLIN_TRIP
```

11 Navigate to the Administration - Server Configuration screen, then the Synchronize view and click Synchronize.

12 Check that the Workflow Monitor Agent is running.

If it is not activated, then start the Workflow Monitor Agent task again.

13 Navigate to the Administration - Server Management screen, then the Tasks view.

14 Navigate to the Parameters view.

15 In the Tasks list, query for the Workflow Monitor Agent in the Component Field.

16 In the Task Parameters list, query for Action Interval in the Parameter field and set the value to 10.

# Configuring Web Services for Siebel Clinical

This task describes how to configure Web services for Siebel Clinical. For more information about configuring Web services, see *Integration Platform Technologies: Siebel Enterprise Application Integration*.

**NOTE:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide*.

### *To configure Web services for Siebel Clinical*

1 Navigate to the Administration - Web Services screen, then the Inbound Web Services view.

2 Query for the ClinicalSubject Inbound Web service.

3 On the Service Ports applet, update the Address field to point to your Web server, and configure the Language field.

4 Query for the SWILSClinicalQueryProtocolSite_SiteVisits Web service.

5 On the Service Ports applet, update the Address field to point to your Web server, and configure the Language field.

6 Query for the SWILSClinicalCreateSiteVisitGeoLocation Web service.

7 On the Service Ports applet, update the Address field to point to your Web server, and configure the Language field.

8 Click Clear Cache on the Inbound Web Services applet.

# Setting Up Mobile Integration for Clinical Trip Reports

For information about setting up mobile integration for clinical trip reports, see "Process of Setting Up Mobile Integration for Clinical Trip Reports" on page 192.

# Setting Up Siebel Clinical for Integration with a Third-Party Payments Application

For information about setting up Siebel Clinical for integration with a third-party payments application, see "Process of Setting Up Clinical Payments Integration" on page 229.

# Administrative Setup Tasks for Siebel Clinical

Table 3 lists the administrative setup procedures that are specific to Siebel Clinical and procedures that might differ from those of the other Siebel Business Applications. The table also directs you to documentation containing information about each task.

When setting up Siebel Clinical, use Table 3 in combination with the main resource, *Siebel Applications Administration Guide*.

Table 3. Siebel Clinical Administration Tasks

| Administrative Task | Description | For More Information |
|---|---|---|
| Managing accounts contacts in Siebel Life Sciences | ■ Activating workflows for accounts contacts<br>■ Enabling server components for accounts contacts<br>■ Generating column maps for accounts contacts list<br>■ Creating product data to appear in accounts contacts list | *Siebel Life Sciences Guide* |
| Creating a clinical program | ■ Creating protocols<br>■ Revising protocols<br>■ (Optional) Setting up regions<br>■ Defining a subject visit template | Chapter 4, "Setting Up Clinical Trials"<br>Chapter 5, "Administering Clinical Subjects and Clinical Visits"<br>Chapter 6, "Managing Sites and Contacts for Clinical Trials" |

Table 3. Siebel Clinical Administration Tasks

| Administrative Task | Description | For More Information |
|---|---|---|
| Managing sites | ■ Creating protocol site templates<br>■ Creating assessment templates for contacts and accounts<br>■ Maintaining contact and account information<br>■ Setting up contracts for sites | Chapter 6, "Managing Sites and Contacts for Clinical Trials" |
| Setting up clinical payments | ■ Setting up standard payment amounts in subject visit templates<br>■ Adjusting payment amounts and generating payments for sites | Chapter 8, "Setting Up and Making Clinical Payments" |
| Creating trip report templates | ■ Creating trip report templates<br>■ Approving trip report templates | Chapter 9, "Administering and Using Clinical Trip Reports" |
| Creating activity templates for projects | ■ Creating activity templates for projects | Chapter 10, "Managing Clinical Projects" |
| Importing data | ■ Importing data with Siebel Enterprise Integration Manager<br>■ Importing, extracting, and routing syndicated data<br>■ Charting denormalized syndicated data | *Siebel Life Sciences Guide* |
| Configuring Siebel Clinical | ■ Configuring user properties for business components<br>■ Configuring user properties for business services<br>■ Configuring applet properties<br>■ Configuring field properties<br>■ Configuring workflows<br>■ Customizing Web services | Appendix B, "Developer's Reference for Siebel Clinical" |

# About the My Team's Filter

The visibility filter is found on many screens. It provides a list of filters such as My Contacts, My Team's Contacts, and All Contacts. These filters determine the records that appear in the view.

The behavior of the My Team's filter varies from screen to screen. In some screens, this filter displays those records where the *primary* member of the team reports to the user. In other screens, the filter displays records where *any* of the team members reports to the user.

This behavior is determined in the business component by the Manager List Mode user property.

If the Manager List Mode user property is active and set to Team, then the My Team's filter displays all records where the user's subordinate is on the team but is not necessarily the primary member.

Table 4 lists the default setting of the Manager List Mode user property for some Siebel Clinical screens and business components.

Table 4. The Default Setting for the Manager List Mode Use Property

| Screen | Business Component | Manager List Mode |
|---|---|---|
| Accounts | Accounts | Inactive |
| Contacts | Contact | Inactive |
| Protocols | Clinical Protocol | Active |
| Site Management | Clinical Protocol Site | Active |

# Using Siebel Assignment Manager in Siebel Clinical

Siebel Assignment Manager allows the Siebel administrator to automatically assign tasks to specific people. To do this, however, the Siebel administrator must first define assignment rules for each task. For more information about using and implementing Siebel Assignment Manager, see *Siebel Assignment Manager Administration Guide*. For additional information about creating territories and running territory realignments, see *Siebel Territory Management Guide*.

This topic provides Siebel Assignment Manager information that is specific to Siebel Clinical.

# Predefined Assignment Objects

Some of the predefined assignment objects and underlying criteria described in *Siebel Assignment Manager Administration Guide* have been modified in Siebel Life Sciences to support pharmaceutical business processes. Table 5 describes the assignment objects that are changed in Siebel Life Sciences.

**NOTE:** Assignment Item Type Industry Name is not supported. This assignment rule is defined for Siebel Business Applications and currently conflicts with Siebel Life Sciences assignment rules. Siebel Life Sciences uses the assignment item type SIC (Standard Industrial Classification) Code.

Table 5. Assignment Objects Changes in Siebel Life Sciences

| Assignment Object | Modifications |
|---|---|
| Account | The assignment criteria SIC Code has been renamed Account Class of Trade.<br>Its assignment criteria include:<br>■ Account City State Country<br>■ Account Brick<br>Account Brick source table has been changed to S_CON_ADDR and source column has been changed to BRICK_ID. |
| Contact | This assignment object was created specifically for Siebel Life Sciences and is not described in *Siebel Assignment Manager Administration Guide*.<br>Its assignment criteria include:<br>■ Contact<br>■ Contact Medical Specialty Code<br>■ Contact Wildcard<br>■ Contact City<br>■ Contact State<br>■ Contact Country<br>■ Contact Zip Code<br>■ Contact City State Country<br>■ Contact Brick<br>■ Medical Specialty<br>■ Organization<br>■ Position |

## Contact Assignments in Siebel Clinical

In most Siebel Business Applications, contact assignment is based on primary address. This process is different for Siebel Life Sciences. A contact in Siebel Life Sciences can have multiple addresses, and each representative on the contact's sales team can indicate a different primary address for the same contact. For this reason, do not base the contact assignment on the primary address.

For example, Representative A might indicate a hospital address as the primary address, while Representative B might indicate a private-office address as primary. In the All Contacts and My Team's Contacts views, the primary address that appears is the one assigned by the primary team member. For more information, see "Predefined Assignment Objects" on page 33.

## Contact Denormalization Mode in Siebel Life Sciences

Contact Denormalization mode in Siebel Life Sciences differs from the description in *Siebel Assignment Manager Administration Guide* in the following ways:

- It denormalizes positions from the account team table to the contact team table for all contacts *directly* affiliated with an account. Users can specify a direct affiliation between a contact and an account by selecting:
  - The Direct field in the Account Affiliations view of the Contacts screen.
  - The Direct field in the Contact Affiliations view of the Accounts screen.

  For more information, see *Siebel Life Sciences Guide*.
- It does *not* denormalize positions from the opportunity team table to the contact team table.
- It must be run after separately running batch mode jobs for contacts and accounts. Run the separate batch mode jobs in the following order:
  a. Contacts
  b. Accounts
  c. Contact Denormalization

Contact Denormalization in Siebel Life Sciences has the following additional important rules, requirements, and exceptions:

- **Running Contact Denormalization mode in Dynamic mode.** To activate the Contact Denormalization Policy, set the expiration date to a future date or leave it blank. Then generate the database triggers by running Generate Triggers.
- **Running Contact Denormalization mode in Batch mode**. Remember to specify the following parameters:

  Object Name=Contact Denormalization
  Assignment Mode=Denorm
- **Contact Denormalization mode does not evaluate rules.** Therefore, it is not necessary to create a rule-based object for Contact Denormalization to run Assignment Manager in this mode. Also, because it does not evaluate rules, Contact Denormalization mode does not set the primary team position.

- **Contact Denormalization assigns contacts to employees who are on the Account Team for which the contacts are directly affiliated.** In order to reduce the number of contact-to-position relationship (S_POSTN_CON) rows routed to the manager's local database, the value of the ASGN_DNRM_FLG field is set to “N”. With this default setting, the contacts that team members have been assigned by the Contact Denormalization process are not visible to managers on their local databases. However, if you want managers to see all contacts that are assigned to their team members, regardless the assignment method, then set the ASGN_DNRM_ “Y.”

# Setting Up Mobile Web Clients for Position Rollup

In Siebel Clinical, a CRA (clinical research associate) can create sites and assign employees to positions at the site level. When the CRA clicks the position rollup button, these positions become visible at the region and protocol levels. Typically, the CRA works in a disconnected mode, on a laptop computer.

The administrator must set up each mobile Web client to allow position rollups. The setup requires the following steps in Siebel Clinical:

- The administrator exports workflow processes and data maps from the server database to XML files.
- The administrator connects to a local client, imports the XML files to the client database and activates the workflow processes on the local client.

**NOTE:** Users of the local client must have Workflow Process Definition, EAI DATA Map View, and EAI Data Map Editor in their user responsibilities to accept imported workflow processes and data maps.

## Exporting Workflow Processes to the Local Client

Complete the procedure in this topic to export the workflow processes to the local client.

### *To export the workflow processes to the local client*

1. Export the Clinical Assign Position From Region and Clinical Assign Position From Site workflows to XML files.
2. Import the two XML files to the local client and activate the workflows.

   For information about exporting and importing workflow processes, see *Siebel Business Process Framework: Workflow Guide*.

## Exporting DTE Data Maps From the Server Database to an XML File

Complete the procedure in this topic to export DTE data maps from the server database to an XML file.

### *To export DTE data maps from the server database to an XML file*

1. In Siebel Clinical, connect to the server database.
2. Navigate to the Administration - Integration screen, then the Data Maps view.
3. In the Integration Object Map list, query for Clinical*.

   The query returns the following records: Clinical Region Position to Protocol Position Map, Clinical Site Position to Account Position Map, Clinical Site Position to Protocol Position Map, and Clinical Site Position to Region Position Map.
4. Click the cogwheel icon, and select Export Data Map.
5. In the dialog box, check Export All Rows in Current Query and click Export.
6. In the dialog box, select Save to Disk, select a location, and save the data maps as PositionRollupDataMap.xml.

## Importing DTE Data Maps to a Local Client From an XML File

Complete the procedure in this topic to import DTE data maps to a local client from an XML file.

### *To import DTE data maps to a local client from an XML file*

1. In Siebel Clinical, connect to the local client.
2. Navigate to the Administration - Integration screen, then the Data Maps view.
3. In the Integration Object Map list, click the cogwheel icon, and select Import Data Map.
4. In the dialog box, select Browse and find PositionRollupDataMap.xml.

   For information about creating this file, see “Exporting DTE Data Maps From the Server Database to an XML File” on page 35.
5. In the Integration Object Map list, query for Clinical*Position*.

# Setting Up Left-Hand Navigation

The procedures in this guide assume that you do not use left-hand navigation. However, you can set up left-hand navigation for applications that use Siebel Open UI. For more information about left-hand navigation and about implementing it, see *Siebel Fundamentals for Siebel Open UI*.

# 4 Setting Up Clinical Trials

This chapter describes how to set up a clinical program, protocol, region, and site in Siebel Clinical. It includes the following topics:



## About Setting Up Clinical Trials

This chapter describes the main steps involved in carrying out a clinical trial using Siebel Clinical. Following the procedures given in this chapter you can:

- Create a clinical program and clinical protocols.
- Set up document tracking at the protocol, region, and site levels, and for accounts and contacts.
- Set up and revise subject visit templates for a protocol.
- Enter data on accounts, sites, and contacts.
- Screen and enroll subjects.
- View charts showing subject status and subject enrollment rates.
- Review payments made to the protocol.

Figure 1 illustrates the important hierarchical relationship of programs, protocols, regions, and sites. In this example, the Bristol General Hospital in the USA region is participating in the AMXN 98447 protocol, which is being carried out as part of the Anemia program.


Figure 1. Siebel Clinical Hierarchical Relationships

# Scenario for Clinical Trials

This topic gives one example of how clinical trials might be used. You might use clinical trials differently, depending on your business model.

The clinical director and the study manager, working for a CRO (clinical research organization), or pharmaceutical, biotech, or medical device company, have administrator responsibilities in Siebel Clinical to:

- Set up a new program for the treatment study.
- Create one or more protocols designed to assess the safety and efficacy of certain compounds in the treatment of the disease.
- Set up the geographic regions where the protocols are to be carried out.
- Compile a list of documents that are critical to the study and implement tracking at the protocol, region, and site levels, and for accounts and contacts.
- Create a subject visit template to facilitate consistent application of the protocol across sites and subjects. This template is used to set up subject visit schedules and activities according to the guidelines laid out in the protocol.

  When the program, protocol, and subject visit templates have been set up, the CRAs (clinical research associates) who are the end users of the Siebel Clinical product do the following:

  - Enter data about the:
    - Sites where the protocols are carried out.
    - Members to be assigned to the teams at the site, region, and protocol levels.
    - Accounts, institutions such as hospitals and clinics where the studies are conducted.

- Contacts, site personnel such as investigators, site coordinators, and nurse practitioners who carry out the protocols.
- Subjects recruited for the clinical trial.

- Screen and enroll subjects and, if necessary, rescreen the subjects.

- Use the subject visit template to set up detailed schedules for the subjects' visits to the sites.
- Track required documents at the protocol, region, or site level, or for accounts or contacts.

**NOTE:** The tasks of entering subject data, and setting up screening and enrollment schedules for subject visits, can also be performed by the site personnel using Siebel Site Portal. For more information about Siebel Site Portal, see *Siebel Life Sciences Portals Guide.*

At various times after subjects have been enrolled in the trial, the clinical director, study manager, or CRAs can use the charting features of Siebel Clinical to review the progress of the trial. Two informative metrics are the subject status and subject enrollment rate. These are plotted for an individual site, for a region, and for the protocol.

# Process of Managing Clinical Trials

This topic details sample tasks often performed by administrators and end users when managing clinical trials. Your company might follow a different process according to its business requirements.

The tasks in this topic must be performed in the order presented. For example, a protocol must exist before its subject visit template can be created.

## Administrator Procedures

The following list shows tasks administrators typically perform to manage a clinical trial:

1. "Creating Clinical Programs" on page 40
2. "Setting Up Clinical Protocols" on page 40
3. "Tracking and Revising Team Assignment History" on page 43
4. "Creating and Revising Versions for Clinical Protocols" on page 44
5. "Associating Clinical Protocols with Accounts" on page 45
6. (Optional) "Setting Up Clinical Regions" on page 46
7. "Associating Clinical Regions with Accounts" on page 49

## End-User Procedures

The following list shows tasks end users typically perform when managing a clinical trial. The procedures are performed by the CRA (clinical research associate) at the site level:

1. (Optional) "Creating Accounts and Contacts for Clinical Trials" on page 49
2. "Creating Sites for Clinical Trials" on page 51
3. "Associating Sites with Accounts" on page 55

# Creating Clinical Programs

The clinical program is the highest-level initiative in Siebel Clinical. Protocols, regions, sites, and subjects must be associated with a program. Multiple regulatory applications can be associated with a program.

This task is a step in "Process of Managing Clinical Trials" on page 39.

### *To create a clinical program*

1. Navigate to the Clinical Programs screen, then the Program List view.
2. In the Program list, create a new record and complete the necessary fields.

   **NOTE:** Before you can create an application, the associated product must be correctly defined. For more information about defining products, see *Siebel Life Sciences Guide*.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Application | A multi-value field containing details of the application.<br>**Filed.** Whether the application has been filed with the specified regulatory agency.<br>**Indication.** The clinical indication for the application.<br>**Number.** The number assigned to the application when submitted to the regulatory agency, for example the (A)NDA or IND number.<br>**Product.** This field must be completed before a protocol can be created for the program.<br>**Sub-Type.** Who filed the application. For example, a company or an investigator.<br>**Type.** The type of application, such as CTN, IND, or CTX. |
| Mechanism | Partners associated with the clinical program. |
| Program | The name of the clinical program. |

3. (Optional) Drill down on the Program field of the new record and associate files with the clinical program.

# Setting Up Clinical Protocols

Multiple protocols can be associated with a program. When you have created a protocol record, you can also add extra information about the protocol, such as financial information, central lab information, and so on.

This task is a step in "Process of Managing Clinical Trials" on page 39.

### *To set up a clinical protocol*

1 Navigate to the Administration - Clinical screen, then the Protocol List view.

2 In the Protocol list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| # Planned Sites | Number of sites planned for the protocol. |
| # Planned Subjects | Number of subjects planned for the protocol. |
| Actual End Date | The date on which the study concludes. |
| Actual Start Date | The date on which the study begins. |
| Approval Date | The date on which the protocol was approved by the regulatory authority. |
| Central Lab | The name of the laboratory associated with the study. This is entered through the Accounts screen. |
| CRO | Name of the clinical research organization that is sponsoring the trial. |
| Currency Code | The currency that is used to display the payments, costs, and budgets for the protocol. The default value is USD (United States dollars).<br>**NOTE:** You must specify the Currency Code for the protocol. |
| Design | Information about the type of study. |
| Exchange Date | The date that determines the exchange rate of the currency used. By default, the exchange date for the protocol is the date the protocol is created. |
| Objective | The objective for the clinical trial. |
| Phase | Phase of clinical trial, such as Phase I, II, or III. |
| Planned End Date | The planned end date for the study. |
| Planned Start Date | The planned start date for the study. |
| Product | Only products that have been associated with the clinical program, through the Application field in the Program List view, can be selected from the Clinical Product and Indication dialog box. For more information about creating a clinical program, see "Creating Clinical Programs" on page 40. |
| Program | Name of the program for the clinical trial. |
| Protocol # | Identifying number assigned to the protocol. |

| Field | Comments |
|---|---|
| Regions Required | The flag to indicate the sites for this protocol must belong to a region. For information about regions, see "Setting Up Clinical Regions" on page 46.<br><br>When this field is selected, you cannot create sites directly under protocols. You must create regions first and then create sites that are associated with regions. |
| Sponsor | The clinical trial sponsor. |
| Status | The status of the protocol, such as planned, in progress, or completed. |
| Team | Enter the names of those who need access to the protocol, the study manager and others who monitor the clinical trial. For more information, see Step 3. |
| Title | Descriptive title for the protocol. |
| Type | Purpose of the protocol. |
| Withholding Amount | The amount to be withheld from each of the payments to the investigators until the trial is complete. This value can be overwritten at the region and site levels. |
| Withholding % | The percentage to be withheld from each of the payments to the investigators until the trial is complete. This value can be overwritten at the region and site levels. |

3 To add team members to the protocol, click the select button in the Team field to open the Team dialog box, and complete the following steps:

a Move the record for an available team member to the list of selected team members.

b Click Position Rolldown.

Multi-selected team members are added to the protocol as well as to all regions and sites belonging to the protocol.

c Click OK.

Each time a member is added to the team of a protocol, a tracking record is created in the Team History view with a proper start date for this Tracking record. For more information, see "About Automatically Assigning Team Members to a Protocol Using the Position Rolldown Button" on page 44.

If a member is removed from the team of a protocol, then the end date of this record is automatically filled in. For more information, see "About Removing Team Members From the Team of a Protocol" on page 44.

4 Drill down on the protocol number field, and navigate to the More Info view to add more information.

5 Drill down on the protocol number field, and navigate to the Team History view to view the details of the team member that was automatically added to the protocol in the previous step.

From the Team History view you can administer and track team members who have worked on the protocol. It also provides details about what the role was as well as the start and end dates. To administer and track the history of team members who have worked on a protocol and to determine what their role was, see "Tracking and Revising Team Assignment History" on page 43.

# Tracking and Revising Team Assignment History

A typical clinical trial can span many months to years and often requires changes of study members. Clinical organizations are required by rules and regulation to keep records of study team assignments, and to promote tight access controls so that only those who are assigned roles and responsibilities for a trial have the proper access to trial data.

When a person is no longer part of the clinical trial team, all access rights to the trial data cease as well. When necessary, the study manager can also manually create a tracking record independent of the team assignment. Similar functionality applies to region team and site team assignment. The Team History view allows you to administer and track who has worked on the protocol, region, or site. It also provides details about what the role was as well as the start and end dates.

This task is a step in "Process of Managing Clinical Trials" on page 39.

### *To revise team assignment history*

1 Navigate to the Administration - Clinical screen, then the Protocol List view.

2 In the Protocol list, drill down on the protocol number field of the protocol for which you want to create a new team assignment history.

3 Navigate to the Team History view.

4 In the History list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Role | Select the value that best describes each individual's role. |
| Start Date | If a member is added from the team of a protocol (either manually or by using the Position Rollup mechanism), then the start date is populated with the system date, and the end date is blank. |

| Field | Comments |
|---|---|
| End Date | If a member is removed from the team of a protocol (either manually or through reverse of Position Rollup mechanism), then the end date of the team member's record is auto-populated with the system date. The system date overrides whatever date exists in the End Date field if the record is not set to read-only. |
| Lock Record | When checked, the record becomes read-only, and the End Date field becomes a required field. |

### About Automatically Assigning Team Members to a Protocol Using the Position Rolldown Button

When a team member is added to a protocol, click the Position Rolldown button to allow the member to be added to all regions and all sites under the protocol. You can add a member to the team only once.

When you use the Position Rolldown button to add a member to the team of a protocol, a record is created, where applicable, in each of the Team History views for all regions and all sites belonging to the protocol. The Position Rolldown mechanism automates the addition of team members to the Site Team History and Region Team History views as if they had been assigned manually.

### About Removing Team Members From the Team of a Protocol

When you remove a team member from the protocol, the team member is removed from either the protocol, or from all protocols, regions and sites belonging to the protocol.

When a member is removed from the team of a protocol (either manually or through Position Rollup or Position Rolldown), the End Date field of the team member's record, if present, is updated with the system date. However, if the record is already read-only, then the initial value in the End Date field is not updated. The Position Rolldown mechanism automates the update of the End Date field of the assignment records as if they are manually removed from the team of the sites and regions.

**NOTE:** A prompt appears asking whether to remove the member from only the protocol or from all protocols, regions, and sites belonging to the protocol.

# Creating and Revising Versions for Clinical Protocols

Protocol versions can be tracked and managed using Siebel Clinical. The study manager can create a tracking record for the original protocol as well as for each subsequent version.

This task is a step in "Process of Managing Clinical Trials" on page 39.

#### *To create a version for a clinical protocol*

1 Navigate to the Administration - Clinical screen, then the Protocol List view.

2 In the Protocol list, drill down on the protocol number field of the protocol for which you want to create a new protocol version.

3 Navigate to the Protocol Versions view.

4 In the Protocol Versions list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Original Version | If this is the first version of the protocol, then check this field. If this field is checked, then the Amendment Version field becomes read-only. |
| Amendment Version | The version number of the protocol version. For example, Version 1, Version 2, and so on. |
| Date | The date on which the new version was approved. |

# Associating Clinical Protocols with Accounts

An account is the institution from which clinical trials are managed. Typically, it is the facility where the investigators conduct the trials. IRBs (institutional review boards), central labs, CROs (clinical research organizations), and other subcontractors can also be tracked as accounts. A clinical protocol can be associated with multiple accounts.

This task is a step in "Process of Managing Clinical Trials" on page 39.

### *To associate a clinical protocol with an account*

1 Navigate to the Administration - Clinical screen, then the Protocol List view.

2 In the Protocol list, drill down on the protocol number field of the protocol that you want to associate with an account.

3 Navigate to the Accounts view.

4 In the Accounts list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments | Mandatory |
|---|---|---|
| Account | The name of the account. | Yes |
| Central IRB | A flag to indicate whether a central institutional review board is used across all sites. | No |

| Field | Comments | Mandatory |
|---|---|---|
| Regional CRO | A flag to indicate whether a clinical research organization is providing services to all sites in the clinical region. | No |
| Type | The type of account, such as IRB, CRO, or vendor. The Type pick list is configurable. | Yes |

# Setting Up Clinical Regions

Clinical trials are often global, taking place in multiple countries. The region level in Siebel Clinical allows you to track and view study data by country and region.

Regions are optional for protocols. However, if you choose to use regions by selecting the Regions Required field in the protocol record, then each site associated with the protocol must belong to a region. One of the advantages of using regions is that it provides another way of grouping sites and subjects. For example, you can chart subject enrollment by region in addition to by protocol and by site.

**NOTE:** You cannot create regions for a protocol unless the Regions Required field has been selected for the protocol. For more information, see the description of the Regions Required field in "Setting Up Clinical Protocols" on page 40.

This task is a step in "Process of Managing Clinical Trials" on page 39.

### *To set up clinical regions*

1 Navigate to the Administration - Clinical screen, then the Region List view.

2 In the Region list, create a new record and complete the necessary fields.

Create a region record for each country or geographical area where there are or will be sites participating in the protocol.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Currency Code | The currency that is used to display the payments, costs, and budgets in the Regions screen. The default value is USD (United States dollars).<br><br>**NOTE:** You must specify the currency code for each region if multiple currencies are used for the trial. |
| Exchange Date | The date that determines the exchange rate of the currency used. By default, the exchange date for the region is the date the region is created.<br><br>This date can be changed in response to changes in currency rates. However, changes made to the exchange date at the region level take effect only when the exchange date also changes at the system level. For more information, see *Siebel Applications Administration Guide*. |
| No Site Info | Select this field when there is no site information available under a region. Only summary information about site enrollment is available for such a region. |
| Protocol # | Only protocols where regions are required are listed in the Pick Protocol dialog box. |
| # Planned Sites | Number of sites planned for the region. |
| # Planned Subjects | Number of subjects planned for the region. |
| Protocol Region | A name for the region. This is automatically filled in with the protocol number and the region name. |
| Region | Geographic region to which the site belongs. |
| Team | Team members associated with the protocol to which the region belongs. For more information, see Step 3. |
| Withholding Amount | The amount to be withheld from each of the payments to the investigators until the trial is complete. The default value is the Withholding Amount field for the protocol. However, the Withholding Amount field for the protocol can be overwritten in this field at the region level. |
| Withholding % | The percentage to be withheld from each of the payments to the investigators until the trial is complete. The default value is the Withholding % field for the protocol. However, the Withholding % field for the protocol can be overwritten in this field at the region level. |

3 To add team members to the region, click the select button in the Team field to open the Team dialog box, and complete the following steps:

   a Move the record for an available team member to the list of selected team members.

   b Click Position Rolldown.

      Multi-selected team members are added to all the site teams of this region.

      **NOTE:** The Position Rolldown button for region applies only to the sites below a region.

   c Click Position Rollup.

      Multi-selected team members are added to the protocol to which the region belongs. To administer and track the history of team members who have worked on a protocol in a region and what their role was, see "Tracking and Revising Team Assignment History" on page 43.

   d Click OK.

4 (Optional) Drill down on the Region field, and navigate to the More Info view to add more information.

## About Automatically Assigning Team Members Using the Position Rollup and Rolldown Buttons

When you use the Position Rolldown and Position Rollup button, a record is created, where applicable, in each of the Team History views for the protocol and all sites belonging to the region. The Position Rolldown mechanism automates the addition of team members to the Team History view for sites and the Team History view for protocols as if they had been assigned manually. To remove a team member from the protocol, see "About Removing Team Members From the Team of a Protocol" on page 44.

## Creating Assignment Team History for Regions

The Team History view allows you to administer and track who has worked in the region. It also provides details about the roles as well as the start and end dates.

### *To create assignment team history for a region*

1 Navigate to the Administration - Clinical screen, then the Region List view.

2 In the Region list, drill down on the Region field of the region for which you want to create a new team assignment history.

3 Navigate to the Team History view.

4 In the History list, create a new record and complete the necessary fields.

# Associating Clinical Regions with Accounts

An account is the institution from which clinical trials are managed. Typically, it is the facility where the investigators conduct the trials. IRBs (institutional review boards), central labs, CROs (clinical research organizations), and other subcontractors can also be tracked as accounts. A clinical region can be associated with multiple accounts.

This task is a step in "Process of Managing Clinical Trials" on page 39.

### *To associate a clinical region with an account*

1. Navigate to the Administration - Clinical screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region that you want to associate with an account.
3. Navigate to the Accounts view.
4. In the Accounts list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments | Mandatory |
|---|---|---|
| Account | The name of the account. | Yes |
| Central IRB | Select this field if a central institutional review board is used across all sites. | No |
| Regional CRO | Select this field to indicate that a clinical research organization is providing services to all sites in the clinical region. | No |
| Type | The type of account, such as IRB, CRO, or vendor. The Type pick list is configurable. | Yes |

# Creating Accounts and Contacts for Clinical Trials

An *account* is the institution from which clinical trials are managed. Typically, it is the facility where the investigators conduct the trials. More than one site can be associated with an account and one account can carry out multiple protocols. IRBs (institutional review boards), central labs, CROs (clinical research organizations), and other subcontractors can also be tracked as accounts.

*Contacts* is the term used for personnel working at clinical sites. This includes the investigators, typically medical professionals who are also researchers and site coordinators, who might be the practicing nurses administering the treatment plan according to the clinical protocol.

Bulk loading of data on accounts and contacts is generally performed by the Siebel administrator, but end users can create and modify these records as needed. For information about importing data into your Siebel Life Sciences database, see *Siebel Life Sciences Guide*.

This task is a step in "Process of Managing Clinical Trials" on page 39.

## Creating Accounts

Complete the procedure in this topic to create an account.

### *To create an account*

1 Navigate to the Accounts screen, then the Accounts List view.

2 In the Accounts list, create a new record and complete the necessary fields.

To access more fields, click the show more button in the account form.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Account Type | Hospital, Clinic, IRB, and so on. |
| Address Line 1 | Allows you to add addresses for the account by picking from existing addresses or by entering new addresses. Avoid duplicating addresses by checking if the address exists before entering a new one. |
| Site | Description of the location or function of the account, such as headquarters, corporate, or San Francisco. |
| Synonyms | Allows you to refer to accounts in the way that you prefer. For example, an account named A/B Products, Inc., might have the following synonyms: AB, A/B, and AB Products.<br><br>When you search for an account or enter an account in another part of your Siebel Business Application, you can use a synonym instead of the actual name. |
| Team | Multiple users can be assigned to the account team. The team member who creates the account record is indicated as primary team member. |

3 Navigate to views, such as Activities, Addresses, and so on to add more information to the account record.

For more information about creating and maintaining account affiliations, see *Siebel Life Sciences Guide*.

## Creating Contact Records

Complete the procedure in this topic to create a contact record.

### *To create a contact record*

1 Navigate to the Contacts screen, then the Contacts List view.

2 In the Contacts list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| My Address | The contact can have more than one address. One address must be specified as primary. Each CRA (clinical research associate) assigned to the contact can specify a different address as primary. For example, one CRA might specify a private office as the primary address, while another CRA might specify a hospital department as the primary address. |
| Team | Multiple CRAs can be assigned to the contact. The team member who created the record is indicated as primary. |

3 Add or associate additional information with the contact record, using the other views on the screen.

For example, use the Relationships view to associate site coordinators and other site personnel with the contact. For more information about creating and maintaining contact records, see *Siebel Life Sciences Guide*.

# Creating Sites for Clinical Trials

The *site* is the group at an account, headed by a principal investigator, who carries out a particular protocol. In Siebel Clinical, a separate site record must exist for each unique combination of a protocol, account, and principal investigator.

This task is a step in "Process of Managing Clinical Trials" on page 39.

### *To create a site for clinical trial*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Account | The institution where the protocol is to be carried out. |
| Currency Code | The currency that is used to display the payments, costs, and budgets for the site. |

| Field | Comments |
|---|---|
| Exchange Date | The date that determines the exchange rate of the currency used. By default, the exchange date for the site is the date the site is created.<br><br>This date can be changed in response to changes in currency rates. However, changes made to the exchange date at the site level take effect only when the exchange date also changes at the system level. For more information, see *Siebel Applications Administration Guide*. |
| Last Completed Visit Date | Select this field to use the last completed clinical visit date for rescheduling subject visits.<br><br>Deselect this field to prompt the user to enter a new start date for rescheduled visits. All uncompleted subject visits are rescheduled using the new date. |
| No Subject Info | Select this field when there is no subject information available for a site. Only summary information about subject enrollment is available for such a site. |
| PI Last Name | Last name of the principal investigator.<br><br>If an account has already been specified for the site, then click the Affiliated Contacts button in the Pick Contacts dialog box to view only those contacts who are affiliated with the account. |
| Protocol # | Select from list of existing protocols in the Pick Protocol dialog box. |
| Region | If regions are required for this protocol, then enter a region name. |
| Site # | The number that is to be assigned to the site. This field is not required when the Status field for the site is Planned or Not Initiated. This field becomes required after a site has been initiated. |
| Status | Planned, Initiated, Enrolling, and Closed. A state model is preconfigured to make sure structured state transition. |
| Team | The Primary field is populated for the creator of the site record, and can be changed only by the manager of the team through the My Team's Sites view. It is recommended that resource management is a manager's responsibility. For more information, see Step 3. |
| Versions | For more information, see Step 4. |
| Withholding Amount | The amount of the total payment to be withheld from the investigators until the trial is complete. The default value is that of the region or protocol, but can be overwritten at the site level. |
| Withholding % | The percentage of the total payment to be withheld from the investigators until the trial is complete. The default value can be set at the region or protocol level, but can be overwritten at the site level. |

3 To enter team members, click the select button in the Team field, select a team member in the Team picklist and click OK.

If you multi-select team members and click Position Rollup, and if the Regions Required field is selected, then the team members are added to the region that the site belongs to and are added to the protocol to which the site belongs.

4 Click the select button in the Versions field and complete the following steps:

a Select the version for the subject visit template to be used at the site.

The versions are filtered to display only the templates related to your protocol.

b Enter a date in IRB Approval Date field for the selected version.

The template version cannot be activated without the IRB (institutional review board) approval date.

c Select the Active field to make the selected version the active version at the site.

Only one version can be active at a time. The active template is used when activities are generated for a subject. For more information about protocol versions, see "Tracking and Revising Team Assignment History" on page 43.

**NOTE:** The IRB Approval Date must be entered before the template can be activated.

5 Create records for the principal investigator and other key site personnel.

For information, see "Creating and Updating Sites, Contacts, and Accounts" on page 95.

6 (Optional) Drill down on the site number field, and navigate to the More Info view to add more information.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Address | Select one of the principal investigator's addresses as the site address. |
| Contract Amount | Lists the sum of all contract amounts for the site. This field is read-only. For more information, see "Associating Contracts with Sites" on page 92. |
| # Early Terminated | The number of subjects who have terminated the study before it has been completed. |
| Earned To Date | The amount of money earned to date by the investigators. |
| First Subject Enrolled | The date that the first subject was enrolled to the study. (This field is automatically rolled-up from the subject data.) |
| Last Subject Off Study | The date that the last of the subjects has completed the study. (This field is automatically rolled-up from the subject data.) |
| Paid To Date | The amount of money paid to date to the investigators. |
| # Screen Failure | Number of subjects that have failed the screening. |

| Field | Comments |
|---|---|
| Primary Site Address | This field sets the primary site location for the study in Siebel Clinical, and is populated by the Pick Location applet. The Pick Location applet displays all addresses that have been defined for the site.<br><br>This field is required for integration with Oracle Clinical, and is used to populate the site address when the site is created in Oracle Clinical. |
| Activate for Synchronization | This field is required for integration with Oracle Clinical. When this field is checked, it triggers the sending of a new integration object for the protocol site to Oracle Clinical. The integration object creates the site in Oracle Clinical, or updates the site, if it already exists.<br><br>This field is read-only until the following conditions are met:<br><br>■ The Synchronize Active Study Sites field of the protocol is set to true.<br><br>■ The Primary Site Address field is populated. |

## About Automatically Assigning Team Members to a Site Using the Position Rollup Button

When a member is added to the team for a site (either manually or through the Position Rollup mechanism), a record is created in the Team History view, with the Start Date field set to the system date by default, and with a blank End Date field. To remove a team member from the protocol, see "About Removing Team Members From the Team of a Protocol" on page 44.

## Creating Assignment Team History for Sites

The Team History view allows you to administer and track who has worked on the site. It also provides details about the roles as well as the start and end dates.

### *To create assignment team history for a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to create a new team assignment history.
3. Navigate to the Team History view.
4. In the Team History list, create a new record and complete the necessary fields.

### About Removing Team Members From the Team of a Site

When a member is removed from the team of a site (either manually or through Position Rollup), the End Date field of the team member's record, if present, is updated with the system date. However, if the record is already read-only, then the initial value in the End Date field is not updated. The Position Rollup mechanism automates the update of the End Date field of the assignment record as if it was manually removed from the team.

**NOTE:** A prompt appears asking whether to remove the member from only the site or from all sites, regions, and protocols belonging to the site including both these particular sites as well as all other sites within this protocol that include this user as a team member.

# Associating Sites with Accounts

An account is the institution from which clinical trials are managed. Typically, it is the facility where the investigators conduct the trials. IRBs (institutional review boards), central labs, CROs (clinical research organizations), and other subcontractors can also be tracked as accounts. A clinical site can be associated with multiple accounts.

This task is a step in "Process of Managing Clinical Trials" on page 39.

### *To associate a site with an account*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site that you want to associate with an account.
3. Navigate to the Accounts view.
4. In the Accounts list, create a new record and complete the necessary fields.

# 5 Administering Clinical Subjects and Clinical Visits

This chapter covers administering clinical subjects and clinical visits. It includes the following topics:

# About Subject Visit Templates

Subject visit templates allow you to set up a clinical visit schedule using the clinical protocol. The template is then used to generate screening, rescreening, and enrollment schedules for each subject, according to the subject's screening, rescreening, and enrollment dates.

If the protocol is amended, then you must create new versions of the subject visit template to reflect the modifications made to the protocol.

# Process of Defining Subject Visit Templates

To define a subject visit template for scheduling subject visits, perform the following tasks:

- "Creating Subject Visit Templates" on page 58
- "Defining Versions for Subject Visit Templates" on page 59
- "Defining Subject Visits" on page 59
- "Defining Planned Subject Visits" on page 63
- "Defining Activities for Subject Visits" on page 63

## Creating Subject Visit Templates

This topic describes how to create a subject visit template.

This task is a step in "Process of Defining Subject Visit Templates" on page 58.

### *To create a subject visit template*

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Subject Visit Templates list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Name | Name of the new subject visit template. |
| Protocol # | Protocol to which this subject visit template is to be associated. Select from the list of existing protocols in the Pick Protocol dialog box. |
| Title | Tied to the protocol number field. |
| Comments | Text field for comments. |

# Defining Versions for Subject Visit Templates

This topic describes how to version a subject visit template.

This task is a step in "Process of Defining Subject Visit Templates" on page 58.

### *To define a version for a subject visit template*

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Template Versions list, create a new template version record or select a version that you have created using the Versions view.

   Some fields are described in the following table.

| Field | Comments | Mandatory |
|---|---|---|
| Version | The version of the subject visit template. | Yes |
| Start Date | The start date for creating the subject visit template. | No |
| End Date | The date by which the subject visit template must be completed. | No |
| Status | The status of the subject visit template. The following values are provided:<br>■ In Progress<br>■ Approved<br>■ Obsolete<br>When a new version of the subject visit template is created, the Status is populated with a value of In Progress. | Yes |
| Approval Date | Date on which this version of the subject visit template was approved. | No |
| Change Summary | A summary of changes made to this version of the subject visit template. | No |
| Comments | Text field with a maximum character length of 250 characters. This field is not copied when the subject visit template is copied. | No |

# Defining Subject Visits

This topic describes how to define subject visits in a subject visit template.

This task is a step in "Process of Defining Subject Visit Templates" on page 58.

### *To define subject visits*

1 Navigate to the Administration - Clinical screen, then the Visit Templates view.

2 For the new template version record, create a visit record in the Visits list for each visit that a subject is to make to the site.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| # CRF Pages | Number of CRF (case report form) pages. |
| Lead | The lead time from the start date. The start date is defined in the Schedule Date field when scheduling the subject. |
| Lead Units | Units for lead time. |
| Max | The time after the lead time that the visit can take place.<br>For example, if Max is 2 and Min/Max Units is days, then the visit can take place up to two days after the scheduled visit.<br>Do not leave this field blank. |
| Min | The time before the lead time that the visit can take place.<br>For example, if Min is 1 and Min/Max Units is days, then the visit can take place one day before the scheduled date.<br>Do not leave this field empty. |
| Min/Max Units | Units for the Min and Max values.<br>Do not leave this field empty. |
| Name | Name of the visit; for example, screening or baseline. |
| Planned | Select this field to define a subject visit as a planned visit. This field is selected by default. |
| Sequence | Sequence number of the visits. Typically, the first visit that is made has order number 1. |

| Field | Comments |
| --- | --- |
| Status | The following subject status values are provided:<br>■ Screened<br>■ Screen Failure<br>■ Randomized<br>■ Enrolled<br>■ Completed<br>■ Early Terminated<br>■ Re-screened<br>■ Withdrawn<br>The Status field is not copied when the subject visit template is copied to the subject's visit plan. |

| Field | Comments |
|---|---|
| Status Tracking Visit | Select this field to enable automatic tracking of the status in the Subject Status MVG (multi value group) for each visit type. Only one visit can be set as the status tracking visit for each visit type. For example, if a Treatment visit type has TreatmentPhase1, TreatmentPhase2, and TreatmentPhase3 clinical visits defined, then only TreatmentPhase3 can be set as the status tracking visit. When the Status Tracking Visit field is selected for a visit, the following status records are automatically created in the Subject Status MVG when each predefined visit type is processed:<br>■ A Visit Type value of Screening creates a Screened status record in the Subject Status MVG.<br>■ A Visit Type value of Re-Screening creates a Re-screened status record in the Subject Status MVG.<br>■ A Visit Type value of Enrollment creates an Enrolled status record in the Subject Status MVG.<br>■ A Visit Type value of End of Study creates a Completed status record in the Subject Status MVG.<br>You can manually override the automatic value in the Subject Status MVG.<br>Any create, update, or delete operations on the tracked status fields trigger automatic create, update, and delete operations in the Subject Status MVG.<br>Automatic status tracking is not enabled for custom values in the Visit Type list.<br>The Status Tracking Visit field can be edited only in the subject visit template. This field is read-only when copied to the subject's visit plan.<br>If you do not enable automatic status tracking for a clinical visit, then you can manually create, update, and delete status records in the Subject Status MVG. The following conditions apply:<br>■ Only one status record can be created for each visit type. Multiple status records for the same visit type are not permitted. If Visit Type is not null, then it must be unique.<br>■ When Visit Type is null, the status value must be unique. Multiple status records with the same Status value, and a null Visit Type, are not permitted. The value pair of Visit Type and Status must be unique. |

| Field | Comments |
|---|---|
| Visit Type | This field indicates the type of clinical visit. The following preconfigured values are available:<br>■ Screening<br>■ Rescreening<br>■ Enrollment<br>■ End of Study<br>Visit Type values can be added, modified, or deleted. |

## Defining Planned Subject Visits

This task describes how to define planned subject visits for the clinical trial. For example, complete this task to define whether treatment visits or surgery visits are planned for a subject.

This task is a step in "Process of Defining Subject Visit Templates" on page 58.

### *To define planned subject visits*

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Visits list, define the planned subject visits using one of the following methods:
   a. To define all the subject visits as planned visits, click Plan All.
   b. To define selected subject visits as planned visits, select the Planned field for each visit.

## Defining Activities for Subject Visits

This task describes how to define activities for subject visits in the clinical trial.

This task is a step in "Process of Defining Subject Visit Templates" on page 58.

### *To define activities for a subject visit*

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.

2 For each visit record, create a set of activity records in the Activities list to describe the procedures and tasks required for the visit.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Duration | Length of time the activity is estimated to take. |
| Payment Amount | The standard amount that the investigator is to be paid for this activity. This amount can be adjusted for each site or each individual. |
| Payment Flag | This flag is selected by default. It indicates that the investigator is to be paid for this activity. For more information about payments, see Chapter 8, "Setting Up and Making Clinical Payments." |

# Approving Subject Visit Templates

Setting the status of a subject visit template to approved sets the subject visit template as read-only. Only the Approved Date field of an approved subject visit template can be modified.

### *To approve a clinical subject visit template*

1 Navigate to the Administration - Clinical screen, then the Visit Templates view.

2 In the Template Versions list, select the version of the template to approve.

3 Enter the date in the Approval Date field.

4 Select Approved in the Status field.

# About Automatic Tracking of Subject Status

This topic describes the fields that are used by the mechanism for automatically tracking subject status, and the automatic operations that they trigger in the Subject Status MVG (multi value group). The Subject Status MVG contains a history of the subject's status. It contains the following fields.

- **Date.** The date the status was changed or updated.
- **Status.** The status of the subject, for example, Screened, Enrolled, or Re-screened.
- **Primary.** This flag sets the current status, which appears in the Status field of the Subjects view.
- **Comments.** Comments about the subject's status.
- **Visit Type.** The type of clinical subject visit, such as Screening or Enrollment. This field is null for status records such as Randomized and Withdrawn.

## Status Tracking Fields that Trigger Create and Delete Operations on Records in Subject Status MVG

Table 6 lists the status tracking fields that trigger create and delete operations on the records in the Subject Status MVG. The records in the Subject Status MVG are automatically updated as follows:

- Populating a status tracking field listed in Table 6 automatically creates the corresponding status record in the Subject Status MVG, including Status, Date, and Visit Type fields, where applicable
- Deleting a status tracking field listed in Table 6 automatically deletes the entire corresponding status record in the Subject Status MVG, including the Status, Date, and Visit Type fields, where applicable.

Table 6. Status Tracking Fields that Trigger Create and Delete Operations on Records in Subject Status MVG

| Status Tracking Field | Record in Subject Status MVG Automatically Created or Deleted |
|---|---|
| Random ID | Randomized |
| Screen Failure Reason | Screen Failure |
| Withdrawn Reason | Withdrawn |
| Early Termination Reason | Early Terminated |
| Missed | Missed |
| Completed | Status defined by the status value in the Visits list for that visit |
| Override Status | Missed or the status defined by the status value in the Visits list for that visit |

## Status Tracking Fields that Trigger Update Operations on Fields of Subject Status MVG

Table 7 lists the status tracking fields that trigger update operations on the Date and Status fields of the Subject Status MVG. The fields of the Subject Status MVG are automatically updated as follows:

- Populating or updating a status tracking field listed in Table 7 automatically triggers an update to the corresponding Date or Status field value in the Subject Status MVG.

- Deleting a status tracking field listed in Table 7 automatically triggers a delete operation on the corresponding Date or Status field value in the Subject Status MVG.

Table 7. Status Tracking Fields that Trigger Update Operations on Fields of Subject Status MVG

| Status Tracking Field | Field of Subject Status MVG Automatically Updated |
|---|---|
| Randomized Date | Date field in the record of the Subject Status MVG with a Status field of Randomized |
| Screen Failure Date | Date field in the record of the Subject Status MVG with a Status field of Screen Failure |
| Withdrawn Date | Date field in the record of the Subject Status MVG with a Status field of Withdrawn |
| Early Terminated Date | Date field in the record of the Subject Status MVG with a Status field of Early Terminated |
| Completed Date | Date field in the record of Subject Status MVG |
| Override Status | Status field in the Subject Status MVG is updated to Missed or the status value defined in the Visits list for that visit. |

# Creating Records for Clinical Subjects

CRAs (clinical research associates) can enter information about clinical subjects. When the subject record has been created, the subject visit template that is active for the site can be applied to set up a schedule of visits and activities for the subject.

### *To create a record for a clinical subject*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site to which you want to add subjects.
3. Navigate to the Subjects view.

4 In the Subjects list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Early Termination Reason | This field records the reason the subject's participation in the trial was terminated early. The following values are provided:<br>■ Adverse Event<br>■ Completed<br>■ Death<br>■ Lack of Efficacy<br>■ Lost to Follow-Up<br>■ Non-Compliance with Study Drug<br>■ Other<br>■ Physician Decision<br>■ Pregnancy<br>■ Progressive Disease<br>■ Protocol Violation<br>■ Recovery<br>■ Screen Failure<br>■ Study Terminated by Sponsor<br>■ Technical Problems<br>■ Withdrawal by Subject<br>■ Not Done |
| Early Terminated Date | This field records the date on which the subject's participation in the trial was terminated. |
| Encounter Date | This field records the date on which the subject was first registered for the trial. |
| Enrollment ID | This is the principal ID number for the subject. |
| Informed Consent Date | The date on which the subject signed the informed consent form for participation in the clinical trial. Informed consent must be obtained prior to initiation of any clinical screening procedures. |
| Last Completed Visit Date | Select this field to use the last completed clinical visit date for rescheduling clinical visits. |

| Field | Comments |
|---|---|
| Randomization ID | An ID number for the subject, which can be used in randomized studies where both an enrollment ID and a randomization ID are required. |
| Randomized Date | This field records the date on which the subject was randomized into an arm of the trial. |
| Screen Failure Date | This field records the date on which the subject failed screening. |
| Screen Failure Reason | This field records the reason why the subject failed screening. |
| Screening # | This field is generated from the Subject ID field and the Encounter Date field. The screening number is automatically generated after the Subject ID field and the Encounter Date field are entered, and the record is saved. |
| Status | A multi-value field that contains a history of the subject's status.<br>■ **Date.** The date the status was changed or updated.<br>■ **Status.** The status of the subject, for example, screened, enrolled, or re-screened.<br>■ **Primary.** This flag sets the current status, which appears in the Status field of the Subjects view.<br>■ **Comments.** Comments about the subject's status.<br>■ **Visit Type.** The type of clinical subject visit, such as Screening or Enrollment.<br>The user can override automatic status updates. |
| Subject ID | This field contains a unique identifier for the subject. |
| Withdrawn Date | This field records the date on which the subject withdrew from the clinical trial. |
| Withdrawn Reason | This field records the reason the subject withdrew from the clinical trial. |

# Scheduling Clinical Subjects

Scheduling a subject applies the activated subject visit template. A single start date is entered for all subject visit types in the Schedule Date field.

### *To schedule a clinical subject*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to schedule subjects.
3. Navigate to the Subjects view.
4. In the Subjects list, select the subject to schedule.
5. Click Schedule.

   The Schedule applet is launched.
6. Select a date in the Schedule Date field, and click OK.

   The subject visits record updates as follows:

   - All the visits defined in the active subject visit template are copied to the Visits list.
   - The Visit Type, Name, Start Date, Planned, Status Tracking Visit, and Status fields are copied from the subject visit template.
   - The planned dates and due dates are calculated using the lead time defined in the subject visit template and the start date defined in the Schedule Date field. The planned dates and due dates are calculated as follows:

     planned or due date equals schedule date plus lead time.

**NOTE:** You can also schedule subjects through workflows. Set the business component property Enroll Screen Rescreen Through WorkFlow to true to execute the schedule subject tasks in workflows instead of executing these tasks through applets and business component methods.

If the Enroll Screen Rescreen Through WorkFlow user property is set to true, then workflows in other user properties get executed based upon context. Workflow names can be changed to execute custom workflows. You can also modify other workflows and business service methods according to your needs. For more information about the Enroll Screen Rescreen Through WorkFlow user property, see Table 21 on page 246.

# Rescheduling Clinical Subjects

Clinical subject visits can be rescheduled using a fixed date, or using the delay between the Planned Date and Completed Date for the last completed visit. The Last Completed Visit Date field is selected to base the rescheduling of subject visits on the date of the last completed visit, and is deselected to base the rescheduling of subject visits on a fixed date. The rescheduling mechanism can be defined at the site level. The rescheduling option selected at the subject level overrides the option selected at the site level.

### *To reschedule a clinical subject*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to reschedule a subject.

3 Navigate to the Subjects view.

4 In the Subjects list, select the subject to reschedule, and complete one of the following steps:

- Deselect the Last Completed Visit Date field to reschedule subject visits using a fixed date.
- Select the Last Completed Visit Date field to reschedule subject visits using the date of the last completed visit.

5 Click Reschedule.

6 To reschedule subject visits using a fixed date, enter a date in the Reschedule Date applet.

The subject visit dates are rescheduled as described in the following table.

| Reschedule Option | Reschedule Mechanism |
|---|---|
| Fixed Date | The remaining subject visit dates are rescheduled using the date entered in the Reschedule Date applet. |
| Last Completed Visit Date | The remaining subject visit dates are rescheduled using the delay between Planed Date and Completed Date for the last completed visit. The rescheduled dates for the planned dates and due sates are calculated as follows:<br><br>Planned or Due Date equals Planned Date or Due Date plus Delay |

# Administering Subject Visits in Batch Mode

The Visit Types view displays the subject visit plan by visit type. Each distinct visit type for that subject is listed in the Visit Types applet, with a read-only field indicating whether or not each visit type is planned for the subject. Associated visits for each visit type are listed for batch administration, and associated activities for each visit are also listed. The Visit Types view provides for the following administration tasks:

- Viewing clinical visit types for each subject, the associated visits, and the associated activities.
- Planning and unplanning clinical visits in batch mode, by visit type.
- Deleting clinical visits in batch mode, by visit type.

### *To administer subject visits in batch mode*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, drill down on the site number field of the site for which you want to administer visits.

3 Navigate to the Subjects view.

4 In the Subjects list, select the subject for which you want to administer visits.

5 Navigate to the Visit Types view.

The visit types, associated visits, and associated activities appear.

6 Complete one of the following steps:

- To plan all visits associated with a visit type, select the visit type, and click Plan.
- To unplan all visits associated with a visit type, select the visit type, and click Unplan.
- To delete a visit type and all associated visits, select the visit type, and click Delete Visits.

# Screening Clinical Subjects

The screening visits can be scheduled when the subject signs the informed consent form. The Subject Status MVG (multi value group) is automatically updated for the screening visit that was selected as the status tracking visit in the subject visit template.

### *To screen a clinical subject*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, drill down on the site number field of the site for which you want to screen subjects.

3 Navigate to the Subjects view.

4 In the Subjects list, select the subject to screen.

5 Enter the informed consent date as follows:

a Click the select button in the Informed Consent Dates field to open the Informed Consent dialog box.

b Select the appropriate version.

c Enter an informed consent date for the subject, and click OK.

6 Drill down on the screening number field of the subject.

The Visits view of the Subjects screen appears.

7 (Optional) Edit subject visit dates or activities.

For example, you might want to edit some subject visit dates so that visits are not scheduled on weekends. If the rescheduled date falls outside the range specified by the subject visit template, then a warning message appears, but *still reschedules the visit* according to the new date.

8 Select the Completed field for the screening visit in the Visits list.

9 Enter the completion date in the Completed Date field.

If the subject clinical visit is a status tracking milestone visit, then the subject record automatically updates as follows:

- A record with a value of Screening in the Visit Type field is added to the Subject Status MVG.
- The Status field is updated to Screened.
- The Date field of the Subject Status MVG is populated with the date entered in the Completed Date field of the Visits list.

# Rescreening Clinical Subjects

A subject who initially fails screening can be rescreened. The Re-screening visit type must be defined in the visit plan for the subject. The Subject Status MVG (multi value group) is automatically updated for the re-screening visit that was selected as the status tracking visit in the subject visit template.

### *To rescreen a clinical subject*

1. Navigate to the Subjects screen.
2. Drill down on the screening number field of the subject who has failed screening.

   The Visits view of the Subjects screen appears.
3. (Optional) Edit subject visit dates or activities.
4. Select the Completed field for the Re-screening visit in the Visits list.
5. Enter the completion date in the Completed Date field.

   If the subject clinical visit is a status tracking milestone visit, then the Subject record automatically updates as follows:

   - A record with a value of Re-screening in the Visit Type field is added to the Subject Status MVG.
   - The Status field is updated to Re-screened.
   - The Data field of the Subject Status MVG is populated with the date entered in the Completed Date field of the Visits list.

# Enrolling Clinical Subjects

A subject who has successfully passed screening or rescreening is then enrolled in the study. The Subject Status MVG (multi value group) is automatically updated for the enrollment visit that was selected as the status tracking visit in the subject visit template.

### *To enroll a clinical subject*

1. Navigate to the Subjects screen.
2. Drill down on the screening number field for the subject.
3. Navigate to the Visits view.
4. (Optional) Edit subject visit dates or activities.

5 Enter the enrollment ID in the Subjects applet.

6 In the Visit Plans list, complete the following steps:

a Select the Completed field for the enrollment visit.

b Enter the completion date in the Completed Date field.

If the subject clinical visit is a status tracking milestone visit, then the Subject record automatically updates as follows:

- A record with a value of Enrollment in the Visit Type field is added to the Subject Status MVG.
- The Status field is updated to Enrolled.
- The Date field of the Subject Status MVG is populated with the date entered in the Completed Date field of the Visits list.

# Randomizing Clinical Subjects

This topic describes how to randomize a subject for a randomized clinical trial.

### *To randomize a clinical subject*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, drill down on the site number field of the site for which you want to randomize subjects.

3 Navigate to the Subjects view.

4 In the Subjects list, select the subject to randomize, and complete the required fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Randomization ID | The ID number assigned to the subject for the randomized trial. |
| Randomized Date | The date on which the subject was randomized into an arm of the trial. |

5 Save the record.

The Subject record automatically updates as follows:

- A Randomized status record is added to the Subject Status MVG (multi value group), and the value in the Randomized Date field is copied to the Date field of the Subject Status MVG.
- The Status field is updated to Randomized.

# Overriding Initial Subject Status

You can override the initial subject status for a status tracking clinical visit by selecting a new status in the Override Status field. For example, a status tracking clinical visit that has been set to Missed can subsequently be set to Completed in the Override Status field.

When the Completed value is selected from the Override Status field, the previous Missed value is updated to the status value defined for that visit in the Visits list, for example, the status value for the Screening visit type is updated to Screened.

When the Missed value is selected in the Override Status field, the previous status record for that visit is updated to Missed.

### *To override initial subject status*

1. Navigate to the Subjects screen.
2. Drill down on the screening number field for the subject.
3. Navigate to the Visits view.
4. Select one of the following values from the Override Status field:
   - Completed
   - Missed
5. For a completed visit, enter the completion date in the Completed Date field.

# Creating Unscheduled Subject Visits

On occasion, it might be necessary to create an unscheduled subject visit.

## Creating a Subject Visit From the Subjects Screen

Complete the procedure in this topic to create a subject visit from the Subjects screen.

### *To create a subject visit from the Subjects screen*

1. Navigate to the Subjects screen, then the Subject List view.
2. In the Subject list, drill down on the screening number field of the subject for whom you want to add an unscheduled visit.
3. Navigate to the Visits view.
4. In the Visits list, create a new record and complete the necessary fields.

   The type of the visit is automatically populated as an Unscheduled Visit.

## Creating a Subject Visit From the Calendars for Sites

Complete the procedure in this topic to create a subject visit from the calendar for a site.

### *To create a subject visit from the calendar for a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to add subject visits.
3. Navigate to the Calendar view.
4. Click the plus icon (+) to create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Assigned To | Person to whom the subject visit is assigned. |
| Calendar Planned | Date on which the subject visit is due. This field value is automatically populated in the Due field. |
| Done | Indicates whether or not the visit has taken place. |
| Done Date | Indicates the date on which the visit took place. |
| Lock Assignment | Determine whether to select the Lock Assignment field. If the activity is locked, then Assignment Manager cannot access it. If it is unlocked, then Assignment Manager can reassign it. |

# Terminating Clinical Trials Early for Clinical Subjects

On occasion, it might be necessary to terminate a subject's participation in a trial before completion of the trial. For example, the subject no longer wants to take part in the trial or because the subject failed a screening.

### *To terminate a clinical trial early for a clinical subject*

1. Navigate to the Subjects screen, then the Subject List view.
2. In the Subject list, drill down on the screening number field of the subject of the trial you want to terminate.
3. Enter the reason for terminating the subject's trial using one of the following methods:
   - To indicate that the subject failed the screening, enter the reason in the Screen Failure Reason field.
   - To indicate that the subject was withdrawn from the trial, enter the reason in the Withdrawn Reason field.
   - To indicate that the subject's trial was terminated early, select the reason in the Early Termination Reason field.
4. Enter the date for terminating the subject's trial using one of the following methods:

- To indicate that the subject failed the screening, enter the date in the Screen Failure Date field.
- To indicate that the subject was withdrawn from the trial, enter the date in the Withdrawn Date field.
- To indicate that the subject's trial was terminated early, enter the date in the Early Terminated Date field.

5 Save the record.

| Subject Termination Event | Automatic Status Updates |
|---|---|
| Screen Failure | The Subject record automatically updates as follows:<br>■ A record with a Status field value of Screen Failure is added to the Subject Status MVG (multi value group), and the value in the Screen Failure Date field is copied to the Date field of the Subject Status MVG.<br>■ The Status field is updated to Screen Failure. |
| Early Terminated | The Subject record automatically updates as follows:<br>■ A record with a Status field value of Early Terminated is added to the Subject Status MVG, and the value in the Early Terminated Date field is copied to the Date field of the Subject Status MVG.<br>■ The Status field is updated to Early Terminated. |
| Withdrawn | The Subject record automatically updates as follows:<br>■ A record with a Status field value of Withdrawn is added to the Subject Status MVG, and the value in the Withdrawn Date field is copied to the Date field of the Subject Status MVG.<br>■ The Status field is updated to Withdrawn. |

When a Screen Failure or Early Terminated event occurs, all remaining visits for the subject are deleted.

# Applying Protocol Amendments to Sites and Clinical Subjects

When a protocol is revised mid-study, apply the protocol amendments and update:

- The subject visit template version associated with the site.
- The visit schedules of any subjects who are still in the study.

# Applying Revised Subject Visit Templates to Sites

This topic describes how to apply a new version of the subject visit template to a site when a protocol has been revised mid-study. When the new version of the subject visit template has been activated at the site, the Schedule button is enabled in the Subjects view.

### *To apply a revised subject visit template to a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, select the site for which you want to apply a new version of the subject visit template.
3. In the Versions field, click the select button and complete the following steps:
   a. Select the new version of the subject visit template.
   b. Enter a date in IRB Approval Date field for the new version.
   c. Select the Active field for the new version.
   d. Click OK.

# Applying Revised Subject Visit Templates to Clinical Subjects

This topic describes how to apply a new version of the subject visit template for a subject when a protocol has been revised mid-study. When the new version of the subject visit template has been activated at the site, the Schedule button is enabled in the Subjects view.

### *To apply a revised subject visit template for a clinical subject*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to update subject visits.
3. Navigate to the Subjects view.
4. Click Apply Active Version.

   New records for the new version of the template are created in the Informed Consent Dates field for all subjects in this site except for those subjects with a status of Early Terminated or Completed.
5. Navigate to the Subjects screen, and drill down on the screening number field of the enrolled subject of the schedule you want to update for the revised subject visit template.
6. Navigate to the Visits view.
7. Enter the informed consent date for the newer version.
8. In the Subjects form, click Schedule, and complete the following steps:

a Enter the Schedule Date.

A dialog box prompts if you want to delete uncompleted visits from the old version of the subject visit template, and completed visits from the new version of the subject visit template. Non-applicable visits are those visits generated from the old template version that are scheduled to take place after the new Informed Consent Date and those visits generated by the new template version that have due dates prior to the new Informed Consent Date.

b Complete one of the following steps:

- Click OK. If you click OK, then the non-applicable visits are deleted.
- Click Cancel. If you click Cancel, then the new visits for the new protocol version are appended to the existing Visits list. No visits are deleted. Typically, if you click Cancel, then you can return at a later stage to the Visits list and delete future-scheduled visits from the original version of the subject visit template and past-scheduled visits from the new version of the subject visit template.

For more information, see "Rules for Applying Protocol Amendments" on page 78.

The Subject Visits record updates as follows:

- All the visits defined in the new active subject visit template are copied to the Visits list.
- The Visit Type, Name, Start Date, Planned, Status Tracking Visit, and Status fields are copied from the subject visit template.
- The Planned Dates and Due Dates are calculated using the Lead time defined in the subject visit template, and the start date defined in the Schedule Date field. The planned dates and due dates are calculated as follows: Planned or Due Date equals Schedule Date plus Lead time.

For more information, see "Rules for Applying Protocol Amendments" on page 78.

## Rules for Applying Protocol Amendments

If you choose Cancel in response to the delete uncompleted visits from the old version and completed visits from the new version dialog, then a new set of visits is created and added on top of the visits already created from prior versions.

If you choose OK, then a new set of visits is created, the two sets of visits are compared, and the non-applicable visits are deleted when the following conditions are satisfied:

1 The Subject's Informed Consent date is used for the new version as a cut-off date for transitioning from the old version to the newer version.

2 Equivalent Visits are those that have the same Visit Name.

3 For an old visit (created from the old template version) that has the Completed date filled in:

a If the Completed date is less than the Informed Consent date, then the old completed visit is left intact, and the corresponding visit from the more recent amended version is deleted. In other words, visits under the old version that are completed before an amendment takes effect are preserved, and the equivalent visits from the new version are deleted.

b If the Completed date is greater than or equal to the Informed Consent date, then the following rules apply:

- If the Due date of the corresponding new visit is less than the Informed Consent date, then the old completed visit is left intact. In other words, visits that are scheduled under the old version to complete before an amendment takes place but are actually completed later are also preserved. The equivalent visits from the new version are deleted.
- If the Due date of the corresponding new visit is greater than or equal to the Informed Consent date, then the visits from the old version are deleted, but the completed dates are copied to the equivalent visits from the new version. In addition, all child activities of the completed visits are set to Completed and have the same completed date of the parent visit. This rule applies in situations where the Subject has already switched to the new version before Siebel Clinical is setup in time to cater for such a scenario. In such a case, the visit records generated under the old version are marked Complete instead of the visits from the new version.

4 For an old clinical visit that does not have the Completed date filled in:

a If the Due date is greater than or equal to the Informed Consent date, then the visit generated from the old version of the subject visit template is deleted. In other words, future visits generated from the old version that have not yet been completed are deleted, and their equivalent visits from the new version are preserved.

b If the Due date is less than the Informed Consent date, then the visit from the old version is left intact. In other words, visits under the old version that have not been completed (those are presumably the visits that a Subject has missed in the past) are preserved, and the equivalent visit from the new version is deleted.

5 For a new visit generated under the new template version:

a If the Due date is less than the Informed Consent date, then the new visit is deleted.

b If the Due date is greater than or equal to the Informed Consent date, then the new visit is left intact, although it could still be deleted using other rules specified above.

## Rules for Deleting Subject Visits When Deemed Non-Applicable by Early Termination

In addition to automatically deleting non-applicable visits for each protocol amendments, the following automation rules are applied to delete visits deemed non-applicable by early termination.

1 Delete non-applicable visits after a subject terminates the study.

When the Status of a Subject is changed to Early Terminated and the Early Terminated date is filled in, all the remaining visits are deleted. The remaining visits are identified as visits with Due date, and then Early Terminated date.

2 Delete non-applicable visits after a subject fails screening.

When the Status of a Subject is changed to Screen Failure and the Screen Failure date is filled in), all future visits are deleted. Future visits are defined as visits with Due date, and then Screen Failure date.

# About Rolling Up Information for Subject Enrollment

One of the key capabilities of Siebel Clinical is supporting clinical organizations to better manage subject enrollment for their trials in real-time. This tracking is implemented though rolling up subject information from the site level to the region level and then to the protocol level or directly from the site level to the protocol level. However, it is often the case that this data is not available to the clinical organization, which presents significant business challenges.

For example, if trials are out sourced to CROs (clinical research organizations), then it is not always possible for the clinical organization to receive subject level information. The enhanced subject rollup functionality allows accurate subject enrollment data to be available at the region and protocol level, even when subject level information is not available for each site, or when site level information is not available for each region.

## Characteristics of Trials Where Subject Level Data is Available for Each Site

Trials, for which subject level information is available for each site, display the following rollup characteristics:

- Subject enrollment information is automatically rolled up from the subject level to the site level, from the subject level to the region level, and from the subject level to the protocol level.
- When a subject is the first subject to enroll to a site, region, or protocol, the First Subject Enrolled Date for that site, region, or protocol, is automatically populated.
- When a subject is the last subject to complete or drop off the trial for the site, region, or protocol, the Last Off Study Date for that site, region or protocol is automatically populated.

## Characteristics of Trials Where Subject Level Data is Not Available for Each Site

Trials, for which subject level information is not available for a site, display the following characteristics:

- You can select the No Subject Info field for sites that do not have subject level information available.
- CRAs (clinical research associates) can enter information in the following fields for sites that do not have subject or site level information:
  - # Screened
  - # Re-Screened
  - # Screen Failure
  - # Enrolled
  - # Completed
  - # Early Terminated

- First Subject Enrolled
- Last Subject Off Study
- Initiated Date
- Terminated Date

- Information manually entered for sites without subject data is rolled up in the same manner as the information for sites with subject data.

### Characteristics of Trials Where Site Level Data is Not Available for a Region

Trials, for which site level information is not available for a region, display the following characteristics:

- The No Site Info field is selected for regions that do not have site level information available. You do not have to select the No Subject Info field.
- CRAs (clinical research associates) can enter information in the following fields for regions that do not have site level information:
  - # Screened
  - # Re-Screened
  - # Screen Failure
  - # Enrolled
  - # Completed
  - # Early Terminated
  - First Subject Enrolled
  - Last Subject Off Study
  - Initiated Date
  - Terminated Date
  - First Site Initiated Date
  - Last Site Terminated Date
- Information manually entered for regions without site data is rolled up in the same manner as the information for regions with subject data.

# Viewing Status Accruals for Clinical Subjects of Sites

Clinical subject data is automatically rolled up to the clinical site record. This task describes how to view subject status accruals for each subject status and visit type of a specified clinical site.

### *To view status accruals for clinical subjects of a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to view subject accruals.
3. Navigate to the Subject Status Accruals view.

   This view displays the number of the subject status accrual for each status and visit type assigned to the site.

# Viewing Status Accruals for Clinical Subjects of Clinical Regions

Clinical subject data is automatically rolled up to the clinical region record. This task describes how to view subject status accruals for each subject status and visit type of a specified clinical region.

### *To view status accruals for clinical subjects of a clinical region*

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to view subject accruals.
3. Navigate to the Subject Status Accruals view.

   This view displays the number of the subject status accrual for each status and visit type assigned to the region.

# Viewing Status Accruals for Clinical Subjects of Clinical Protocols

Clinical subject data is automatically rolled up to the clinical protocol record. This task describes how to view subject status accruals for each subject status and visit type of a specified clinical protocol.

### *To view status accruals for clinical subjects of a clinical protocol*

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to view subject accruals.
3. Navigate to the Subject Status Accruals view.

   This view displays the number of the subject status accrual for each status and visit type assigned to the protocol.

# Monitoring Rates for Subject Enrollment

The Subject Status feature in the Charts view provides a graphical representation of subject enrollment rates. You can display the charts by protocol, region, or site, and in a variety of pie chart and bar chart formats.

### *To monitor rates for subject enrollment*

1. Navigate to the Protocols, Regions, or Site Management screen.
2. In the list, select the record for which you want to create the charts.
3. Navigate to the Charts view.
4. From the first drop-down list, select Subject Status.
5. From the second drop-down list, select Subject Enrollment Rates.
6. From the third drop-down list, select the time frame.
7. From the fourth drop-down list, select the display type, such as bar chart or pie chart.

   The following values are available:

   - 2dBar
   - 2dStackedBar
   - 2dHorizBar
   - 2dPie
   - 3dBar
   - 3dStackedBar
   - 3dHorizBar
   - 3dPie
8. Click Go.

# Monitoring Status Accruals for Clinical Subjects by Visit Type

The Subject Status Analysis feature in the Charts view provides a graphical representation of subject status accruals by visit type. You can display the charts by protocol, region, or site, and in a variety of pie chart and bar chart formats.

### *To monitor status accruals for clinical subjects by visit type*

1. Navigate to the Protocols, Regions, or Site Management screen.
2. In the list, select the record for which you want to create the charts.
3. Navigate to the Charts view.

4 From the first drop-down list, select Subject Status Analysis.

5 From the second drop-down list, select Subject Accruals.

6 From the third drop-down list, select the time frame.

7 From the fourth drop-down list, select the display type, such as bar chart or pie chart.

The following values are available:

- 2dBar
- 2dStackedBar
- 2dHorizBar
- 2dPie
- 3dBar
- 3dStackedBar
- 3dHorizBar
- 3dPie

8 Click Go.

# Using Audit Trail for Changes to Subject Status

The Status Audit Trail view provides a detailed history of the changes that have been made to Subject Status records, including the dates and times of changes, and the details of the users who completed the changes.

### *To use the audit trail for changes to subject status*

1 Navigate to the Subjects screen, then the Subject List view.

2 In the Subject list, drill down on the screening number field of the subject.

3 Navigate to the Status Audit Trail view.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Base Table | Displays the name of the primary database table where the database change occurred. |
| Business Component | Displays the business component for the record where the database change occurred. |
| Column | Displays the name of the column in which the change occurred. |

| Field | Comments |
|---|---|
| Date | Displays the timestamp of the change. |
| Employee ID | Displays the unique identifier of the user who changed the record. |
| Employee Login | Displays the username of the user who changed the record. |
| Field | Displays the name of the field where the change occurred. |
| Group ID | Displays the unique identifier of the group to which the user who changed the record belonged. |
| New Value | Displays the value in the field after the database change occurred. |
| Node | Displays the name of the database table node where the change occurred. |
| Old Value | Displays the value in the field before the database change occurred. |
| Operation | Displays the type of operation that was performed, for example, New Record, or Modify. |
| Record ID | Displays the unique identifier of the record that was changed. |
| Row ID | Displays the unique identifier of the row in which the change occurred. |
| Table | Displays the name of table to which the selected field belongs in the Siebel database. |

# Generating Oracle BI Publisher Reports for Site Enrollment Status

Siebel Clinical can be integrated with Oracle Business Intelligence Publisher (BI Publisher) for generating reports. You can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical. The preconfigured Site Enrollment Status report is provided for clinical trials. For more information about using Siebel Reports, and integrating with Oracle BI Publisher, see *Siebel Reports Guide*.

### *To generate an Oracle BI Publisher report for the site enrollment status*

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to generate an Oracle BI Publisher report.
3. Navigate to the Sites view.
4. On the application toolbar, click the Reports icon.

5 In the Run Report pane, complete the appropriate fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Site Enrollment Status report. |
| Output Type | Select the output type for the report. |

6 Click Submit.

The report runs.

7 Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*.

# 6 Managing Sites and Contacts for Clinical Trials

This chapter describes how to manage sites and contacts for clinical trials. It includes the following topics:

# About Managing Sites and Contacts for Clinical Trials

This chapter describes the tasks that the administrator and end users perform to update and maintain information about:

- Sites for clinical trials
- Contacts (investigators and other site personnel)
- Accounts (hospitals and clinics where the trials are carried out)
- Employees on the site team
- Regulatory documentation relevant to recording the trials
- Contracts associated with individual sites

Siebel Adverse Events and Complaints Management feature set allows you to record the relationships among these six entities.

This chapter also describes setting up and using:

- Activity plans for sites
- Account and contact assessments

# Scenario for Managing Sites and Contacts for Clinical Trials

This topic gives one example of how to manage sites and contacts for clinical trials. You might manage sites and contacts for clinical trials differently, depending on your business model.

In preparation for the clinical trial, the administrator sets up templates to generate activity plans for site initiation and to track documents. The administrator also creates templates that the CRA (clinical research associate) uses towards the end of the trial to assess contacts and accounts associated with the trial. The administrator might have to update contact and account information before the CRA can begin work on the site. Another important task that the administrator might have to carry out is to associate contracts with a site. Often, the administrator might have to associate multiple contracts with individual sites.

When the CRAs begin work on a new clinical trial, they must set up a number of site visits that dictate whether the site can be used to carry out the trial. After this, they add new information and update existing information about accounts, contacts, and sites, and about the affiliations and associations among them. Maintaining accurate data is critical to successful clinical trials.

When a new contact record is entered, the CRAs request that the administrator enter the contact's primary specialty. Data cannot be entered to this fields from the CRAs' views. After this, the CRAs must appoint a team of employees that is to be assigned to that site. This allows the study manager to keep track of the members of each site team.

CRAs plan how the protocol is to be carried out at the site by creating an activity plan for the site. This plan determines how the trial is conducted. The CRAs use the clinical protocol site template that has been created by the administrator. CRAs also track any number of extra documents that are associated with a site. This can include regulatory or clinical trial documentation.

From time to time, CRAs enter account or contact records incorrectly or they discover that some account or contact records have become obsolete. The CRA then puts in a request to the administrator to delete those accounts and contacts. CRAs do not have the permissions to delete these records.

Before the clinical trial ends, the administrator or the study manager creates a contact assessment template that each CRA can use to evaluate the performance of the investigators at the conclusion of the trial.

**CAUTION:** In some countries, it is not permitted to evaluate the performance of site personnel. Obtain legal advice before using the contact assessment feature in Siebel Clinical.

# Process of Managing Sites and Contacts for Clinical Trials

This topic details sample tasks often performed by administrators and end users when managing site and contact information. Your company might follow a different process according to its business requirements.

The administrative tasks described in this topic must be performed before the related end-user task can be performed. For example, a clinical protocol site template must exist before the corresponding activity plan for the site can be created.

## Administrator Procedures

The following list shows tasks administrators typically perform to manage site and contact information:

- "Creating Clinical Protocol Site Templates" on page 91. An administrator creates templates that detail the activities that must be performed at all sites that are carrying out the same protocol.
- "Creating Contact and Account Assessment Templates" on page 91. An administrator or the study manager creates assessment templates that define weighted attributes for assessing a contact or account.
- "Maintaining Contacts and Accounts" on page 92. An administrator maintains records of contact license numbers and deletes erroneous or obsolete account and contact data.
- "Associating Contracts with Sites" on page 92. An administrator or a study manager enters details about the contracts for a site and the payment details for each contract.
- "Associating Accounts with Contracts" on page 93. An administrator or a study manager enters details about the accounts for a site.

## End-User Procedures

The following list shows tasks end users typically perform when managing site and contact information:

- "Creating and Managing Site Visits" on page 93. CRAs (clinical research associates) create site visits to evaluate, initiate, monitor, and close out sites.
- "Creating and Updating Sites, Contacts, and Accounts" on page 95. CRAs record details about contacts, accounts, and sites.
- "Adding Address Types for Sites" on page 95. Users can add a specific type of addresses for each site.
- "Assigning Employees to Site Teams" on page 96. Managers or CRAs add employees to the team associated with the site.
- "Creating Activity Plans for Sites" on page 96. CRAs use the clinical protocol site template that has been created by an administrator to plan a list of activities for each site.
- "Applying Activity Templates to Sites" on page 98. Users can simultaneously apply one or multiple activity templates across one or multiple sites for a study.
- "Tracking and Adding Documents at Sites" on page 99. CRAs and regional study managers post clinical trial and regulatory documentation for review at site, region, and protocol levels.
- "Creating Activities for Document Tracking" on page 100. CRAs attach and track documents at the protocol, region, and site levels, or for accounts or contacts.
- "Creating Tracking Activities for Case Report Forms" on page 102. Users can create tracking activities for CRFs (case report forms).
- "Tracking Case Report Forms" on page 103. Users can create and track CRFs as part of a protocol, site, and region.
- "Creating Correspondence Activities for Sites" on page 104. Users can track all correspondence (phone, fax, email, and letters delivered by the postal service) between a site and a study team member as correspondence activities for the site.
- "Adding Notes to Sites" on page 106. Users can add notes to a site.
- "Assessing Contacts and Accounts" on page 106. CRAs evaluate contacts and accounts, using the attributes defined in an assessment template.
- "Generating Oracle BI Publisher Reports for Document Tracking" on page 107. Users can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical.
- "Generating Reports for Actual Visits" on page 110. Users can generate a report for completed clinical subject visits.
- "Generating Reports for Planned and Actual Dates of Subject Visits" on page 111. Users can generate a report for completed clinical subject visit dates.

# Creating Clinical Protocol Site Templates

Activities can be associated directly with sites. For example, all sites carrying out the same protocol perform similar activities for site initiation and submit similar documents to the regulatory agencies. When many activities are common to multiple sites, the clinical protocol site template helps CRAs (clinical research associates) create activities for the sites.

To create a clinical protocol site template, create an activity template with a Type field of Clinical Protocol Site. Make sure that Protocol Title field is completed and correct. For information about how to create activity templates, see *Siebel Applications Administration Guide*.

If an activity template with a Type field of Clinical Protocol Site is not associated with a protocol title, then the template can be applied to all sites in the Activity Plans view of the Site Management screen. If an activity template with a Type field of Clinical Protocol Site is associated with a protocol title, then the activity template can be applied only to the sites associated with the protocol.

**NOTE:** Unlike trip report templates, clinical protocol site templates are protocol-specific. To use a clinical protocol site template in association with more than one protocol, either duplicate the record, and then edit the Protocol Title field, or delete the protocol title to make the template available to all sites.

The clinical protocol site template is one of other activity templates used in Siebel Clinical. The following other activity templates are used in Siebel Clinical:

- Subject visit templates. For more information, see "About Subject Visit Templates" on page 58.
- Activity templates for projects. For more information, see "Creating Activity Templates for Clinical Projects" on page 161.
- Trip report templates. For more information, see "Creating Clinical Trip Report Templates" on page 140.
- Contact assessment templates. For more information, see "Creating Contact and Account Assessment Templates" on page 91.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

# Creating Contact and Account Assessment Templates

The purpose of the assessment is to determine a single total score or a percentage that can be used to rank a contact or account. For information about creating an assessment template, see *Siebel Applications Administration Guide*

For contact assessment templates, set the template type to Contact. For account assessment templates, set the template type to Account.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

# Maintaining Contacts and Accounts

The end users are responsible for much of the day-to-day maintenance of their contact and account data. For information about managing contacts and accounts, see *Siebel Life Sciences Guide*.

However, the administrator is responsible for the following tasks:

- Entering data into the primary specialty field for contacts.
- Deleting contact and account records that were created in error or are obsolete.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

# Associating Contracts with Sites

Contracts that define the total payments that are to be made to a site can be associated with each site. Some sites might need only one contract that governs the entire payment for the site. However, depending on the site in question, it might be necessary to associate multiple contracts with the site. There can also be multiple payees associated with each contract. It is possible to associate multiple contracts and multiple payees with a site through the Contracts view in the Site Management screen.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To associate a contract with a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site with which you want to associate a contract.
3. Navigate to the Contracts view.
4. In the Contracts list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Contract # | The number assigned to this contract. This field is automatically populated. |
| Type | The type of contract to associate with the site. |
| Contract Amount | The amount of money that this contract is worth. If multiple contracts are entered, then the total value of all contract amounts is equal to the total contract amount for the site. This total appears in the Contract Amount field on the site form. |
| Payee Last Name | The name of the person to whom the payments for this contract are made. This is a multi-value field and multiple payees for the contract can be entered using the multi-value picklist. |
| Address | The address associated with the payee. |

# Associating Accounts with Contracts

This topic describes how to associate accounts with a contract for clinical site. Multiple accounts can be associated with a contract for clinical site. Accounts are associated with a contract by adding them to the selected list in the Accounts MVG (multi value group). One account must be set as the primary account. The first account added to the Accounts MVG is set as the primary account by default. The primary account can be changed by selecting the Primary field in the Accounts MVG.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To associate an account with a contract*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site.
3. Navigate to the Contracts view.
4. Click the select button in the Account field to open the Accounts dialog box, and complete the following steps:
   a. Move the record for an available account to the list of selected accounts.

      The first account that is associated with the contract is the primary account by default.
   b. Configure the primary account for the contract by selecting the Primary field.
   c. Click OK.

# Creating and Managing Site Visits

CRAs (clinical research associates) typically carry out the following types of visits to a site:

- **Site evaluation.** A site visit to evaluate a site's qualification for a study
- **Site initiation.** A site visit to initiate a site
- **Site monitoring.** A site visit to monitor study progress and to monitor and retrieve CRFs (case report forms)
- **Site close-out.** A site visit to close out or terminate a site at the conclusion of a study
- **Unscheduled.** (Optional) An unexpected site visit that a CRA can carry out

CRAs create these visits for each site for which they are responsible. When a CRA creates a site visit, it appears in the CRA's calendar, the site investigator's calendar, and the study manager's calendar. This means that the study manager can keep track of all site visits for all CRAs. It also acts as a useful reminder for investigators of when site visits are to be made.

Site visits are created using the Protocol Site List view of the Site Management screen. From this view, it is possible for CRAs to view all their site visits and all follow-up activities that arise from the visits. It is also possible to view all site visits and follow-up activities associated with these visits. Study managers can also filter site visits to see the visits that are assigned to their teams and view follow-up activities in order to assess the most pressing issues.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To create a site visit*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field for the site with which you want to create a visit.
3. Navigate to the Site Visits view.
4. Create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Assigned To | User ID for the person assigned to the site visit. |
| Trip Report Completed | The date on which the trip report for this visit has been completed. |
| Trip Report Status | The status of the trip report. The following values are available:<br>■ Not Started<br>■ In Progress<br>■ Completed<br>■ Submitted<br>■ Approved<br>■ Rejected<br>A state model is preconfigured to allow for structured state transition. For more information about trip reports, see Chapter 9, "Administering and Using Clinical Trip Reports." |
| Visit Name | A descriptive name for the visit. |
| Visit Start | The date on which the visit is due to take place. When you drill down on this field, you are brought to the trip report for the visit. |
| Visit Status | The status of the site visit. |

## Monitoring Site Visits Using the Calendar

All CRA (clinical research associate) visits to a site can also be monitored from the Calendar view. The calendar can be used to view visits on a daily, weekly, or monthly basis.

# Creating and Updating Sites, Contacts, and Accounts

To maintain accurate information in the Siebel Clinical database, end users can keep data about their sites, accounts, and investigators up to date. To do this, they create new records, modify existing records, and request that their administrator delete obsolete records. In addition, they create and maintain the relationships (affiliations) among their contacts, accounts, and sites.

For more information, see:

- "Creating Accounts and Contacts for Clinical Trials" on page 49.
- "Creating Sites for Clinical Trials" on page 51.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To associate contacts with a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field for the site with which you want to associate contacts.
3. Navigate to the Contacts view.
4. In the Contacts list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Last Name | The Affiliated Contacts button filters the names in the Pick Contacts dialog box, displaying only those contacts associated with the account for the site. |

# Adding Address Types for Sites

Users can add a specific type of addresses for each site.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To add an address type for a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to add an address type.
3. Navigate to the Addresses view.

4 In the Addresses list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Description | Enter a description for the address. |
| Address Type | Select an address type from the list of values to associate with the site. |
| Address Line 1 | Select the appropriate site location from the MVG (multi value group). |

# Assigning Employees to Site Teams

CRAs (clinical research associates) assign employees to the site team. The team members can be rolled up and made visible at the region and protocol levels.

**NOTE:** If the CRA is working from a mobile Web client, then the administrator must set up position rollup on the Web client. For more information, see "Setting Up Mobile Web Clients for Position Rollup" on page 35.

Before an employee can be added to the site team, an administrator must set up the employee record. For more information, see *Siebel Security Guide*.

You can also automatically assign an employee to the site team using the Position Rollup button or Position Rolldown button. For more information, see "About Automatically Assigning Team Members to a Site Using the Position Rollup Button" on page 54. For more information about removing employees from the site team, see "About Removing Team Members From the Team of a Site" on page 55.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To assign employees to the site team*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, select the site to which you want to add employees.

3 Edit the Team field of the site record.

The employees are added to the site team and can also be rolled up to the region and protocol levels.

# Creating Activity Plans for Sites

An activity plan for a site is a list of activities and documents associated with the site.

Although activities can be created without a template, using a clinical protocol site template as described in this topic makes creating activities for sites more efficient. For more information, see "Creating Clinical Protocol Site Templates" on page 91.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To create an activity plan for a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site to which you want to assign activities.
3. Navigate to the Activity Plans view.
4. In the Activity Plans list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Planned Start | Make sure that this date is correct before you choose a template. The due dates for the template-generated activities are based on this start date and on the lead time set in the template. |
| Lock Assignment | Determine whether to select the Lock Assignment field. If the activity is locked, then Assignment Manager cannot access it. If it is unlocked, then Assignment Manager can reassign it. |
| Template | Only templates with a type of Clinical Protocol Site and with a protocol that matches the protocol at the site appear.<br><br>Only activities with type of Document or Site-Initiation appear in the document tracking views. |

5. Edit the activities in the Activities list or create more activities.

   **NOTE:** To view additional fields in this list, click the cogwheel icon and select Columns Displayed.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Expiration Date | This field is tied to the Status field. When a date is entered in this field, the status field is automatically set to Done. |
| Expected Date | For document tracking: The date that the signed document is expected to come back from the site. |
| Received Date | For document tracking: The date that the signed document returns from the site. |
| Sent Date | For document tracking: The date that the document is sent to the site. |

| Field | Comments |
|---|---|
| Status | This field is tied to the Completed Date field. When this field is set to Done, the Completed Date field is automatically set to the current date. |
| Displayed In | A check mark in this field indicates that the activity does not appear on the user's calendar. |

# Applying Activity Templates to Sites

You can simultaneously apply one or multiple activity templates across one or multiple sites for a study. Activity records with a type of Document and Site-Initiation appear in the Document Tracking view of the Site Management screen. Activity records with a type of Correspondence appear in the Activities view of the Site Management screen.

The applied templates also appear in the Activity Plans view of the Site Management screen for each of the selected sites.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

## Applying Activity Templates to Sites in a Region

Complete the procedure in this topic to simultaneously apply one or multiple activity templates to multiple sites in a region.

### *To simultaneously apply one or multiple activity templates to multiple sites in a region*

1. Navigate to the Regions screen, then the Region List view.
2. In the Region list, drill down on the Region field of the region for which you want to apply an activity template.
3. In the Sites view, select the sites to which you want to apply an activity template.
4. Click Apply Template.
5. From the Templates dialog, select one or multiple activity templates that you want to apply to the selected site, and click OK.

## Applying Activity Templates to Sites in a Protocol

Complete the procedure in this topic to simultaneously apply one or multiple activity templates to multiple sites in a protocol.

### *To simultaneously apply one or multiple activity templates to multiple sites in a protocol*

1. Navigate to the Protocols screen, then the Protocol List view.

2 In the Protocol list, drill down on the protocol number field of the protocol for which you want to apply an activity template.

3 Navigate to the Sites view.

4 In the Sites list, select the sites to which you want to apply an activity template.

5 Click Apply Template.

6 From the Templates dialog, select one or multiple activity templates that you want to apply to the selected site, and click OK.

# Tracking and Adding Documents at Sites

During the life of a clinical trial, CRAs (clinical research associates) collect and track numerous documents, including critical regulatory documents. CRAs can take advantage of the activity plans to generate a list of documents for tracking. In the document tracking views, they can also create their own lists of activities to track important dates.

**NOTE:** Regional study managers can use similar procedures to add and track documents at the region level in the Regions screen.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

## Tracking Documentation Milestones

Complete the procedure in this topic to track documentation milestones.

### *To track documentation milestones*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, drill down on the site number field of the site for which you want to track documentation.

3 Navigate to the Document Tracking view.

A list of documents associated with the clinical trial appears.

4 Query for the document of interest and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Activity | By default, the activity is Document. |
| Assigned To | The person to whom responsibility for the document has been assigned. |
| Expected Date | The date that the signed document is expected to come back from the site. |
| Expiration Date | The date the document expires. |

| Field | Comments |
|---|---|
| Lock Assignment | Determine whether to select the Lock Assignment field. If the activity is locked, then Assignment Manager cannot access it. If it is unlocked, then Assignment Manager can reassign it. |
| Name | The name of the document. This field is a hypertext link to the Attachments view. |
| Received Date | The date that the signed document returns from the site. |
| Sent Date | The date that the document is sent to the site. |

## Adding Documents to Sites

Complete the procedure in this topic to add a document to a site.

### *To add a document to a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to track documentation.
3. Navigate to the Document Tracking view.

   A list of documents associated with the clinical trial appears.
4. Create a new record and complete the necessary fields.
5. Step off the record you just added and drill down on the Name field.

   The Attachments view appears.
6. Create a new record and in the Name field specify the file name or URL.
7. Select the Auto Update field if you want to have the file automatically updated during synchronization.

   Synchronization applies only to local files. If a file is not local, then it cannot be updated during synchronization.

# Creating Activities for Document Tracking

Numerous documents are collected during clinical trials, either as electronic files or as paper. These documents must be tracked and periodically updated. Documents can be associated with sites, regions, protocols, contacts, or accounts.

This task is a step in “Process of Managing Sites and Contacts for Clinical Trials” on page 89.

### *To create an activity for document tracking*

1 Navigate to the Document Tracking screen.

2 In the Document Tracking list, create a new record and complete the necessary fields.

**NOTE:** An activity for document tracking can be associated with only one of the available tracking levels or entities.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Name | The document name.<br><br>In the Document Tracking list, this field links to the associated Attachments view. |
| Site #, Region, Protocol, Contact, or Account. | Assign the activity for document tracking to one of these five levels.<br><br>In the Document Tracking list, the selected field links to the Activities view. |

## Reviewing, Updating, and Adding Existing Documents for Tracking

Complete the procedure in this topic to review, update, and add existing documents for tracking.

### *To review, update, and add existing documents for tracking*

1 Navigate to the Document Tracking screen.

2 In the Document Tracking list, query for the document you want to update.

3 Drill down on the Name field of the document.

The associated Attachment view appears.

4 In the Attachment list, query for the document and click the document name.

5 Open, update, and save the document.

6 Use the thread bar to return to the document record on the Document Tracking list.

7 Copy the original document record and revise the associated site number, Region, Protocol, Contact, or Account field.

Alternatively, activities for document tracking can be created and reviewed in the Document Tracking view for a site. Similarly, activities for document tracking at the protocol and region levels can be created and reviewed in the Document Tracking view for the protocol and region.

# Creating Tracking Activities for Case Report Forms

Numerous CRFs (case report forms) are collected during clinical trials, either as electronic files or as paper. These forms must be tracked and periodically updated. CRFs can be associated with sites, regions, or protocols.

CRF tracking records are created when you apply a subject visit template in addition to subject visit records. You can also create an activity for CRF tracking from the CRF Tracking View of a site.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

## Viewing Tracking Activities for Case Report Forms

Complete the procedure in this topic to view tracking activities for CRFs (case report forms).

### *To view tracking activities for a case report form*

- Navigate to the Document Tracking screen, then the CRF Tracking view.

  The CRF Tracking list displays all of the tracking records.

  **NOTE:** A tracking activity for a CRF can be associated with only one of the available tracking levels or entities.

  Some fields are described in the following table.

| Field | Comments |
|---|---|
| Name | The name of the subject visit for which CRFs were collected. |
| Site #, Region, or Protocol # | CRF tracking can be assigned to the site, region, or protocol. |

## Reviewing, Updating, and Adding Existing Case Report Forms for Tracking

Complete the procedure in this topic to review, update, and add existing CRFs (case report forms) for tracking.

### *To review, update, and add existing case report forms for tracking*

1. Navigate to the Document Tracking screen, then the CRF Tracking view.
2. In the CRF Tracking list, query for the document you want to update.
3. Open, update, and save the CRF.
4. Use the thread bar to return to the CRF record on the CRF Tracking list.
5. Copy the original CRF record, and revise the associated site number, Region, and protocol number field.

Alternatively, you can create and review activities for CRF tracking from the CRF Tracking view of a site. Similarly, at the protocol and region levels, you can also create and review activities for CRF tracking from the CRF Tracking view.

# Tracking Case Report Forms

Users can create and track CRFs (case report forms) as part of a protocol, site, and region. Relevant information, such as whether the CRFs are source verified, retrieved from a site, in-house, or by a data management process, is captured for each CRF record within a protocol, site and region.

When you apply a subject visit template, in addition to creating subject visit records and the child activity records as existed in the current product, a duplicate set of visit records with a Type of Case Report Form are created (with the number of pages specified in the template).

These visit records with the number of CRF pages are listed in the CRF Tracking view in the Protocol Site List view of the Site Management screen. You can also create records for CRF tracking in this view.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To track case report forms*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to track CRFs.
3. Navigate to the CRF Tracking view
4. In the CRF Tracking list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Activity | Lists the activities associated with the site. |
| Activity Type | Populated with the CRF activity type. Only activity records with the CRF activity type appear in this view. |
| # CRF Pages | The number of pages contained in the CRF. |
| Retrieved | Checked if the CRA (clinical research associate) was retrieved by Data Management. |
| Retrieved Date | Date when the CRF was retrieved. |
| Received in House | Date when the CRA retrieved the CRF in house. |
| Received by Data Management | Date when the CRA retrieved the CRF by data management. |
| Source Verified | Indicates whether the CRF is a verified source document. |

| Field | Comments |
|---|---|
| Source Verified Date | The date when the CRF was source verified. |
| Comments | Enter a relevant comment about the CRF. |

# Creating Correspondence Activities for Sites

You can track all correspondence (phone, fax, email, and letters delivered by the postal service) between a site and a study team member as correspondence activities for the site. You can create such activities for multiple sites. This feature provides an easy way of capturing all forms of communication between a site and an employee, or between business partners, such as a CRO (clinical research organization), or central lab.

For each created correspondence activity, an activity record is created in the Activities view of the Contacts screen for each of the contacts.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

## Creating Correspondence Activities for Sites

Complete the procedure in this topic to create a correspondence activity for a site.

### *To create a correspondence activity for a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to create a correspondence activity.
3. Navigate to the Activities view.
4. In the Activities list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Activity | Populated with a value of Correspondence. |
| Activity Type | Select from one of the following activity types:<br>■ Case Report Form<br>■ Email<br>■ Fax<br>■ Mail<br>■ Phone |

| Field | Comments |
|---|---|
| Description | Enter a brief description for the correspondence activity. |
| Screen # | The number of screens for the correspondence. |
| Comments | Enter a relevant comment about the correspondence activity. |
| Last Name | Enter the last name of the creator of the correspondence activity. This is a required field. |

## Creating New Role Correspondence for Sites

Complete the procedure in this topic to create a new role correspondence for a site.

### *To create a new role correspondence for a site*

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol for which you want to create a new role.
3. Navigate to the Sites view
4. In the Sites list, select one or multiple sites for which you want to apply a new role for the correspondence.
5. Click New Correspondence.
6. From the Roles of Contacts dialog box, select the role or multi-select the roles that best describe the individual's role, and click OK.

## Creating Partner Correspondence Activities

You can track all correspondence (phone, fax, email, and letters delivered by the postal service) between business partners, such as a CRO (clinical research organization), or central lab.

### *To create partner correspondence activities*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to create a partner correspondence activity.
3. Navigate to the Activities view.
4. In the Activities list, create a new record and complete the necessary fields.

# Adding Notes to Sites

When you are working with site records, you often find that you want to make notes. In the Notes view, you can enter public notes or private notes. Use the link bar in the Notes view to switch between public and private notes. A *public note* can be seen by anyone who has access to the record. A *private note* can be seen only by the person who enters the note.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To add a note to a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to add notes.
3. Navigate to the Notes view, then the Private Notes view or Public Notes view.
4. Create a new record and complete the necessary fields.

   The Created By Name and the Created Date fields are automatically completed with your User ID and system date.
5. In the Type field, select the note type.

   Examples of note types are Exclusion, Pre-existing Condition, Permanent, System, Temporary, Business Description, Regional Plans, and Contracts Process.
6. In the Description field, enter the note text.
7. Click Check Spelling to make sure your note has no spelling errors.

# Assessing Contacts and Accounts

Assessments allow end users to calculate a single numerical value that expresses the fitness of a contact or account, according to a set of attributes defined in the assessment template. For example, an investigator can be assessed to determine competence to carry out a large scale clinical trial in phase III or a hospital can be assessed to determine suitability to carry out a similar trial. The results of this assessment help CRAs (clinical research associates) find suitable investigators and hospitals for subsequent trials. For more information, see "Creating Contact and Account Assessment Templates" on page 91.

**NOTE:** The score values in the Assessment Attributes list and the (total) score value in the Assessments list are automatically updated.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To assess a contact or account*

1. Complete one of the following steps, depending on whether you want to assess a contact or account:

- Navigate to the Contacts screen, then the Contacts List view, and in the Contacts list, drill down on the Last Name field of the contact that you want to assess.
- Navigate to the Accounts screen, then the Accounts List view, and in the Accounts list, drill down on the Name field of the account that you want to assess.

2. Navigate to the Assessments view.
3. In the Assessments list, create a new record.
4. In the Template Name field, select the assessment template that has been prepared for you.

   For more information, see "Creating Contact and Account Assessment Templates" on page 91.

   The other fields in the record are populated when the record is saved.
5. In the Assessment Attributes list, for each attribute:
   a. Enter a Value by selecting from the Pick Attribute Value dialog box.
   b. Add or edit comments in the Comment field of the attribute.

# Generating Oracle BI Publisher Reports for Document Tracking

Siebel Clinical can be integrated with Oracle Business Intelligence Publisher (BI Publisher) for generating reports. You can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical. For more information about using Siebel Reports and integrating with Oracle BI Publisher, see *Siebel Reports Guide*.

The following preconfigured clinical document tracking reports are provided:

- Site Document Tracking
- Protocol Level Document Tracking
- Region Level Document Tracking
- Protocol Document Tracking Across Sites
- Regional Document Tracking Across Sites

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

## Generating Reports for Site Document Tracking

This topic describes how to generate the preconfigured Site Document Tracking report for Oracle BI Publisher.

### *To generate a report for site document tracking*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate an Oracle BI Publisher report.

3 Navigate to the Document Tracking view.

4 On the application toolbar, click the Reports icon.

5 In the Run Report pane, complete the appropriate fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Site Document Tracking report. |
| Output Type | Select the output type for the report. |

6 Click Submit.

The report runs.

7 Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*

## Generating Reports for Protocol Level Document Tracking

This topic describes how to generate the preconfigured Protocol Level Document Tracking report for Oracle BI Publisher.

### *To generate a report for protocol level document tracking*

1 Navigate to the Protocols screen, then the Protocol List view.

2 In the Protocol list, drill down on the protocol number field of the protocol for which you want to generate an Oracle BI Publisher report.

3 Navigate to the Document Tracking view.

4 On the application toolbar, click the Reports icon.

5 In the Run Report pane, complete the appropriate fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Protocol Level Document Tracking report. |
| Output Type | Select the output type for the report. |

6 Click Submit.

The report runs.

7 Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*.

## Generating Reports for Region Level Document Tracking

This topic describes how to generate the preconfigured Region Level Document Tracking report for Oracle BI Publisher.

### *To generate a report for region level document tracking*

1 Navigate to the Regions screen, then the Region List view.

2 In the Region list, drill down on the Region field of the region for which you want to generate an Oracle BI Publisher report.

3 Navigate to the Document Tracking view.

4 On the application toolbar, click the Reports icon.

5 In the Run Report pane, complete the appropriate fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Region Level Document Tracking report. |
| Output Type | Select the output type for the report. |

6 Click Submit.

The report runs.

7 Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*.

## Generating Reports for Protocol Document Tracking Across Sites

This topic describes how to generate the preconfigured Protocol Document Tracking Across Sites report for Oracle BI Publisher.

### *To generate a report for protocol document tracking across sites*

1 Navigate to the Site Management screen.

2 On the application toolbar, click the Reports icon.

3 In the Run Report pane, complete the appropriate fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Protocol Document Tracking Across Sites report. |
| Output Type | Select the output type for the report. |

4 Click Submit.

The report runs.

5 Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*.

## Generating Reports for Regional Document Tracking Across Sites

This topic describes how to generate the preconfigured Regional Document Tracking Across Sites report for Oracle BI Publisher.

### *To generate a report for regional document tracking across sites*

1 Navigate to the Site Management screen.

2 On the application toolbar, click the Reports icon.

3 In the Run Report pane, complete the appropriate fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Regional Document Tracking Across Sites report. |
| Output Type | Select the output type for the report. |

4 Click Submit.

The report runs.

5 Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*.

# Generating Reports for Actual Visits

This topic describes how to generate the preconfigured Actual Visits report for Oracle BI Publisher. This report lists the completed subject visits for a site.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To generate a report for actual visits*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate an Oracle BI Publisher report.
3. On the application toolbar, click the Reports icon.
4. In the Run Report pane, complete the appropriate fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Actual Visits report. |
| Output Type | Select the output type for the report. |

5. Click Submit.

   The report runs.
6. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*.

# Generating Reports for Planned and Actual Dates of Subject Visits

This topic describes how to generate the preconfigured Planned vs Actual Patient Dates report for Oracle BI Publisher. This report lists the planned and completed subject visit dates for a site.

This task is a step in "Process of Managing Sites and Contacts for Clinical Trials" on page 89.

### *To generate a report for planned and actual dates of subject visits*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate an Oracle BI Publisher report.
3. On the application toolbar, click the Reports icon.

4 In the Run Report pane, complete the appropriate fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Planned vs Actual Patient Dates report. |
| Output Type | Select the output type for the report. |

5 Click Submit.

The report runs.

6 Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*.

# 7 Managing Partial Source Data Verification

This chapter covers how to manage partial source data verification. It includes the following topics:



## About Partial Source Data Verification

To ensure that all of the data collected during the clinical trial is complete, accurate, and verifiable, companies use SDV (source data verification). This key process involves many on-site visits and verification of all the data in the CRF (case report form).

The number of clinical trials is growing, and these trials are becoming more complex. Also, regulatory agencies are more closely monitoring the drug approval process. Consequently, the cost of these trials is drastically rising, and companies and CROs (clinical research organizations) face challenges in keeping budget and time issues for trials under control. Consequently, more companies and CROs are adopting risk based monitoring for their clinical trials. Risk based monitoring moves from the traditional methods involving 100% or complete SDV to PSDV (partial source data verification). It introduces strategic on-site monitoring that is based on risks and assessments about important aspects of clinical trials.

For PSDV, you plan the SDV process by using statistical and historical information about the clinical sites and the involved personnel and about events that occur at various points in the clinical trial. This planning involves decisions at various levels of the clinical trial. Some information included in partial source verification follows:

- Percentage of CRFs to verify
- Specific CRFs to verify
- Specific pages of the CRFs to verify
- Adverse events at specific points in the clinical trial

# Setting Up Partial Source Data Verification for Clinical Protocols

This topic describes how to set up PSDV (partial source data verification) for clinical protocols. You set up this verification by entering PSDV values in some fields when you create a record for a clinical protocol. These values are automatically populated in the same fields for all of the regions and sites that you associate with the clinical protocol. However, you can change these automatically populated values.

If you update the PSDV values in the fields of a clinical protocol, then the updated values are not automatically populated in the same fields of the regions and sites that are already associated with the clinical protocol. If you associate new regions and sites with the clinical protocol, then the updated values are automatically populated in the same fields of the new regions and sites.

If you update the value (from Complete to Partial) in the SDV Policy field for a site that is associated with the clinical protocol, then the PSDV values in the fields of the clinical protocol are automatically populated in the same fields of the site.

### *To set up partial source data verification for a clinical protocol*

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, create a new record and complete the necessary fields.

   For more information, see "Setting Up Clinical Protocols" on page 40.

   Alternatively, you can select an existing protocol record to update it.
3. In the Protocol list, drill down on the protocol number field of the protocol record.
4. Navigate to the More Info view.
5. Scroll down to the Partial Source Data Verification section, and complete the PSDV fields.

   The PSDV fields are described in the following table.

| Field | Comments |
|---|---|
| Number of Initial Subjects | The number of initial subjects with CRFs (case report forms) to completely verify. |
| Subject Auto-Select Rate | For the total number of subjects less the number of initial subjects, the percentage with CRFs that are part of SDV (source data verification). |

# Setting Up Partial Source Data Verification for Clinical Regions

This topic describes how to set up PSDV (partial source data verification) for clinical regions. You set up this verification by entering PSDV values in some fields when you create a record for a clinical region. These values are automatically populated in the same fields for all of the sites that you associate with the clinical region. However, you can change these automatically populated values.

If you update the PSDV values in the fields of a clinical region, then the updated values are not automatically populated in the same fields of the sites that are already associated with the clinical region. If you associate new sites with the clinical region, then the updated values are automatically populated in the same fields of the new sites.

If you update the value (from Complete to Partial) in the SDV Policy field for a site that is associated with the clinical region, then the PSDV values in the fields of the clinical region are automatically populated in the same fields of the site.

### *To set up partial source data verification for a clinical region*

1. Navigate to the Administration - Clinical screen, then the Region List view.
2. In the Region list, create a new record and complete the necessary fields.

   For more information, see "Setting Up Clinical Regions" on page 46.

   Alternatively, you can select an existing region record to update it.
3. In the Region list, drill down on the Region field of the region record.
4. Navigate to the More Info view.
5. Scroll down to the Partial Source Data Verification section, and complete the PSDV fields.

   The PSDV fields are described in the following table.

| Field | Comments |
|---|---|
| Number of Initial Subjects | The number of initial subjects with CRFs (case report forms) to completely verify. |
| Subject Auto-Select Rate | For the total number of subjects less the number of initial subjects, the percentage with CRFs that are part of SDV (source data verification). |

# Setting Up Partial Source Data Verification for Subject Visit Templates

This topic describes how to set up PSDV (partial source data verification) for subject visit templates. You set up this verification by entering PSDV values in some fields when you create a record for a subject visit template. These values are automatically populated in the same fields for all of the CRF (case report form) tracking records that are associated with the subject visit template.

### *To set up partial source data verification for a subject visit template*

1 Navigate to the Administration - Clinical screen, then the Visit Templates view.

2 In the Subject Visit Templates list, create a new record and complete the necessary fields.

For more information, see "Creating Subject Visit Templates" on page 58.

Alternatively, you can select an existing subject visit template record.

3 Scroll down to the Template Versions list, create a new record and complete the necessary fields.

For more information, see "Defining Versions for Subject Visit Templates" on page 59.

Alternatively, you can select an existing version record.

4 Scroll down to the Visits list, create a new record and complete the necessary fields.

Alternatively, you can select an existing visit record to update it.

The PSDV fields are described in the following table.

| Field | Comments |
|---|---|
| SDV Required | Select this field if SDV (source data verification) is necessary for the subject visit associated with the template. |
| Page Numbers to Verify | The page numbers of the CRF that are included in PSDV. If SDV is necessary for all the CRF pages, then enter All Pages. This field provides information to CRAs (clinical research associates) when they review CRFs, and does not affect processing in Siebel Clinical Trial Management System. |

# Setting Up Partial Source Data Verification for Sites

This topic describes how to set up PSDV (partial source data verification) for sites. You set up this verification by entering PSDV values in some fields when you create or update a record for a site.

### *To set up partial source data verification for a site*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, create a new record and complete the necessary fields.

For more information, see "Creating Sites for Clinical Trials" on page 51.

Alternatively, you can select an existing site record to update it.

3 In the Protocol Site list, drill down on the site number field of the site record.

4 Navigate to the More Info view.

5 Scroll down to the Partial Source Data Verification section, and complete the PSDV fields.

The PSDV fields are described in the following table.

| Field | Comments |
|---|---|
| SDV Policy | The policy for SDV (source data verification). Valid values include Complete and Partial. The default value is Complete.<br><br>When the value is Complete, all of the subjects associated with the site record are part of complete SDV, and the SDV Required field in those subject records is set to Yes. |
| Number of Initial Subjects | The number of initial subjects with CRFs (case report forms) to completely verify. You can change this field only if the SDV Policy field has a value of Partial.<br><br>If the protocol or region record that is associated with this site already has a value in this same field, then that value is automatically populated in this field. However, you can change this automatically populated value. |
| Subject Auto-Select Rate | For the total number of subjects less the number of initial subjects, the percentage with CRFs that are part of SDV. You can change this field only if the SDV Policy field has a value of Partial.<br><br>If the protocol or region record that is associated with this site already has a value in this same field, then that value is automatically populated in this field. However, you can change this automatically populated value. |
| Total Subjects Requiring SDV | The number of subjects who are included in SDV. This field is read-only. The calculation of this field value follows:<br><br>(Number of Initial Subjects) plus [(Total Subjects in the Site Pool) less (Number of Initial Subjects) times Subject Auto-Select Rate]<br><br>For more information about this field, see "Recalculating Clinical Subjects Requiring Source Data Verification" on page 120. |
| Total Subjects in Site Pool | The number of subjects in the site pool. This field is read-only. |

# Setting Up Partial Source Data Verification for Clinical Subjects

This topic describes how to set up PSDV (partial source data verification) for clinical subjects. You set up this verification by entering PSDV values in some fields when you create or update a record for a clinical subject.

### *To set up partial source data verification for a clinical subject*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, create a new record and complete the necessary fields.

   For more information, see "Creating Sites for Clinical Trials" on page 51.

   Alternatively, you can select an existing site record.
3. In the Protocol Site list, drill down on the site number field of the site record.
4. Navigate to the Subjects view.

5 In the Subjects list, create a new record and complete the necessary fields.

For more information, see "Creating Records for Clinical Subjects" on page 66

Alternatively, you can select an existing subject record to update it.

The PSDV fields are described in the following table.

| Field | Comments |
|---|---|
| SDV Required | A flag that indicates whether SDV (source data verification) is necessary for the CRFs (case report forms) of the subject. The value in this field can change in the following ways:<br>■ You can manually change the field value. To change the field value, drill down on the screening number field of the subject record to navigate to the subject form.<br>■ The field value can be automatically populated using the PSDV field values of the site record that is associated with the subject record.<br>■ If the value in the SDV Policy field for the associated site record is Complete, then the SDV Required field for the subject record is Yes.<br>■ If the value in the SDV Policy field for the associated site record is Partial, then the SDV Required field for the subject record can be Yes or No. The value depends on the other PSDV field values.<br>■ This field can be automatically populated when a status rule set for the Status field of the subject record exists. If such a rule set exists, then this field is automatically populated with a value of Yes or No. |
| SDV Last Updated Source | The reason for the value in the SDV Required field. This field is read-only. It can have the following values:<br>**Site.** The value in the SDV Required field is the result of the PSDV fields of the site record that is associated with the subject record. The subject records with this value are included in the site pool.<br>**Subject Status.** The value in the SDV Required field is the result of a status rule set for the Status field of the subject record. The subject records with this value are included in the status pool.<br>**Manual.** The user selected the value in the SDV Required field for the subject record. The subject records with this value are included in the subject pool.<br>**External.** The value in the SDV Required field is the result of incoming data from an integrated CDMS (clinical data management system). |

# Viewing Case Report Forms for Partial Source Data Verification

This topic describes how to view the CRFs (case report forms) applicable to PSDV (partial source data verification). During a site visit, CRAs (clinical research associates) do not review all CRFs and all pages on those CRFs. The field values for PSDV in the subject visit template that is associated with the site visit determine the information that the CRA reviews.

### *To view the case report forms for partial source data verification*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site record.
3. Navigate to the CRF Tracking view.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| SDV Required | A flag that indicates whether SDV (source data verification) is necessary for the site visit.<br><br>This field is read-only, and automatically populated from the value of the same field in the subject visit template that is associated with this CRF tracking record. |
| Page Numbers to Verify | The page numbers of the CRF that are included in PSDV.<br><br>This field is read-only, and automatically populated from the value of the same field in the subject visit template that is associated with this CRF tracking record. |

# Recalculating Clinical Subjects Requiring Source Data Verification

If you change the value in the Number of Initial Subjects field or the Subject Auto-Select Rate field of a site record, then you must recalculate the value in the Total Subjects Requiring SDV field of that site record.

If you change the number of subjects in the site pool by changing the value in the SDV Required field of the site's subject records, then you must recalculate the value in the Total Subjects Requiring SDV field of the site record. If you change the number of subjects in other pools, such as the subject pool and the status pool, then you do not have to recalculate the value in Total Subjects Requiring SDV field because these other pools are not included in the calculation of this field. For more information about pools, see "Setting Up Partial Source Data Verification for Clinical Subjects" on page 117.

***To recalculate the subjects requiring source data verification***

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of a site record.
3. Navigate to the More Info view.
4. Click Reapply Auto-Select Rate.

   If the value in the Number of Initial Subjects field or the Subject Auto-Select Rate field has changed, then the value in the Total Subjects Requiring SDV field is recalculated, and this recalculation considers the subjects in the site pool.

# About Partial Source Data Verification for Protocol Amendments

When you change a subject visit template, you create a new version of that template. This new version results in a protocol amendment. When you apply the protocol amendment to the subjects, the following processing occurs:

1. The subject visits that are no longer valid are deleted.
2. CRF (case report form) records associated with the subject visits are deleted.
3. New subject visits are created.
4. New CRFs are created with values for PSDV (partial source data verification) fields from the latest version of the subject visit template.

   For CRFs that already have values for PSDV fields, new CRFs are also created. The values for fields that are not available in the subject visit template are copied from the prior CRFs to the new CRFs, and the values for PSDV fields are copied from latest version of the subject visit template to the new CRFs.
5. Activities are created according to the protocol amendment.

# 8 Setting Up and Making Clinical Payments

This chapter describes how to set up and make clinical payments. It includes the following topics:



## About Setting Up and Making Clinical Payments for Subject Activities

Payments to investigators and sites are set and adjusted at the following levels:

- Standard payment amounts are set by the financial administrator through the subject visit template
- Exceptions to standard payment amounts are set according to agreements negotiated by individual sites
- Payments can be further adjusted on a one-off only basis before the payment is generated

Not all subject activities have payment amounts associated with them. For example, obtaining informed consent might be a subject activity for which the site is not paid, but a site is paid for performing a blood test. Subject activities for which the site can be paid are referred to as *payment subject activities*. (In the Siebel Clinical interface, these activities are indicated by the Payment Flag field.)

In addition to subject activities, sites can be paid for other activities created at the site level, such as IRB (institutional review board) fees and equipment costs. Those activities can be designated as payable to the site with the Payment Flag field. For information about managing budgets at the protocol level, see Chapter 10, "Managing Clinical Projects."

You can use multiple currencies for a protocol. For more information about setting up currency conversions, see *Siebel Applications Administration Guide*.

Currencies and exchange rate dates are set at the following levels:

- **Protocol level.** A single currency code and exchange date is associated with a protocol record. All payments made to sites for the protocol are converted to and rolled up in the protocol currency.
- **Region level.** If regions are used for the protocol, then set a currency code and exchange date for the region. All site payments made in that region are converted to and rolled up in the region's currency.
- **Site level.** Set a currency code and exchange date for each site. When you use a subject visit template to create subject visits and activities, all payment activities are converted to the currency specified for the site on the exchange date that is set at the site level.

# Scenario for Clinical Payments

This topic gives one example of how clinical payments might be used. You might use payments differently, depending on your business model.

Using on the input from the clinical contract or grant negotiations group, the financial administrator sets up the standard payment amounts for procedures and tasks that the site performs. A major pain-point for clinical organizations is managing investigator payments. Often investigators are paid for activities that they have not carried out, or for activities that they have carried out but that are not to the satisfaction of the sponsor. By specifying a withholding amount and a withholding percentage, it is possible to withhold payments from an investigator to make sure that all activities are carried out. This guarantees that investigators are motivated to carry out all activities so that they get paid in full.

The CRAs (clinical research associates) set up the payment exceptions for sites where different payments have been negotiated for subject activities. (In some organizations, this task is done by study manager instead of the CRA.)

As the sites carry out the procedures, the financial administrator verifies successful completion of the procedures and tasks and generates payments for these activities. A payment (minus the withholding amount or percentage) is generated when an activity is completed. If all activities for a site are completed, then the investigator is paid the full amount for all activities including the amount or percentage withheld.

Occasionally, the sponsor or CRO (clinical research organization) must make an additional payment to a site, a payment which is not directly associated with subject activities. These are unplanned payments, for example, reimbursement for an unscheduled visit.

**NOTE:** As the clinical trial progresses, the sites carry out the subject activities for which they are paid. Typically, site personnel at the sites enter completed dates for subject activities using Siebel Site Portal. For more information about Siebel Site Portal, see *Siebel Life Sciences Portals Guide.*

# Setting Up Standard Payment Amounts in Subject Visit Templates

Payment amounts can be set up when the subject visit template is created. For more information, see "About Subject Visit Templates" on page 58.

Also, payment amounts can be added later following the procedure in this topic. Payments at the site level can be entered in any currency. All payment amounts made at the site level are converted to the currency designated for the site and rolled up into the currency that is designated for the region. If a region is not required, then payment amounts at the site level are rolled up into the currency that is designated for the protocol.

**NOTE:** This task requires administrator privileges.

### *To set up standard payment amounts in the subject visit template*

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. Select the subject visit template and template version for which you want to add payment amounts.
3. For each visit and each activity that the sites are to be paid for:
   a. Select the Payment Flag field.

      If the Payment Flag field is not selected, then the activity does not appear in the Payment Activities view and a payment cannot be generated.

   b. In the Payment Amount field, use the currency calculator to enter the amount and currency code.

# Setting Payment Exceptions for Sites

The currency used at the site might differ from the currency used for the standard amount.Also, the amount paid to individual sites for a particular procedure can differ from the standard amount set in the subject visit template. For more information, see "Setting Up Standard Payment Amounts in Subject Visit Templates" on page 125.

The procedure in this topic explains how to use payment exceptions to change the standard amount paid for a payment subject activity for an individual site. After the payment exception has been set for an activity associated with the given site, visit, and template version, each time the activity is generated for a subject the activity shows the site-specific amount.

**NOTE:** When a new subject visit template becomes active, set payment exceptions for the new template.

### *To set payment exceptions for a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to set up payment exceptions.
3. Navigate to the Payment Exceptions view.
4. In the Payment Exceptions list, create a new record.

   The Payment Exceptions dialog box filters payment subject activities to show only those for the current protocol version. However, you can query from the set of all payment subject activities with Payment Flag field selected across all versions and protocols. This way, you can set payment exceptions for activities in protocol version 2 *and* in protocol version 1, for example, if the site is expected to transition to the newer version in the near future.
5. In the Payment Exceptions dialog box, select all activities for which you want to set payment exceptions and click OK.
6. In the Exception Amount fields, enter the new amounts that are to be paid to this site for each activity.

**NOTE:** The Exception Amount to be paid at the site level might be in a different currency than the currency designated in the subject visit template or for the site. When subject activities are created at a site, the currency is converted to the currency designated for the site.

# Splitting Payment Activities Between Multiple Payees

A payment activity can be split between multiple contracts and payees. Each contract and payee combination for each payment activity split must be unique for the payment.

Payment activity splits are defined at the payment exceptions level in the Split Details applet. Payment activity splits can also be defined in the Split Details view for payments that do not have any payment exceptions. Scheduling a subject for the corresponding site applies the subject visit template and creates a payment activity for each split payment defined in the Split Details applet.

### *To split a payment activity between multiple payees*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to set up split payments.

3 Navigate to the Payment Exceptions view.

4 In the Payment Exceptions list, select the record for which you want to create split payments.

5 Navigate to the Split Details list.

6 Create a new record for each payment split, and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Contract | Select the payee contract from the list of contracts. The contract and payee combination for each payment split must be unique for the payment. |
| Account | This field is automatically populated with the primary account for the selected contract. |
| Payee First Name | Select the payee first name from the list. |
| Payee Last Name | Select the payee last name from the list. The list displays all contacts for the primary account of the selected contract. |
| Split Percentage | Enter the split percentage for each payment split. The total split percentage for all of the payment splits must be one hundred percent.<br><br>The split percentage is automatically calculated if you enter the amount manually in the Split Amount field. |
| Split Amount | This field is automatically calculated using the split percentage of the total payment amount. You can also enter the amount manually. |

7 When all payment splits have been created, verify that the Split Status icon in the Payment Exceptions view is green, to indicate that the total splits for the payment amount to one hundred percent.

# Copying Details for Payment Splits

The details of a split payment activity can be copied to multiple payment activities. Payment activity splits are copied at the payment exceptions level.

### *To copy details for a payment split*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, drill down on the site number field of the site for which you want to copy split payment details.

3 Navigate to the Payment Exceptions view.

4 In the Payment Exceptions list, select the record that you want to copy.

5 Click Apply Split to Other.

The Payment Activities Select Applet appears.

6 Select the payment activities to which you want to apply the split details, and click OK.

The split details are created in the Split Details applet for all of the selected payment activities.

7 Navigate to the Split Details applet and make any required amendments.

# Reversing Splits for Payment Activities

This topic describes how to reverse a payment activity split. The split details for each payment are deleted from the Split Details applet.

### *To reverse a split for a payment activity*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, drill down on the site number field of the site for which you want to reverse payment activity splits.

3 Navigate to the Payment Exceptions view.

4 In the Payment Exceptions list, select the records that you want to reverse.

5 Click Unsplit.

6 Click OK to delete the split details for the selected payment activities.

The split details for each selected payment activity are deleted from the Split Details applet.

# Marking Subject Activities as Completed

Usually the site personnel use Siebel Site Portal to enter when subjects complete activities. However, this task can also be performed by the CRA (clinical research associate) using Siebel Clinical.

### *To mark subject activities as completed*

1 Navigate to the Subjects screen, then the Subjects List view.

2 In the Subject list, drill down on the screening number field of the subject with completed activities.

3 Navigate to the Visits view.

4 In the Visits list, select the visit that has just been completed and click Complete Activities.

The selected visit and all of its activities are marked as completed as follows:

- The Completed field is selected.
- The Completed Date field of all activities for the selected visit are populated with the same value in the Completed Date field of the parent visit.

- The Status field is set to Done.

5 If necessary, edit the fields for the visit in the Activities list.

# Creating Payment Activities for Sites

This task describes how to create a payment activity record for a clinical site, including the contract, account, and payee details.

### *To create a payment activity for a site*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, drill down on the site number field of the site for which you want to create a payment activity.

3 Navigate to the Payment Activities view.

4 In the Payment Activities list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Payment | This field must be selected to define the activity as a payment activity. |
| Standard Amount | The payment amount prior to any adjustment. The Actual Amount is calculated as follows:<br><br>Standard Amount plus Deviation Amount equals Actual Amount |
| Deviation Amount | Adjust the Actual Amount by entering a value in the Deviation Amount field. The Actual Amount is calculated as follows:<br><br>Standard Amount plus Deviation Amount equals Actual Amount |
| Actual Amount | The actual amount to be paid to the site. The Actual Amount is calculated as follows:<br><br>Standard Amount plus Deviation Amount equals Actual Amount |
| Contract | Select the payee contract from the list of contracts. |
| Account | This field is automatically populated with the primary account for the selected contract. |
| Payee First Name | Select the payee first name from the list. |
| Payee Last Name | Select the payee last name from the list. The list displays all primary accounts for the selected contract. |

# Generating Payment Records for Sites

This topic describes how to generate payment records from payment activities. Payments are generated for each unique contract, account and payee combination for the payment activities that are marked as Completed.

### *To generate a payment record for a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate a payment.
3. Navigate to the Payment Activities view.
4. In the Payment Activities list, select the Completed field for each payment activity to be used for generating the payment record.
5. Click Generate Payment.

   The completed payments are removed from the Payment Activities list. Payment records for each unique contract, account and payee combination are generated in the Payments list.

# Generating Payment Records for Unplanned Payment Activities

Unplanned payments not associated with subject activities can be created for clinical sites.

### *To generate a payment record for an unplanned payment activity*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to generate a payment.
3. Navigate to the Payment Activities view.
4. In the Payment Activities list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Payment | This field must be selected to define the activity as a payment activity. |

| Field | Comments |
|---|---|
| Completed | This field must be selected. When you click the Generate Payment button, the process uses only payment activity records that are completed to generate payment records. |
| Standard Amount | The payment amount prior to any adjustment. The Actual Amount is calculated as follows:<br><br>Standard Amount plus Deviation Amount equals Actual Amount |

5 Click Generate Payment.

The completed payments are removed from the Payment Activities list, and the payment record is created in the Payments list.

6 To complete the payment, follow Step 6 to Step 8 in "Adjusting Payment Amounts and Generating Payment Records for Sites" on page 131.

# Adjusting Payment Amounts and Generating Payment Records for Sites

Although payments are generally set for each site, occasionally the financial administrator might want to make additional adjustments to the amount paid for a given payment activity. For more information, see "Setting Payment Exceptions for Sites" on page 125.

When the financial administrator has finalized the amounts, payments are generated for all completed payment subject activities in the currency specified for the site. Each payment record is given a unique identity number. Other information, such as check number, check date, and check amount, can be entered later, either manually or by importing the data from a back-office finance system.

**NOTE:** This task requires administrator privileges.

### *To adjust the payment amounts and generate payment records for a site*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, drill down on the site number field of the site for which you want to generate payments.

3 Navigate to the Payment Activities view.

This view lists all scheduled payment subject activities for subjects associated with the site.

4 (Optional) Adjust the Actual Amount to be paid to the site by entering a value in the Deviation Amount field.

Standard Amount plus Deviation Amount equals Actual Amount

5 Select the Completed field and click Generate Payment.

The completed payments are removed from the Payment Activities list.

6 Navigate to the Payments view.

The payment generated in Step 5 appears in the Payments list.

7 Complete the fields in the payment record.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Account | This field is read-only and displays the primary account for the contract that the payment record is associated with. |
| Check Amount | The amount of money for which the check is to be made out. This is usually, but does not have to be, the same as the Earned Amount.<br><br>The sum of all values in the Check Amount fields for a site is equal to the Paid to Date value of the site. |
| Check Date | The date on which the check was issued. |
| Check Number | The number assigned to the check. |
| Contract # | The contract with which the payment is associated. |
| Earned Amount | The sum of the Actual Payment amounts for the completed payment activities.<br><br>The sum of all values in the Earned Amount column equals the Earned to Date value of the site. |
| Payment # | This unique number is automatically generated. |
| Requested Amount | The requested amount of payment for the payment activities carried out at this site. This field is calculated as follows:<br><br>Requested Amount equals Earned Amount times [(100 less Withholding Percentage divided by 100) less Withholding Amount] |
| Type | For payment subject activities that are generated from the Generate Payment button, this field is populated with a value of Interim Payments.<br><br>For payment subject activities that are generated from a back office system, this field is populated with a value of Initial Payments. |
| Status | The status of the payment record, for example, To be Processed, In Progress, Processed, and so on. A preconfigured state model is supplied to allow for a structured state transition. |
| VAT Amount | Enter the value added tax for the site payment. The total VAT amount for all payments is rolled up to the region, protocol, and program levels, and appears in the VAT to Date field. |

Information can also be automatically loaded from a back-office finance system.

8 (Optional) Drill down on the payment number field to view the payment activities associated with this payment.

# Generating Final Payments for Sites

Final payments can be made to sites when all payment activities have been completed.

**NOTE:** All prior final payments to sites must be completed and information for these payments updated before new final payments can be generated.

### *To generate final payments for a site*

1 Navigate to the Site Management screen, then the Protocol Site List view.

2 In the Protocol Site list, drill down on the site number field of the site for which you want to generate a payment.

3 Navigate to the Payments view.

4 Make sure that all Check Amount fields for past payments are up to date.

5 In the Payments list, create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Account | This field is read-only and displays the primary account for the contract that the payment record is associated with. |
| Contract | Select the payee contract from the list of contracts. |
| Check Amount | The amount of money for which the check is to be made out. This field is usually, but does not have to be, the same as the Earned Amount field. |
| Check Date | The date on which the check was issued. |
| Check Number | The number assigned to the check. |
| Status | This field is populated with a value of To Be Processed. |
| Type | You must set this field to Final Payment. When this field is set, the Requested Amount field for the final payment is automatically calculated as equal to the amount in the Earned to Date field for the site minus the amount in the Paid to Date field for the site. |
| VAT Amount | Enter the value added tax for the site payment. The total VAT amount for all payments is rolled up to the region, protocol, and program levels, and appears in the VAT to Date field. |

When you step-off and save the record, the Requested Amount field is automatically updated by subtracting the amount in the Paid to Date field for the site (that is, the amount in the Check Amount field) from the amount in the Earned to Date field for the site.

# Reverting Payment Records

A payment record can be reverted to modify the payment details. The Revert button is enabled when a single payment record with one of the following statuses is selected:

- In Progress
- To Be Processed

The Revert button is disabled for other statuses, and if multiple records are selected.

Your system administrator can modify the payment status values for which the Revert button is enabled by configuring the LS Clinical Enable Revert On Status property in Siebel Tools. For more information, see "User Properties for Business Components in Siebel Clinical" on page 246.

A reverted payment activity record is removed from the Payments view and returned to the Payment Activities view.

### *To revert a payment record*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to revert a payment.
3. Navigate to the Payments view.
4. Select the payment to revert.
5. Click Revert.

   The payment records and split payment activities are updated as follows:

   - The reverted payment activity record is removed from the Payments view and returned to the Payment Activities view for further processing.
   - If the payment record consisted of multiple payment activities, and if only some of the payment activities have been reverted, then the Earned Amount and Requested Amount fields are recalculated for the Payment record.

# Generating Oracle BI Publisher Reports for Clinical Payments

Siebel Clinical can be integrated with Oracle Business Intelligence Publisher (BI Publisher) for generating reports. You can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical. The preconfigured Protocol Payments report is provided for clinical payments. For more information about using Siebel Reports and integrating with Oracle BI Publisher, see *Siebel Reports Guide*.

### *To generate an Oracle BI Publisher report for Siebel clinical payments*

1. Navigate to the Protocols screen, then the Protocols List view.

2 In the Protocol list, drill down on the protocol number field of the protocol for which you want to generate an Oracle BI Publisher report.

3 Navigate to the Payments view.

4 On the application toolbar, click the Reports icon.

5 In the Run Report pane, complete the appropriate fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Protocol Payments report. |
| Output Type | Select the output type for the report. |

6 Click Submit.

The report runs.

7 Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*.

# 9 Administering and Using Clinical Trip Reports

This chapter describes how to set up and use clinical trip reports in Siebel Clinical. It includes the following topics:



## About Administering and Using Clinical Trip Reports

The study managers or clinical administrators can set up templates for trip reports. These templates are then used by the CRAs (clinical research associates) when they create trip reports to record their visits to sites.

Advantages of using the trip reports in Siebel Clinical are:

- Trip reports are made consistent across the organization and are based on GCP (good clinical practice) and SOPs (standard operating procedures).
- CRAs save time planning trips and writing trip reports.
- Managers save time reviewing trip reports.
- A formatted, tamper-proof report for print or PDF can be generated from the trip report record.
- A central repository exists for all trip reports.

# Scenario for Managing Clinical Trip Reports

This topic gives one example of how to manage clinical trip reports. You might manage clinical trip reports differently, depending on your business model.

This topic includes the following information:


- "Preparing Trip Report Templates" on page 138
- "Preparing Trip Reports" on page 138


## Preparing Trip Report Templates

A clinical administrator prepares a set of trip report templates for the CRAs (clinical research associates) to use when preparing for and writing up their visits to clinical sites. For more information about site visits, see "Creating and Managing Site Visits" on page 93.

The clinical administrator prepares the following templates for each type of site visit the CRAs are typically required to perform:

- Site evaluation
- Site initiation
- Site monitoring
- Site close-out

## Preparing Trip Reports

The CRA (clinical research associate) is the end user of the Siebel Clinical product. Before visiting a site, the CRA uses the trip report to prepare for the visit. The follow-up items list reminds the CRA of the open activities arising from previous visits that the CRA can close.

After preparing a draft trip report, the CRA makes a hard copy of the report and takes this copy on the site visit. The report can be used as a reference to help keep track of the activities that are carried out while at the site.

Upon return from a site visit, the CRA completes the trip report and generates a final report. This report is then submitted to the study manager for approval. The manager reviews the report and approves it if it is satisfactory. If the manager approves the trip report, then it is then locked to prevent the CRA from making any further changes. If the trip report is not satisfactory, then the manager can reject the report and return it to the CRA for further attention.

# Creating Questions for Clinical Trip Reports Using Siebel SmartScript

Siebel SmartScript can be used for creating questionnaires for clinical trip reports. For information about how to create questions using Siebel SmartScript, see *Siebel SmartScript Administration Guide*.

Some SmartScript question settings listed in *Siebel SmartScript Administration Guide* are not applicable for clinical trip reports.Table 8 lists the question settings that are not applicable to clinical trip reports.

Table 8. Exceptions for SmartScript Question Settings

| Question Setting | Questionnaire Exception for Clinical Trip Report |
|---|---|
| Answer Type | The Currency data type is not supported. |
| Auto Sub Parm | This setting is not applicable. |
| Search Spec | This setting is not applicable. |
| Save Business Object | This setting is not applicable because the answers to questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports. |
| Save Bus Comp | This setting is not applicable because the answers to questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports. |
| Save Field | This setting is not applicable because the answers to questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports. |
| Save User Parameters | This setting is not applicable. |
| Save Currency Field | This setting is not applicable because the answers to questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports. |
| Pick Applet | This setting is not supported. |
| Mvg Applet | This setting is not supported. |
| Detail Applet | This setting is not supported. |

Table 8. Exceptions for SmartScript Question Settings

| Question Setting | Questionnaire Exception for Clinical Trip Report |
|---|---|
| Save Answer Table | This setting is not applicable because the answers to c questionnaires for clinical trip reports are automatically saved as part of the clinical trip reports. |
| Currency | This setting is not applicable. |

A SmartScript questionnaire can be assigned to a clinical trip report template after it has been released using Siebel SmartScript. For information about how to release a script using Siebel SmartScript, see *Siebel SmartScript Administration Guide*.

# Creating Clinical Trip Report Templates

Typically, the clinical administrator prepares a number of generic trip report templates, perhaps one designed for each of the different stages in the study. This topic describes how to create a clinical trip report. Additional activities, such as follow-up tasks to complete after the visit to the clinical site, can be defined in the Trip Report Template Details view.

### *To create a clinical trip report template*

1 Navigate to the Administration - Clinical screen, then the Trip Report Templates view.

2 Create a new record and complete the necessary fields.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Name | The name of the clinical trip report template. |
| Protocol # | Select the protocol for the clinical site. |
| Region | Select the region for the clinical site. |
| SmartScript | Assign a SmartScript questionnaire to the trip report template. The questionnaire is copied to the Questions view of the trip report when the trip report template is applied to the trip report.<br><br>The questionnaire uses branching logic to dynamically determine the flow of questions, by using answers to prior questions. The question hierarchy is determined by the Siebel Clinical Trial Management System administrator using Siebel SmartScript. For more information about Siebel SmartScript, see *Siebel SmartScript Administration Guide*. |
| Visit Type | The type of site visit, for example, Site Evaluation, Site Initiation, or Site Monitoring. |

3 Drill down on the Name field of the trip report template to display the Trip Report Template Details view.

4 Create new records for any trip report activities to define.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Activity | The type of trip report activity. The following values are available:<br>■ Checklist<br>■ Follow-Up<br>■ Issues |
| Priority | The priority of the trip report activity. |

# Applying Clinical Trip Report Templates

The Template field of the Site Visits view displays all of the trip report templates that are applicable protocol, region, and visit type details for that site visit. When a trip report template is applied to a trip report, all of the details in the template are copied to the trip report.

Checklist and follow-up activities defined in the Trip Report Template Details view of the trip report template are copied to the trip report, and overwrite any existing checklist and follow-up activities defined in the trip report.

SmartScript questionnaires defined in the SmartScript field of the trip report template are applied to the trip report, and appear in the Questions view. For performance reasons, the SmartScript questionnaire does not appear in the Questions view until after the SmartScript questionnaire has been launched by the user. For more information about SmartScript questionnaires, see "Completing Questionnaires for Clinical Trip Reports" on page 143.

### *To apply a clinical trip report template*

1 Navigate to the Site Visits screen, then the Clinical Site Visits List view.

2 In the Clinical Site Visits list, drill down on the Visit Start field of the site visit to which you want to apply a trip report template.

The Trip Report form for the selected site visit appears.

3 Click the select button in the Template field.

A list of templates that correspond to the protocol, region, and visit type details for the site appears.

4 Select the name of the trip report template that you want to apply.

When you save the Template field, the activities defined in the template appear in the Checklist Activities list and Follow-Up Items list.

# Completing Clinical Trip Reports

After the site visit, the trip report details are recorded, such as:

- The planned activities that were completed
- Additional activities that were carried out
- Site personnel that they met
- Any follow-up items arising from the trip
- Comments on any of the above

The records in the Trip Report Detail view can be updated and edited at any time. For this reason, it is likely that the end user wants to create a static report at the completion of the site visit, using the Siebel Report Viewer. This read-only document is ideal for archiving: as a printed document, as a file, or as an attachment to the site record in the Siebel Life Sciences database.

### *To complete a clinical trip report*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to complete a trip report.

   The Trip Report form for the selected site visit appears.
3. Complete or edit fields in the Trip Report form.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Attendees | The contacts (site personnel) whom you met during the visit. |
| Approver | The user assigned to approve the trip report. An automated email notification is sent to the approver when the status of the trip report is updated to Submitted for Approval. |
| Approver Comments | This field must be populated if an approver submits a trip report with status Rejected. |
| Assigned To | Multiple users can be assigned to the trip report. The team member who creates the trip report is indicated as the primary owner. |
| Completed | The date and time when the site visit was completed. This field is populated with the system date and time when the Visit Status field is updated to Done. The filter in the All Follow-Up Items list uses this date to determine which closed follow-up items to show. |
| Reviewer | The user assigned to review the trip report. An automated email notification is sent to the reviewer when the status of the trip report is updated to Submitted. |

| Field | Comments |
|---|---|
| Reviewer Comments | This field must be populated if a reviewer submits a trip report with status Rejected. |
| Site Visit Status | The status of the site visit, for example, Planned or Completed. |
| Trip Report Completed | The date when the trip report is complete and ready for submission. This field is populated with the system date when the Status field of the trip report is updated to Completed. |
| Visit Type | The nature of the visit, for example, Pre-Study, Site Initiation, or Site Monitoring. |

4 Navigate to the Checklist Activities view, and complete the Status and Comments fields for planned activities and add any unplanned activities that you might have carried out.

5 Navigate to the Follow-Up Items view, and add any follow-up activities resulting from the site visit.

6 In the Current Trip Follow-Up Items list, click the cogwheel icon, and choose Select All to display all open follow-up items and those closed between the current and previous trip.

7 Update the records for those follow-up items that were addressed during the site visit.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Completed Date | The resolution date of the follow-up issue. This field must be populated because the filter in the All Follow-Up Items list uses this date to determine the closed follow-up items to show. |
| Status | This field automatically changes to Done when a completed date is entered for the item. |

8 Set the Trip Report Status field to Submitted.

The report is submitted to the reviewer for review.

# Completing Questionnaires for Clinical Trip Reports

This topic describes how to complete a questionnaire for a clinical trip report. The questionnaire is launched in the SmartScript player from the Questions view of the trip report. Questions and responses are saved in the Questions list.

### *To complete a questionnaire for a clinical trip report*

1 Navigate to the Site Visits screen, then the Clinical Site Visits List view.

2 In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for the required trip report.

The Trip Report form for the selected site visit appears.

3 Navigate to the Questions view.

4 Click Answer to launch the questionnaire for the trip report in the SmartScript player.

5 Complete the questionnaire and click Finish, or Finish Later.

The responses are saved with the questions in the Questions list. You can filter questions as follows:

- To display only those questions that are answered, select Show Answered.
- To display all questions in the questionnaire for the trip report, select Show All.

# Deleting Unanswered Questions from Questionnaires of Clinical Trip Reports

This topic describes how to delete unanswered questions from a questionnaire for a clinical trip report, using the LS Clinical Questions Batch Clean-up repository workflow process.

**NOTE:** This task requires administrator privileges.

### *To delete unanswered questions from a questionnaire of a clinical trip report*

1 Navigate to the Administration - Server Management screen, then the Jobs view.

2 Create a new record and complete the necessary fields.

3 Set the Component/Job field to Workflow Process Manager.

4 Navigate to Job Parameters list, create a new record and complete the necessary fields.

5 Set Name field to Workflow Process Name.

6 Set the Value field to LS Clinical Questions Batch Clean-up.

7 Select the record in the Jobs list and click Submit Job.

8 Refresh the screen and verify that the State field updates to Success.

All unanswered questions in the questionnaire for the clinical trip report are now deleted.

# Tracking Case Report Forms

This task describes how to create a CRF (case report form) tracking activity. Relevant information, such as review date and page numbers verified, is captured for each CRF record.

### *To track case report forms*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to track CRFs.

   The Summary view for the trip report of the selected site visit appears.
3. Navigate to the Case Report Forms Tracking view.
4. In the Case Report Forms Tracking list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Charts Reviewed Date | The date on which the clinical charts were reviewed. |
| Forms Signed Date | The date on which the CRFs were signed. |
| Page Numbers Verified | The list of CRF page numbers that have been verified. |
| Retrieved | This field is checked when the CRA (clinical research associate) retrieves the CRFs from the site. |
| Source Document Verified | This field is checked when the CRF has been verified against the source document. |

# Automated Validation and Notification Messages for Clinical Trip Reports

The state model for the trip report provides the order of transition for values in the Trip Report Status field, to indicate the progress of the trip report. Table 9 describes the values for the Trip Report Status field, update type (such as automatic or user), trip report validation, and the automated notification emails sent to the assignee's Universal Inbox for each status, where applicable.

Table 9. Values in Trip Report Status Field, Validation, and Messages

| Value in Trip Report Status Field | Description | Update Type | Validation | Automated Email Notification |
|---|---|---|---|---|
| Not Started | The trip report has been created, but processing has not yet started. This status is the initial default value for all trip reports. | System | Not applicable. | Not applicable. |
| In Progress | The author has started to work on the trip report, and it is not yet complete. | ■ System update if the trip report is created using a template.<br>■ User update if the trip report is not created using a template. | Not applicable. | Not applicable. |
| Completed | The trip report is complete and ready to be submitted for review. | User | The Completed Date is a prerequisite for selecting Completed.<br>The trip report is validated to ensure that the Completed Date has been populated. | Not applicable. |

Table 9. Values in Trip Report Status Field, Validation, and Messages

| Value in Trip Report Status Field | Description | Update Type | Validation | Automated Email Notification |
|---|---|---|---|---|
| Submitted | This trip report has been submitted to the reviewer for review. | User | The trip report is validated to ensure that a reviewer has been assigned. | The following automated email is sent to the reviewer:<br>Review Trip Report [Trip Report Name].<br>If the reviewer is changed when the Trip Report Status field is Submitted, then the above notification email is sent to the new reviewer. |
| Reviewed with Comments | The reviewer or approver has added review comments requiring a modification to the trip report. | User | Not applicable. | The following automated email is sent to the trip report owner:<br>Rectify Trip Report [Trip Report Name]. |
| Rejected | The reviewer or approver has rejected the trip report. | User | The trip report is validated to ensure that one of the following fields has been completed:<br>■ Reviewer Comments<br>■ Approver Comments | The following automated message is sent to the trip report owner:<br>Rectify Trip Report [Trip Report Name]. |

Table 9. Values in Trip Report Status Field, Validation, and Messages

| Value in Trip Report Status Field | Description | Update Type | Validation | Automated Email Notification |
|---|---|---|---|---|
| Revised | The rejected trip report is being modified, and has not yet been resubmitted for review. | User | Not applicable. | Not applicable. |
| Submitted for Approval | The reviewer submits the trip report for formal review, without comments, or with comments that do not require a change to the trip report. | User | The trip report is validated to ensure that an approver has been assigned. | The following automated email is sent to the approver:<br>Approve Trip Report [Trip Report Name].<br>If the approver is changed when the Trip Report Status field is Submitted for Approval, then the above notification email is sent to the new approver. |
| Approved | The trip report has been approved by the assigned approver, and is now read-only. When the Approved button is clicked, the Trip Report Status field is updated to Approved. | System | Not applicable. | Not applicable. |

# Tracking Completion Status for Clinical Trip Reports

This task describes how to track the real-time progress for a trip report in the Summary view. Status is tracked for the following fields in the clinical trip report:

- Checklists Completed
- Questions Answered
- Current Follow-Ups Completed
- All Follow-Ups Completed
- CRF Tracking Completed
- Total Attendees

The drill-down links from the Summary view to the related records are supported for Siebel Open UI, and are not supported for Siebel High Interactivity.

### *To track the completion status for a clinical trip report*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to track the status of the trip report.

   The Trip Report form for the selected site visit appears.

3 Navigate to the Summary view.

The summary status appears in the Summary applet.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Checklists Completed | Displays the number of completed checklists, and the total number of checklists. The drill-down links to the Checklist Activities view. All checklists in the Checklist Activities view that have a Status of Done or Completed are listed as completed in the Summary view. |
| Questions Answered | Displays the number of questions that have been answered, the total number of SmartScript questions assigned to the trip report, and the SmartScript questionnaire status. The value ranges are as follows:<br>■ **0 of 0, Not Assigned.** A SmartScript questionnaire has not been assigned to the trip report.<br>■ **[Total Answered] of [Total Questions], In Progress.** The SmartScript questionnaire has been launched by the user and is in progress.<br>■ **[Total Answered] of [Total Questions], Finished.** The user has completed answering all of the questions.<br>The drill-down links to the Questions view. |
| Current Follow-Ups Completed | Displays the number of completed follow-up activities, and the total number of follow-up activities, for the current trip report. The drill-down links to the Current Trip Follow-Up Items view. All follow-ups in the Current Trip Follow-Up Items view that have been assigned a Completed Date are listed as completed in the Summary view. |
| All Follow-Ups Completed | Displays the number of completed follow-up activities, and the total number of follow-up activities, for all trip reports that have been assigned to the clinical site. The drill-down links to the All Follow-Up Items view. All follow-ups in the All Follow-Up Items view that been assigned a Completed Date are listed as completed in the Summary view. |

| Field | Comments |
|---|---|
| CRF Tracking Completed | Displays the number of completed CRF (case report form) tracking activities, and the total number of CRF tracking activities. The drill-down links to the CRF Tracking view. All CRF tracking activities in the CRF Tracking view that have a status of Source Verified are listed as completed in the Summary view. |
| Total Attendees | Displays the total number of attendees assigned to the trip report. |

# Tracking Status Accruals for Clinical Subjects of Sites

This task describes how to track the progress of subject status accruals for a clinical site by creating a real-time snapshot of the current subject status accruals for the site. The CRA (clinical research associate) can use the snapshot to verify the subject status data that is manually recorded during a site visit.

### *To track status accruals for clinical subjects of a site*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to track the status accruals for subjects.

   The Trip Report form for the selected site visit appears.
3. Navigate to the Summary view.
4. Click Capture in the Subject Status Snapshot applet to generate a real-time snapshot of subject status accruals.

   Some fields are described in the following table.

| Field | Read-Only | Comments |
|---|---|---|
| Accruals Number | Yes | The automatically generated total number of subject status accruals in Siebel Clinical Trial Management System. |
| Actual Number | No | The total number of subject status accruals that the CRA manually records during the site visit. |
| Comments | No | Text field to describe any discrepancy between Accruals Total and Actual Total. |
| Reviewer Comments | No | Text field for reviewer comments about the trip report. Only the assigned reviewer can modify this field. |

| Field | Read-Only | Comments |
|---|---|---|
| Status Code | Yes | The subject status. The following subject visit statuses are preconfigured:<br>■ Screened<br>■ Screen Failure<br>■ Randomized<br>■ Enrolled<br>■ Completed<br>■ Early Terminated<br>■ Re-screened<br>■ Withdrawn |
| Time Stamp | Yes | The date and time when the snapshot was generated. |
| Visit Type | Yes | The type of clinical visit. The following clinical visit types are preconfigured:<br>■ Screening<br>■ Rescreening<br>■ Enrollment<br>■ End of Study |

# Viewing Universal Inbox Notifications for Action Items of Clinical Trip Reports

The Inbox provides a centralized list of items requiring your attention, such as clinical trip reports requiring review, revision, and approval.

### *To view Universal Inbox notifications for action items of a clinical trip report*

1. From the application-level menu, choose Navigate, then Site Map.
2. Click Inbox.

   The views available for the inbox appear.
3. Click Inbox Items List.

   The list of notifications for your trip reports appears. The action required for each trip report is listed in the Name field.
4. Drill down on the Name field to view each trip report requiring action.

# Reviewing Clinical Trip Reports

Trip reports with a status of Submitted can be reviewed by the user assigned in the Reviewer field of the Trip Report form. An automated notification email is sent to the reviewer when the trip report's status is updated to Submitted.

Access control is applied to the Reviewer Comments field. Only the user assigned in the Reviewer field of the Trip Report form can edit the Reviewer Comments field.

### *To review a clinical trip report*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, select My Team's Site Visits in the visibility filter.

   All site visits for your team appear.
3. Query the list for site visits with a Visit Status field value of Submitted or Submitted for Approval.
4. For the required report, drill down on the Visit Start field.

   The Trip Report form appears.
5. Review the report.
6. Set the Trip Report Status field to one of the following values:
   - **Reviewed with Comments.** Use this value if minor changes to the trip report are required. Enter the required corrections in the Reviewer Comments field.
   - **Rejected.** Use this value if major changes to the trip report are required. Enter the required corrections in the Reviewer Comments field.
   - **Submitted for Approval.** Use this value if the trip report does not require additional changes, and is ready for review by the approver.

   The date and time of the review of the clinical trip report are recorded in the Reviewed Date field.

# Approving Clinical Trip Reports

Trip reports with a status of Submitted for Approval can be approved by the assigned approver. Only the user assigned to the Approver field of the trip report has approval permissions. An automated notification email is sent to the approver when the trip report's status is updated to Submitted for Approval. If you set the Trip Report Status field to Rejected, then the CRA (clinical research associate) has the opportunity to revise the report and then resubmit it for approval.

**NOTE:** The User Authentication applet for approver verification of a trip report is not enabled by default. To enable this functionality, your system administrator must set the Enable Verification option to Y in Siebel Tools. For more information, see the Named Method 2 property in "User Properties for Business Components in Siebel Clinical" on page 246.

Access control is applied to the Approver Comments field. Only the user assigned in the Approver field of the Trip Report form can edit the Approver Comments field.

### *To approve a clinical trip report*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, select My Team's Site Visits in the visibility filter.

   All site visits for your team appear.
3. Query the list for site visits with a Visit Status field value of Submitted or Submitted for Approval.
4. For the required report, drill down on the Visit Start field.

   The Trip Report form appears.
5. Review the report.
6. (Optional) Add approval comments in the Approver Comments field.
7. Click Approve.

   The User Authentication view appears.
8. Enter user credentials and click Verify.

   The Trip Report Status field is updated to Approved, the approval date and time are recorded in the Approved Date field, and the site visit record and trip report become read-only.

# Viewing Geographical Location Details for Clinical Trip Reports

Dates, times, and geographical location details for sites are recorded in the trip report for each site monitor's visit to each clinical site.

Multiple site monitors can create multiple site visit records in the trip report for the same site visit. Each site monitor can create multiple site visit records in the trip report for different times on the same site visit.

### *To view geographical location details for a clinical trip report*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to view geographical location details.

   The Trip Report form for the selected site visit appears.

3 Navigate to the Geo Location Details view.

Some fields are described in the following table.

| Field | Comments | Editable Field |
|---|---|---|
| User ID | User ID of the site monitor who logged the geographical location details in the third-party clinical application. | No |
| Latitude | Latitude coordinates are represented in decimal degree format. The range of acceptable values is 0 to plus or minus 90. Northern hemisphere latitudes are represented by a positive number. The number is preceded by a minus sign to represent southern hemisphere latitudes. | No |
| Longitude | Longitude coordinates are represented in decimal degree format. The range of acceptable values is 0 to plus or minus 180. Eastern hemisphere latitudes are represented by a positive number. The number is preceded by a minus sign to represent western hemisphere longitudes. | No |
| Comments | This field is populated by the site monitor with any comments relating to the site visit. | Yes |
| Date | Date and time the geographical location details were logged in the third-party clinical application. | No |

# Using Audit Trail for Reviews and Approvals of Clinical Trip Reports

The Approvals view provides a summary audit trail of the changes that have been made to the trip report status, including the dates and times of review and approval operations, and the details of the users who completed those operations.

### *To use audit trail for reviews and approvals of a clinical trip report*

1 Navigate to the Site Visits screen, then the Clinical Site Visits List view.

2 In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for the required trip report.

The Trip Report form for the selected site visit appears.

3 Navigate to the Approvals view.

The Approvals applet appears.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Login | The login credentials of the user who modified the field. |
| Status | The value in the Trip Report Status field after the change occurred. |
| Old Status | The value in the Trip Report Status field before the change occurred. |
| Updated | The date and time that the field was modified. |

# Using Audit Trail for Changes to Clinical Trip Reports

The Audit Trail view provides a detailed history of the changes that have been made to trip report records. The audit trail records for the trip report show operations for the following fields:

- Comments
- Reviewer
- Reviewer Comments
- Approver
- Approver Comments
- Trip Report Status

### *To use audit trail for changes to a clinical trip report*

1 Navigate to the Site Visits screen, then the Clinical Site Visits List view.

2 In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for the required trip report.

The Trip Report form for the selected site visit appears.

3 Navigate to the Audit Trail view.

Some fields are described in the following table.

| Field | Comments |
|---|---|
| Base Table | Displays the name of the primary database table where the database change occurred. |
| Business Component | Displays the business component for the record where the database change occurred. |

| Field | Comments |
|---|---|
| Column | Displays the name of the column in which the change occurred. |
| Date | Displays the timestamp of the change. |
| Employee Login | Displays the username of the user who changed the record. |
| Field | Displays the name of the field where the change occurred. |
| Group ID | Displays the unique identifier of the group to which the user who changed the record belonged. |
| New Value | Displays the value in the field after the database change occurred. |
| Old Value | Displays the value in the field before the database change occurred. |
| Operation | Displays the type of operation that was performed, for example, New Record, or Modify. |
| Record ID | Displays the unique identifier of the record that was changed. |
| Row ID | Displays the unique identifier of the row in which the change occurred. |
| Table | Displays the name of table to which the selected field belongs in the Siebel database. |

# Deleting Clinical Trip Reports

A trip report can be deleted if the Trip Report Status field is set to one of the following:

- Not Started
- In Progress
- Rejected

### *To delete a clinical trip report*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to delete a trip report.

   The Trip Report form for the selected site visit appears.
3. Click Delete.

   The following warning message appears: Are you sure you want to delete the selected trip report?
4. Click OK.

# Generating Oracle BI Publisher Reports for Site Visits

Siebel Clinical can be integrated with Oracle Business Intelligence Publisher (BI Publisher) for generating reports. You can generate, view, and schedule preconfigured Oracle BI Publisher reports in Siebel Clinical. For more information about using Siebel Reports and integrating with Oracle BI Publisher, see *Siebel Reports Guide*.

The following preconfigured reports are provided for site visits:

- Clinical Trip Report With CRF
- Clinical Trip Report Without CRF

### *To generate an Oracle BI Publisher report for a site visit*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to generate an Oracle BI Publisher report.
3. On the application toolbar, click the Reports icon.
4. In the Run Report pane, complete the appropriate fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Report Name | Select the Clinical Trip Report With CRF report or the Clinical Trip Report Without CRF report. |
| Output Type | Select the output type for the report. |

5. Click Submit.

   The report runs.

6. Click My Reports to navigate to the Reports view of the BI Publisher Reports screen.

   A record for the report appears in the Reports view. For information about viewing and printing the report, see *Siebel Fundamentals for Siebel Open UI*.

# 10 Managing Clinical Projects

This chapter describes how to manage clinical projects. It includes the following topics:



## About Managing Clinical Projects

This chapter is meant to be used as a supplement to the information about project management. For information about project management, see *Siebel Project and Resource Management Administration Guide*.

Projects in Siebel Clinical are designed to help project managers manage projects for clinical trials. The projects are associated with individual protocols. Timelines, milestones, costs, and resources can be entered, viewed, and updated from the Projects screen.

## Scenario for Managing Clinical Projects

This topic gives one example of how to manage clinical projects. You might manage clinical projects differently, depending on your business model.

This topic includes the following information:

### Setting Up and Staffing the Project

A product manager works for a large CRO (clinical research organization) that has been awarded a contract to carry out a clinical trial for a pharmaceutical company and is responsible for setting up and running the project for a clinical trial.

First, the product manager enters some basic information about the project into Siebel Clinical and determines the employees that can have visibility to the project data by entering them in the project access list.

To optimize the resource assignment, the product manager first enters the resource requirements in the team workbook and then uses Siebel Assignment Manager to help with the staffing. The product manager specifies the roles, skills, competencies, and availability required for the team and lets Resource Manager find the best candidate for the roles.

For this large project the CRO might need some subcontractors to complete certain aspects of the project. Because the subcontractors are paid on an hourly rate, the product manager associates the appropriate billing rate list to the project. The product manager also must add employees of the subcontracting company to the subcontractor resource list.

Other external contacts and accounts can also be added to the project. For example, information about the central laboratory and the primary contact at this laboratory are added.

### Managing Tasks, Activities, and Risks

Milestones can be set as tasks or activities. The product manager can create them within projects in Siebel Clinical. Each Siebel activity has a budget and the actual costs of these activities are updated as the project progresses. Periodically, the product manager reviews these project costs, making sure that the project is staying within budget. Payments made to sites for subject activities are rolled up to the project costs.

Project risks are documented as they arise, as well as the resolution activities to address the risks.

# Process of Managing Clinical Projects

This topic details sample tasks often performed by administrators and end users when managing clinical projects. Your company might follow a different process according to its business requirements.

### Administrator Tasks

The following list shows tasks administrators typically perform to manage clinical projects. The procedures that an administrator must carry out in support of projects depends upon which features of the projects are used by the organization. You might not have to perform all the procedures listed in this topic. These tasks must occur before the project manager creates the project:

- "Creating Activity Templates for Clinical Projects" on page 161. These templates are used by many project managers carrying out similar clinical trials.
- "Setting Up Employee Profiles for Clinical Projects" on page 162. Maintain the employee profiles of skills and competencies that are used by Siebel Assignment Manager.

- "Setting Up Position Types and Rate Lists for Billing" on page 162. The position types and rate lists are required to allow subcontractors (and employees) to bill the project for their time.
- "Creating Clinical Projects" on page 163. You associate protocols with projects.

### End-User Procedures

These tasks can be performed only after the administrator has completed the required preparatory work described in the preceding topics. These tasks can be carried out according to your company's business needs:

- "Creating Clinical Projects" on page 163. You associate protocols with projects.
- "Associating People and Accounts with Clinical Projects" on page 164. Give employees access to the project; add contacts and accounts to the project team workbook.
- "Creating Activities and Tasks for Clinical Projects" on page 165. Standalone activities are not associated with tasks.
- "Monitoring Costs for Clinical Projects" on page 166. View costs for clinical projects.
- "Managing Risk for Clinical Projects" on page 167. Document project risks and resolution activities.

# Creating Activity Templates for Clinical Projects

Activities can be created in the Projects screen. If the study managers are primarily entering activities in the Projects screen, then creating activity templates for projects is advantageous.

To create an activity template for projects, you create an activity template with a Project type. The Protocol Type field is optional because the activity template can be applied to any project, regardless of the protocol associated with the project. In the Activity Template Details list, create records to describe activities and milestones for the project. For information about how to create activity templates, see *Siebel Applications Administration Guide*.

Typically, the administrator prepares numerous activity templates, perhaps each designed for a different stage in the life of a study. The following other activity templates are used in Siebel Clinical:

- Subject visit templates. For more information, see "About Subject Visit Templates" on page 58.
- Clinical protocol site templates. For more information, see "Creating Clinical Protocol Site Templates" on page 91
- Trip report templates. For more information, see "Creating Clinical Trip Report Templates" on page 140.
- Contact assessment templates. For more information, see "Creating Contact and Account Assessment Templates" on page 91.

This task is a step in "Process of Managing Clinical Projects" on page 160.

# Setting Up Employee Profiles for Clinical Projects

The end user can use Siebel Assignment Manager to automatically search the employee database for the available employees whose skills best fit the needs of the project. Siebel Assignment Manager requires that profiles of skills and competencies be set up for employees. For information about using Siebel Assignment Manager, see *Siebel Assignment Manager Administration Guide*.

Use of Siebel Assignment Manager is not required. The end user can assign team members directly into the Team Workbook view, without using Siebel Assignment Manager.

This task is a step in "Process of Managing Clinical Projects" on page 160.

# Setting Up Position Types and Rate Lists for Billing

If project team members are to bill their time to the project through the Team Workbook view, then set position types and rate lists.

Position types, such as consultant, are set up as products and designated as resources. Lists of hourly rates for the position types are then set up. When the rate list is applied to the project, the hourly rates for the team members are automatically supplied in the team workbook. For more information about position types and rate lists for Professional Services, see *Siebel Applications Administration Guide*.

This task is a step in "Process of Managing Clinical Projects" on page 160.

## Creating Position Types as Products

Complete the procedure in this topic to create position types as products.

### *To create position types as products*

1. Navigate to the Administration - Product screen, then the Products view.
2. In the Products list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Product | A product (resource) name, for example, Consultant. |
| Project Resource | Select this field. |

## Creating Rate Lists

Complete the procedure in this topic to create a rate list.

### *To create a rate list*

1. Navigate to the Administration - Pricing screen, then the Rate List view.
2. In the Rate Lists list, create a new record and complete the necessary fields.
3. In the Rate Lists list, drill down on the Rate List field.
4. In the Rate List Line Items list, create a new record.
5. In the Add Position Types dialog box, select the Position Type and click OK.

   This list of resources has been created as a product.
6. In the Rate List Line Items list, complete the remaining fields.

# Creating Clinical Projects

The first step is to create the project record and to associate a protocol with the project.

**NOTE:** It is recommended that only one project be associated with a protocol. However, you are not prevented from associating a protocol with multiple projects. In this case, costs associated with payments to sites are rolled up to each project.

This task is a step in "Process of Managing Clinical Projects" on page 160.

### *To create a clinical project*

1. Navigate to the Projects screen, then the List view.
2. In the Project list, create a new record.
   a. Enter the Start date and End date for the project.
   b. Associate a protocol with the project.
   c. Complete the remaining fields as necessary.

      Some fields are described in the following table.

| Field | Comments |
|---|---|
| Account | For example, enter the name of the pharmaceutical company for whom this project is being carried out. |
| Actual Cost | This field is calculated by summing the actual costs of all the tasks, activities, and site payments associated with the project. |
| Budgeted Cost | This field is calculated by summing the budgeted costs of all the tasks, activities, and site payments associated with the project. |
| Revenue | The total Revenue for the project. Click the select button for this field to enter the amount of revenue, the currency, and the exchange date for the currency. |
| Project ID | A unique identification number for the project. |

| Field | Comments |
|---|---|
| Protocol # | All protocols in the database can be selected from the Pick Protocol dialog box. The creator of the project is not required to be a member of the protocol team. |
| Rate List | If a rate list has been set up for the project team members, then enter it in this field. Click the show more button if this field is not visible. For more information, see "Setting Up Position Types and Rate Lists for Billing" on page 162. |

# Associating People and Accounts with Clinical Projects

**Employees.** Employees in Siebel Clinical can be given access to the project and added to the team workbook.

**Contacts.** Contacts can be associated with projects through the Contacts view and the Organizational Analysis view. The same contacts appear in the Contacts view and the Organizational Analysis view.

**Accounts.** Accounts can be associated with projects through the Partners view and the Subcontractors view. Adding accounts to the Subcontractors view allows you to add employees from the subcontracting accounts to the project team workbook. For more information about adding subcontractors, see *Siebel Project and Resource Management Administration Guide*.

This task is a step in "Process of Managing Clinical Projects" on page 160.

## Adding Employees to Projects

Complete the procedure in this topic to add employees to a project.

### *To add employees to a project*

1. Give employees visibility to a project by adding them to the Access view.

   For more information about providing access to a project, see *Siebel Project and Resource Management Administration Guide*.

2. Allow employees and subcontractors to be assigned to activities and to bill time to the project by adding them to the Team Workbook view.

   If a rate list has been set up, then make sure that the Resource field on the Resource Detail form of the Team Workbook view is set for the team members. For more information about the team workbook for project management, see *Siebel Project and Resource Management Administration Guide*.

## Adding Contacts to Projects

Complete the procedure in this topic to add a contact to a project using the Organization Analysis view.

### *To add a contact to a project*

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Organization Analysis view.
4. From the Organization Analysis drop-down list, select Contacts.
5. In the Contacts list, create a new record and complete the necessary fields.
6. From the Contacts drop-down list, select Organization Analysis.

   An organization chart of the contacts appears. Any employee-manager relationships set in Step 5 are indicated.

## Adding Partner Accounts to Projects

Complete the procedure in this topic to add a partner account to a project.

### *To add a partner account to a project*

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Partners view.
4. In the Partners list, create a new record and complete the necessary fields.

   Some fields are described in the following table.

| Field | Comments |
|---|---|
| Site | This is the site for the account, a unique identifier for the account. It is not related to the sites where clinical trials are carried out. |

# Creating Activities and Tasks for Clinical Projects

Activities can be created for the project in the following ways:

- Enter activities in the Activities view.
- Generate activities in the Activity Plans view by applying an activity template for projects.
- Enter activities manually in the Activity Plans view. These activities must be associated with an activity plan that is based on a template.

- Create a task in the Task view and associate activities with the task.

A task is a container for activities. Activities associated with tasks are different from regular *standalone* activities. Activities that belong to tasks cannot be generated by activity templates for projects. They can only be created manually from within the Project Task Activity view. A standalone activity cannot be added to a task, nor can an activity for a task be disassociated from the task. For more information about creating activities and tasks for project management, see *Siebel Project and Resource Management Administration Guide*.

This task is a step in "Process of Managing Clinical Projects" on page 160.

## Creating Activities for Projects

Complete the procedure in this topic to create an activity for a project using an activity template.

**NOTE:** Activities can also be created manually in the Activities view.

### *To create an activity for a project*

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Activity Plans view.
4. In the Activity Plans list, create a new record.
5. In the Template field, select a template from the drop-down list.

   The activities associated with the activity plan appear in the Activities list.

## Creating Tasks and Associated Activities

Complete the procedure in this topic to create a task and associated activities.

### *To create a task and associated activities*

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Tasks view.
4. In the Tasks list, create a new record and complete the necessary fields.
5. In the Tasks list, drill down on the Name field.
6. In the Activities list, create a new record and complete the necessary fields.

# Monitoring Costs for Clinical Projects

The Cost view provides the end user with a valuable summary of all costs associated with a particular project and protocol.

The cost items appear in the following lists:

- **Project Activities.** Displays those activities from the Activities view where the Cost field is selected.
- **Project Tasks.** Displays those tasks from the Tasks view where the Cost field for the *task* is selected. The actual cost and budgeted cost for a task are determined by summing the costs of the activities contained in the task.
- **Clinical Payments.** Displays payments made to the sites associated with the protocol. These payment amounts are rolled up into the Actual Cost field in the project record.

End users cannot create, modify, or delete records in this view.

**NOTE:** All costs in this view are in the default currency set for the project.

This task is a step in "Process of Managing Clinical Projects" on page 160.

### *To monitor costs for clinical projects*

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Costs view.
4. Click a hyperlink in the Clinical Payments or Project Tasks list to see the activities associated with a cost item.

# Managing Risk for Clinical Projects

An important aspect of project management is risk management. The features of the Risks view allow the end user to enter information about project risks and create and assign resolution activities to address the risks. For more information about assessing risks for project management, see *Siebel Project and Resource Management Administration Guide*.

This task is a step in "Process of Managing Clinical Projects" on page 160.

### *To manage risk for clinical projects*

1. Navigate to the Projects screen, then the List view.
2. In the Project list, drill down on the Name field of the project.
3. Navigate to the Risks view.
4. In the Risks list, create a new record and complete the necessary fields.
5. In the Risks list, drill down on the Name field.
6. In the Resolution Activities list, create a new record and complete the necessary fields.

# About Views in the Projects Screen

Many views are available in the Projects screen of the Siebel Clinical. Many implementations can choose to use only some of these views. Table 10 describes the views that are available in the Projects screen.

Table 10. Views in the Projects Screen

| View | Comments |
|---|---|
| Access | Use this view to provide project access. Add the names of the project team members and also managers or executives who want visibility to monitor the progress of the project. The Access view has a similar function to the Team field in other screens. |
| Activities | This view lists activities associated with the project. Activities in this view might have been created manually or by activity templates for projects. Activities belonging to tasks do not appear in this view. |
| Activity Plans | Use this view to generate activities from activity templates for projects. Additional activities can be added manually to the activities already associated with an activity plan. |
| Attachments | Attach project documents in this view. For general information about attachments, see *Siebel Fundamentals*. |
| Calendar | This view shows a monthly calendar of the activities associated with the project. Activities belonging to tasks and standalone activities appear in this view. For general information about the calendar views, see *Siebel Fundamentals*. |
| Contacts | Use this view to maintain a list of contacts associated with the project. Enter names of employees in subcontracting or partner organizations. |
| Financial Profile | Use this view to gain an overall perspective of a project's financial information, status, and progress. Use this view to change the Delivery status for the project (green, yellow, or red). For more information, see *Siebel Project and Resource Management Administration Guide*. |
| Invoices | Use this view to create invoices for time and expenses logged against a project. For more information, see *Siebel Project and Resource Management Administration Guide*. |
| Notes | Use this view to keep private and public notes about the project. For general information about the Notes view, see *Siebel Fundamentals*. |
| Orders | Use this view to create a product or material order and associate it with the project. For more information, see *Siebel Project and Resource Management Administration Guide*. |
| Organizational Analysis | This view displays an organizational chart of contacts, showing the relationships between them. |

Table 10. Views in the Projects Screen

| View | Comments |
|---|---|
| Partners | Use this view to maintain a list of partner accounts associated with the project.<br><br>Use this view to keep a list of accounts associated with the project, such as vendors who handle printing of the clinical trial materials or the shipping of sample drugs.<br><br>Because the views for Partners, Subcontractors, and Clinical Contacts contain account information, depending on your business process, you can use one or more of these views to keep track of accounts associated with a project. |
| Risks | Use this view to maintain a list of the risks associated with the project and resolution activities required to address those risks. |
| Status Report | Use this view to create a status report summarizing the project's progress, forecast, and issues. For more information, see *Siebel Project and Resource Management Administration Guide*. |
| Subcontractors | Use this view to keep a list of subcontractors associated with the project. For more information, see the description of the Partners field. |
| Tasks | Use this view to create and modify tasks for the project. |
| Team Workbook | Use this view to assign team members to roles in the project. This can be done manually or it can be done automatically using Siebel Assignment Manager. Team members must be listed in the workbook before they can be assigned to activities. |
| Time & Expense | Use this view to adjust and summarize time sheets and expense reports associated with the project. For more information about time sheets and expense reporting, see *Siebel Project and Resource Management Administration Guide*. |

# 11 Setting Up and Configuring Clinical Operations Integration

This chapter covers setting up and configuring Siebel Clinical Trial Management System for integration with clinical operations software, such as budgeting and tracking applications. This integration can be customized for integration with any third-party budgeting and tracking application. This chapter uses ClearTrial integration examples, and includes the following topics:



## Overview of Clinical Operations Integration

Integration Web services are provided for integrating Oracle's Siebel Clinical Trial Management System with budgeting and tracking applications. The Web services can be customized for integration with any third-party application. For information about configuring ClearTrial for integration with Siebel Clinical Trial Management System, see Appendix A, "ClearTrial Clinical Trial Management System Connector."

Oracle's Siebel Clinical Trial Management System is certified for integration with the following ClearTrial applications:

- Oracle ClearTrial Plan and Source Cloud Service Application
- Oracle ClearTrial Track Cloud Service Application

## About Customizing Web Services for Clinical Operations Integration

Siebel Clinical ClearTrial integration Web services can be customized for integration with any third-party planning and tracking application, or for specific business requirements. For more information about customizing Siebel Web services, see *Siebel CRM Web Services Reference.*

The following Web services are provided for ClearTrial integration:

- LS Clinical CRF Tracking Interface
- LS Clinical Protocol Site Interface Service
- LS Clinical Subject Information Interface Service

# Process of Setting Up ClearTrial Integration

To set up ClearTrial integration for clinical trip reports, perform the following tasks:


- "Completing Prerequisites for ClearTrial Integration" on page 172
- "Activating Workflows for ClearTrial Integration" on page 172
- "Configuring Web Services for ClearTrial Integration" on page 173
- "Configuring the Date and Time Format for ClearTrial Integration" on page 173
- "Configuring System Preferences for Clinical Operations Integration" on page 173


## Completing Prerequisites for ClearTrial Integration

To configure the ClearTrial integration, the ClearTrial connector must be configured and running. For more information about the ClearTrial connector, see Appendix A, "ClearTrial Clinical Trial Management System Connector."

This task is a step in "Process of Setting Up ClearTrial Integration" on page 172.

## Activating Workflows for ClearTrial Integration

This task describes how to activate the workflows that are required for ClearTrial integration. You can modify the workflows to suit your own business model, using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

This task is a step in "Process of Setting Up ClearTrial Integration" on page 172.

### *To activate workflows for ClearTrial integration*

1. Navigate to the Administration - Business Process screen, then the Workflow Deployment view.
2. Query for and activate the LS Clinical Get Study Plan Information workflow.
3. Verify that the activated workflows are added to the Active Workflow Processes view at the bottom of the screen.

# Configuring Web Services for ClearTrial Integration

This task describes how to configure the inbound Web services that are required for ClearTrial integration. For more information about configuring Web services, see *Integration Platform Technologies: Siebel Enterprise Application Integration*.

**NOTE:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide*.

This task is a step in "Process of Setting Up ClearTrial Integration" on page 172.

### *To configure Web services for ClearTrial integration*

1. Navigate to the Administration - Web Services screen, then the Inbound Web Services view.
2. Query for each of the following Web services, and update the language and address variables:
   - LS Clinical CRF Tracking Interface
   - LS Clinical Protocol Site Interface Service
   - LS Clinical Subject Information Interface Service
3. Click Clear Cache on the Inbound Web Services applet.

# Configuring the Date and Time Format for ClearTrial Integration

The Universal Time Coordinated date and time format is required for ClearTrial integration. When integrating with ClearTrial, the UTCCanonical attribute in each ClearTrial integration Web service must be set to Y.

This task is a step in "Process of Setting Up ClearTrial Integration" on page 172.

The date and time format is configured in each integration Web service as follows:

- Setting UTCCanonical to Y exports the dates in Universal Time Coordinated (UTC) format.
- Setting UTCCanonical to N or null exports the dates in the format currently configured in Siebel Clinical.

The default value is null. Change the value to:

```
<asi:UTCCanonical>Y</asi:UTCCanonical>
```

# Configuring System Preferences for Clinical Operations Integration

This topic describes the system preferences to configure for an integration with a clinical operations application. The examples provided are for integration with Oracle ClearTrial.

This task is a step in "Process of Setting Up ClearTrial Integration" on page 172.

### *To configure system preferences for clinical operations integration*

1 Navigate to the Administration - Application screen, then the System Preferences view.

2 Configure the system preferences described in the following table.

| System Preference | Comments |
|---|---|
| CL - BudgetingApp CustomerCode | Set the value to the ID number of the sponsor or organization conducting the trial. When integrating with ClearTrial, this field is populated with the value in the Customer Code field. |
| CL - BudgetingApp RequestURL | Set the value to the budgeting or tracking application's Web service request URL, such as http://<host name>:<port name>/<external budgeting application>-ws/. When integrating with ClearTrial, this field is set to http://<host name>:<port name>/cleartrial-ws/. |

3 Restart the Siebel Server.

# Configuring Protocol Integration Fields for ClearTrial Integration

This topic describes how to configure the protocol integration fields for a ClearTrial integration. The Study ID in ClearTrial must be entered in the Plan Study ID field before the plan data is imported from ClearTrial.

### *To configure protocol integration fields for ClearTrial integration*

1 Navigate to the Administration - Clinical screen, then the Protocol List view.

2 In the Protocol list, query for the correct protocol.

3 Drill down on the protocol number field.

4 Navigate to the integration section of the More Info view.

5 Verify the integration fields.

The integration fields are described in the following table.

| Field | Comments | Required |
|---|---|---|
| CDMS Study ID | This field is not applicable for ClearTrial integration. | No |
| Plan Study ID | This field must be populated with the Study ID in ClearTrial to map a protocol record in Siebel Clinical Trial Management System to the corresponding Study record in ClearTrial.<br><br>When this field is populated, the Import Study Plan button is enabled. | Yes |
| Safety Study ID | This field is not applicable for ClearTrial integration. | No |
| Synchronize Active Study Sites | This field is not applicable for ClearTrial integration. | No |

# Importing Plan Data From Budgeting Applications

This task imports plan data from a budgeting application to Siebel Clinical Trial Management System. The Plan Study ID field in Siebel Clinical Trial Management System must be populated with the Study ID from the budgeting application before the plan data can be imported. The plan for a study must have a status of Baseline in ClearTrial before it can be exported to Siebel Clinical Trial Management System.

### *To import plan data from a budgeting application*

1 Navigate to the Administration - Clinical screen, then the Protocol List view.

2 In the Protocol list, drill down on the protocol number field of the protocol for which you want to import budgeting plan data.

3 Navigate to the integration section of the More Info view.

4 Click Import Study Plan.

The protocol fields with imported plan data are described in the following table.

| Field | Comments |
|---|---|
| Currency Code | This field is populated with the value in the ClearTrial Default Monitoring Currency field of the plan study. |
| Planned Start Date | This field is populated with the value in the ClearTrial Project Activity Start Date field of the plan study. |

| Field | Comments |
|---|---|
| Planned End Date | This field is populated with the value in the ClearTrial Study End Date field of the plan study. |
| Planned Budget Amount | This field is populated with the value in the ClearTrial Total Study Costs field of the plan study. |
| Total Contracts Amount | This field is populated with the value in the ClearTrial Total Study Costs field for all the providers.<br><br>The Total Contracts Amount field is the rolled-up amount from all of the contract views for sites that show the total payments to be made. The data is rolled up from the sites to the region, then to the protocol, and then to the program. |

# About Exporting Data for Sites

The LS Clinical Protocol Site Interface Service Web service is used to export the data in the Protocol Site List view from Siebel Clinical Trial Management System to ClearTrial. For information about the Protocol Site List view, see "Creating Sites for Clinical Trials" on page 51.

The following data is exported:

- Account
- Initiation completed date
- Primary investigator
- Protocol number
- Region
- Site number
- Status

# About Exporting Data for Clinical Subjects

The LS Clinical Subject Information Interface Service Web service is used to export the data in the Subjects view from Siebel Clinical Trial Management System to ClearTrial. Subjects can be filtered by status, status change date, protocol, region, and site. For information about subjects, see "Creating Records for Clinical Subjects" on page 66.

The following data is exported:

- Subject ID
- Encounter date
- Status

- Status date
- Protocol
- Region
- Site

# About Exporting Data for Case Report Forms

The LS Clinical CRF Tracking Interface Web service is used to export the data in the CRF Tracking view of the Site Management screen from Siebel Clinical Trial Management System to ClearTrial. The filter is based on protocol, region, and source verified date. For information about CRF (case report form) tracking, see "Tracking Case Report Forms" on page 103.

The following data is exported:

- Activity type
- Number of CRF pages
- Protocol ID
- Protocol site ID
- Region
- Site number
- Source verified
- Source verified date

# 12 Setting Up and Configuring Site Visit Data Integration

This chapter covers setting up and configuring Siebel Clinical for site visit data integration with a third-party clinical application, including an on-site mobile application. It includes the following topics:



## Overview of Site Visit Data Integration

This integration supports regulatory requirements to track completion of site visits. Siebel Clinical supports integration with third-party applications, including on-site mobile applications, to integrate site visit data.

Web service support is provided to export the following data from Siebel Clinical to a third-party application:

- Clinical protocol details
- Site ID and address details
- Site visit and trip report details
- Investigator details

Web service support is provided to export the following records from a third-party application, including an on-site mobile application, to Siebel Clinical:

- Site visit ID
- Site visit date and time
- User ID of the site monitor
- Latitude coordinates of the site
- Longitude coordinates of the site
- Comments on the site visit

# About Customizing Web Services for Site Visit Data Integration

Integration Web services can be customized for integration with any third-party clinical application, or for specific business requirements. For more information about customizing Siebel Web services, see *Siebel CRM Web Services Reference.*

The following Web services are provided for third-party application integration:

- SWILSClinicalQueryProtocolSite_SiteVisits
- SWILSClinicalCreateSiteVisitGeoLocation

# Process of Setting Up Site Visit Data Integration

To set up site visit data integration for Siebel Clinical, perform the following tasks:

- "Activating Workflows for Site Visit Data Integration" on page 180
- "Configuring Web Services for Site Visit Data Integration" on page 181
- "Enabling Siebel Server Component Groups for Site Visit Data Integration" on page 181

## Activating Workflows for Site Visit Data Integration

This task describes how to activate the workflows that are required for site visit data integration. You can modify the workflows to suit your own business model, using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

This task is a step in "Process of Setting Up Site Visit Data Integration" on page 180.

### *To activate workflows for site visit data integration*

1. Navigate to the Administration - Business Process screen, then the Workflow Deployment view.
2. Query for and activate each of the following workflows:
   - SWI LS Clinical Query Protocol Site_Site Visits
   - SWI LS Clinical Create Site Visit Geo Location
3. Verify that each activated workflow is added to the Active Workflow Processes view at the bottom of the screen.

# Configuring Web Services for Site Visit Data Integration

This task describes how to configure the inbound Web services that are required for site visit data integration. For more information about configuring Web services, see *Integration Platform Technologies: Siebel Enterprise Application Integration*.

**NOTE:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide*.

This task is a step in "Process of Setting Up Site Visit Data Integration" on page 180.

### *To configure Web services for site visit data integration*

1. Navigate to the Administration - Web Services screen, then the Inbound Web Services view.
2. Query for the SWILSClinicalQueryProtocolSite_SiteVisits Web service.
3. On the Service Ports applet, update the Address variable to point to your Web server.
4. Configure the Language variable.
5. Query for the SWILSClinicalCreateSiteVisitGeoLocation Web service.
6. On the Service Ports applet, update the Address variable to point to your Web server.
7. Configure the Language variable.
8. Click Clear Cache on the Inbound Web Services applet.

# Enabling Siebel Server Component Groups for Site Visit Data Integration

This task describes how to activate the component groups that are required for site visit data integration.

This task is a step in "Process of Setting Up Site Visit Data Integration" on page 180.

### *To enable Siebel Server component groups for site visit data integration*

1. Navigate to the Administration - Server Configuration screen, then the Component Groups view.
2. Query for the Workflow Management Component Group.
3. On the Component Groups applet, click Enable.
4. Query for the EAI Component Group.
5. On the Component Groups applet, click Enable.
6. Restart the Siebel Server.
7. Navigate to the Administration – Server Management screen, then the Servers and Component Groups view.

8 Verify that the State value for the Workflow Management and EAI Component Groups is set to Online.

# About Exporting Data for Site Visits

The SWILSClinicalQueryProtocolSite_SiteVisits Web service is used by third-party applications to request site monitor, site, and site visit records from Siebel Clinical. The third-party application submits the data queries to Siebel Clinical in XML format. Table 11 lists the XML queries supported by the SWILSClinicalQueryProtocolSite_SiteVisits Web service for exporting site visit data to a third-party application.

Table 11. SWILSClinicalQueryProtocolSite_SiteVisits XML Queries Supported for Exporting Site Visit Data

| Third-Party XML Query | Description | Validation |
|---|---|---|
| `<ls:UserId>SIAADMIN</ls:UserId>`<br><br>`<ls:ProtocolNumber>*</ls:ProtocolNumber>` | When Siebel Clinical receives a validated Siebel User ID in the Web service request, the Siebel Web service response provides the records for the sites, site visits, and protocols which that User ID is associated with. | User ID must be a team member listed in the Assigned To list for the site visit. For more information about the Assigned To list for site visits, see "Creating and Managing Site Visits" on page 93. |
| `<ls:UserId>*</ls:UserId>`<br><br>`<ls:ProtocolNumber>AMXN 9374</ls:ProtocolNumber>` | When Siebel Clinical receives a validated Siebel protocol number in the Web service request, the Siebel Web service response provides the records for the sites and site visits which that protocol number is associated with. | Not applicable. |
| `<ls:UserId>SIAADMIN</ls:UserId>`<br><br>`<ls:ProtocolNumber>AMXN 9374</ls:ProtocolNumber>` | When Siebel Clinical receives a validated Siebel User ID and protocol number in the Web service request, the Siebel Web service response provides the records for the sites and site visits which that User ID and protocol number are associated with. | User ID must be a team member listed in the Assigned To list for the site visit. |
| `<ls:UserId>*</ls:UserId>`<br><br>`<ls:ProtocolNumber>*</ls:ProtocolNumber>` | The Siebel Web service response returns the records for all clinical sites and site visits. | Not applicable. |

### Example of Configuring SWILSClinicalQueryProtocolSite_SiteVisits Web Service Request

This extract provides an example of configuring the SWILSClinicalQueryProtocolSite_SiteVisits Web service request. It returns all site and site visit records associated with user SIAADMIN. For more information about configuring the SWILSClinicalQueryProtocolSite_SiteVisits Web service, see *Siebel CRM Web Services Reference*.

```
<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:cus="http://siebel.com/CustomUI" xmlns:ls="http://www.siebel.com/xml/
LS%20Clinical%20Protocol%20Site_Site%20Visits%20Input%20IO">

   <soapenv:Header>

   <UsernameToken xmlns="http://siebel.com/webservices">SADMIN</UsernameToken>

   <PasswordText xmlns="http://siebel.com/webservices">SADMIN</PasswordText>

   <SessionType xmlns="http://siebel.com/webservices">None</SessionType>

   </soapenv:Header>

   <soapenv:Body>

   <cus:query_Input>

   <ls:ListOfLsClinicalProtocolSite_SiteVisitsInputIo>

   <ls:ClinicalProtocolSiteQuery>

   <ls:UserId>SIAADMIN</ls:UserId>

   <ls:ProtocolNumber>*</ls:ProtocolNumber>

   </ls:ClinicalProtocolSiteQuery>

   </ls:ListOfLsClinicalProtocolSite_SiteVisitsInputIo>

   <cus:PageSize>2</cus:PageSize>

   <cus:StartRowNum>0</cus:StartRowNum>

   </cus:query_Input>

   </soapenv:Body>

   </soapenv:Envelope>
```

# About Exporting Geographical Location Details for Sites

The SWILSClinicalCreateSiteVisitGeoLocation Web service supports regulatory requirements to track completion of site visits. Support is provided to export site visit and geographical location details from a third-party application, including an on-site mobile application, to Siebel Clinical.

Table 12 lists the site visit data that can be exported to Siebel Clinical from a third-party application. The logged in user must be a team member listed in the Assigned To list for the site visit. For more information about the Assigned To list, see "Creating and Managing Site Visits" on page 93.

Table 12. Site Visit Data Exported to Siebel Clinical

| Data | Description | Validation | Required |
|---|---|---|---|
| SiteVisitId | This field is populated with the site visit ID. Each separate visit to the site is assigned a separate ID number. | Must be a valid site visit ID. | Yes |
| VisitDate | This field is populated with the date and time for the site visit. | Must be a valid time and date in the format yyyy-mm-dd hh:mm:ss | Yes |
| UserId | The user ID of the site monitor. | The User ID must be a team member listed in the Assigned To list for the site visit. | Yes |
| Latitude | Latitude coordinates in decimal degree format. Northern hemisphere latitudes must be input as a positive number. The number is preceded by a minus sign to represent southern hemisphere latitudes.<br>**NOTE:** Using the letters N and S to indicate north and south is not supported, and results in an error. Northern hemisphere values must be preceded by a plus sign (+). Southern hemisphere values must be preceded by a minus sign (-). | The value must be within the range of 0 to plus or minus 90. | No |

Table 12. Site Visit Data Exported to Siebel Clinical

| Data | Description | Validation | Required |
|---|---|---|---|
| Longitude | Longitude coordinates in decimal degree format. Eastern hemisphere latitudes must be input as a positive number. The number is preceded by a minus sign to represent western hemisphere longitudes.<br><br>**NOTE:** Using the letters E and W to indicate east and west is not supported, and results in an error. Eastern hemisphere values must be preceded by a plus sign (+). Western hemisphere values must be preceded by a minus sign (-). | The value must be within the range of 0 to plus or minus 180. | No |
| Comments | This field is populated by the site monitor with any comments relating to the site visit. | Not applicable.<br><br>The comments field is truncated if it exceeds 250 characters. | No |

## Example of SWILSClinicalCreateSiteVisitGeoLocation Web Service Request

This extract provides an example of configuring the SWILSClinicalCreateSiteVisitGeoLocation Web service request. It exports site visit and geographical location details for user SIAADMIN to Siebel Clinical. For more information about configuring the SWILSClinicalCreateSiteVisitGeoLocation Web service, see *Siebel CRM Web Services Reference*.

```
<?xml version="1.0" encoding="UTF-8" ?>

- <soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:cus="http://siebel.com/CustomUI" xmlns:ls="http://www.siebel.com/xml/
LS%20Clinical%20Site%20Visits%20Geo%20Loc%20IO">

   <soapenv:Header>

   <UsernameToken xmlns="http://siebel.com/webservices">SIAADMIN</UsernameToken>

   <PasswordText xmlns="http://siebel.com/webservices">SIAADMIN</PasswordText>

   <SessionType xmlns="http://siebel.com/webservices">None</SessionType>

   </soapenv:Header>

   <soapenv:Body>

   <cus:insert_Input>
```

```
   <ls:ListOfLsClinicalSiteVisitsGeoLocIo>
   <!-- Zero or more repetitions:  -->
- <ls:LsClinicalSiteVisitLocation>
- <!-- Optional:  -->
   <ls:Latitude>89</ls:Latitude>
- <!-- Optional: -->
   <ls:Longitude>91</ls:Longitude>
   <ls:SiteVisitId>88-22X7M</ls:SiteVisitId>
   <ls:VisitDate>2000-10-10 01:09:09</ls:VisitDate>
- <!-- Optional:  -->
   <ls:Comments>Clinical trial site monitoring visit tracking complete</ls:Comments>
   <ls:UserId>1SIA-8FKI</ls:UserId>
   </ls:LsClinicalSiteVisitLocation>
   </ls:ListOfLsClinicalSiteVisitsGeoLocIo>
   </cus:insert_Input>
   </soapenv:Body>
   </soapenv:Envelope>
```

# Viewing Geographical Location Details for Site Visits in Clinical Trip Reports

Dates, times, and geographical location details for sites are recorded in the trip report for each site monitor's visit to each site. For more information about site visits, see "Creating and Managing Site Visits" on page 93.

Multiple site monitors can create multiple site visit records in the trip report for the same site visit. Each site monitor can create multiple site visit records in the trip report for different times on the same site visit.

### *To view geographical location details for a site visit in a clinical trip report*

1. Navigate to the Site Visits screen, then the Clinical Site Visits List view.
2. In the Clinical Site Visits list, drill down on the Visit Start field of the site visit for which you want to view geographical location details.

   The Trip Report form for the selected site visit appears.

3 Navigate to the Geo Location Details view.

Some fields are described in the following table.

| Field | Comments | Editable Field |
|---|---|---|
| User Id | User ID of the site monitor who logged the geographical location details in the third-party clinical application. | No |
| Latitude | Latitude coordinates are represented in decimal degree format. The range of acceptable values is 0 to plus or minus 90. Northern hemisphere latitudes are represented by a positive number. The number is preceded by a minus sign to represent southern hemisphere latitudes. | No |
| Longitude | Longitude coordinates are represented in decimal degree format. The range of acceptable values is 0 to plus or minus 180. Eastern hemisphere latitudes are represented by a positive number. The number is preceded by a minus sign to represent western hemisphere longitudes. | No |
| Comments | This field is populated by the site monitor with any comments relating to the site visit. | Yes |
| Date | Date and time the geographical location details were logged in the third-party clinical application. | No |

# 13 Setting Up and Configuring Mobile Integration of Clinical Trip Reports

This chapter covers setting up and configuring clinical trip reports for mobile integration. It includes the following topics:



## Overview of Mobile Integration for Clinical Trip Reports

Clinical trip reports can be integrated with a third-party mobile application. The provided Web services can be used by third-party applications to request details for clinical trip reports from Siebel Clinical, and to remotely update details for clinical trip reports in Siebel Clinical.

# About Customizing Web Services for Mobile Integration of Clinical Trip Reports

Web services for mobile integration can be customized for integration with any third-party mobile application, or for specific business requirements. For more information about customizing Siebel Web services, see *Siebel CRM Web Services Reference.*

The following Web services are provided for mobile integration:

- SWILSClinicalGetStateModelService
- SWILSClinicalGetSubjectVisitDetails
- SWILSClinicalProtocolSiteGetSites
- SWILSClinicalTripReportInterfaceService
- SWILSClinicalActivityTemplate
- SWILSClinicalGetEmployees
- SWILSClinicalGetSiteContacts
- SWILSClinicalInsertEmployees
- SWILSClinicalListOfValues
- SWILSClinicalGetSiteSnapshot
- SWILSClinicalTripReportTemplates
- SWILSClinicalGetSmartScriptDetails

# Workflows for Mobile Integration of Clinical Trip Reports

This topic describes workflows for mobile integration functionality in Siebel Clinical Trial Management System. By modifying these workflows, you can configure the mobile integration functionality according to the business requirements of your organization. For more information about workflows, and about customizing workflows, see *Siebel Business Process Framework: Workflow Guide*.

This topic includes the following information:

## LS Clinical Protocol Site Get Sites Workflow

This workflow returns all of the sites that include the position of the logged-in user in the site team. For example, if this workflow is called for an authenticated user with a position of consultant, then it returns all of the sites for users with a position of consultant. Figure 2 shows this workflow.

This workflow is not called within Siebel Clinical Trial Management System. A third-party application can call this workflow using the SWILSClinicalProtocolSiteGetSites Web service. For more information, see "About Exporting Data for Sites" on page 198.

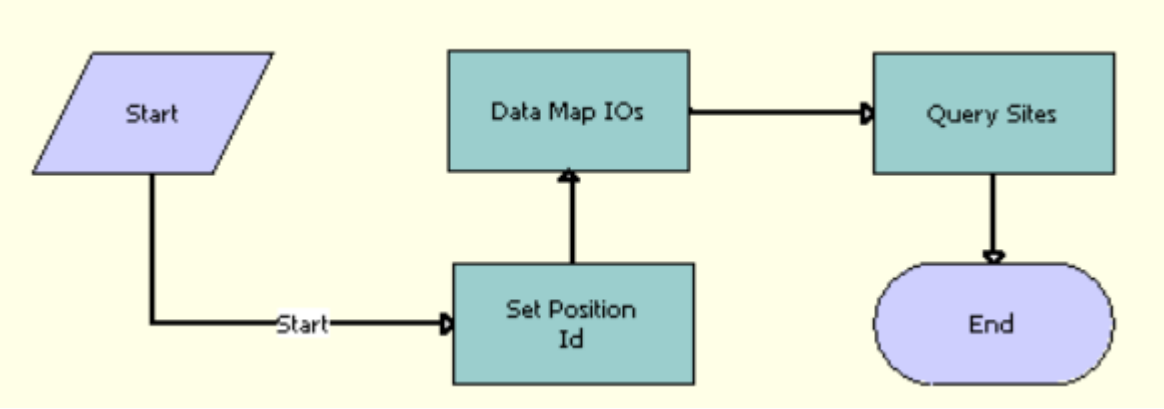


Figure 2. LS Clinical Protocol Site Get Sites Workflow

**Workflow Description.** This workflow performs the following actions:

1. **Set Position Id**. This step gets the position ID of an authenticated user and sets the ID in the input Integration Object.
2. **Data Map IOs**. This step maps the input integration object to the intermediate integration object.
3. **Query Sites**. This step finds the site data using the intermediate integration object, and sends the output to the output integration object.

## LS Clinical Get Site Snapshot Service Workflow

This workflow captures the snapshot data for the subject status accruals of a site and includes this data in the trip report for a site visit. Figure 3 shows this workflow.

This workflow is not called within Siebel Clinical Trial Management System. A third-party application can call this workflow using the SWILSClinicalGetSiteSnapshot Web service. For more information, see "About Exporting Snapshot Data for Site Enrollments" on page 199.

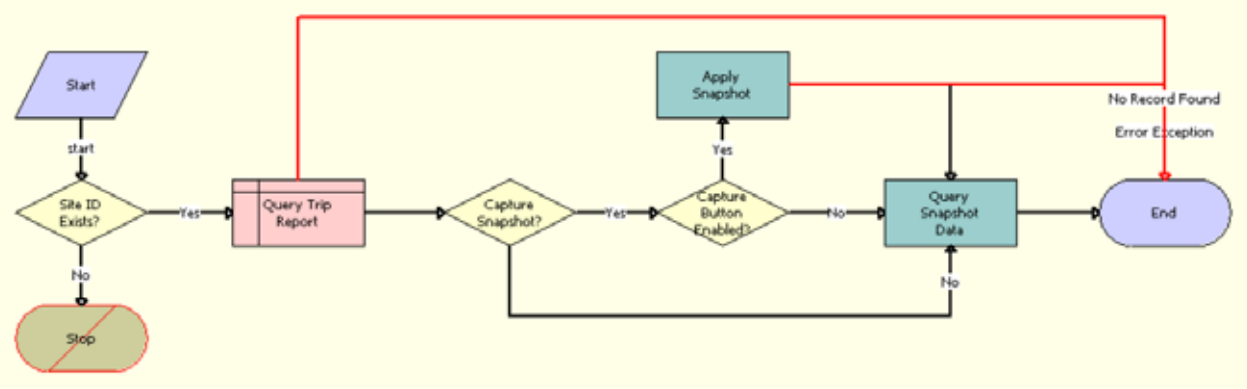


Figure 3. LS Clinical Get Site Snapshot Service Workflow

**Workflow Description.** This workflow performs the following actions:

1. **Site ID Exists?** This step determines whether the user passes a value for the site visit ID.
2. **Query Trip Report.** If the user passes a value for the site visit ID, then this step finds the trip report for the site visit ID.
3. **Capture Snapshot?** This step determines whether the CaptureSnapshot attribute is Y, N, or null.
4. **Capture Button Enabled?** If the CaptureSnapshot attribute is Y, then this step determines whether the Capture button in the Subject Status Snapshot applet is enabled.
5. **Apply Snapshot.** If the Capture button is enabled, then this step gets the real-time snapshot data for the site. The data is sent from Siebel Clinical Trial Management System to the third-party application that uses the SWILSClinicalGetSiteSnapshot Web service to call this workflow.
6. **Query Snapshot Data.** This step gets and returns the current snapshot data for the site. The data is sent from Siebel Clinical Trial Management System to the third-party application that uses the SWILSClinicalGetSiteSnapshot Web service to call this workflow

# Process of Setting Up Mobile Integration for Clinical Trip Reports

To set up mobile integration for clinical trip reports, perform the following tasks:

- "Completing Integration Prerequisites for Mobile Integration" on page 193
- "Activating Workflows for Mobile Integration" on page 193
- "Configuring Web Services for Mobile Integration" on page 193

# Completing Integration Prerequisites for Mobile Integration

The site visit data integration features are a prerequisite for setting up mobile integration for clinical trip reports. For more information about setting up site visit data integration, see "Process of Setting Up Site Visit Data Integration" on page 180.

This task is a step in "Process of Setting Up Mobile Integration for Clinical Trip Reports" on page 192.

# Activating Workflows for Mobile Integration

This task describes how to activate the workflows that are required for mobile integration. You can modify the workflows to suit your own business model, using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

This task is a step in "Process of Setting Up Mobile Integration for Clinical Trip Reports" on page 192.

### *To activate workflows for mobile integration*

1. Navigate to the Administration - Business Process screen, then the Workflow Deployment view.
2. Query for and activate the following workflows:
   - LS Clinical Protocol Site Get Sites
   - LS Clinical Get Site Snapshot Service
3. Verify that the activated workflows are added to the Active Workflow Processes view at the bottom of the screen.

# Configuring Web Services for Mobile Integration

This task describes how to configure the inbound Web services that are required for mobile integration. For more information about configuring Web services, see *Integration Platform Technologies: Siebel Enterprise Application Integration*.

**NOTE:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide*.

This task is a step in "Process of Setting Up Mobile Integration for Clinical Trip Reports" on page 192.

### *To configure Web services for mobile integration*

1. Navigate to the Administration - Web Services screen, then the Inbound Web Services view.
2. Query for each of the following Web services, and update the language and address variables:
   - SWILSClinicalGetStateModelService
   - SWILSClinicalGetSubjectVisitDetails

- SWILSClinicalProtocolSiteGetSites
- SWILSClinicalTripReportInterfaceService
- SWILSClinicalActivityTemplate
- SWILSClinicalGetEmployees
- SWILSClinicalGetSiteContacts
- SWILSClinicalInsertEmployees
- SWILSClinicalListOfValues
- SWILSClinicalGetSiteSnapshot
- SWILSClinicalTripReportTemplates
- SWILSClinicalGetSmartScriptDetails

3 Click Clear Cache on the Inbound Web Services applet.

# About Exporting Data for Lists of Values

The SWILSClinicalListOfValues Web service is used by third-party applications to request list of value (LOV) records from Siebel Clinical Trial Management System.

The following data is exported:

- Visit types
- Visit status
- Trip report status
- Activity
- Activity type
- Status
- Display in

The third-party application submits the data queries to Siebel Clinical in XML format. Table 13 lists the XML queries supported by the SWILSClinicalListOfValues Web service for exporting list of value records to a third-party application.

Table 13. SWILSClinicalListOfValues XML Queries Supported for Exporting List of Value Records

| Third-Party XML Query Example | Description |
|---|---|
| <asi:LOVQueryByExample_Input><br><list:Type>AAG*</list:Type> | When Siebel Clinical receives a validated value for Type in the Web service request, the Siebel Web service response provides all the LOV records for the specified Type. |
| <asi:LOVQueryPage_Input><br><asi:PageSize>100</asi:PageSize><br><list:ListOfListOfValues><br><list:ListOfValues><br><list:Id>*</list:Id><br><list:Language>*</list:Language><br><list:LanguageName>*</list:LanguageName><br><list:Modifiabl>*</list:Modifiable><br><list:Multilingual>*</list:Multilingual><br><list:Name>*</list:Name><br><list:ReplicationLevel>*</list:ReplicationLevel><br><list:Translate>*</list:Translate><br><list:Type>AAG*</list:Type><br><list:Value>*</list:Value><br><asi:StartRowNum>50</asi:StartRowNum> | When Siebel Clinical receives a validated value for PageSize and Type in the Web service request, the Siebel Web service response provides the LOV records for the specified type, page size, and starting row. A PageSize value of 100 and StartRowNum value of 50 returns 100 records, starting at row 50.<br>The page size is a required argument, and cannot be greater than the MaximumPageSize set on the server.<br>StartRowNum is an optional argument, and the default value is 0. |

# About Exporting Data for Clinical Templates

The SWILSClinicalActivityTemplate Web service is used by third-party applications to request clinical template details from Siebel Clinical Trial Management System. This Web service returns details for each of the following clinical template types:

- Clinical protocol
- Clinical site

- Clinical region
- Clinical trip report

The following data is exported for each template type:

- Name
- Type
- Description
- Protocol title
- Automatic trigger flag
- Public flag

# About Exporting Data for Siebel Clinical Users

The SWILSClinicalGetEmployees Web service is used by third-party applications to request user records from Siebel Clinical. The exported data is then added to or deleted from the MVG (multi value group) for the Assigned To field using the SWILSClinicalInsertEmployees Web service.

The Web service response includes the following user data:

- Division
- Employee ID
- Email
- First name
- Job title
- Last name
- Primary
- Responsibility
- User ID
- Work phone number

# About Adding Users to MVG for Assigned To Fields

The SWILSClinicalInsertEmployees Web service is used to populate the MVG (multi value group) for the Assigned To field with the records exported by the SWILSClinicalGetEmployees Web service. The external application can invoke this Web service using any valid Siebel application user credentials for authentication.

This Web service is used to populate the MVG for Assigned To field in the following applets for clinical trip reports:

- Site Visits
- Checklist Items
- Trip Follow-Up Items

# About Exporting Data for Contacts of Sites

The SWILSClinicalGetSiteContacts Web service is used by third-party applications to request contact records for sites from Siebel Clinical. The external application can invoke this Web service using any valid Siebel application user credentials for authentication.

The Web service response includes the following contact data for sites:

- Role
- First name
- Last name
- Address
- City
- State
- Country
- Postal code
- Main phone
- Main fax
- Email
- Specialty

# About Exporting Data for Subject Visits

The SWILSClinicalGetSubjectVisitDetails Web service is used by third-party applications to request subject visit records from Siebel Clinical Trial Management System.

This Web service returns the following subject visit data:

- Screen number
- Visit type
- Visit
- Version

- Number of CRF (case report form) pages

# About Exporting Data for Sites

The SWILSClinicalProtocolSiteGetSites Web service is used by third-party applications to request clinical site records from Siebel Clinical Trial Management System. This Web service returns the site records that include the position of the logged-in user in the site team.

The following data is exported:

- Site number
- Site study
- Site region
- Site version
- Site IRB (institutional review board) approval dates
- Site contract amount
- Site account details
- Site contact details

# About Exporting and Importing Data for Clinical Trip Reports

The SWILSClinicalTripReportInterfaceService Web service is used by third-party applications to request details for clinical trip reports from Siebel Clinical, and to update details for clinical trip reports in Siebel Clinical. The user credentials of a team member of the site visit must be used to invoke this Web service from an external application.

This Web service updates the following clinical data:

- Trip report data
- Checklist items
- Follow-up items for trip reports
- CRF (case report form) tracking data
- Geo location data

# About Exporting State Transition Data for Clinical Trip Reports

The SWILSClinicalGetStateModelService Web service is used by third-party applications to request state model transitions for a given field. To support mobile integration for completion, review, and approval of clinical trip reports, this Web service can be used to request the state model transitions for the Status field of trip reports. The external application can invoke this Web service using any valid Siebel application user credentials for authentication.

The Web service response includes the following state model transition data:

- From state
- To state
- Public
- Rule field
- Rule operator
- Rule value
- Rule expression

# About Exporting Snapshot Data for Site Enrollments

The SWILSClinicalGetSiteSnapshot Web service generates the real-time snapshot data for the subject status accruals of a site ID if the CaptureSnapshot attribute is set to Y.

If the CaptureSnapshot attribute is not set to Y, then the Web service returns the last-recorded snapshot data for the subject status accruals of the site ID. For more information about the SWILSClinicalGetSiteSnapshot Web service, see *Siebel CRM Web Services Reference*.

# About Exporting Template Data for Clinical Trip Reports

Use the SWILSClinicalTripReportTemplates Web service to export data for clinical trip report templates from Siebel to a mobile application. For more information about clinical trip report templates, see "Creating Clinical Trip Report Templates" on page 140. For more information about the SWILSClinicalTripReportTemplates Web service, see *Siebel CRM Web Services Reference*.

The following data is exported:

- Name
- Protocol number
- Region

- SmartScript
- Visit type

# About Exporting SmartScript Metadata for Clinical Trip Reports

Use the SWILSClinicalGetSmartScriptDetails Web service to export SmartScript questionnaire data for trip reports from Siebel to a mobile application. For more information about SmartScript questionnaires for trip reports, see "Creating Questions for Clinical Trip Reports Using Siebel SmartScript" on page 139. For more information about the SWILSClinicalGetSmartScriptDetails Web service, see *Siebel CRM Web Services Reference*.

# 14 Setting Up and Configuring Clinical Data Capture and Query Management System Integration

This chapter covers setting up and configuring Siebel Clinical Trial Management System for integration with a clinical data capture and query management system, such as Oracle InForm. It includes the following topics:



## Overview of Clinical Data Capture and Query Management System Integration

Integration Web services are provided for integrating Oracle's Siebel Clinical Trial Management System with clinical data capture and query management systems. Oracle's Siebel Clinical Trial Management System is certified for integration with Oracle InForm. For more information about the integration with Oracle InForm, see *Oracle Health Sciences InForm Publisher On Demand 2.1 Integration Guide*.

The Web services can be customized for integration with any third-party clinical application, or for specific business requirements. For more information about customizing Siebel Web services, see *Siebel CRM Web Services Reference*.

The following integration processes are provided for clinical data capture integration:

- **Study subject integration.** A Siebel Clinical Web service creates screening and enrollment subjects, and enables screening and enrolling against the active subject visit template. Web services create subjects in Siebel Clinical when screening or enrollment data is entered in Oracle InForm.
- **Activity completion data integration.** The integration Web services update the completion dates of visits and activities in the subject visit template. The Siebel Clinical visit and activity completion data is updated using changes to the patient data that is entered in Oracle InForm.

# Process of Setting Up Clinical Data Capture and Query Management System Integration

To set up clinical data capture and query management system integration for Siebel Clinical, perform the following tasks:

- "Activating Workflows for Clinical Data Capture and Query Management System Integration" on page 202
- "Setting Up LS Clinical Integration Workflow Monitor Agent for Clinical Data Capture and Query Management System Integration" on page 203
- "Configuring Web Services for Clinical Data Capture and Query Management System Integration" on page 203

## Activating Workflows for Clinical Data Capture and Query Management System Integration

This task describes how to activate the workflows that are required for clinical data capture and query management system integration. You can modify the workflows to suit your own business model, using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

This task is a step in "Process of Setting Up Clinical Data Capture and Query Management System Integration" on page 202.

### *To activate workflows for clinical data capture and query management system integration*

1. Navigate to the Administration - Business Process screen, then the Workflow Deployment view.
2. Query for and activate each of the following workflows:
   - SWI LS Clinical Subject Inbound - Subject
   - SWI LS Clinical Subject Inbound - Activity
   - SWI - Protocol Number Lookup
   - LS Clinical - DeleteNonAppVisits Process
3. Verify that each activated workflow is added to the Active Workflow Processes view at the bottom of the screen.

# Setting Up LS Clinical Integration Workflow Monitor Agent for Clinical Data Capture and Query Management System Integration

This topic describes how to set up the LS Clinical Integration workflow monitor agent for clinical data capture and query management system integration.

This task is a step in "Process of Setting Up Clinical Data Capture and Query Management System Integration" on page 202.

### *To set up the LS Clinical Integration workflow monitor agent for clinical data capture and query management system integration*

1. Navigate to the Administration - Server Configuration screen, then the Enterprises view.
2. Navigate to the Component Definitions view, and query for Workflow*.
3. Make a copy of the Workflow Monitor Agent component definition, and change the name to LS Clinical Integration.
4. Change the Alias name to LSClinicalInteg.
5. Set Component Group to Workflow Management.
6. Under Component Parameters, query for Group Name and change the Group Name to LS Clinical Site Integration in the Component Parameter applet.
7. Change the Action Interval to 5.
8. Click Advanced, change the Sleep Time to 15, and change the Default Task to 1.
9. Click Activate to change the status of the new component to Active.
10. Synchronize the components.
11. Restart the Siebel server.

# Configuring Web Services for Clinical Data Capture and Query Management System Integration

This task describes how to configure the Web services that are required for clinical data capture and query management system integration. For more information about configuring Web services, see *Integration Platform Technologies: Siebel Enterprise Application Integration*.

**NOTE:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide*.

This task is a step in "Process of Setting Up Clinical Data Capture and Query Management System Integration" on page 202.

### *To configure Web services for clinical data capture and query management system integration*

1. Navigate to the Administration - Web Services screen, then the Inbound Web Services view.
2. Query for each of the following Web services, and update the language and address variables:
   - ClinicalSubject Inbound Web service.
   - LS Clinical Protocol Site Interface Service
3. Click Clear Cache on the Inbound Web Services applet.

# Configuring Protocol Integration Fields for Oracle InForm Integration

The CDMS Study ID field in Siebel Clinical maps a protocol in Siebel Clinical to a clinical trial in Oracle InForm. Multiple protocols can be associated with a clinical program in Siebel Clinical. When you create a protocol record, you can also add extra information about the protocol, such as financial information, central laboratory information, and so on.

### *To configure protocol integration fields for Oracle InForm integration*

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, query for the correct protocol.
3. Drill down on the protocol number field.
4. Navigate to the integration section of the More Info view.
5. Complete the integration fields.

   The integration fields are described in the following table.

| Field | Comments | Required |
|---|---|---|
| CDMS Study ID | This field links a clinical protocol in Siebel Clinical to a clinical study in an external application.<br><br>For integration with Oracle InForm, set the value to the trial name in Oracle InForm. | Yes |
| Plan Study ID | This field is not applicable for InForm integration. | No |
| Safety Study ID | This field is not applicable for InForm integration. | No |
| Synchronize Active Study Sites | This field is not applicable for InForm integration. | No |

# Integrating Data for Subject Visits with Data for Activities

Subject visit templates allow you to set up a template schedule. The template schedule is based on the protocol document. You use the template schedule to generate screening, rescreening, and enrollment schedules for each subject, according to the subject's screening, rescreening, and enrollment dates.

The Clinical Item Integration field in the subject visit template is used for integrating visit data with activity data between Siebel Clinical and Oracle InForm.

### *To integrate data for subject visits data with data for activities*

1. Navigate to the Administration - Clinical screen, then the Visit Templates view.
2. In the Subject Visit Templates list, create a new record and complete the necessary fields.

   The Clinical Item fields in the Visits and Activities applets are populated automatically.
3. Verify that the Clinical Item fields in the Visits and Activities applets are populated as specified in the following table.

| Field | Comments |
|---|---|
| Visits - Clinical Item | When a visit is created, the clinical item in the Visits applet is populated with the name of the visit.<br><br>The clinical item value is used to define the completion criteria for the visit in Oracle InForm. If multiple versions of the subject visit template exist, and some visits are the same in both template versions, then the same clinical item value can be specified. This feature allows both visits to have the same completion criteria in Oracle InForm.<br><br>**NOTE:** The clinical item value for a visit must be unique within a version of a subject visit template. |
| Activities - Clinical Item | When a visit activity is created, the clinical item in the Activities applet is populated with the value in the Activities Description field.<br><br>The clinical item value is used to define the completion criteria for the activity in Oracle InForm. The same activity is often carried out at multiple visits, therefore the user can assign the same clinical item value to each activity, and then define the completion criteria only once in Oracle InForm.<br><br>**NOTE:** The clinical item value for an activity must be unique within a visit in a version of a subject visit template. |

# About Exporting Data for Sites

The LS Clinical Protocol Site Interface Service Web service is used to export the data in the Protocol Site List view from Siebel Clinical Trial Management System to an external application. For information about the Protocol Site List view, see "Creating Sites for Clinical Trials" on page 51.

The following data is exported:

- Account
- Initiation completed date
- Primary investigator
- Protocol number
- Region
- Site number
- Status

# About Integrating Data for Activity Completion

Oracle InForm controls the integration of activity completion data between Siebel Clinical and Oracle InForm. In Oracle InForm, when patient data is entered that complies with the criteria defined for the clinical item value for a visit or activity, Siebel Clinical receives a message containing a completion date. The visit or activity is updated with the status of Complete, and the completion date is populated.

If the message from Oracle InForm does not contain a completion date, and the visit or activity in Siebel Clinical already has a status of Complete, then no change is made to the completion date or status in Siebel Clinical.

Oracle InForm integrates activity completion data with Siebel Clinical as follows:

- Siebel Clinical searches for the subject using the unique subject identifier (row ID). When the subject is found, it searches for the activity as follows:
  - Siebel Clinical searches for the activity using the clinical item defined for the visit and the clinical item defined for the visit activity as follows:
    - If the clinical item in the update corresponds to a subject visit, then the completed date for that visit is updated.
    - If the clinical item in the update corresponds to an activity for a subject visit, then the completed date for that activity is updated.
  - If the clinical item sent from Oracle InForm cannot be mapped to an activity completion item in Siebel Clinical, then an error is generated to indicate that the update has failed.

# 15 Setting Up and Configuring Clinical Data Management System Integration

This chapter covers setting up and configuring Siebel Clinical for integration with a clinical data management system. It includes the following topics:



## Overview of Clinical Data Management System Integration

The following integration processes are provided for clinical trial integration:

- **Protocol site integration.** Protocol site information can be sent to other systems, such as a CDMS (clinical data management system). A Process Integration Pack exists for integration with Oracle Clinical to take the information sent by Siebel Clinical and create investigators, sites and study sites in Oracle Clinical.
- **Study subject integration.** A Siebel Clinical Web service creates screening and enrollment subjects, and enables screening and enrolling against the active subject visit template. A Process Integration Pack exists for Siebel Clinical and Oracle Clinical that uses this Web service to create subjects in Siebel Clinical when screening or enrollment data is entered in Oracle Clinical.
- **Activity completion data integration.** The Process integration Pack for Siebel Clinical and Oracle Clinical uses a Siebel Clinical Web service to update the completion dates of visits and activities in the subject visit template. The Siebel Clinical visit and activity completion data is updated using changes to the patient data that is entered in Oracle Clinical.

This integration enables the timely exchange of data between Siebel Clinical and a CDMS, such as Oracle Clinical. Data sent from Siebel Clinical to Oracle Clinical, including investigator details and site details, facilitates the automatic creation of a study site, and removes the necessity of creating site, investigator, and study site data manually. Data sent from Oracle Clinical to Siebel Clinical, including the number of patients and Oracle Clinical completion items such as visits, Data Collection Instruments (DCIs), Data Collection Modules (DCMs), and questions, facilitates more efficient and accurate tracking of the number of patients and activity completion in Siebel Clinical.

The automation of these processes enables the timely and accurate payments to investigators. It also provides a means to more accurately track and respond to issues relating to site performance and protocol adherence.

For information about configuring Oracle Clinical for integration with Siebel Clinical Trial Management System, see *Oracle Study, Subject, and Visit Synchronization Integration Pack for Siebel Clinical and Oracle Clinical 2.5 - Implementation Guide*.

# About Customizing Web Services for Clinical Data Management System Integration

ClinicalSubject Inbound Web service can be customized for integration with any third-party clinical study application, or for specific business requirements. For more information about customizing Siebel Web services, see *Siebel CRM Web Services Reference*.

# Process of Setting Up Clinical Data Management System Integration

To set up clinical data management system integration for Siebel Clinical, perform the following tasks:


- "Configuring Siebel Tools for Clinical Data Management System Integration" on page 209
- "Activating Workflows for Clinical Data Management System Integration" on page 210
- "Setting Up the LS Clinical Integration Workflow Monitor Agent for Clinical Data Management System Integration" on page 210
- "Configuring Web Services for Clinical Data Management System Integration" on page 211
- "Creating Directory Structure on Siebel Server for Clinical Data Management System Integration" on page 211
- "Creating Oracle WebLogic Full Client JAR for Clinical Data Management System Integration" on page 212
- "Creating JNDI Properties File for Clinical Data Management System Integration" on page 212
- "Configuring JVM Subsystem for Clinical Data Management System Integration" on page 213

- "Configuring Java Message Service Parameters for Clinical Data Management System Integration" on page 214
- "Populating Domain Value Maps" on page 215

# Configuring Siebel Tools for Clinical Data Management System Integration

This task describes how to configure Siebel Tools to activate the fields that are required for clinical data management system integration.

**NOTE:** This Siebel Tools configuration task is not required in version 8.1.1.10 and later.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

### *To configure Siebel Tools for clinical data management system integration*

1. In Siebel Tools, lock the following projects:
   - LS Clinical Protocol
   - LS Clinical Protocol Site
2. Lock the following objects:
   - Clinical Protocol Admin Form Applet
   - Clinical Protocol Form Applet
   - Clinical Protocol Site Entry Applet
3. Right click Clinical Protocol Admin Form Applet and select Edit Weblayout.
4. Right click Integration and select View Properties.
5. Set the Visible option to True for each of the following:
   - CDMS Study ID
   - Synchronize Active Study Sites
6. Right click Clinical Protocol Form Applet and select Edit Weblayout.
7. Right click Integration and select View Properties.
8. Set the Visible option to True for each of the following:
   - CDMS Study ID
   - Synchronize Active Study Sites
9. Right click Clinical Protocol Site Entry Applet and select Edit Weblayout.
10. Right click Integration and select View Properties.
11. Set the Visible option to True for each of the following:
    - Integration

- Activate for Synchronization
- Primary Site Address

12 Compile the locked projects.

## Activating Workflows for Clinical Data Management System Integration

This task describes how to activate the workflows that are required for clinical data management system integration. You can modify the workflows to suit your own business model, using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

### *To activate workflows for clinical data management system integration*

1 Navigate to the Administration - Business Process screen, then the Workflow Deployment view.

2 Query for and activate each of the following workflows:

- LS Clinical Protocol Site New
- LS Clinical Protocol Site Update
- SWI LS Clinical Subject Inbound - Subject
- SWI LS Clinical Subject Inbound - Activity
- SWI - Protocol Number Lookup
- LS Clinical - DeleteNonAppVisits Process

3 Verify that each activated workflow is added to the Active Workflow Processes view at the bottom of the screen.

## Setting Up the LS Clinical Integration Workflow Monitor Agent for Clinical Data Management System Integration

This topic describes how to set up the LS Clinical Integration workflow monitor agent for clinical data management system integration.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

### *To set up the LS Clinical Integration workflow monitor agent for clinical data management system integration*

1 Navigate to the Administration - Server Configuration screen, then the Enterprises view.

2 Navigate to the Component Definitions view, and query for Workflow*.

3 Make a copy of the Workflow Monitor Agent component definition, and change the name to LS Clinical Integration.

4 Change the Alias name to LSClinicalInteg.

5 Set Component Group to Workflow Management.

6 Under Component Parameters, query for Group Name and change the Group Name to LS Clinical Site Integration in the Component Parameter applet.

7 Change the Action Interval to 5.

8 Click Advanced, change the Sleep Time to 15, and change the Default Task to 1.

9 Click Activate to change the status of the new component to Active.

10 Synchronize the components.

11 Restart the Siebel server.

## Configuring Web Services for Clinical Data Management System Integration

This task describes how to configure the Web services that are required for clinical data management system integration. For more information about configuring Web services, see *Integration Platform Technologies: Siebel Enterprise Application Integration*.

**NOTE:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide*.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

### *To configure Web services for clinical data management system integration*

1 Navigate to the Administration - Web Services screen, then the Inbound Web Services view.

2 Query for each of the following Web services, and update the language and address variables:

- ClinicalSubject Inbound Web service.
- LS Clinical Protocol Site Interface Service

3 Click Clear Cache on the Inbound Web Services applet.

## Creating Directory Structure on Siebel Server for Clinical Data Management System Integration

This task describes how to set up the directory structure required for JMS (Java Message Service) communication with the Oracle WebLogic Server.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

### *To create the directory structure on the Siebel Server for clinical data management system integration*

1. Create the following directory for storing the JNDI (Java Naming and Directory Interface) properties file and JAR (Java Archive) files on the Siebel Server: `D:\WLSJMS`.
2. Create the following directory for storing the log file on the Siebel Server: `D:\WLSJMS\log`.
3. Copy Siebel.jar and SiebelJI_enu.jar from the Siebel installation directory to `D:\WLSJMS`.

## Creating Oracle WebLogic Full Client JAR for Clinical Data Management System Integration

This task describes how to create the Oracle WebLogic full client JAR (Java Archive) required for clinical data management system integration. You use the Oracle WebLogic JarBuilder tool to generate the full client JAR. The JAR file is then added to the classpath.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

### *To create the Oracle WebLogic full client JAR for clinical data management system integration*

1. Log on to the Oracle WebLogic server.
2. Change the directory to the `server/lib` directory, using the following command:

   ```
   cd WL_HOME/server/lib
   ```

3. Create wlfullclient.jar in the `server/lib` directory, using one of the commands in the following table.

| JDK Version | Command |
|---|---|
| Version 1.5 | `java -jar wljarbuilder.jar -profile wlfullclient5` |
| Version 1.6 | `java -jar wljarbuilder.jar` |

4. To add the Oracle WebLogic full client JAR to the classpath, copy it to the `D:\WLSJMS` directory on the Siebel Server.

## Creating JNDI Properties File for Clinical Data Management System Integration

This task describes how to create the JNDI (Java Naming and Directory Interface) properties file required for clinical data management system integration.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

### *To create the JNDI properties file for clinical data management system integration*

1 Create the file, `D:\WLSJMS\jndi.properties`, on the Siebel Server.

2 Add the following JNDI properties to the file:

`java.naming.factory.initial=weblogic.jndi.WLInitialContextFactory`

`java.naming.provider.url=t3://`*`Host IP Address`*`:`*`Port`*

where:

*Host IP Address* is the IP address of the AIA server.

*Port* is the port where the Web server instance is listening for connections.

**NOTE:** Make sure there are no spaces at the end of the lines in the file jndi.properties. Spaces cause the connection to fail.

## Configuring JVM Subsystem for Clinical Data Management System Integration

This task describes how to configure the JVM (Java Virtual Machine) subsystem required for clinical data management system integration.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

### *To configure the JVM Subsystem for clinical data management system integration*

1 Navigate to the Administration - Server Configuration screen, then the Enterprises view.

2 Select the Enterprise Server that you want to configure.

3 Navigate to the Profile Configuration view.

4 Create a new component profile.

5 Set the parameters in the following table.

| Name | Value |
|---|---|
| Profile | JAVA |
| Alias | JAVA |
| Subsystem Type | JVMSubsys |

6 Set the parameters in the following table in the Profile Parameters list.

| Name | Alias | Data Type | Value |
|---|---|---|---|
| JVM Classpath | CLASSPATH | String | Set the classpath value as follows:<br>■ **Windows.** The files in the classpath must be separated by semicolons (;) and end with a semicolon and period (;.), for example:<br>`D:\WLSJMS;D:\WLSJMS\Siebel.jar;D:\WLSJMS\SiebelJI_enu.jar;D:\WLSJMS\wlfullclient.jar;.`<br>■ **UNIX.** The files in the classpath must be separated by colons (:) and end with a colon and period (:.), for example:<br>`/usr/wlsjms:/usr/wlsjms/Siebel.jar:/usr/wlsjms/SiebelJI_enu.jar:/usr/wlsjms:.` |
| JVM DLL Name | DLL | String | Set the path to the JVM library file, for example:<br>■ **Windows:**<br>`<JAVA_HOME>/jdk/jre/bin/server/jvm.dll`<br>■ **UNIX:**<br>`<JAVA_HOME>/jre/lib/sparc/client/libjvm.so` |
| JVM Options | VMOPTIONS | String | Set the JVM-specific options for the log file, for example:<br>■ **Windows:**<br>`-Djms.log=D:\WLSJMS\log\jms.log`<br>■ **UNIX:**<br>`-Xusealtsigs -Xrs -Djms.log=/usr/wlsjms/log/jms.log` |

## Configuring Java Message Service Parameters for Clinical Data Management System Integration

This task describes how to configure Java Message Service parameters required for clinical data management system integration.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

### *To configure Java Message Service parameters for clinical data management system integration*

1. Navigate to the Administration - Server Configuration screen, then the Enterprises view.
2. Select the Enterprise Server that you want to configure.
3. Navigate to the Profile Configuration view.
4. Create a new component profile.
5. Set the parameters in the following table.

| Name | Value |
|---|---|
| Profile | JMSParameters_study |
| Alias | JMSParameters_study |
| Subsystem Type | JMSSubsys |

6. Set the parameters in the following table in the Profile Parameters list.

| Name | Value |
|---|---|
| ConnectionFactory | jms/aia/AIA_SiebelClinical_ClinicalStudyJMSQueueCF |
| SendQueue | jms/aia/AIA_SiebelClinical_ClinicalStudyJMSQueue |
| SendUsername | Set the value to the Oracle WebLogic server user name.<br>**NOTE:** The Oracle WebLogic user must have access to the JMS (Java Message Service) queue. |
| SendPassword | Set the value to the Oracle WebLogic server user password.<br>The password is visible in plain text until the profile is saved and refreshed. |

7. Restart the Siebel Server.

## Populating Domain Value Maps

This topic describes how to configure domain value maps required for clinical data management system integration.

You must populate the domain value maps (DVMs) before integrating Siebel Clinical with Oracle Clinical. Siebel Clinical provides a list of values for states and countries that each company can customize.

Domain value maps are a standard feature of the Oracle SOA Suite and enable you to map equivalent entities in different applications. Domain value maps are static. Administrators can add additional domain value maps, as required. Transactional business processes never update domain value maps. They only read from them. The domain value maps are stored in XML files and cached in memory at run time.

You must update domain value maps before synchronizing data between Siebel Clinical and Oracle Clinical. Table 14 describes the domain value mappings for integrating Siebel Clinical with Oracle Clinical. Administrators can extend the list of mapped values by adding more domain value maps. To add, modify, or delete a domain value map, use the Oracle Enterprise Service Bus Control DVM user interface. For more information about domain value maps (DVMs), see *Oracle Enterprise Service Bus Developer's Guide 10g* on My Oracle Support.

This task is a step in "Process of Setting Up Clinical Data Management System Integration" on page 208.

Table 14. Domain Value Maps for Integrating Siebel Clinical with Oracle Clinical

| DVM Type | Enterprise Service Bus DVM Column Name | Description |
|---|---|---|
| Country | COMMON, SEBLCLIN_01, OC_O1 | This DVM maps the country codes between Siebel Clinical and Oracle Clinical. |
| State | COMMON, SEBLCLIN_01, OC_O1 | This DVM maps the state codes between Siebel Clinical and Oracle Clinical. |
| ClinicalStudySubject_Status | COMMON, SEBLCLIN_01, OC_01 | This DVM maps the patient statuses defined by customers in Oracle Clinical to subject statuses in Siebel Clinical. |

# Integration Entitles for Siebel Clinical and Oracle Clinical

Table 15 lists the entities that are involved in the areas of the Siebel Clinical and Oracle Clinical applications that are supported for integration, and describes the entity mapping between Siebel Clinical and Oracle Clinical.

Table 15. Integration Entitles for Siebel Clinical and Oracle Clinical

| Siebel Clinical Entity | Oracle Clinical Entity | Description |
|---|---|---|
| Protocol | Study | A document that describes the objectives, design, methodology, statistical considerations, and organization of a clinical trial. In Siebel Clinical, *protocol* is synonymous with *study*. |
| Protocol site | Study site | A protocol site, or study site, is the site at which an investigator carries out a clinical trial. It is used for planning, budgeting, and payments related to a clinical trial. In Siebel Clinical, sites are created at the protocol level to associate accounts (locations) with investigators (physicians). Oracle Clinical uses study sites at a protocol level to associate sites (locations) with investigators (physicians). |
| Account address | Site | The organization that the investigator on the study is associated with. This entity is not associated with a study. An account is not equivalent to a site in Oracle Clinical. In Siebel Clinical, the account includes all the locations of an organization.<br><br>In Oracle Clinical, a site is a particular location where a clinical study can be conducted. In Oracle Clinical, the same site cannot be included in the study with different principal investigators.<br><br>In Siebel Clinical, an account can belong to multiple protocol sites in a protocol with a different principal investigator assigned to each one.<br><br>The account and primary address for the protocol site is used to create a site in Oracle Clinical. |
| Principal investigator (PI) | Investigator | The physician or clinician responsible for conducting the trial. |

Table 15. Integration Entitles for Siebel Clinical and Oracle Clinical

| Siebel Clinical Entity | Oracle Clinical Entity | Description |
|---|---|---|
| Not applicable | Patient position | In Oracle Clinical, an identifier is a placeholder for a participant in a clinical study. Patient positions are created using the target enrollment in a study and assigned to a study site. As each subject is enrolled, or data is collected for that subject, the subject is assigned to a patient position. |
| Subject | Patient | Persons recruited by investigators. Patients participate in a clinical trial at a study site. |
| Subject visit template | Data Collection Instrument (DCI) Book | The expected events that are conducted during the clinical trial, as specified in the study protocol. Expected events include visits and activities or procedures. |
| Subject visit schedule | Not applicable | The planned schedule of events for a particular subject at a site, defined in the subject visit template. After the events occur, the information in the Siebel Subject Visit Schedule is updated, and the activities for subject visits are marked as complete. |
| Not applicable | Completion criteria | A set of parameters that is defined in Oracle Clinical. The parameters are based on responses to the following: visit, clinical planned event, received Data Collection Instrument, received Data Collection Module, or question responses that can be used to assign a completion date to an activity in Siebel Clinical. |
| Activity | Not applicable | In Siebel Clinical, required procedures or tasks in the visit schedule. |

# Integrating Oracle Clinical Studies with Siebel Clinical Protocols

The CDMS Study ID field in Siebel Clinical maps a protocol in Siebel Clinical to a study in Oracle Clinical. The Synchronize Active Study Sites field enables integration between Siebel Clinical and Oracle Clinical.

Multiple protocols can be associated with a clinical program in Siebel Clinical. When you create a protocol record, you can also add extra information about the protocol, such as financial information, central laboratory information, and so on.

### *To integrate an Oracle clinical study with a Siebel clinical protocol*

1. Navigate to the Administration - Clinical screen, then the Protocol List view.
2. In the Protocol list, create a new record.
3. Complete the necessary fields.

   Click the show more button to view hidden fields.

   Some fields are described in the following table.

| Field | Comments | Required |
|---|---|---|
| CDMS Study ID | The Oracle Clinical Study ID. This field is required for integration with Oracle Clinical and links a protocol in Siebel Clinical to a study in Oracle Clinical. | Yes |
| Central Lab | The name of the laboratory associated with the study. You enter this name in the Accounts screen. | No |
| CRO | The name of the clinical research organization that is sponsoring the trial. | No |
| Currency Code | The currency that is used to display the payments, costs, and budgets for the protocol. The default value is USD (United States dollars).<br><br>**NOTE:** You must specify the currency code for the protocol. | No |
| Design | Information about the type of study. | No |
| Exchange Date | The date that determines the exchange rate of the currency used. By default, the exchange date for the protocol is the date the protocol is created. | No |
| Phase | The phase of the clinical trial, such as Phase I or II. | Yes |
| Planned Sites Number | The number of sites planned for the protocol. | Yes |
| Planned Subjects Number | The number of subjects planned for the protocol. | Yes |
| Product | The name of the clinical product associated with the study. Only products that have been associated with the clinical program, through the Application field in the Program List view, can be selected from the Clinical Product and Indication dialog box. | Yes |
| Program | The name of the program for the clinical trial. | Yes |
| Protocol # | The number assigned to the protocol.<br><br>For integrating data with the study site code in Oracle Clinical, this field must not be more than ten characters in length. | Yes |

| Field | Comments | Required |
|---|---|---|
| Regions Required | The flag to indicate that the sites for this protocol must belong to a region. When this field is selected, you cannot create sites directly under protocols. You must create regions first, and then create sites that are associated with regions. | No |
| Status | The protocol status, such as Planned, In Progress, Completed. | Yes |
| Synchronize Active Study Sites | This field must be selected to enable the protocol for integration with Oracle Clinical.<br><br>You can review all protocols that are currently set up for synchronization by navigating to the More Info view for each protocol, and reviewing the integration section. | Yes |
| Team | Enter the names of those who require access to the protocol, the study manager, and others who monitor the clinical trial. | No |
| Title | The descriptive title for the protocol. | Yes |
| Type | The purpose of the protocol. | Yes |
| Withholding Amount | The amount to be withheld from each of the payments to the investigators until the trial is complete. This amount can be overwritten at the region and site levels. | No |
| Withholding % | The percentage to be withheld from each of the payments to the investigators until the trial is complete. This percentage can be overwritten at the region and site levels. | No |

4 Navigate to the integration section of the More Info view.

5 Enter the Oracle Clinical Study ID in the CDMS Study ID field.

6 Select Synchronize Active Study Sites.

# About Integrating Data for Investigators

Siebel Clinical controls the integration of investigator data between Siebel Clinical and Oracle Clinical. When Siebel Clinical triggers the synchronization of protocol sites, and a protocol site is synchronized between Siebel Clinical and Oracle Clinical, the investigator is created in Oracle Clinical if it does not exist, or it is updated if the investigator name or phone number has changed. Deleting investigator data in Siebel Clinical does not trigger the same operation in Oracle Clinical. Investigator data for Siebel Clinical and Oracle Clinical is integrated and processed as follows:

- **Principal investigator.** In Siebel Clinical, the principal investigator (PI) is stored directly with the protocol site, the PI Last Name is used to search for the row ID at the contact level. This row ID is the UID for the investigator that is used in Oracle Clinical for the investigator ID. However, if the row ID is more than 10 characters long, then the system ID from Oracle Clinical for the investigator is used as the ID for the investigator.
- **Investigator phone number**. This field is required in Oracle Clinical, but it is an optional field in Siebel Clinical. The principal investigator phone number must be populated in Siebel Clinical so that the integration can create the investigator in Oracle Clinical.
- **Investigator data deleted in Siebel Clinical does not trigger a deletion in Oracle Clinical.** If the contact specified as the principal investigator for the protocol site in Siebel Clinical is deleted, then this deletion does not trigger the deletion of the investigator in Oracle Clinical. The investigator might have been assigned to another study that is not participating in the integration.
- **Start date.** This value, which does not exist by default in Siebel Clinical, is set in Oracle Clinical to the date on which the principal investigator was assigned to the study site by the integration.
- **End date.** This value, which does not exist by default in Siebel Clinical, is set in Oracle Clinical to the date on which a different investigator was assigned to the study site by the integration. That is, the start date of the newly assigned investigator also serves as the end date for the previously assigned investigator. The end date for a given investigator cannot be prior to the corresponding start date.
- **All investigators transferred as active.** All investigators transferred by the integration are created with a status of Active.
- **Updates in Oracle Clinical to investigator data might be overwritten.** Any updates made in Oracle Clinical to the investigator data assigned to a study site in an integrated study might be overwritten by updates from Siebel Clinical.
- **Updates in the Contacts screen to the principal investigator.** Updates made to the principal investigator on the Contacts screen in Siebel Clinical, such as a name or phone number, are not sent to Oracle Clinical until a change is made to a protocol site that the principal investigator is assigned to, or the principal investigator is assigned to a protocol site that is synchronized.

# Integrating Data for Subject Visits with Data for Activities

Subject visit templates allow you to set up a template schedule. The template schedule is based on the protocol document. You use the template schedule to generate screening, rescreening, and enrollment schedules for each subject, according to the subject's screening, rescreening, and enrollment dates.

The Clinical Item Integration field in the subject visit template is used for integrating visit data with activity data between Siebel Clinical and Oracle Clinical.

### *To integrate data for subject visits with data for activities*

1 Navigate to the Administration - Clinical screen, then the Visit Templates view.

2 In the Subject Visit Templates list, create a new record and complete the necessary fields.

The Clinical Item fields in the Visits and Activities applets are populated automatically.

3 Verify that the Clinical Item fields in the Visits and Activities applets are populated as specified in the following table.

| Field | Comments |
|---|---|
| Visits - Clinical Item | When a visit is created, the clinical item in the Visits applet is populated with the name of the visit.<br><br>The clinical item value is used to define the completion criteria for the visit in Oracle Clinical. If multiple versions of the subject visit template exist, and some visits are the same in both template versions, then the same clinical item value can be specified. This feature allows both visits to have the same completion criteria in Oracle Clinical.<br><br>**NOTE:** The clinical item value for a visit must be unique within a version of a subject visit template. |
| Activities - Clinical Item | When a visit activity is created, the clinical item in the Activities applet is populated with the value in the Activities Description field.<br><br>The clinical item value is used to define the completion criteria for the activity in Oracle Clinical. The same activity is often carried out at multiple visits, therefore the user can assign the same clinical item value to each activity, and then define the completion criteria only once in Oracle Clinical.<br><br>**NOTE:** The clinical item value for an activity must be unique within a visit in a version of a subject visit template. |

# Activating Synchronization of Data for Sites

Siebel Clinical controls the synchronization of protocol site data. When a protocol site is created in Siebel Clinical, the integration triggers the creation of a study site in Oracle Clinical. The investigator and site data are also created in Oracle Clinical if they do not already exist. Updates in Siebel Clinical to the protocol site, principal investigator, and primary address data are exported to the study sites, investigators, and sites, respectively, in Oracle Clinical. Deleting data in Siebel Clinical does not trigger deletions in Oracle Clinical.

The following fields in Siebel Clinical must be populated for integration with Oracle Clinical: account name, primary address for the protocol site, investigator name, and site number. Oracle Clinical uses this information to create investigators, sites, and study sites for the corresponding study in Oracle Clinical.

### *To activate the synchronization of data for a site*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, query for the correct protocol.
3. Drill down on the site number field of the site.
4. Complete the integration fields in the More Info view.

   The integration fields are described in the following table.

| Field | Comments | Required |
|---|---|---|
| Locale | This field defines the locale for the protocol site. | No |
| Maximum Enrollment Number | This field defines the maximum number of subjects that can be enrolled for the clinical protocol site. The value must be greater than or equal to the number of planned subjects for the site. | No |
| Primary Site Address | This field sets the primary location of the protocol site for the study in Siebel Clinical, and is populated by the Pick Location applet. The Pick Location applet displays all addresses that have been defined for the protocol site.<br><br>This field is also used to populate the site address when the site is created in Oracle Clinical. | Yes |
| Time Zone | This field sets the time zone for the protocol site. | No |
| Activate for Synchronization | When this field is checked, it triggers the sending of a new integration object for the protocol site to Oracle Clinical. The integration object creates the site in Oracle Clinical or updates the site if it already exists.<br><br>This field is read-only until the following conditions are met:<br><br>■ The Synchronize Active Study Sites field of the protocol is set to True.<br><br>■ The Primary Site Address field is populated. | Yes |

# Viewing Clinical Protocols Enabled for Synchronization

You can review all protocols that are currently set up for synchronization by navigating to the Protocol List view, and reviewing the integration section for each protocol.

***To view clinical protocols enabled for synchronization***

1. Navigate to the Protocols screen, then the Protocol List view.
2. In the Protocol list, drill down on the protocol number field of the protocol.
3. Navigate to the integration section of the More Info view.

   The Integration section displays the synchronization status for each protocol.

# About Synchronizing Sites

Oracle Clinical and Siebel Clinical use different definitions for sites and study sites. In Oracle Clinical, a *site* is a physical location where studies can be conducted. A site in Oracle Clinical can have only one address and phone number. In Oracle Clinical, a *study site* denotes a site where a principal investigator has carried out a particular study.

In order to create the necessary site in Oracle Clinical, Siebel Clinical uses the combination of the account specified for the protocol site and the primary address of the protocol site. To specify a primary address for a protocol site in Siebel Clinical, a new field has been created, the Primary Site Address field, to indicate the primary address of the site.

You cannot delete a site after it has been assigned as a study site in Oracle Clinical. If you delete the primary address, then you must reassign the primary address to another address. Updates to integrated protocol sites in Siebel Clinical are applied to the corresponding study site in Oracle Clinical.

# About Integrating Data for Clinical Subjects

Oracle Clinical controls the integration of subject data between Siebel Clinical and Oracle Clinical. When patients are assigned to patient positions in Oracle Clinical, or patient data is entered for a patient position, the integration triggers the creation of a subject in Siebel Clinical. Updates to the information for the patient in Oracle Clinical are exported to Siebel Clinical. Deleted data in Oracle Clinical is not reflected in Siebel Clinical. Patient data for Oracle Clinical and subject data for Siebel Clinical is integrated as follows:

- **Subject messages.** When a subject message is received by Siebel Clinical from Oracle Clinical, Siebel Clinical evaluates it to determine if a new subject must be created or if an existing subject must be updated. Siebel Clinical searches for the system ID of the subject. If the system ID does not exist, then Siebel Clinical creates a new subject. If it does exist, then Siebel Clinical updates the subject.
- **Enrollment Date Specified.** If an enrollment date is entered for a patient in Oracle Clinical, then a subject is created in Siebel Clinical if it does not already exist, and the subject are enrolled using the active subject visit template for the protocol site.
- **Enrollment Date Not Specified.** When a patient has data entered in Oracle Clinical, but no enrollment date has been specified, a subject with a status of Screened is created in Siebel Clinical, and the subject is screened against the active subject visit template for the protocol site.

- **Patient Initials.** Siebel Clinical does not record the subject's initials, or any personally identifiable information. The Patient Initials field in Oracle Clinical is mapped to the Subject ID field in Siebel Clinical. The user must change the exported value in Siebel Clinical. Patient Initials is an optional field in Oracle Clinical. Subject ID field is a mandatory field in Siebel Clinical. If patient initials were not entered in Oracle Clinical, then the Subject ID field in Siebel Clinical is populated with the Oracle Patient Position ID.
- **Birth Date.** Siebel Clinical does not record the subject's date of birth, or any personally identifiable information. The patient's Birth Date field in Oracle Clinical is mapped to the Encounter Date field in Siebel Clinical. The user must change the exported value in Siebel Clinical. Birth date is an optional field in Oracle Clinical. Encounter Date is a mandatory field in Siebel Clinical. If birth date was not entered in Oracle Clinical, then the Encounter Date in Siebel Clinical is populated with a value of Jan 1, 1800.
- **Screen Date.** If no screening date is collected in Oracle Clinical, then the screening date is populated with the subject's birth date. Users must correct the Screen Date field in Siebel Clinical and screen the subject again using the correct screening date.
- **Informed Consent Date.** Informed Consent Date is required for enrolled patients in Siebel Clinical but is an optional field in Oracle Clinical. If no informed consent date is specified in Oracle Clinical, then the informed consent date is populated with a value of to Jan 1, 1900. The user must change any default informed consent dates in Siebel Clinical to reflect the date when the informed consent form was signed. Informed consent date is used when enrolling a subject against a new version of a subject visit template and must be accurate.

# About Integrating Data for Activity Completion

Oracle Clinical controls the integration of activity completion data between Siebel Clinical and Oracle Clinical. In Oracle Clinical, when patient data is entered that complies with the criteria defined for the clinical item value for a visit or activity, Siebel Clinical receives a message containing a completion date. The visit or activity is updated with the status of Complete, and the completion date is populated.

If the message from Oracle Clinical does not contain a completion date, and the visit or activity in Siebel Clinical already has a status of Complete, then no change is made to the completion date or status in Siebel Clinical.

Oracle Clinical and Siebel Clinical integrate activity completion data as follows:

- Siebel Clinical searches for the subject using the unique subject identifier (row ID). When the subject is found, it searches for the activity as follows:
  - Siebel Clinical searches for the activity using the clinical item defined for the visit and the clinical item defined for the visit activity as follows:
    - If the clinical item in the update corresponds to a subject visit, then the completed date for that visit is updated.
    - If the clinical item in the update corresponds to an activity for a subject visit, then the completed date for that activity is updated.

- If the clinical item sent from Oracle Clinical cannot be mapped to an activity completion item in Siebel Clinical, then an error is generated to indicate that the update has failed.

# 16 Setting Up and Configuring Clinical Payments Integration

This chapter covers setting up and configuring Siebel Clinical for integration with a third-party payments application. It includes the following topics:



## Overview of Clinical Payments Integration

Siebel Clinical provides the ability to integrate the processing of Siebel Clinical payments with third-party applications. The following integration processes are provided:

- **Sending a payment request for processing.** The payment request records in Siebel Clinical can be sent to a third-party application for processing and payment. The Status field for the payment request is updated to Waiting for Acknowledgement when the payment request has been submitted.
- **Capturing the delivery status of a payment request.** The delivery status of the payment request is processed as follows:
  - **Waiting for Acknowledgement.** This Status field for the payment request is updated to Waiting for Acknowledgement when the Siebel workflow successfully writes the payment message to the JMS (Java Message Service) queue.
  - **Request Failed.** This Status field for the payment request is updated to Request Failed when writing to the JMS queue fails, and an error message appears.
  - **Submitted.** This Status field for the payment request is updated to Submitted when the payment request has been successfully delivered to the third-party application from the JMS queue.
- **Capturing feedback for a payment request.** Feedback information from the third-party application is captured in the Feedback field for the payment request.
- **Capturing final payment data.** Final payment information, such as check number, and check amount, is captured from the third-party application, and the Status field for the payment request is updated to Paid.

The Status field for the payment request triggers the integration processes. Table 16 describes the status values for the integration.

Table 16. Payment Request Status for Clinical Payments Integration

| Status | Description |
|---|---|
| To Be Processed | The payment request has been created, but processing has not yet started. This status is the default value for all new payment requests. The payment request has not yet been submitted to the third-party application. |
| In Progress | Processing of the payment request is in progress. The payment request has not yet been submitted to the third-party application. |
| To Be Submitted | The payment request is ready to be submitted to the third-party application for processing. This status value triggers the LS Clinical Payments Outbound workflow to send the payment request to the third-party application. |
| Waiting for Acknowledgement | The Status field for the payment request is automatically updated to Waiting for Acknowledgement when the payment request has been submitted |
| Submitted | This value is automatically populated when the payment request has been successfully delivered to the third-party application from the JMS queue. |
| Request Failed | This value is automatically populated when writing to the JMS queue fails. |
| Withdraw | This value is manually populated.<br>A payment request that has a status of Waiting for Acknowledgement or Submitted can be set to Withdraw. |
| Rejected | This value is automatically populated when the third-party application has rejected the payment request. You cannot change this value manually. |
| Paid | This value is automatically populated by the third-party application when a payment has been made. The Status field for the payment request becomes read-only after it has been set to Paid. |
| Processed | This value is not applicable to the integration. |
| Update Failed | This value is not applicable to Siebel Clinical payments integration. |

# About Customizing Web Services for Clinical Payments Integration

SWI LS Clinical Payment Inbound Web service can be customized for integration with any third-party payments system, or for specific business requirements. For more information about customizing Siebel Web services, see *Siebel CRM Web Services Reference*.

# Process of Setting Up Clinical Payments Integration

To set up the integration of clinical payments between Siebel Clinical and a third-party application, perform the following tasks:

- "Configuring Siebel Tools for Clinical Payments Integration" on page 229
- "Activating Workflows for Clinical Payments Integration" on page 231
- "Configuring the Inbound Web Service for Clinical Payments Integration" on page 231
- "Configuring Java Message Service Parameters for Clinical Payments Integration" on page 232

## Configuring Siebel Tools for Clinical Payments Integration

This task describes how to create and configure Siebel Tools objects that are required for Siebel Clinical payments integration. The status value that triggers the workflow to send the payment request to the third-party application can be configured in Siebel Tools.

This task is a step in "Process of Setting Up Clinical Payments Integration" on page 229.

### *To configure Siebel Tools for clinical payments integration*

1. In Siebel Tools, lock the LS Clinical Payments project.
2. Select Business Component Object type in the object explorer.
3. Query for Clinical Payments.
4. Select Business Component User property under Business Component in the object explorer.

5 Create the user properties in the following table.

| Business Component User Property Name | Value | Description |
|---|---|---|
| Named Method n | "SendPayment", "INVOKESVC", "Clinical Payments", "Workflow Process Manager", "RunProcess", ' "ProcessName" ', ' "LS Clinical Payments Outbound" ', " 'Object Id' ", " [Id] " | This property is used to configure the LS Clinical Payments Outbound workflow. |
| On Field Update Invoke n | "", "Clinical Payments", "SendPayment", "[Status] = LookupValue('FUNDRQ_STATUS','To Be Submitted') AND [Status] IS NOT NULL" | This property sets the status trigger for the LS Clinical Payments Outbound workflow. By default, a status of To Be Submitted for a payment request triggers the LS Clinical Payments Outbound workflow to send the payment request to the third-party application.<br><br>This property can be configured to use a different Status value to trigger the LS Clinical Payments Outbound workflow. |
| Status Confirmation Popup 1 | "Status", "Waiting for Acknowledgement", "In Progress", "FUNDRQ_STATUS", "<optional custom status message>" | This property adds In Progress to the values of the Status field for manual configuration.<br><br>The <optional custom message> field can be customized to override the following default warning message:<br><br>A payment request is in the process of being sent to the target system. Changing the status may lead to a duplicate payment request being sent in the future. Do you want to continue? |
| Status Confirmation Popup 2 | "Status", "Waiting for Acknowledgement", "Withdraw", "FUNDRQ_STATUS", "<optional custom message>" | This property adds Withdraw to the values of the Status field for manual configuration. |

6 Compile the locked and updated project.

For information about compiling projects, see *Developing and Deploying Siebel Business Applications*.

## Activating Workflows for Clinical Payments Integration

This task describes how to activate the workflows required for Siebel Clinical payments integration.

This task is a step in "Process of Setting Up Clinical Payments Integration" on page 229.

### *To activate workflows for clinical payments integration*

1 Navigate to the Administration - Business Process screen, then the Workflow Deployment view.

2 Query for, and activate, each of the following workflows:

- LS Clinical Payments Outbound
- SWI LS Clinical Payments Inbound
- LS Clinical State Validation

3 Verify that each activated workflow is added to the Active Workflow Processes view at the bottom of the screen.

**NOTE:** You perform this procedure only the first time that you want to access the integration feature for the clinical payments. The workflow remains activated.

## Configuring the Inbound Web Service for Clinical Payments Integration

This task describes how to configure the SWI LS Clinical Payment Inbound Web service, which is required for Siebel Clinical payments integration.

**NOTE:** It is recommended that you use HTTPS authentication. For information about configuring Secure Sockets Layer (SSL) for HTTPS authentication, see *Siebel Security Guide*.

This task is a step in "Process of Setting Up Clinical Payments Integration" on page 229.

### *To configure the inbound Web service for clinical payments integration*

1 Navigate to the Administration - Web Services screen, then the Inbound Web Services view.

2 Query for the SWI LS Clinical Payment Inbound Web service.

3 On the Service Ports applet, update the Address variable to point to your Web server.

4 Configure the Language variable.

5 Click Clear Cache on the Inbound Web Services applet.

6 Restart the Siebel Server.

## Configuring Java Message Service Parameters for Clinical Payments Integration

This task describes how to configure Java Message Service parameters required for Siebel Clinical payments integration.

This task is a step in "Process of Setting Up Clinical Payments Integration" on page 229.

### *To configure Java Message Service parameters for clinical payments integration*

1. Navigate to the Administration - Server Configuration screen, then the Enterprises view.
2. Select the Enterprise Server that you want to configure.
3. Navigate to the Profile Configuration view.
4. Query for the profile alias JMSParameter.
5. Set the value of SendUsername to the user name for the WebLogic server.
6. Set the value of SendPassword to the password for the WebLogic server.
7. Restart the Siebel Server.
8. Verify the CLASSPATH and jndi.properties configurations.

   For information about verifying the CLASSPATH and jndi.properties configurations, see *Transports and Interfaces: Siebel Enterprise Application Integration.*

# Sending Payment Requests to Third-Party Payments Application

This topic describes sending the payment request records in Siebel Clinical to a third-party application for processing and payment.

### *To send a payment request to a third-party application*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to send a payment request.
3. Navigate to the Payments view.

   This view lists all scheduled payment requests for the activities of subject visits associated with the site.
4. Set the Status field as follows: To Be Submitted.

   This step sends the payment request record to the third-party application.

   The (System) LS Clinical Payments Outbound workflow submits the payment data to the JMS (Java Message Service) queue and updates the Status field, as follows:

- **Waiting for Acknowledgement.** This status appears when the Siebel workflow successfully writes the payment message to the JMS queue.
- **Request Failed.** This value is automatically populated when writing to the JMS queue fails. Failed payment requests can be resubmitted to the third-party application.
- **Submitted.** This value is automatically populated when the payment request has been successfully delivered to the third-party application from the JMS queue.

# Withdrawing Payment Requests

You can withdraw a payment request that has a status of Waiting for Acknowledgement or Submitted.

### *To withdraw a payment request*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to withdraw a payment request.
3. Navigate to the Payments view.
4. Set the Status field to Withdraw.
5. Click OK to execute the status change.

# Viewing Feedback for Payment Requests

You use the Feedback field to capture feedback for payment requests from the third-party application, such as why a payment was rejected.

### *To view feedback for a payment request*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to view the payment details.
3. Navigate to the Payments view.

   The Feedback field displays the feedback data that the third-party application returns for the payment request.

# Verifying Processed Payments

The Status value is automatically updated to Paid by the third-party application when a payment has been made. The Status field for the payment request becomes read-only after it has been set to Paid.

### *To verify processed payments*

1. Navigate to the Site Management screen, then the Protocol Site List view.
2. In the Protocol Site list, drill down on the site number field of the site for which you want to view the payment details.
3. Navigate to the Payments view.

   The Status appears as Paid. The Check Number, Check Date, and Check Amount fields display the payment details returned by the third-party application.

# A ClearTrial Clinical Trial Management System Connector

This appendix contains information about configuring the ClearTrial Clinical Trial Management System Connector. It includes the following topics:



## About the ClearTrial Clinical Trial Management System Connector

The ClearTrial Clinical Trial Management System Connector provides integration between ClearTrial Plan and ClearTrial Track, cloud-hosted Software as a Service (SaaS) applications, and Siebel Clinical. The connector extracts data from Siebel Clinical by invoking the ASI SOAP (Application Service Interface Simple Object Application Protocol) Web services. It then transfers the data into ClearTrial Track by invoking the ClearTrial Web services API hosted in the cloud at

https://cleartrial-api.oracleindustry.com/cleartrial-ws

Table 17 describes the required applications for connector processing.

Table 17. Required Applications for Connector Processing

| Application | Description |
|---|---|
| ClearTrial Plan | A cloud-hosted SaaS application that you use to plan a clinical trial. In ClearTrial Plan, you can run different scenarios and arrive at a satisfactory budget and date milestones. |
| ClearTrial Track | A cloud-hosted SaaS application you use to enter the actual data from a clinical trial. In ClearTrial Track, you see how the clinical trial planned in ClearTrial Plan progresses during execution. |
| Clinical Trial Management System | An application that records the details of a clinical trial. |
| ClearTrial Clinical Trial Management System Connector | An application that provides an automated way of importing the actual data in Siebel Clinical into ClearTrial Track. |

For more information about ClearTrial Plan and ClearTrial Track, access Oracle Health Sciences ClearTrial Cloud Service documentation at

http://docs.oracle.com/cd/E40601_02/index.htm

# Supported Integration Points for the ClearTrial Clinical Trial Management System Connector

ClearTrial Track supports a large number of data points in the user interface. The connector supports a subset of data points or the actual data that can be imported automatically. Consequently, a large amount of actual data is included in the automatic import of the connector.

For ClearTrial Track, the week begins on a Monday for all integration points, such as sites approved, subjects enrolled, and CRF (case report form) pages collected.

For example, a site approved on Sunday, February 16, 2014 at 11:59 P.M. is counted against the week starting on Monday, February 10, 2014. Therefore, it is important to capture the accurate dates for the site initiated, subject enrolled, and source verified events in the user interface for Siebel Clinical.

Table 18 describes the supported integration points for the ClearTrial Clinical Trial Management System Connector.

Table 18. Supported Integration Points for the ClearTrial Clinical Trial Management System Connector

| Integration Point | Description |
|---|---|
| Sites Approved | The number of sites that are approved (or initiated) and recorded in Siebel Clinical, rolled up by week, location, and region.<br><br>**NOTE:** The connector ignores initiated sites without a corresponding date. |
| Subjects Enrolled | The number of subjects that are enrolled and recorded in Siebel Clinical, rolled up by week, location, and region.<br><br>You must capture the accurate dates for the subject enrolled event in the Status field. For information about navigating to this field, see “Creating Records for Clinical Subjects” on page 66. |
| CRF Pages Collected | The number of CRF pages that are source verified in Siebel Clinical, rolled up by week, location, and region.<br><br>You must capture the accurate dates for the Source Verified event in the Source Verified Date field. For information about navigating to this field, see “Tracking Case Report Forms” on page 103. |

## About Logging for the ClearTrial Clinical Trial Management System Connector

You can configure logging for the ClearTrial Clinical Trial Management System Connector, if required, in the log4j.properties file in the *User Home*/ClearTrialCtmsData directory. When the connector executes, it creates logs at the command prompt or shell window in which it executes. You can view these logs in the connector.log file in the *User Home*/ClearTrialCtmsData/logs directory. The logs are rotated automatically according to their size.

# Sample Configuration Files for the ClearTrial Clinical Trial Management System Connector

The connector configuration process requires the following files:

- ctmsProtocolBaselinePlan.properties

  This file contains mappings between the Protocol ID in Siebel Clinical and the ClearTrial Baseline Plan ID in ClearTrial Track. You can create any number of mappings in this file. In each execution, the connector imports the actual data for all the Protocol IDs in this file into ClearTrial Track.

  The ClearTrial Baseline Plan ID is the ID of the plan that you select as the baseline plan for a study. The baseline plan is the modeled plan with acceptable milestones and a budget.

  Table 19 shows an example of the mapping in this file.

  Table 19. Example of the Mapping in the File

| Siebel Clinical | ClearTrial Track |
|---|---|
| 88-3CDYK | 56529 |
| 88-3CIEN | 57830 |

- application.properties

  This file contains connection and communication parameters for the integration between Siebel Clinical and ClearTrial Track.

Table 20 describes the parameters that must be defined in this file.

Table 20. Parameters for application.propertie Files

| Parameter | Description |
|---|---|
| proxy.server=myproxy.com | The proxy address that the server for the connector requires to access the internet.<br><br>For a proxy server, this parameter is required. |
| proxy.port=80 | The port on which the proxy listens.<br><br>The default port is 80. For a proxy server, this parameter is required. |
| ctms.server=myCtmsServer.com | The fully qualified domain name of the middle-tier application server for Siebel Clinical.<br><br>This parameter is required. You must specify this parameter even if the connector is installed and executed on the same server as Siebel Clinical. |
| ctms.port=80 | The port on which the middle-tier application server for Siebel Clinical listens for the ASI SOAP (Application Service Interface Simple Object Application Protocol) Web services calls.<br><br>The default port is 80. You must specify this parameter only if the Siebel Clinical listens on a different port. |
| ctms.protocol=http | A value that determines if the Siebel Clinical server is running in secure (https) or non secure mode (http). The default value is http. |
| ctms.environment=eai_enu | A value that determines the locale of the Siebel Clinical instance. The default value is eai_enu. |
| ctms.connection.timeout.millis=60000 | The timeout (in milliseconds) after which the connector declares a connection failure to the middle-tier application server for Siebel Clinical.<br><br>The default value is 60 seconds or 60,000 milliseconds. You can use this parameter if the network is slow. This parameter is not required. |
| ctms.read.timeout.millis=60000 | The timeout (in milliseconds) after which the connector declares a read failure for the request to the middle-tier application server for Siebel Clinical.<br><br>The default value is 60 seconds or 60,000 milliseconds. You can use this parameter if the network is slow. This parameter is not required. |

Table 20. Parameters for application.propertie Files

| Parameter | Description |
|---|---|
| ctms.page.size=10 | The number of pages requested from Siebel Clinical in each request to the ASI SOAP Web services.<br><br>The default value is 10. You can use this parameter if large data sets (SOAP XML content) are extracted in each request, which can lead to broken pipe type errors. This parameter is not required. |
| cleartrial.wsapi.connection .timeout.millis=60000 | The timeout (in milliseconds) after which the connector declares a connection failure to the ClearTrial Web services API.<br><br>The default value is 60 seconds or 60,000 milliseconds. You can use this parameter if the network is slow. This parameter is not required. |
| cleartrial.wsapi.read.timeout. millis=60000 | The timeout (in milliseconds) after which the connector declares a read failure for a request to the ClearTrial Web services API.<br><br>By default, the value is 60 seconds or 60,000 milliseconds. You can use this parameter if the network is slow. This parameter is not required. |

- locationMap.properties

  This file provides mappings between the region names in Siebel Clinical and location names in ClearTrial Track. In ClearTrial Track, the location names are fixed. In Siebel Clinical, a few region names are provided at installation. However, you can create custom region names.

  The locationMap.properties file must contain the region-to-location mapping for every unique region across all protocols with data imported into ClearTrial Track.

  For example, Protocol 1 has region names of Switzerland, Swiss, BELGIUM, and US of A. Protocol 2 has region names of USA, Belgium, and Switzerland. The corresponding location names in ClearTrial Track are Switzerland, Belgium, and USA. In this example, the locationMap.properties file must contain the following information:

```
Switzerland=Switzerland
Swiss=Switzerland
BELGIUM=Belgium
Belgium=Belgium
USA=USA
US\ of\ A=USA
```

  In this information, the left value is the region name in Siebel Clinical and the right value is the location name in the ClearTrial Track. Region and location names are case sensitive. If the region name contains spaces, then you must prefix the spaces with a backward slash (\). For example, if the region name is US of A, then it must appear as US\ of\ A.

  You do not have to configure the connector to recognize the following mappings:

```
Australia=Australia
Brazil=Brazil
France=France
Germany=Germany
Japan=Japan
UK=UK
USA=USA
```

- ctmsLabel.properties

  This file matches the status customization in Siebel Clinical. For example, the default status for the site initiation event is Initiated. However, you can customize this status to Approved. Both of the statuses can exist for the integrated protocols.

  In the this example, the ctmsLabel.properties file has the following content:

  ```
  site.approval.status=Initiated,Approved
  subject.enrollment.status=Enrolled
  ```

  The logic for the status of the initiation event also applies to the status of the subject enrollment.

# Configuring the ClearTrial Clinical Trial Management System Connector

You configure the connector on the middle-tier application server for Siebel Clinical by editing sample property files located in *User Home*\ses\siebsrvr\CLASSES\ctconnector\samples directory, where *User Home* is the account or login that executes the Siebel Clinical installation. Copy the files to another location before you begin editing. The connector configuration must include these files in the *User Home*/ClearTrialCtmsData directory.

### *To configure the ClearTrial Clinical Trial Management System Connector*

1. Copy the following configuration property files from the *User Home*\ses\siebsrvr\CLASSES\ctconnector\samples directory into the *User Home*/ClearTrialCtmsData directory:
   - ctmsProtocolBaselinePlan.properties
   - application.properties
   - locationMap.properties
   - ctmsLabel.properties

     For information about the data to include in these files, see "Sample Configuration Files for the ClearTrial Clinical Trial Management System Connector" on page 237.
2. To obtain each Protocol ID in the ctmsProtocolBaselinePlan.properties file, complete the following steps:
   a. In the Clinical Trial Management System, navigate to the Protocols screen.
   b. Query for the protocol name in the protocol number field, and then select the record for the protocol name.

c Click the cogwheel icon, and select About Record.

In the About Record dialog box that appears, the row number designates the Protocol ID.

3 To obtain each ClearTrial Baseline Plan ID in the ctmsProtocolBaselinePlan.properties file, complete the following steps:

a In the ClearTrial Track, select the plan name for the study with a baseline status.

b Click View.

The plan ID appears in the address field of the browser as follows:

*ClearTrial URL*/cleartrial/plan/ViewPlan?id=*planid*&curPage=1

4 In the application.properties file, include the necessary parameters.

The parameters are described in Table 20 on page 238.

5 If you need any location mappings not already included in the locationMap.properties file, then add them to the file.

6 If you need any status customization not already included in the ctmsLabel.properties file, then add them to the file.

# Configuring Security for the ClearTrial Clinical Trial Management System Connector

The connector is a Java Standard Edition (SE) application that uses the Java 1.7 JRE on the server where it is installed. Install the connector on the middle-tier application server for Siebel Clinical in the *User Home*/connector directory.

The ASI SOAP (Application Service Interface Simple Object Application Protocol) Web services in Siebel Clinical and the ClearTrial Web services API are secured services that need credentials. You must configure the connector with the credentials for both Siebel Clinical and ClearTrial Track.

The procedure in this topic assumes that you installed the connector on the Microsoft Windows 7 operating system on the middle-tier application server for Siebel Clinical.

### *To configure security for the ClearTrial Clinical Trial Management System Connector*

1 Execute the following at the command prompt:

```
cd %HOMEPATH%
cd connector
java -jar cleartrial-ctms-managecreds.jar
```

**NOTE:** If you installed the connector on a UNIX operating system, then replace the cd %HOMEPATH% command with cd ~.

This java command displays the following command line interface for the Credential Management Subsystem of the connector:

```
Create Credential Store [1]
Manage Credentials      [2]
Internet Proxy          [3]
Quit                    [4]
Enter choice :
```

2 Select option 1 if you are configuring the connector credentials on this server for the first time.

After the command has executed, the screen displays the following:

```
Created Credential Store...
```

3 Select option 2 to manage credentials.

After the command has executed, the screen displays the following:

```
Target system
CTMS       [1]
ClearTrial [2]
Go Back    [3]
Enter choice :
```

4 Select option 1 to enter the credentials for Siebel Clinical.

After the command has executed, the screen displays the following:

```
User Name : sadmin
Password  :
Credential for map siebelCtms and key credentials is:
PasswordCredential

Target system
CTMS       [1]
ClearTrial [2]
Go Back    [3]
Enter choice :
```

For security reasons, the password does not appear on the screen.

The user whose credentials are configured for Siebel Clinical must be authorized to access all the protocols and sites that are configured for the integration.

5 Select option 2 to configure the credentials for ClearTrial Track.

After the command has executed, the screen displays the following:

```
Customer Code : XYZ
User Name : jdoe
Password  :
Credential for map cleartrial and key customerCode is:
GenericCredential
Credential for map cleartrial and key credentials is:
PasswordCredential
```

```
Target system
CTMS       [1]
ClearTrial [2]
Go Back    [3]
Enter choice :
```

The credentials must be of a user in ClearTrial who has the Can Access WS- API role. Also, the Customer Code must be for the customer who purchased the ClearTrial Web services API license.

If the credentials are changed after this initial configuration, then you must reconfigure the security for the connector. In this case, do not use the Create Credential Store option because this option deletes all credentials, and you must configure the credentials again for both Siebel Clinical and ClearTrial Track.

## Configuring a Proxy Server for the ClearTrial Clinical Trial Management System Connector

Complete the procedure in this topic only if the connector is configured with an internet proxy server.

### *To configure a proxy server for the ClearTrial Clinical Trial Management System Connector*

1 Execute the following at the command prompt:

```
cd %HOMEPATH%
cd connector
java -jar cleartrial-ctms-managecreds.jar
```

**NOTE:** If you installed the connector on a UNIX operating system, then replace the cd %HOMEPATH% command with cd ~.

This java command displays the following command line interface for the Credential Management Subsystem of the connector:

```
Create Credential Store [1]
Manage Credentials      [2]
Internet Proxy          [3]
Quit                    [4]
Enter choice :
```

2 Select option 3 to configure the proxy server credentials.

After the command has executed, the screen displays the following:

```
Proxy User Name : jsmith
Proxy Password  :
```

3 Enter the user name and password used to access the proxy server.

# Importing Data from Siebel Clinical to ClearTrial Track

You can run a Java program to import data from Siebel Clinical to ClearTrial Track.

### *To import data from Siebel Clinical to ClearTrial Track*

1 Execute the following at the command prompt:

```
cd %HOMEPATH%
cd connector
java -jar cleartrial-ctms.jar
```

**NOTE:** If you installed the connector on the UNIX operating system, then replace the cd %HOMEPATH% command with cd ~.

You can add this command to the Task Scheduler (for Windows) or to cron (for UNIX). Schedule this command once a week when you expect minimal activity in Siebel Clinical.

2 After the program exits, check the ClearTrial Track user interface for the import results.

# B Developer's Reference for Siebel Clinical

This appendix contains information about configuring and customizing Siebel Clinical using Siebel Tools, and customizing Siebel Clinical Web services. It assumes that you are familiar with the processes and conventions of working with Siebel Tools to change one or more object properties. For more information about changing properties in Siebel Tools, see *Configuring Siebel Business Applications*.

This appendix includes the following topics:



## Overview of User Properties for Siebel Clinical

User properties are object definitions that are added as children to an applet, business component, control, field, or list column to configure specialized behavior beyond what is configured in the properties of the parent object definition.

Some Siebel Clinical functionalities are driven by user properties. You can customize these functionalities through their respective user properties. With user properties, you can control UI behavior, change default settings or leave them as they are, and enable or disable functionalities.

This appendix lists user properties that are specific to Siebel Clinical. For more information about user properties and user properties that apply to all Siebel Business Applications, see *Siebel Developer's Reference*.

# User Properties for Business Components in Siebel Clinical

Table 21 describes the business component user properties that are used to enable and configure functionality for Siebel Clinical.

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Apply Templates WorkFlow Process Name | LS Subject Schedule Date VBC | This property defines the workflow process that is invoked when the property Enroll Screen Rescreen Through WorkFlow is set to Y, and when the property Disable Delete Non App Visit is set to N.<br><br>The default value is LS Clinical - ApplyTemplates Process.<br><br>If the user clicks No on the pop-up message enabled by the Disable Delete Non App Visit property, then LS Clinical - ApplyTemplates Process is invoked, and the subject visit template is applied. |
| Automatic Missed Status Tracking | Visit Plan | This property is used to configure whether or not Missed status is automatically tracked in the Subject Status MVG (multi value group) for status tracking visits. The status tracking visit for each visit type is configured in the subject visit template.<br><br>This property is configured as follows:<br><br>■ To enable automatic tracking of Missed status for status tracking visits, set the value to Y.<br><br>■ To disable automatic tracking of Missed status for status tracking visits, set the value to N.<br><br>The default value is Y. |
| Completed Status Code | Visit Plan | This property is used for automatic status tracking.<br><br>The default value is as follows:<br><br>Completed.<br><br>**NOTE:** This value must not be changed. |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Delete NonApp WorkFlow Process Name | LS Subject Schedule Date VBC | This property defines the workflow process that is invoked when the property Enroll Screen Rescreen Through WorkFlow is set to Y, and when the property Disable Delete Non App Visit is set to N.<br><br>The default value is LS Clinical - DeleteNonAppVisits Process.<br><br>If the user clicks OK on the pop-up message enabled by the Disable Delete Non App Visit property, then LS Clinical - DeleteNonAppVisits Process is invoked to delete incomplete clinical visits in the previous version of a subject visit template. |
| Disable Delete Non App Visit | Clinical Subject | This property is used to turn deletion of non applicable clinical subject visits on or off. When clinical subject visits are scheduled using a revised subject visit template, a pop-up message appears to confirm if incomplete visits in the previous template version must be deleted, and if complete visits in the new template version must be deleted. Clicking OK in the pop-up message deletes the non applicable subject visits. Clicking Cancel retains the non applicable subject visits.The value is configured as follows:<br><br>■ To enable deletion of non applicable subject visits, set the value to N.<br><br>■ To disable deletion of non applicable subject visits, set the value to Y.<br><br>The default value is N. |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Enroll Screen Rescreen Through WorkFlow | LS Subject Schedule Date VBC | This property specifies whether subject visit scheduling tasks are executed through workflows or business component methods.<br><br>The value is configured as follows:<br><br>■ To execute subject visit scheduling tasks through workflows, set the value to Y.<br><br>■ To execute subject visit scheduling tasks through business component methods, set the value to N.<br><br>The default value is N.<br><br>The workflows used to execute the scheduling tasks are configured in the following business component properties:<br><br>■ WorkFlow Process Name<br><br>■ Apply Templates WorkFlow Process Name<br><br>■ Delete NonApp WorkFlow Process Name |
| LS Amount Rollup Field 1 | Clinical Payments | This property is used for automatic rollup of Amount Paid To Date from the payment record to the site record.<br><br>The value takes the following parameters:<br><br>"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"<br><br>The value is set as follows:<br><br>"Amount Paid To Date", "Amount Paid To Date", "Rollup Parent Buscomp Name"<br><br>**NOTE:** This value must not be changed. |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| LS Amount Rollup Field 2 | Clinical Payments | This property is used for automatic rollup of Amount Earned To Date from the payment record to the site record.<br>The value takes the following parameters:<br>"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"<br>The value is set as follows:<br>"Amount Earned To Date", "Amount Earned To Date", "Rollup Parent Buscomp Name"<br>**NOTE:** This value must not be changed. |
| LS Amount Rollup Field 3 | Clinical Payments | This property is used for automatic rollup of VAT amounts from the payment record to the site record.<br>The value takes the following parameters:<br>"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"<br>The value is set as follows:<br>"VAT Amount", "VAT Amount", "Rollup Parent Buscomp Name"<br>**NOTE:** This value must not be changed. |
| LS Amount Rollup Field 3 | Clinical Protocol Site | This property is used for automatic rollup of VAT amounts from the site record to the region record.<br>The value takes the following parameters:<br>"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"<br>The value is set as follows:<br>"VAT Amount", "VAT Amount", "Rollup Parent Buscomp Name"<br>**NOTE:** This value must not be changed. |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| LS Amount Rollup Field 3 | Clinical Region | This property is used for automatic rollup of VAT amounts from the region record to the clinical protocol record.<br>The value takes the following parameters:<br>"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"<br>The value is set as follows:<br>"VAT Amount", "VAT Amount", "Rollup Parent Buscomp Name"<br>**NOTE:** This value must not be changed. |
| LS Amount Rollup Field 3 | Clinical Protocol | This property is used for automatic rollup of VAT amounts from the protocol record to the program record.<br>The value takes the following parameters:<br>"<Source BC Field Name>", "<Target BC Field Name>", "<Rollup Parent Buscomp Name>"<br>The value is set as follows:<br>"VAT Amount", "VAT Amount", "Rollup Parent Buscomp Name"<br>**NOTE:** This value must not be changed. |
| LS Amount Rollup On Status 1 | Clinical Payments | This property defines the payment status values that are used to calculate the Paid to Date amount.<br>By default, only payments with a status of Paid are used to calculate the Paid to Date amount.<br>This property takes a comma delimited list of values, as follows:<br>"Amount Paid to Date","Paid" |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| LS Clinical Enable Revert On Status | Clinical Payments | This property defines the payment status values for which the Revert button is enabled.<br><br>The value takes a comma delimited list of payment statuses, as follows:<br><br>"<Status1>", "<Status2>"<br><br>By default, the Revert button is enabled for the following payment Status values:<br><br>■ In Progress<br><br>■ To Be Processed |
| Missed Status Code | Visit Plan | This property is used for automatic status tracking.<br><br>The value is set to Missed.<br><br>**NOTE:** This value must not be changed. |
| Named Method 1 | Action (No Owner Lock) | This property is used for generating payment records.<br><br>The value string is set as follows:<br><br>"GenerateNewPayment", "INVOKESVC", "Action (No Owner Lock)", "LS SubjectVisits Service", "GeneratePayment", "'Site Id'", "[Protocol Site Id]", "'srcBusComp'", "'Action (No Owner Lock)'", "'srcBusObj'", "'Clinical Protocol Site'", "'tgtBusObj'", "'Clinical Payments'", "'tgtBusComp'", "'Clinical Payments'"<br><br>**NOTE:** This value must not be changed. |
| Named Method 1 | LS Clinical Subject Status Snapshot | This property is used for generating the subject status snapshot for a clinical site.<br><br>The value string is set as follows:<br><br>"SiteSnap", "INVOKESVC", "LS Clinical Subject Status Snapshot", "LS Clinical Trip Report Svc", "GetSiteSnapshot", '"SVId"', "ParentFieldValue('Id')"<br><br>**NOTE:** This value must not be changed. |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Named Method 2 | Clinical Trip Report | This property is used to turn on or off approver verification for trip reports. When enabled, the User Verification screen is launched during the approval process for trip reports, to verify the user logon credentials of the approver.<br><br>The value is configured as follows:<br><br>■ To enable this property, set the value as follows:<br><br>"ValidateUser", "INVOKESVCSEL", "Clinical Trip Report", "Workflow Process Manager", "RunProcess", "ProcessName", "LS Clinical Trip Report Approval", "RowId", "[Id]", "Enable Verification", "Y"<br><br>■ To disable this property, set the value as follows:<br><br>"ValidateUser", "INVOKESVCSEL", "Clinical Trip Report", "Workflow Process Manager", "RunProcess", "ProcessName", "LS Clinical Trip Report Approval", "RowId", "[Id]", "Enable Verification", "N"<br><br>This property is disabled by default, and cannot be null.<br><br>**NOTE:** Customers who do not have a license for Siebel Tools can use the CL – Verify TripReportApprover system preference to configure this functionality. For more information about configuring system preferences, see "System Preferences in Siebel Clinical" on page 263. |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Status Field RollUp *n* | Clinical Subject Status | This property is used to collate subject numbers for each status value. It can also be configured to collate subjects status and visit type value pairs. The subject accruals data is rolled up to the site record.<br><br>The following comma-delimited parameter configurations are supported:<br><br>■ "[Subject Status]", "[Business Component Field Name]", "[Visit Type]"<br><br>■ "[Subject Status]", "[Business Component Field Name]", "[Null]"<br><br>■ "[Subject Status]", "[Business Component Field Name]"<br><br>The Subject Status and Business Component Field Name parameters are mandatory. The Visit Type parameter is optional. The Visit Type value is not populated by default.<br><br>The following example provides the default configuration for the Enrolled status, and collates the subjects with status Enrolled for automatic rollup to the site record:<br><br>"Enrolled", "# Enrolled" |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Status RollUp Fields:Protocol *n* | Clinical Protocol Site | This property is used to collate subject numbers for each status value. It can also be configured to collate subjects status and visit type value pairs. The subject accruals data is rolled up to the protocol record.<br><br>The following comma-delimited parameter configurations are supported:<br><br>■ "[Subject Status]", "[Business Component Field Name]", "[Visit Type]"<br><br>■ "[Subject Status]", "[Business Component Field Name]", "[Null]"<br><br>■ "[Subject Status]", "[Business Component Field Name]"<br><br>The Subject Status and Business Component Field Name parameters are mandatory. The Visit Type parameter is optional. The Visit Type value is not populated by default.<br><br>The following example provides the default configuration for the Enrolled status, and collates the subjects with status Enrolled for automatic rollup to the protocol record:<br><br>"Enrolled", "# Enrolled" |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Status RollUp Fields:Region *n* | Clinical Protocol Site | This property is used to collate subject numbers for each status value. It can also be configured to collate subject status and visit type value pairs. The subject accruals data is rolled up to the region record.<br><br>The following comma-delimited parameter configurations are supported:<br><br>■ "[Subject Status]", "[Business Component Field Name]", "[Visit Type]"<br><br>■ "[Subject Status]", "[Business Component Field Name]", "[Null]"<br><br>■ "[Subject Status]", "[Business Component Field Name]"<br><br>The Subject Status and Business Component Field Name parameters are mandatory. The Visit Type parameter is optional. The Visit Type value is not populated by default.<br><br>The following example provides the default configuration for the Enrolled status, and collates the subjects with status Enrolled for automatic rollup to the region record:<br><br>"Enrolled", "# Enrolled" |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Status Tracking Field *n* | Clinical Subject | This property is used to configure automatic status tracking for subject status. By, default, automatic subject status tracking is provided for fields related to the following subject statuses:<br>■ Screen Failure<br>■ Randomized<br>■ Withdrawn<br>■ Early Terminated<br>Additional custom subject statuses can be tracked by configuring additional values for this property type. This property takes the following comma-delimited list of parameters:<br>"[Business Component Field Name]", "[Date Field]", "[Status Value]"<br>■ [Business Component Field Name] is the name of the business component field that is tracked for automatic status tracking, for example, Randomization ID.<br>■ [Date Field] is the name of the corresponding date field that is tracked for automatic status tracking, for example, Randomized Date.<br>■ [Status Value] is the corresponding status value that is tracked for automatic status tracking, for example, Randomized. |
| Status Tracking Field 1 | Clinical Subject | This property is used for automatic status tracking for the subject status of Randomized.<br>The default value is as follows:<br>"Randomization Id", "Randomized Date", "Randomized"<br>To track additional custom subject statuses, see Status Tracking Field *n*. |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Status Tracking Field 2 | Clinical Subject | This property is used for automatic status tracking for the subject status of Screen Failure.<br>The default value is as follows:<br>"Reason Excluded", "Screen Failure Date", "Screen Failure"<br>To track additional custom subject statuses, see Status Tracking Field *n*. |
| Status Tracking Field 3 | Clinical Subject | This property is used for automatic status tracking for the subject status of Withdrawn.<br>The default value is as follows:<br>"Withdrawn Reason", "Withdrawn Date", "Withdrawn"<br>To track additional custom subject statuses, see Status Tracking Field *n*. |
| Status Tracking Field 4 | Clinical Subject | This property is used for automatic status tracking for the subject status of Early Terminated.<br>The default value is as follows:<br>“Early Termination Reason”, "Early Terminated Date", "Early Terminated"<br>To track additional custom subject statuses, see Status Tracking Field *n*. |
| Validate Field | LS Subject Enrollment Date VBC | **NOTE:** This property is deprecated in version 8.1.1.9 and later.<br>Represents the name of the field to be validated.<br>The default value is Enrollment ID. |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Validate On 1 | Clinical Trip Report | This property is used to turn on or off validation for trip reports that have a status of Rejected.<br><br>When enabled, trip reports that have a status of Rejected are validated to ensure that one of the following fields has been completed:<br><br>■ Reviewer Comments<br>■ Approver Comments<br><br>The value is configured as follows:<br><br>■ To enable the property, set the value as follows:<br><br>"Rejected", "Y"<br><br>■ To disable the property, set the value as follows:<br><br>"Rejected", "N"<br><br>This property is enabled by default. |
| Validate On 2 | Clinical Trip Report | This property is used to turn on or off validation for trip reports that have a status of Submitted.<br><br>When enabled, trip reports that have a status of Submitted are validated to ensure that a Reviewer has been assigned to the trip report.<br><br>The value is configured as follows:<br><br>■ To enable this property, set the value as follows:<br><br>"Submitted", "Y"<br><br>■ To disable this property, set the value as follows:<br><br>"Submitted", "N"<br><br>This property is enabled by default. |

Table 21. User Properties for Business Components in Siebel Clinical

| Property | Business Component | Description |
|---|---|---|
| Validate On 3 | Clinical Trip Report | This property is used to turn on or off validation for trip reports that have a status of Submitted for Approval.<br><br>When enabled, trip reports that have a status of Submitted for Approval are validated to ensure that an Approver has been assigned to the trip report.<br><br>The value is configured as follows:<br><br>■ To enable this property, set the value as follows:<br><br>"Submitted for Approval", "Y"<br><br>■ To disable this property, set the value as follows:<br><br>"Submitted for Approval", "N"<br><br>This property is enabled by default. |
| WorkFlow Process Name | LS Subject Schedule Date VBC | This property defines the workflow process that is invoked when the property Enroll Screen Rescreen Through WorkFlow is set to Y.<br><br>The default value is LS Clinical - SubjectVisits Process.<br><br>This workflow process applies the approved subject visit template to the subject.<br><br>If the subject visit template being applied is different to the previous version of the subject visit template that was applied, and if the business component property Disable Delete Non App Visit is set to N, then a pop-up message appears to confirm if incomplete visits in the previous template version must be deleted, and if complete visits in the new template version must be deleted. Clicking OK in the pop-up message deletes the non applicable subject visits. Clicking Cancel retains the non applicable subject visits. |

# User Properties for Business Services in Siebel Clinical

Table 22 describes the business service user properties that are used to enable and configure functionality for Siebel Clinical.

Table 22. User Properties for Business Services in Siebel Clinical

| Property | Business Service | Project | Description |
|---|---|---|---|
| Data Rollup Is On | LS Data Rollup | LS Clinical Enhancement | This property is used to configure rollup of subject status data to sites, regions, and protocols.<br>The value is configured as follows:<br>■ To enable this property, set the value to Y.<br>■ To disable this property, set the value to N.<br>This property is enabled by default. |

# Applet Properties in Siebel Clinical

Table 23 describes the applet properties that are used to enable and configure functionality for Siebel Clinical.

Table 23. Applet Properties in Siebel Clinical

| Property | Applet | Description |
|---|---|---|
| History Target BC<br><br>(Internal) | ■ Clinical Protocol Team Mvg Applet<br>■ Clinical Region Team Mvg Applet | This property specifies the target business component.<br><br>The default values follow:<br><br>■ Clinical Protocol Site Team Assignment History BC<br>■ Clinical Protocol Team Assignment History BC<br>■ Clinical Region Team Assignment History BC<br><br>The information about the positions added to or deleted from the team list is added to the specified business component. |
| Search Specification | Clinical Protocol Site Template Version Assoc Applet | The Search Specification property is used to configure the versions of the subject visit template that appear in the Site Management Versions MVG (multi value group).<br><br>This property is configured as follows:<br><br>■ To display only the versions of the subject visit templates with a status of Approved, set the value as follows:<br><br>[Status Cd] = LookupValue("CLNCL_VERSION_STATUS","Approved")<br><br>■ To display the versions of the subject visit templates with a status of Reviewed or Approved, set the value as follows:<br><br>[Status Cd] = LookupValue("CLNCL_VERSION_STATUS","Approved") OR [Status Cd] = LookupValue("CLNCL_VERSION_STATUS","Reviewed")<br><br>The default configuration displays only subject visit templates with a status of Approved in the Site Management Versions MVG. |

# Field Properties in Siebel Clinical

Table 24 lists the field properties that are used to enable and configure functionality for Siebel Clinical.

Table 24. Field Properties in Siebel Clinical

| Property | Parent Field | Description |
|---|---|---|
| Append All Activities | Enrollment Date<br>Screen Date<br>Rescreen Date | **NOTE:** This property is deprecated in version 8.1.1.9 and later.<br>This property is used to configure whether or not the activities in the subject visit template can be copied multiple times.<br>This property is configured as follows:<br>■ Set the value to Y to allow the activities in the subject visit template to be copied multiple times.<br>■ Set the value to N to disallow the activities in the subject visit template to be copied multiple times.<br>The default property value for each field is as follows:<br>Enrollment Date = N<br>Screen Date = N<br>Rescreen Date = Y |

Table 24. Field Properties in Siebel Clinical

| Property | Parent Field | Description |
|---|---|---|
| Subject Consent Required | Screen Date | This property is used to configure whether or not subject informed consent is mandatory when scheduling a clinical subject. When enabled, the Informed Consent Date field is checked for data when the user clicks Schedule.<br>This property is configured as follows:<br>■ To set the Informed Consent Date as a mandatory field when scheduling a clinical subject, set the value to Y.<br>■ To set the Informed Consent Date as an optional field when scheduling a clinical subject, set the value to N.<br>The default value is N. |
| Template Type Code] | Enrollment Date<br>Screen Date<br>Rescreen Date | **NOTE:** This property is deprecated in version 8.1.1.9 and later.<br>This property is used to configure the subject visit template type that is used when applying a template.<br>The following are the default configurations:<br>Screen Date = 'Screening'<br>Rescreen Date ='Re-Screening'<br>Enrollment Date = 'Enrollment' |

# System Preferences in Siebel Clinical

Table 25 lists the system preferences that are used to configure core functionality in Siebel Clinical Trial Management System, and integration with third-party applications. For more information about each system preference, see the corresponding functional area in this guide.

Table 25. System Preferences in Siebel Clinical

| System Preference | Functionality |
|---|---|
| CL - BudgetingApp CustomerCode | Clinical operations integration |
| CL - BudgetingApp RequestURL | Clinical operations integration |
| CL – Verify TripReportApprover | This setting is used to turn on or off approver verification for trip reports. When enabled, the User Verification screen is launched during the approval process for trip reports to verify the user login credentials of the approver. To enable approver verification for trip reports, set the value to Y. The value is set to N by default. |

# Workflows in Siebel Clinical

Table 26 lists the workflows that are required for Siebel Clinical core functionality, and for integrating with third-party applications. For more information about each workflow, see the corresponding functional area in this guide. You can modify the workflows to suit your own business model, using Siebel Business Process Designer. For information about configuring workflows, see *Siebel Business Process Framework: Workflow Guide*.

Table 26. Workflows in Siebel Clinical

| Workflow Name | Siebel Clinical Functionality |
|---|---|
| Clinical Assign Position From Protocol | Clinical Protocol |
| Clinical Assign Position From Region Rolldown | Clinical Region |
| Clinical Assign Position From Region | Clinical Region |
| Clinical Assign Position From Site Rollup | Clinical Site |
| Clinical Assign Position From Site | Clinical Site |
| Clinical Protocol Position History Update | Clinical Protocol |
| Clinical Region Delete Rollup | Clinical Region |
| Clinical Region First Site Initiation Date Upsert Rollup | Clinical Region |
| Clinical Region First Subject Enrolled Date Upsert Rollup | Clinical Region |
| Clinical Region Last Site Terminated Date Upsert Rollup | Clinical Region |
| Clinical Region Last Subject Off Study Date Upsert Rollup | Clinical Region |
| Clinical Region Position History Update | Clinical Region |
| Clinical Region Status Fields Rollup | Clinical Region |
| Clinical Remove Position From Protocol | Clinical Protocol |
| Clinical Remove Position From Region | Clinical Region |
| Clinical Remove Position From Site | Clinical Site |
| Clinical Rollup Batch Process | Clinical Site |
| Clinical Site Delete Rollup to Protocol | Clinical Site |
| Clinical Site Delete Rollup to Region | Clinical Site |
| Clinical Site Delete Rollup | Clinical Site |
| Clinical Site First Subject Enrolled Date Upsert Rollup | Clinical Subject |
| Clinical Site Initiation Completed Date Upsert Rollup | Clinical Site |
| Clinical Site Last Subject Off Study Date Upsert Rollup | Clinical Site |
| Clinical Site Position History Update | Clinical Site |
| Clinical Site Status Fields Rollup | Clinical Site |

Table 26. Workflows in Siebel Clinical

| Workflow Name | Siebel Clinical Functionality |
|---|---|
| Clinical Site Termination Date Upsert Rollup (With Subject Info) | Clinical Site |
| Clinical Site Termination Date Upsert Rollup (Without Subject Info) | Clinical Site |
| Clinical Status Delete Rollup | Clinical Subject |
| Clinical Status Upsert Rollup | Clinical Subject |
| Clinical Subject Delete Rollup | Clinical Subject |
| LS Clinical - ApplyTemplates Process | Clinical Template |
| LS Clinical - DeleteNonAppVisits Process | Clinical Subject Visits |
| LS Clinical - SubjectVisits Process | Clinical Subject Visits |
| LS Clinical Contract Rollup | Clinical Contract |
| LS Clinical Create Inbox Item for New Trip Report Owner | Clinical Trip Report |
| LS Clinical Create Inbox Item for Trip Report Approver | Clinical Trip Report |
| LS Clinical Create Inbox Item for Trip Report Owner | Clinical Trip Report |
| LS Clinical Create Inbox Item for Trip Report Reviewer | Clinical Trip Report |
| LS Clinical Earned To Date Rollup | Clinical Payments |
| LS Clinical Paid To Date Rollup | Clinical Payments |
| LS Clinical Payment Delete Rollup | Clinical Payments |
| LS Clinical Payments Outbound | Third-party payments application integration |
| LS Clinical Protocol Delete Rollup | Clinical Protocol |
| LS Clinical Protocol Site Get Sites | Clinical Site |
| LS Clinical Protocol Site Get User Position | Clinical Site |
| LS Clinical Site Accruals Rollup | Clinical Site |
| LS Clinical Site Subject Delete Accruals Rollup | Clinical Subject |
| LS Clinical State Validation | Third-party payments application integration |
| LS Clinical Trip Report Approval | Clinical Trip Report |
| LS ClinicalProtocolSite Outbound - NewSite | Site visit data integration |
| LS ClinicalProtocolSite Outbound - UpdatedSite | Clinical Protocol |
| SWI LS Clinical Create Site Visit Geo Location | Site visit data integration |

Table 26. Workflows in Siebel Clinical

| Workflow Name | Siebel Clinical Functionality |
|---|---|
| SWI LS Clinical Payments Inbound | Third-party payments application integration |
| SWI LS Clinical Query Protocol Site_Site Visits | Site visit data integration |
| SWI LS Clinical Subject Inbound - Activity | Clinical data management system integration |
| SWI LS Clinical Subject Inbound - Subject | Clinical data management system integration |
| SWI LS Clinical Subject Inbound | Clinical data management system integration |
| SWI - Protocol Number Lookup | Clinical data management system integration |

# Web Services in Siebel Clinical

Web services in Siebel Clinical can be customized for integration with any third-party clinical application, or for specific business requirements. Table 27 lists the Web services that are provided for mobile and external application integration. For more information about each Web service, see the corresponding integration chapter in this guide. For information about customizing Web services, see *Siebel CRM Web Services Reference*.

Table 27. Web Services in Siebel Clinical

| Web Service Name | Siebel Clinical Feature |
|---|---|
| ClinicalSubject | Clinical data capture integration |
| LS Clinical CRF Tracking Interface | Clinical operations integration |
| LS Clinical Protocol Site Interface Service | Clinical data capture integration<br>Clinical operations integration |
| LS Clinical Subject Information Interface Service | Clinical operations integration |
| SWI LS Clinical Payments Inbound | Payments application integration |
| SWILSClinicalActivityTemplate | Mobile integration |
| SWILSClinicalCreateSiteVisitGeoLocation | Site visit data integration |
| SWILSClinicalGetEmployees | Mobile integration |
| SWILSClinicalGetSiteContacts | Mobile integration |
| SWILSClinicalGetSiteSnapshot | Mobile integration |
| SWILSClinicalGetSmartScriptDetails | Mobile integration |

Table 27. Web Services in Siebel Clinical

| Web Service Name | Siebel Clinical Feature |
|---|---|
| SWILSClinicalGetStateModelService | Mobile integration |
| SWILSClinicalGetSubjectVisitDetails | Mobile integration |
| SWILSClinicalInsertEmployees | Mobile integration |
| SWILSClinicalListOfValues | Mobile integration |
| SWILSClinicalProtocolSiteGetSites | Mobile integration |
| SWILSClinicalQueryProtocolSite_SiteVisits | Site visit data integration |
| SWILSClinicalTripReportInterfaceService | Mobile integration |
| SWILSClinicalTripReportTemplates | Mobile integration |

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